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Getting Even Less than What They Paid for: The Plight of Generic Drug Consumers Under the Levine-Mensing Dichotomy

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GETTING EVEN LESS THAN WHAT THEY PAID FOR: THE PLIGHT OF GENERIC DRUG CONSUMERS UNDER THE *LEVINE-* *MENSING* DICHOTOMY

VIKRAMA CHANDRASHEKAR*

The Drug Price Competition and Patent Restoration Act of 1984, known as the Hatch-Waxman Amendments, allows manufacturers to begin developing generic versions of patented, brand-name pharmaceuticals while the patent terms are in force, and to bring those generic versions to market as soon as the patent terms expire. The generic versions are to mimic the brand-name drug in every respect; thus, they are produced at a significantly reduced cost, and those savings are passed on to generic drug consumers. Under federal regulations, a generic drug's label must also mimic that of the brand-name drug, and generic drug manufacturers may not change their label to warn of a newly discovered risk unless the brand-name manufacturer does so first. Under the constitutional doctrine of impossibility preemption, any state law that imposes requirements that would make it impossible for an actor to comply with both state and federal law is trumped, or preempted, by federal law.

Three decisions of the Supreme Court of the United States construe the relationship between state tort laws and federal drug labeling regulations. These decisions reveal a dichotomy that is stark, and frankly, quite absurd: alleged injuries that result from consumption of generic drugs are not subject to the same tort principles under state laws as

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those that result from consumption of brand-name drugs. Thus, generic drug consumers lack any legal remedy when injured as a result of their drugs' faulty labeling. This Comment argues that a two-part legislative solution will most effectively resolve this dichotomy. First, Congress can, and should, impose liability on generic manufacturers for faulty labeling (to which they are not currently subject). Second, Congress should provide generic drug manufacturers with the option to implead the brand-name manufacturer to most appropriately place liability on the responsible party.

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INTRODUCTION

During a routine checkup visit to the doctor’s office, Martina discovers that the heartburn she has been experiencing cannot be treated by normal antacid heartburn medications.¹ Her physician writes her a prescription for the drug metoclopramide. On the prescription pad, the physician does not specify whether the prescription is to be filled by Reglan, the brand-name version of the drug, or by any of the other versions produced by several generic drug manufacturers. Since federal regulations require the chemical composition of the generic version of the drug to be as safe and effective as the brand-name version, the law of the state where Martina lives allows a prescription to be filled by the lower-

1. The following story is loosely based on the facts of *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572–73 (2011). However, many liberties have been taken with respect to the details of the story.

priced, generic version of the drug, which is the version that the pharmacist uses to fill Martina's prescription. Like the brand-name label, this drug's warning label does not warn against using metoclopramide continuously for longer than one year. After more than one year of using the drug, Martina begins to experience strange, uncontrolled movements. A visit to her physician confirms that Martina has developed tardive dyskinesia.² Studies show that this disease is directly linked to long-term use of metoclopramide.³ Martina's attorney advises her to bring a products-liability claim against the manufacturer of the drug on the theory that the label inadequately warned of the danger of developing tardive dyskinesia.

However, after some research, Martina's attorney learns that, because Martina is a consumer of a generic drug, she is unable to sue the drug manufacturer for a defective or inadequate label. The attorney discovers that due to the combination of three decisions of the Supreme Court of the United States—*Wyeth v. Levine*,⁴ *PLIVA, Inc. v. Mensing*,⁵ and *Mutual Pharmaceutical Co. v. Bartlett*⁶—Martina may have had the opportunity to file suit against the drug's manufacturer for her injuries if she had taken the brand-name drug Reglan. However, claims against *generic* drug manufacturers based on precisely the same legal theory cannot be brought, because federal labeling regulations preempt her from bringing any claims against these drug manufacturers for an allegedly defective label.⁷ And because the law of Martina's home state allowed—and in fact encouraged—the drug substitution, Martina is out of luck.⁸

2. Tardive dyskinesia is "a disorder that involves involuntary movements. Most commonly, the movements affect the lower face." Joseph P. Campellone, *Tardive Dyskinesia*, MEDLINE PLUS, <http://www.nlm.nih.gov/medlineplus/ency/article/000685.htm>, archived at <http://perma.cc/J88K-D2CB> (last updated May 20, 2014). Stopping use of the drug may reverse the symptoms, but in some cases the disorder may be permanent or symptoms may continue to worsen. *Id.*

3. U.S. FOOD & DRUG ADMIN., MEDICATION GUIDE: REGLAN at 1 (June 2009), available at <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM176362.pdf>, archived at <http://perma.cc/D3J6-HHVK>.

4. 555 U.S. 555 (2009).

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

6. 133 S. Ct. 2466 (2013).

7. See, e.g., *Mensing*, 131 S. Ct. at 2581; *Bartlett*, 133 S. Ct. at 2470. For a detailed explanation of how these cases preclude certain lawsuits against generic manufacturers, see *infra* Parts II.C and II.D.

8. If a plaintiff recovers in full from her suit against a drug manufacturer,

That such a huge difference in results could turn on this sort of distinction is unfathomable, and yet, such is the state of the law today. The decisions mentioned above create a dichotomy that prevents a generic drug consumer from bringing the same state law claims against the manufacturer of his or her drug that a brand-name drug consumer could bring against a brand-name manufacturer. This dichotomy is the product of different federal labeling requirements for generic and brand-name manufacturers. Federal regulations require the generic manufacturer to mimic the brand-name drug's labeling.⁹ Specifically, the inability of generic manufacturers to unilaterally change their labels under federal laws and regulations means that any state laws that would impose heightened labeling requirements on these manufacturers are preempted. Under this regulatory scheme, injured consumers of generic drugs with inadequate warning labels cannot sue the manufacturer for their injuries, nor can they sue the brand-name manufacturer—the only manufacturer able to unilaterally modify a drug's label.¹⁰

To rectify this significant problem, this Comment argues for legislation that does two things: (1) expressly permits the imposition of state tort liability on generic manufacturers, and (2) allows a defendant generic firm to implead¹¹ the brand-name firm that first manufactured the drug in question. The new legislation would ideally be placed in the Hatch-Waxman Amendments (“Hatch-Waxman” or “Amendments”), which govern the introduction of all drugs to the pharmaceutical marketplace.¹² This remedy is preferable to other solutions because it maintains federal labeling requirements in effect as of September 2014 and does not depend on any novel legal theories for its implementation. It nevertheless adequately

all claims against her pharmacist or physician for the same injury are precluded. See Daniel Kazhdan, *Wyeth and PLIVA: The Law of Inadequate Drug Labeling*, 27 BERKELEY TECH. L.J. 893, 914–15 (2012). If the plaintiff does not recover from the manufacturer (or only partially recovers), she may sue her physician for some recovery. *Id.* However, nearly every circuit has held that failure-to-warn claims, among other strict liability claims, are generally improper against pharmacists and physicians. See LAW JOURNAL PRESS, DRUG AND DEVICE PRODUCT LIABILITY DESKBOOK §§ 8.03[1] n.4, 8.06[1] (2013).

9. See *infra* Parts I.A.2, I.C.2.

10. See *infra* notes 86–88, 91 and accompanying text.

11. Impleader is a method of joining a third-party defendant to an existing lawsuit. See FED. R. CIV. P. 14. See also *infra* Part IV.A.1.

12. Hatch-Waxman Amendments, 21 U.S.C. § 355 (2013).

addresses the issue raised by the Supreme Court's untenable and unfair dichotomy and provides an accurate mechanism to place liability for consumer injuries on the responsible party.

Part I first describes the statutory differences in how brand-name and generic manufacturers bring their drugs to market. It then explains key provisions of the Hatch-Waxman Amendments that allow for the hastened placement of generic versions of existing drugs into the marketplace. Part I concludes by demonstrating the interaction of brand-name and generic drugs in the marketplace through an examination of state drug substitution statutes and federal post-marketing surveillance regulations. These provisions contextualize the Supreme Court's recent jurisprudence in the area of pharmaceutical regulation, discussed in Part II. An analysis of three decisions in particular reveals a strange dichotomy: because of the differences discussed in Part I, an injured brand-name drug consumer may bring state tort claims against his or her drug manufacturer, but a generic drug consumer may not bring the same claims against either manufacturer. In search of a way to resolve the dichotomy, Part III briefly discusses the primary and collateral effects of the Supreme Court's jurisprudence and then evaluates existing proposals intended to provide a legal remedy to generic drug consumers. As none of these proposals adequately addresses the problem identified in Part II, Part IV proposes a novel solution to benefit generic drug consumers by more precisely apportioning fault to the offending party. This solution combines elements of legislative reform and transferred liability, and adheres to the purposes of the Hatch-Waxman Amendments and traditional American tort law.

I. THE HATCH-WAXMAN AMENDMENTS TO THE FOOD, DRUG, AND COSMETIC ACT

In 1984, the United States Congress passed the Drug Price Competition and Patent Restoration Act of 1984,¹³ commonly known as the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act (FDCA).¹⁴ Under the FDCA, two types of

13. 21 U.S.C. § 355; see Natalie Pous, *Shifting the Balance Between Branded and Generic Pharmaceutical Companies: Amendments to Hatch-Waxman Past, Present, and Future*, 19 FED. CIR. B.J. 301, 302 (2009).

14. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L.

drugs may exist in the pharmaceutical marketplace: brand-name drugs and generic drugs.¹⁵ However, the firm holding the patent to the chemical composition of the drug manufactures the brand-name drug, and no other firm may compete with the brand-name manufacturer in the market for that drug while the patent term is in force.¹⁶ Once the patent term has expired, the Hatch-Waxman Amendments provide for the expedited introduction of generic drugs to the pharmaceutical marketplace.¹⁷ Generic manufacturers face fewer hurdles in placing their drugs on the market, as they need only “show[] equivalence to a reference listed drug that has already been approved by the [Food and Drug Administration].”¹⁸ The reduced cost of entry permits a generic manufacturer to compete with the brand-name manufacturer by offering the same therapeutic value as the brand-name drug at reduced cost.¹⁹ The first section of Part I examines the difference between the New Drug Application (NDA)²⁰ and Abbreviated New Drug Application (ANDA)²¹ processes, which govern the applications for, and approval of, brand-name and generic drugs, respectively. The second section describes the provisions in the United States Code that provide for the faster placement of generic drugs in the market. The final section explores the interaction between the laws and rules governing brand-name and generic drugs through a brief overview of states’ drug substitution laws and federal rules governing post-market surveillance to ensure the drugs’ continued safety and efficacy.

No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.).

15. See 21 U.S.C. § 355(b), (j) (2012).

16. See *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). Patent terms remain in force for twenty years after approval by the United States Patent and Trademark Office (USPTO). 35 U.S.C. § 154(a)(2) (2013).

17. *Caraco*, 132 S. Ct. at 1676; see also *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

18. *PLIVA v. Mensing*, 131 S. Ct. 2567, 2574 (2011). Compare 21 U.S.C. § 355(b), with 21 U.S.C. § 355(j) (describing the new drug filing application process and the abbreviated new drug application process for generic drugs).

19. *Caraco*, 132 S. Ct. at 1676; see also *Eli Lilly*, 496 U.S. at 676.

20. 21 U.S.C. § 355(b).

21. *Id.* § 355(j).

A. *The New Drug Approval Process and Abbreviated New Drug Approval Process*

1. The New Drug Approval Process

The Food and Drug Administration (FDA) is responsible for the premarket approval of new drugs and the creation and enforcement of manufacturing standards for the pharmaceutical industry.²² Manufacturers of original, patented drugs seeking to market those drugs must first gain regulatory approval from the FDA before going to market²³ by submitting an NDA.²⁴ A complete NDA contains information about the safety and efficacy of the drug; a list of the drug's components and a statement of the drug's composition; a description of the methods and processes of "manufactur[ing], processing and packaging the drug," samples of the drug and its component parts; proposed labeling; and assessments.²⁵ Labeling, according to FDA regulations, includes not only the list of ingredients, methods of use, and warnings on the drug's packaging, but also extends to "virtually any dissemination of information by the drug manufacturer, packer, or distributor to medical professionals."²⁶ The brand-name manufacturer must also provide in the NDA:

22. See Allison Stoddart, *Missing After Mensing: A Remedy for Generic Drug Consumers*, 53 B.C. L. REV. 1967, 1971 (2012); see also *Wyeth v. Levine*, 555 U.S. 555, 566 (2009) (explaining that enactment of the FDCA added the requirement that the FDA is responsible for premarket approval of new drugs). The task of ensuring the safety and efficacy of drugs sold to consumers belongs to the Center for Drug Evaluation and Research (CDER), a division of the FDA that evaluates brand-name and generic drugs alike. *About the Center for Drug Evaluation and Research*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/default.htm>, archived at <http://perma.cc/EH4A-3FYQ> (last updated June 10, 2014).

23. "No person shall introduce or deliver for introduction into interstate commerce any *new drug*, unless an approval of an application filed pursuant to subsection (b) or (j) [of this statute] is effective with respect to such drug." 21 U.S.C. § 355(a) (emphasis added). Section (b) governs the NDA process, while section (j) governs the ANDA process. See *id.* § 355(b), (j).

24. See *id.* § 355(b).

25. 21 U.S.C. § 355(b)(1)(A)–(G). The required assessments "shall contain data, gathered using appropriate formulations for each age group for which the assessment is required, that are adequate . . . (i) to assess the safety and effectiveness of the drug or the biological product for the claimed indications in all relevant pediatric subpopulations; and (ii) to support dosing and administration for each pediatric subpopulation for which the drug or the biological product is safe and effective." 21 U.S.C. § 355c(a)(2)(A)(i)–(ii) (2012).

26. Stoddart, *supra* note 22, at 1974–75.

[T]he patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.²⁷

The research required for a complete NDA often takes several years to compile and several more years before the new drug is approved.²⁸ By contrast, the reduced requirements for generic drug approval allow generic drugs to be sold quickly after the patent expires on the brand-name drug, at much lower prices.²⁹

2. The Abbreviated New Drug Approval Process

As the name of the application suggests, an ANDA has fewer requirements than the NDA.³⁰ ANDA applicants that simply seek to reproduce the brand-name drug must show that (1) the conditions for use of the generic drug have been previously approved; (2) the ingredient(s) of the generic drug is/are the same as that which was previously approved for that drug; (3) “the route of administration, the dosage form, and the strength of the new drug are the same as those of the [brand-name] drug”; (4) the drug in question is the biological equivalent of the previously approved drug; and (5) the label of the generic drug mirrors the label of the brand-name drug.³¹ The more identical the generic drug to the original, the more likely that the ANDA will be approved.³² As the rate of substitution of generic drugs for brand-name drugs has increased tremendously since the passage of Hatch-Waxman,³³ the FDA must be certain that consumers of the former are not

27. 21 U.S.C. § 355(b)(1) (2013).

28. Martin S. Lipsky & Lisa K. Sharp, Ph.D., *From Idea to Market: The Drug Approval Process*, 14 J. AM. BD. FAM. PRAC. 362, 364 (2001) (“Overall, this entire process, on average, takes between 8 and 12 years.”).

29. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012); *see also* 21 U.S.C. § 355(j).

30. *Compare* 21 U.S.C. § 355(j), *with* 21 U.S.C. § 355(b).

31. 21 U.S.C. § 355(j)(2)(A)(i)–(v) (2013).

32. Stoddart, *supra* note 22, at 1973–74. *See infra* Part I.B for a discussion of why, and how, generic manufacturers may begin to produce generic versions of patented drugs without infringing the patents while the patent terms are in force.

33. *See infra* note 67 and accompanying text.

receiving a product of inferior quality.³⁴ In order for the FDA to ensure that both drugs are equally safe and effective, the agency requires the generic drug to be as similar as possible to the patented brand-name drug in *all respects*, including labeling.³⁵

The generic manufacturer may satisfy each of these requirements through the same materials required of the pioneer drug's NDA (e.g., reports of safety and efficacy, descriptions of various manufacturing processes, and labeling specimens).³⁶ Generic manufacturers may even use the research provided in the NDA to meet these requirements, rather than conduct their own independent research.³⁷ Even where the composition, dosage form, or strength is modified slightly from the original, the ANDA will be approved if the Secretary of Health and Human Services (Secretary)³⁸ determines that the safety and effectiveness of the drug in question meets FDA standards despite these differences.³⁹ Since generic manufacturers do not incur the substantial costs borne by brand-name manufacturers involved in researching and developing the drug, or in putting together independent research for the application, these savings are passed on to consumers.⁴⁰ Before ANDAs could achieve their intended purpose, however, the Hatch-Waxman Amendments required some modifications.

34. See Brief of Rep. Henry Waxman as Amicus Curiae in Support of Respondents Urging Affirmance at 8, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (No. 09-993) [hereinafter Waxman Amicus Brief].

35. "The ANDA process set forth in the Hatch-Waxman Amendments was premised on the idea that a generic pharmaceutical would be shown to be the *same as* the brand-name drug in every significant way—including the labeling." *Id.*

36. 21 U.S.C. § 355(j)(2)(A)(vi).

37. See *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (describing how an ANDA may "piggy-back[]" on the research of the NDA). See also *Sanofi-Aventis U.S. LLC v. FDA*, 842 F. Supp. 2d 195, 198 (D.D.C. 2012) (While "relieved of the obligation to supply the extensive testing demonstrating safety and effectiveness that is the hallmark of the NDA process . . . ANDA applications are still required to supply the other information required of a new drug applicant" pursuant to § 355(j)(2)(A)(vi).).

38. "Secretary" for the purposes of the Hatch-Waxman Amendments is defined as the "Secretary of Health and Human Services." 21 U.S.C. § 321(d). Recall that the FDA is an agency within the Department of Health and Human Services, of which the Secretary is the head. See Stoddart, *supra* note 22, at 1971.

39. 21 U.S.C. § 355(j)(2)(A)(viii)(C).

40. See *Caraco*, 132 S.Ct. at 1676.

B. The Safe Harbor Provision for Expedited Introduction of Generic Drugs

Until 1984, a distortion in the FDCA prevented consumers from realizing savings in the pharmaceutical market⁴¹: the de facto extension of the brand-name drug's effective patent life.⁴² The distortion resulted from the Federal Circuit's interpretation of the FDCA that made it an act of infringement for a generic manufacturer to undertake *any* activity involving the patented product.⁴³ Under this interpretation, even activities undertaken merely to gain FDA regulatory approval, such as experimentation using the original drug, were made illegal.⁴⁴ This interpretation threatened to delay the market entry of generic drugs, since generic manufacturers would be forced to wait until the patent term expired to even begin the ANDA process.⁴⁵ Because a generic drug cannot be sold without FDA approval, these manufacturers would be unable to compete with brand-name manufacturers for a significant period of time after the expiration of the patent term, which effectively extended the patent term and its monopoly benefits.⁴⁶ To correct this distortion, the Hatch-Waxman Amendments instituted a safe harbor provision⁴⁷ that allows a generic manufacturer to use an already-patented invention "for uses reasonably related to the development and submission" of a drug or product for FDA approval, without such use being an act of infringement.⁴⁸ This allows generic competitors to create and submit an ANDA while the original patent term is still in force.⁴⁹

Hatch-Waxman further encourages generic manufacturers

41. Pous, *supra* note 13, at 303–04.

42. *Id.*

43. *Proveris Sci. Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1261 (Fed. Cir. 2008).

44. *See Roche Prods. v. Bolar Pharm. Co.*, 733 F.2d 858, 862 (Fed. Cir. 1984), *superseded by statute*, 21 U.S.C. § 355 (2013), *as recognized in Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1356 (Fed. Cir. 2003).

45. Pous, *supra* note 13, at 303.

46. *Proveris*, 536 F.3d at 1261.

47. *Id.*

48. "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs . . ." 35 U.S.C. § 271(e)(1) (2013).

49. Pous, *supra* note 13, at 304; *see also Proveris*, 536 F.3d at 1261.

to file their ANDA submissions while the brand-name manufacturer's patent term is still in effect. The Amendments contain a 180-day exclusivity period⁵⁰ for the first generic drug manufacturer to file a paragraph IV certification.⁵¹ No other generic manufacturer can enter the market for that particular drug during this period.⁵² A paragraph IV certification is also a means of provoking litigation,⁵³ as the certification operates as a challenge to either the validity of the existing patent, or the generic manufacturer's alleged infringement of that patent.⁵⁴ Hatch-Waxman grants the 180 days of market exclusivity to those generic manufacturers who simply *bring*, but do not necessarily *win*, the ensuing patent infringement lawsuit brought by the brand-name manufacturer.⁵⁵ Since the mere filing of paragraph IV certification is enough to gain 180 days of market exclusivity, generic companies enjoy a significant economic incentive to challenge existing patents, which may further accelerate the ANDA approval process.⁵⁶

50. 21 U.S.C. § 355(j)(5)(B)(iv) (2013).

51. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). A paragraph IV certification is a statement by the generic applicant that "[the brand-name manufacturer's] patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.*; WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., IB10105, THE HATCH-WAXMAN ACT: PROPOSED LEGISLATIVE CHANGES AFFECTING PHARMACEUTICAL PATENTS 3 (2004) ("The first generic applicant to file a Paragraph IV certification is awarded a 180-day market exclusivity period by the FDA.").

52. Pous, *supra* note 13, at 305.

53. Paragraph IV certification is one of several possible certifications a generic manufacturer may make in the ANDA to "assure the FDA" that the generic drug will not infringe any existing patents. Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670, 1672 (2012). "Filing a paragraph IV certification means provoking litigation. The patent statute treats such a filing as itself an act of infringement, which gives the brand[-name manufacturer] an immediate right to sue." *Id.* at 1677 (citing 35 U.S.C. § 271(e)(2)(A)). "Taking [the paragraph IV] route . . . automatically counts as patent infringement . . ." FTC v. Actavis, Inc. 133 S. Ct. 2223, 2228 (2013).

54. See *Actavis*, 133 S. Ct. at 2228.

55. SCHACHT & THOMAS, *supra* note 51, at 4. The race to the exclusivity period has led to concerns over "sham" paragraph IV certifications. *Id.*

56. See Pous, *supra* note 13, at 305. If the brand-name company never sues for infringement, the 180-day period begins to run from the date that the generic company begins marketing its drug. 21 U.S.C. § 355(j)(5)(B)(iv); see U.S. FOOD & DRUG ADMIN., PROCEDURAL GUIDANCE 5, GUIDANCE FOR INDUSTRY: 180-DAY GENERIC DRUG EXCLUSIVITY UNDER THE HATCH-WAXMAN AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 2-4 (1998). On the other hand, when a brand-name company files suit for infringement, the exclusivity period only begins to run upon a court's finding that the patent is invalid, not infringed, or unenforceable. 21 C.F.R. § 314.107(c)(1). In this instance, a generic manufacturer

Hatch-Waxman has thus far achieved its stated purpose: the expedited introduction of generic versions of pharmaceuticals into the healthcare marketplace.⁵⁷ The success of the Amendments has also led to an increase in the quantity and availability of generic drugs.⁵⁸ When drug manufacturers face increased competition, consumers benefit from low-cost treatments earlier than they could before the Amendments were passed.⁵⁹ Thus, the success of the Amendments has also led to an increase in the quantity and availability of generic drugs.⁶⁰ This increase correlates positively with an increase in drug substitution across the country.⁶¹

C. Drug Substitution and Post-Market Monitoring of Approved Drugs

In thirty-two states, pharmacists may substitute generic drugs for brand-name drugs where a physician has not specified which version should be used to fill a prescription; all but three of the remaining eighteen states *require* this substitution.⁶² To ensure the continued safety and efficacy of both types of pharmaceuticals, and thus the continued viability of drug substitution, federal law requires both brand-name and generic manufacturers to monitor the effects of their drugs

could begin marketing its product before the patent term was slated to end. However, when the infringement suit commences, the FDA is prohibited from approving the generic drug for thirty months, unless the generic manufacturer wins the suit. Pous, *supra* note 13, at 305–06. If the generic manufacturer loses, the thirty-month stay continues. *Id.*

57. See Stoddart, *supra* note 22, at 1975.

58. *Id.*

59. See H.R. Rep. No. 98-857(I), at 14–15 (1984) (explaining that a purpose of the legislation was “to make available more low cost generic drugs”); see also 130 CONG. REC. 24,430 (Sept. 6, 1984) (statement of Rep. Waxman) (“The public will benefit . . . by the immediate reduction in drug prices when a generic is on the market as a competitor.”).

60. See Stoddart, *supra* note 22, at 1975.

61. *Id.* For specific data on the increase in drug substitution, see William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFF. 1383, 1383 (2010) [hereinafter Shrank et al., *State Generic Substitution Laws*]; William H. Shrank et al., *The Consequences of Requesting “Dispense as Written,”* 124 AM. J. MED. 309, 311 (2011) [hereinafter Shrank et al., *Consequences*].

62. See *infra* note 68 and accompanying text. Fifteen states require the substitution, while thirty-two merely permit it. Kazhdan, *supra* note 8, at 912. “The laws of Idaho, Louisiana, and Oklahoma are unclear on this point.” *Id.*

after FDA approval.⁶³ This section first examines the various state drug-substitution laws to demonstrate that the prevalence of generic drugs significantly increased after the passage of the Hatch-Waxman Amendments and the creation of the ANDA process. Next, this section describes and explains the importance of the distinct obligations of each type of manufacturer with respect to drug labeling under the federal Hatch-Waxman post-approval surveillance scheme. In the cases analyzed in Part II, these federal provisions come into direct conflict with state laws, creating a difference in the availability of state law tort remedies, permitting recovery for brand-name drug consumers while preventing recovery for generic drug users.⁶⁴ The increase in drug substitution, coupled with the difference in the availability of remedies, creates the liability dichotomy explained in Part III.

1. Drug Substitution Laws

While some states restrict a *pharmacist's* ability to substitute a generic drug,⁶⁵ all states currently have enacted statutes that permit a *physician* to require her patient's prescription to be filled with either a brand-name drug or a generic counterpart that has met the ANDA requirements.⁶⁶ Prior to the passage of Hatch-Waxman, only nineteen percent of prescriptions were filled with generic drugs; since the passage of the Amendments, that figure has skyrocketed to seventy-five percent.⁶⁷ In fact, fifteen states *require* pharmacists to provide the generic drug whenever possible.⁶⁸

63. See 21 C.F.R. § 314.80.

64. See *supra* Introduction.

65. See *supra* note 63 and accompanying text.

66. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2583 (2011) (Sotomayor, J., dissenting); see Thomas P. Christensen, et al., *Drug Product Selection: Legal Issues*, 41 J. AM. PHARMACEUTICAL ASS'N. 868, 869 (2001). However, all states (except perhaps Oklahoma) require filling the prescription with the brand-name drug if the physician specifically prescribes that version. Kazhdan, *supra* note 8, at 909. One reason for this is that, due to the fact that generic drugs are not necessarily identical to their brand-name counterparts, certain patients may experience adverse reactions to the generic, but not the brand-name, version of the drug. *Id.* at 908 n.109.

67. *Mensing*, 131 S. Ct. at 2584.

68. Kazhdan, *supra* note 8, at 912. These states are: Florida, Hawaii, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Rhode Island, Tennessee, Vermont and West Virginia. *Id.* at 911 n.118.

Evidence suggests that state legislatures instituted these substitution requirements to combat the rising costs of healthcare and to provide quality generic prescription drugs to state Medicaid enrollees at a fraction of the brand-name drugs' cost.⁶⁹ The results are startling. One study showed that on average patients paid \$17.90 for generic drugs (compared with \$44.50 for brand-name drugs), while their insurance plans paid \$26.67 for those drugs (compared with \$135.26 for brand-names).⁷⁰ The fact that the vast majority of prescriptions are currently filled with generic drugs is a direct result of the reduced cost of those drugs.⁷¹ It is therefore critical that those drugs are as safe and effective as brand-name drugs.⁷² To avoid confusion between drugs, and to assure consumer and physician confidence in the equivalent effectiveness of the generic drug, the FDA prioritizes consistency between the labels of brand-name and generic drugs.⁷³

2. Post-Approval Surveillance of Drug Labels

To promote this consistency each manufacturer must review all adverse experiences associated with the drug and "submit all followup information on such reports to FDA" as part of their federal post-approval obligations.⁷⁴ In reviewing these reports, a manufacturer may discover a danger of using the drug that was not previously anticipated, or was more serious than previously anticipated. In such circumstances, the responsibilities of each type of manufacturer diverge.⁷⁵

A brand-name manufacturer may change its label to better warn of a side effect or risk of using the drug.⁷⁶ A label change

69. See Shrank et al., *State Generic Substitution Laws*, *supra* note 61, at 1383 (2010).

70. Shrank et al., *Consequences*, *supra* note 61, at 311.

71. Kazhdan, *supra* note 8, at 913; *see also supra* note 67 and accompanying text.

72. See 54 Fed. Reg. 28,884 (1989) (stating that the intention of 21 U.S.C. § 355(j), governing ANDA submissions, is "to ensure the marketing of generic drugs that are as safe and effective as their brand-name counterparts.").

73. Brief of the United States as Amicus Curiae Supporting Respondents at 4, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, 09-1501) [hereinafter *United States Amicus Brief*] (referencing U.S. FOOD & DRUG ADMIN., DIVISION OF GENERIC DRUGS, POLICY AND PROCEDURE GUIDE 37 (1989)).

74. 21 C.F.R. § 314.80(b) (2014).

75. See *United States Amicus Brief*, *supra* note 73, at 25. *See also* 21 C.F.R. § 314.70(c).

76. See *Wyeth v. Levine*, 555 U.S. 555, 570 (2009) (dispensing with brand-

can be classified as either “major,” “minor,” or “moderate”; each type of change is subject to different FDA requirements.⁷⁷ When a change is “major,”⁷⁸ the manufacturer must submit a supplement that details the adverse effects and proposed change, and *must* gain FDA approval before the product can be distributed as amended.⁷⁹ Moderate changes,⁸⁰ on the other hand, may be implemented while the drug continues to be distributed through the “changes-being-effected” (CBE) process.⁸¹ The CBE process allows the change to take effect without initial FDA approval, while still leaving the FDA authority to later reject the change.⁸² “Minor” changes are those that have “minimal potential to have an adverse effect” on the safety or efficacy of a product, and need only be filed in an annual report.⁸³

Because a manufacturer may utilize the CBE process while the drug is still on the market, moderate changes are the only sort of change that may be instituted unilaterally (i.e., prior to FDA approval).⁸⁴ The purpose of the CBE process is to create a “safety valve mechanism” for the implementation of immediate changes without waiting for FDA approval.⁸⁵ The process

name manufacturer's impossibility argument by clarifying that a strengthened label would not be subject to an FDA enforcement action and would not render the drug a “new drug”).

77. 21 C.F.R. § 314.70(b)–(d).

78. Major labeling changes include: “[A]ny change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.” *Id.* § 314.70(b)(1).

79. *See id.* § 314.70(b).

80. Moderate labeling changes include: “add[ing] or strengthen[ing] a contraindication, warning, precaution, or adverse reaction,” “add[ing] or strengthen[ing] a statement about drug abuse, dependence, psychological effect, or overdose,” “add[ing] or strengthen[ing] an instruction about dosage and administration that is intended to increase the safe use of the drug product,” “delet[ing] false, misleading, or unsupported indications for use or claims for effectiveness,” or “[a]ny labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted” *Id.* § 314.70(c)(6)(iii)(A)–(E) (2008).

81. *Id.* § 314.70(c).

82. *Id.*

83. *See id.* § 314.70(d). Minor changes do not require FDA approval; the annual report requires proof that the manufacturer has completed assessments of the effects of the change, data from those assessments, and full descriptions and dates of all implemented minor changes. *Id.* § 314.70(d)(3)(i)–(iv).

84. *See id.* § 314.70(c).

85. Stacey B. Lee, *PLIVA v. Mensing: Generic Consumers' Unfortunate Hand*,

allows brand-name manufacturers to delete “false, misleading, or unsupported indications” about the drug’s use or effectiveness,⁸⁶ or to “add or strengthen a contraindication, warning, precaution, or adverse reaction”⁸⁷ to the drug’s label. The manufacturer must submit a supplement detailing the proposed change to the FDA and may not commence distribution of the drug with the change for thirty days while approval is pending.⁸⁸ This option enables brand-name manufacturers to respond independently to changes in the drug’s safety and to “quickly apprise the public of product changes,” including changes to the label.⁸⁹ Although generic manufacturers must follow any changes by the brand-name manufacturer,⁹⁰ they are not permitted to use the CBE process.⁹¹ The only time ANDA holders may alter their label is to match a label change instituted by the original drug manufacturer.⁹²

As discussed in the following Part, the availability of the CBE process to each manufacturer was critical to the ultimate results of three significant Supreme Court cases that addressed drug labeling since 2008. Since the CBE process provides for the institution of label changes *while the drug is still on the market*, consumers who take a drug that lacks a necessary label change have a salient failure-to-warn claim against any manufacturer that could have utilized the process. Each of the following cases turned on whether the particular manufacturer in question had the authority to unilaterally use the CBE process. The dichotomy that the cases reveal is stark, and frankly, quite absurd: federal law precludes injured consumers

12 YALE J. HEALTH POL’Y L. & ETHICS 209, 218 (2012).

86. 21 C.F.R. § 516.161(b)(1)(i)(B) (2008).

87. 21 C.F.R. § 314.70(c)(6)(iii)(A).

88. *Id.* § 314.70(c)(4).

89. Lee, *supra* note 85, at 218.

90. Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 581 (6th Cir. 2013) (“Although generic-drug manufacturers cannot strengthen labels unilaterally, the FDA requires that they follow changes and strengthenings made by branded-drug manufacturers.”).

91. United States Amicus Brief, *supra* note 73, at 25 (“FDA’s CBE regulation does not apply to ANDA holders.”).

92. Stoddart, *supra* note 22, at 1976 n.64. “By limiting the ability of brand-name manufacturers to implement changes unilaterally, and by requiring generic product’s labeling to be the same as its listed drug, the FDA made clear the premium it places on uniformity (perhaps at the expense of safety).” Lee, *supra* note 85, at 227. See *infra* Part III.A for an explanation of how the premium on uniformity comes at the expense of safety.

from recovering on certain state law tort theories against the manufacturer of the generic version of a drug yet simultaneously permits the same suits to go forward against brand-name manufacturers.

II. THE SUPREME COURT'S PREEMPTION DICHOTOMY

One may easily consider the astounding seventy-five percent rate at which generic pharmaceuticals are used to fill prescriptions⁹³ an indication that Hatch-Waxman works as intended. Estimates show that the availability of generic drugs save consumers between eight and ten billion dollars each year.⁹⁴ However, as with all products—particularly healthcare-related products—consumers occasionally experience adverse effects that result from the use of the product. In the case of pharmaceuticals, state and federal statutes require manufacturers to alert consumers to all known dangers of using the drug by describing the potential adverse effects on the label of the drug's packaging, and impose sanctions for inadequate labels or misbranding.⁹⁵

The following three Supreme Court decisions construe the relationship between state and federal labeling laws. *Wyeth v. Levine* held that the FDCA did not preempt state law failure-to-warn claims against brand-name manufacturers.⁹⁶ However, two years later, in *PLIVA, Inc. v. Mensing*, the Supreme Court concluded that FDA labeling requirements preempt the same claims when brought against a generic manufacturer.⁹⁷ *Mutual Pharmaceutical Co. v. Bartlett* extended *Mensing* with respect to state tort claims that allege defective design due to inadequate warnings.⁹⁸ Each of these cases is discussed in greater detail below,⁹⁹ followed by an explanation of the

93. See *supra* note 67 and accompanying text.

94. Stoddart, *supra* note 22, at 1975.

95. See, e.g., N.Y. EDUC. LAW §§ 6811-a (McKinney 2014), 6815 (McKinney 2014); MINN. STAT. ANN. §§ 151.212, 151.36 (West 2014); see also 21 U.S.C. § 355(b)(1)(F), (j)(2)(v) (2012).

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

97. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577 (2011).

98. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013).

99. Since the *Mutual* decision, the Supreme Court was once more called upon to interpret many of the provisions of the Hatch-Waxman Amendments discussed in Part I. See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013). However, *Actavis* was an antitrust opinion holding that reverse settlement payments between generic and brand-name manufacturers, while not presumptively unlawful, may

untenable dichotomy created when one evaluates the combination of the three holdings. Prior to delving into the cases, however, it will be useful to explain the Supreme Court's preemption jurisprudence in greater detail.

A. *The Law of Impossibility Preemption*

The Supremacy Clause of the U.S. Constitution designates federal law “the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.”¹⁰⁰ When it is impossible for a private party to follow the requirements of both federal and state law, federal law controls—and preempts—state law.¹⁰¹ Congress may expressly provide that a statute is intended to preempt any contrary state laws or regulation—this is the easy case of express preemption.¹⁰² In the absence of express language, preemption may nonetheless exist either where state law is in direct conflict with federal law¹⁰³ or where the scope of a federal statute indicates that Congress intended that federal law exclusively occupy that field.¹⁰⁴ The former is known as conflict preemption; the latter, field preemption.¹⁰⁵ To decide whether the aforementioned impossibility exists, the question is “whether the private party could do independently under federal law what the state requires of it.”¹⁰⁶ If the answer is no, then federal law preempts state law and controls the outcome of the lawsuit.¹⁰⁷ This is known as “impossibility

nonetheless violate the antitrust provisions of the Sherman Act. *Id.* at 2232–33, 2238. The Supreme Court thus reversed the Court of Appeals for the Eleventh Circuit and held that the FTC's suit against Actavis should have been allowed to proceed. *Id.* at 2227.

100. U.S. Const., art. VI, cl. 2.

101. See, e.g., *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (citing *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)).

102. See Susan J. Stabile, *Preemption of State Law by Federal Law: A Task for Congress or the Courts?*, 40 VILL. L. REV. 1, 5 (1995) (“Express preemption occurs where a statute contains an explicit statement that addresses the preemptive effect of the statute on state law claims, rather than leaving it to the courts to decide in any given dispute whether the federal statute preempts state law.”).

103. Peter H. Schuck, *FDA Preemption of State Tort Law in Drug Regulation: Finding the Sweet Spot*, 13 ROGER WILLIAMS U. L. REV. 73, 80 (2008).

104. *Freightliner*, 514 U.S. at 287 (citing *English*, 496 U.S. at 78–79).

105. Schuck, *supra* note 103, at 80.

106. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2579 (2011) (citing *Wyeth v. Levine*, 555 U.S. 555, 573 (2009)).

107. *Id.* (citing *Wyeth v. Levine*, 555 U.S. at 573 (finding no preemption where the defendant could “unilaterally” do what state law required)).

preemption.”¹⁰⁸

Each of the following cases turns on the Supreme Court’s application of impossibility preemption to *state law* products-liability claims. An easy means for generic drug consumers to avoid the preemptive effect of federal law would therefore appear to be to sue under *federal* products-liability law. This solution is foreclosed, however, because there is no federal products-liability law.¹⁰⁹ Opponents of the creation of federal products-liability law argue that creating federal products-liability law would result in (1) a lack of uniformity in application of federal law across jurisdictions, and (2) a violation of federalism principles.¹¹⁰ Thus, plaintiffs who seek to recover for their injuries must necessarily turn to state laws in bringing a lawsuit.

The lack of any set of federal products-liability laws strongly indicates that Congress did not intend for federal law to supplant state law in this area, and FDA statutes and regulations do not address tort liability against manufacturers.¹¹¹ The FDA is, rather, a “gatekeeper” that supervises the marketability of drugs and devices, but does not undertake to impose liability for adverse effects of marketed products.¹¹² Nonetheless, conflict may exist between federal law—codified in the FDCA—and various state products-liability laws. In this situation, impossibility preemption determines the result. The cases described in the succeeding sections demonstrate the varied application of impossibility preemption to the issues with drug labeling. While *Wyeth* held

108. *Id.*

109. *Moe v. Avions Marcel Dassault-Breguet Aviation*, 727 F.2d 917, 932 (10th Cir. 1984).

110. *Hanson v. Williams Cnty.*, 389 N.W.2d 319, 341 n.16 (N.D. 1986) (Erickstad, C.J., dissenting) (“Bills before Congress [to enact federal products-liability laws], however, have experienced little success. Some of this failure may be partially due to the lobbying efforts made by the National Conference of State Legislatures, American Bar Association, and the Conference of Chief Justices which have argued that a federal products liability law would violate the principles of federalism, promote confusion not uniformity, and ‘will disrupt practices and procedures that have been simplified and will require every state to begin again.’”) (citing Frumer & Friedman, 2A *Products Liability*, § 16DD.01).

111. See Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 *YALE J. HEALTH POL’Y L. & ETHICS* 587, 607 (2005) (“[T]here is no private right of action for violation of requirements imposed by the Food, Drug, and Cosmetic Act (FDCA).”).

112. This gatekeeping role has been referred to as “an elaborate system of *prior* restraint.” See *id.* at 587 (emphasis added).

preemption did not apply, that decision nonetheless laid the groundwork for the unfortunate application of the doctrine to the facts of *Mensing* and *Bartlett*.

B. State Law Claims Against Brand-Name Manufacturers Are Not Preempted Under Wyeth v. Levine

Diana Levine had her right forearm amputated as a result of developing gangrene after using the drug Phenergan,¹¹³ a brand-name, anti-nausea medication developed and marketed by Wyeth, Inc.¹¹⁴ Levine sued Wyeth under Vermont law, alleging that Wyeth failed to adequately warn consumers of the risk of administering Phenergan using an “IV-push” method into an artery.¹¹⁵ While the drug’s label did “warn of the danger of gangrene and amputation following inadvertent intra-arterial injection,”¹¹⁶ a jury found that this label inadequately stated the foreseeability of this risk and awarded Levine a total award of \$7,400,000.¹¹⁷ After an unsuccessful appeal to the Vermont Supreme Court,¹¹⁸ Wyeth appealed the issue to the United States Supreme Court, arguing that federal labeling regulations preempted Vermont’s statute.¹¹⁹

Wyeth argued that “it would have been impossible for [the company] to comply with the state law duty to modify Phenergan’s labeling without violating federal law.”¹²⁰ The manufacturer pointed to a federal regulation¹²¹ that required

113. *Wyeth v. Levine*, 555 U.S. 555, 558–59 (2009).

114. *Id.* at 559.

115. *Id.*

116. *Id.* at 559–60.

117. This amount was later reduced to account for earlier settlements with the health center and administering clinician. *Id.* at 562.

118. After the verdict, and on appeal, the Vermont Supreme Court affirmed the trial court’s denial of Wyeth’s motion for judgment as a matter of law, reasoning that the jury’s verdict “did not conflict with FDA’s labeling requirements for Phenergan because [Wyeth] could have warned against IV-push administration without prior FDA approval, and because federal labeling requirements create a floor, not a ceiling, for state regulation.” *Id.* at 562 (quoting *Levine v. Wyeth*, 944 A.2d 179, 184 (Vt. 2006)).

119. *Wyeth*, 555 U.S. at 562.

120. *Id.*

121. *Id.* at 568 (citing 21 C.F.R. § 314.105(b) (2008) (“FDA will approve an application and issue the applicant an approval letter on the basis of draft labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to

FDA approval of the “exact text in the proposed label.”¹²² Wyeth also referenced its continuous interaction with the FDA regarding Phenergan’s label, noting that, in 1988, after the FDA suggested different warnings about the risk of arterial exposure in IV-push administration, Wyeth sent a proposed revision to the label but never received a response from the FDA.¹²³ Several years later, the FDA “instructed [Wyeth] to ‘[r]etain verbiage in current label,’” without mentioning the 1988 submission.¹²⁴ A 1998 instruction to Wyeth further mandated that the language on Phenergan’s final label be identical to the previously approved language.¹²⁵

The Supreme Court rejected this argument and reasoned that, despite these interactions, Wyeth could have changed its label without FDA approval upon newly acquired information about the drug’s IV-push safety risks, by utilizing the CBE process.¹²⁶ The majority opinion clarified that the manufacturer, not the FDA, is responsible for labeling its products,¹²⁷ and that Wyeth had a duty to provide adequate warning of the risk of the IV-push administration method, regardless of whether it first consulted with the FDA.¹²⁸

Wyeth’s second argument—that to require manufacturers’ compliance with state law duties “would obstruct the purposes and objectives of federal drug labeling regulation”—similarly fell flat.¹²⁹ A textual reading of the federal regulations revealed no explicit provision that mandated preemption.¹³⁰ Coupled with the Supreme Court’s belief that Congress intended to allow state tort suits against manufacturers that complied with

marketing.”).

122. *Id.* at 568.

123. *Id.* at 561–62.

124. *Id.* at 562 (second alteration in original).

125. *Id.*

126. *Id.* at 570.

127. “[T]hrough many amendments to the FDCA and to FDA regulations, it has remained a central premise of the federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with creating an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market.” *Id.* at 570–71 (citing 21 C.F.R. § 201.80(e) (requiring a manufacturer to revise its label ‘to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug’); 21 C.F.R. § 314.80(b) (placing responsibility for post-marketing surveillance on the manufacturer)).

128. *Wyeth*, 55 U.S. at 571.

129. *Id.* at 573.

130. *Id.* at 574–76.

FDA regulations, the lack of any express preemption language meant that federal law did not preempt Vermont's laws that governed pharmaceutical warnings.¹³¹

C. State Law Claims Against Generic Manufacturers Are Preempted Under PLIVA, Inc. v. Mensing

While federal law did not preempt state law in *Wyeth*, the decision did create “a sea change in the way courts are to consider issues of federal preemption.”¹³² In the wake of this “sea change” arose the question of whether FDA regulations preempted a state law failure-to-warn claim against a *generic* manufacturer.¹³³ In a 5–4 opinion, the Supreme Court held that it was impossible for generic manufacturers to comply with both state failure-to-warn laws¹³⁴ and the Hatch-Waxman labeling provision.¹³⁵ The rationale for the different results in *Wyeth* and *PLIVA* stems primarily from the fact that “brand-name and generic drug manufacturers have different federal drug labeling duties.”¹³⁶ Specifically, while a brand-name manufacturer may unilaterally strengthen its label,¹³⁷ a generic manufacturer may not.¹³⁸

The injured plaintiffs argued that the CBE process¹³⁹ allows *any* manufacturer to change its label when necessary,¹⁴⁰ since the regulatory language states that “the holder of an approved application may . . . add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,” without waiting for FDA preapproval.¹⁴¹ The FDA, however, disagreed and argued that the CBE regulation allows a generic manufacturer to engage in

131. *Id.* at 574–81.

132. *Mason v. Smithkline Beecham Corp.*, 596 F.3d 387, 389 (7th Cir. 2010).

133. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011).

134. The state laws at issue were those of Minnesota and Louisiana. *Id.* at 2573.

135. *Id.* at 2577.

136. *Id.* at 2581. *See also supra* Part I.C.2.

137. *See Lee, supra* note 85, at 213.

138. Generic manufacturers “[are] responsible for ensuring that [their] warning label is the same as the brand name’s,” and “have an ongoing federal duty of ‘sameness.’” *Mensing*, 131 S. Ct. at 2574–75. *See also supra* note 91 and accompanying text.

139. *Supra* Part I.C.2.

140. *Mensing*, 131 S. Ct. at 2575.

141. 21 C.F.R. § 314.70(c)(6)(iii)(C) (2014).

such labeling changes *only* when it updates its label to match the brand-name label.¹⁴² The Supreme Court deferred to the agency's interpretation¹⁴³ and subsequently ruled that none of the generic manufacturers involved in the suit could have used the CBE process to strengthen the drug's label.¹⁴⁴

Recall that where it is impossible for a party to simultaneously comply with both federal and state law, federal law preempts the law of the state.¹⁴⁵ Federal regulations in this instance completely prevented the generic manufacturers from unilaterally strengthening the drug's label, yet the states' laws simultaneously required such strengthening by *all* manufacturers.¹⁴⁶ The Supreme Court therefore reasoned that impossibility preemption must decide the case, and applied federal law without regard to the state's failure-to-warn laws.¹⁴⁷

Mensing thus rendered state failure-to-warn claims inapplicable against generic manufacturers.¹⁴⁸ When it compared the result in *Mensing* with the result in *Wyeth*, the Supreme Court conceded that "finding preemption here but not in *Wyeth* makes little sense," since the difference in the result of each case turned entirely on whether the consumer had used the generic or brand-name version of the drug.¹⁴⁹ This concession foreshadowed the possibility that the Supreme Court might consider revisiting the result in *Mensing*. Such an

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

143. In doing so, the Court cited to *Auer v. Robbins*, which held that agency interpretations are "controlling unless 'plainly erroneous or inconsistent with the regulation[s]'" or if "the interpretation does not reflect the agency's fair and considered judgment on the matter in question." 519 U.S. 452, 461-62 (1997) (quoting *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 359 (1989)).

144. *Mensing*, 131 S. Ct. at 2575-76.

145. See *supra* notes 106-107 and accompanying text.

146. *Mensing*, 131 S. Ct. at 2577-78.

147. *Id.* at 2577-79. Justice Thomas rejected the argument that the Court's preemption analysis failed because the generic manufacturer could have changed the label if the FDA agreed that such a change was necessary. *Id.* To allow the result to turn on the mere *possibility* of the FDA's agreement, he wrote, would render the Supremacy Clause and preemption meaningless. *Id.* Furthermore, Justice Thomas stated, "[w]e do not think the Supremacy Clause contemplates that sort of contingent supremacy." *Id.* at 2580.

148. Stoddart, *supra* note 22, at 1981.

149. *Mensing*, 131 S. Ct. at 2581. Nonsensical though the outcome of *Mensing* may have been, the Court defended its decision by stating that "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." *Id.* at 2582. (quoting *Cuomo v. Clearing House Ass'n.*, 557 U.S. 519, 556 (2009)).

opportunity arose not long after, in *Mutual Pharmaceutical Co. v. Bartlett*.¹⁵⁰

*D. Mutual Pharmaceutical Co. v. Bartlett Extends
Mensing to Design-Defect Claims*

Bartlett dealt with a design-defect (rather than failure-to-warn) claim brought under New Hampshire law.¹⁵¹ After taking a generic version of the drug sulindac, Karen Bartlett began to suffer from toxic epidermal necrolysis, which burned off the majority of her skin.¹⁵² Comparing Bartlett's case to *Mensing*, the United States Court of Appeals for the First Circuit held that neither the FDCA nor FDA regulations preempted the design-defect claim, since "manufacturers facing [such] claims could simply 'choose not to make the drug at all' in order to comply with both state and federal law."¹⁵³

The Supreme Court feared that this "stop-selling" remedy would render preemption a moot point, and reversed the First Circuit, holding again that impossibility preemption shielded the generic manufacturers from liability.¹⁵⁴ The New Hampshire design-defect law required manufacturers to change a drug's design or label upon a finding that the drug is "unreasonably dangerous."¹⁵⁵ Because this law conflicted directly with the FDCA provisions that require generic drugs to mimic brand-name drugs, the manufacturers were only required to comply with the federal provisions.¹⁵⁶

In considering *Bartlett* and *Mensing* together, a stark practical reality becomes clear: alleged injuries that result from consumption of *generic* drugs are not subject to the same tort principles under state laws as those that result from

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

151. *Id.* at 2470.

152. *Id.* at 2472.

153. *Id.* at 2472 (quoting *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 37 (1st Cir. 2012)).

154. *Bartlett*, 133 S. Ct. at 2477 (stating that a "stop-selling" rationale is incompatible with our preemption jurisprudence," and "[o]ur preemption cases presume 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.").

155. *Id.* at 2474.

156. The FDCA provisions, referred to as the "sameness" provisions, require the generic drug to have "the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." *Id.* at 2475 (citing 21 U.S.C. § 244(j)(2)(A)(ii)-(iv)).

consumption of *brand-name* drugs. Unlike their brand-name consumer counterparts, consumers of the generic drug are thus without remedy under failure-to-warn and design-defect laws. There is, accordingly, an unfair and untenable dichotomy that results from a physician's choice (or, in some cases, obligation)¹⁵⁷ to allow his or her patient's prescription to be filled with the generic version of a drug. Several authors have recognized a number of direct and collateral consequences of this dichotomy, and have proposed various ways to solve the problem. These consequences and solutions are the focus of Part III.

III. THE PROBLEM: CONSUMERS WITHOUT REMEDY

Given the increasing number of pharmaceutical prescriptions filled with generic pharmaceuticals,¹⁵⁸ an increasing number of consumers of these drugs will find themselves without legal remedy or any hope of compensation for adverse side effects that result from the generic manufacturer's failure to warn or defective design. However, if these consumers were explicitly prescribed, or chose to pay more for, the brand-name version of the drug, remedies *would* be available under the exact same failure-to-warn and design-defect theories. The *Mensing* dissent, authored by Justice Sonia Sotomayor, referred to this unfortunate dichotomy of results as "arbitrary."¹⁵⁹ Justice Sotomayor explained that Congress could not possibly have intended such a discrepancy and – that the majority's only rationale for the result was impossibility preemption.¹⁶⁰ She is correct. Rep. Henry Waxman, a named sponsor of the Hatch-Waxman Amendments, stated, "[a]s a matter of policy, Congress . . . did not intend such an outcome. Nothing in the legislative history of the Amendments manifests any congressional intent to leave consumers of generics without any remedy in the event of injury."¹⁶¹ Dean Erwin Chemerinsky emphasized that "preemption analysis is always

157. A physician may be obligated under state drug substitution laws to permit a prescription to be filled with a generic version of a drug. *See supra* notes 62, 68 and accompanying text.

158. Stoddart, *supra* note 22, at 1975.

159. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2592–93 (2011) (Sotomayor, J. dissenting).

160. *Id.* at 2592–93.

161. Waxman Amicus Brief, *supra* note 34, at 9.

a question of legislative intent,"¹⁶² and referred to the *Mensing* decision as "devastating" and "nonsensical."¹⁶³ While each of these critiques holds merit, critiques alone cannot rectify this discrepancy. Prior to addressing several previously proposed solutions, this Part first discusses some stark and unintended consequences that may result from the *Levine-Mensing* dichotomy.¹⁶⁴ The next several sections critique existing proposals to solve the dichotomy, demonstrate that these proposals do not adequately address the problems at hand, and explain why this problem requires a more forceful and thoughtful solution.

A. *Direct and Collateral Risks of the Levine-Mensing Dichotomy*

Besides the myriad problems consumers of generic drugs will face in bringing lawsuits against drug manufacturers, they risk facing a number of other undesirable results if no action is taken to rectify the *Levine-Mensing* dichotomy.¹⁶⁵ One such result is that both types of manufacturers will lack incentive to modify their labels in a timely fashion.¹⁶⁶ This risk may be mitigated somewhat by the fact that brand-name manufacturers must modify their labels because they owe a duty of care to the consumers of the brand-name drug. However, when generic manufacturers, who are not subject to the same strict labeling duties, begin to reproduce the drug, a significant subset of pharmaceutical consumers will lack any legal remedy if they are injured by the generic drug.¹⁶⁷

Mensing may also lead to a decrease in drug substitution, as physicians, pharmacists, and consumers, who know that recovery is precluded if certain adverse effects of the drug were to afflict the consumer, may stop taking advantage of drug substitution laws.¹⁶⁸ Upon facing similar pressures, states may

162. Erwin Chemerinsky, *Supreme Court Review: A Devastating Decision*, 47 TRIAL 54, 56 (2011).

163. *Id.* at 54, 55.

164. A term borrowed from scholar Breanna Jenny. Breanna Jenny, *Recent Developments in Health Law: Did Failure-to-Warn Claims Against Generic Manufacturers Survive Mensing?*, 40 J. L. MED. & ETHICS 165, 165 (2012).

165. *See supra* Part III.

166. Stoddart, *supra* note 22, at 1996–97; Lee, *supra* note 85, at 243.

167. Stoddart, *supra* note 22, at 1996–97; Lee, *supra* note 85, at 243. *See also supra* Part II.D.

168. Kazhdan, *supra* note 8, at 913–15 (2012); *see also* PLIVA, Inc. v. *Mensing*,

choose to alter or repeal their current drug substitution laws.¹⁶⁹ For instance, Maine's current drug substitution statute expressly requires the pharmacist to consider the generic manufacturer's ability to be sued before authorizing a substitution.¹⁷⁰ Other states may choose to follow Maine's lead, preferring decreased drug substitutions to leaving certain consumers with no remedy.

Insurance companies may also be unwilling to cover generic drugs, in which case the cost of healthcare coverage will increase, as patients are made to spend more for the brand-name drug. When faced with this situation, studies show people often choose not purchase the drug at all.¹⁷¹ Under the Patient Protection and Affordable Care Act (PPACA), prescription drugs are an "essential health benefit," which means that more Americans than ever will have insurance coverage for their prescriptions, and it is imperative that this coverage be affordable.¹⁷² Regardless of the underlying reason, a nationwide decrease in drug substitution could mean a reversion to the state of affairs that led to the passage of the Hatch-Waxman Amendments, where the price of drugs skyrocketed due to the lack of any competition by generic drug manufacturers.¹⁷³

As several legal scholars recognize, a solution to the "Levine-Mensing dichotomy" is necessary. Among the previously proposed solutions are (1) permitting suits to go forward directly against the brand-name company,¹⁷⁴ (2) giving

131 S. Ct. 2567, 2593 (2011) (Sotomayor, J. dissenting).

169. Kazhdan, *supra* note 8, at 915-16.

170. *Id.* See also ME. REV. STAT. tit. 32, § 13781 (2014) ("any pharmacist receiving a prescription [that does not specifically require a brand-name drug] shall substitute a generic and therapeutically equivalent drug for the drug specified in the prescription if the substituted drug is distributed by a business entity doing business in the United States that is subject to suit . . . in the United States.") (emphasis added).

171. Kazhdan, *supra* note 8, at 913. There are two primary reasons why drug substitution is good for healthcare: it lowers the cost to society of healthcare, generally, and encourages patients to follow their prescribed drug regimen. *Id.* See also Shrank et al., *Consequences*, *supra* note 61, at 311, 313. "When substitution is forbidden, the chance that patients will not purchase a drug at all increase by 42% and the chances that a patient will not refill a prescription increase by 61% as compared with prescriptions where substitution is permitted." Shrank et al., *Consequences*, *supra* note 61, at 313.

172. See Lee, *supra* note 85, at 239.

173. See H.R. REP. NO. 98-857, at 16-17 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2649-50.

174. See Kazhdan, *supra* note 8 (proposing permitting consumers injured by

generic manufacturers the ability to unilaterally alter drug labels,¹⁷⁵ or (3) simply avoiding failure-to-warn claims by invoking other tort theories.¹⁷⁶ The following sections consider these proposals, examine their strengths and weaknesses, and ultimately conclude that each proposal would be ineffective or unacceptably time-consuming in light of the many collateral effects of this dichotomy.

B. Allow Suits to be Brought Directly Against Brand-Name Manufacturers

Perhaps among the more simple and obvious solutions is for courts to recognize suits brought against the brand-name manufacturer by plaintiffs injured by the generic drug. While convenient, this approach is often neither possible nor desirable.¹⁷⁷ Several years before *Wyeth, Mensing, and Bartlett*, the United States Court of Appeals for the Fourth Circuit held in *Foster v. American Home Products Corp.*¹⁷⁸ that a brand-name manufacturer could not be held liable to a consumer for injuries that resulted from the consumer's use of the generic product.¹⁷⁹ This outcome was based in part on the court's ruling that generic manufacturers *could* alter a drug's label "without prior FDA approval."¹⁸⁰ Notwithstanding *Mensing's* clarification that generic manufacturers are simply unable to unilaterally alter their label,¹⁸¹ courts have approved of the *Foster* holding with surprising consistency and likewise have held that generic drug consumers have no cause of action

generic drugs to sue the brand-name manufacturer directly).

175. See Stoddart, *supra* note 22, at 1990 (proposing allowing generic manufacturers to unilaterally alter their labels).

176. See Jenny, *supra* note 164, at 165.

177. For some critiques of this approach, see *infra* notes 194–96 and accompanying text.

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

179. *Id.* at 167.

180. *Id.* Besides arguing that a generic manufacturer cannot unilaterally alter labels, the plaintiffs also claimed that Wyeth (the brand-name manufacturer) was aware of this fact, and should therefore be held liable for failure to strengthen or otherwise alter the drug's label. *Id.* The court rejected this argument, holding that "[t]here is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control." *Id.* at 170. See also 21 C.F.R. § 314.70(c)(2) (2014).

181. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577–78 (2011).

against brand-name manufacturers.¹⁸² Nearly all of these decisions are premised on the idea that the brand-name manufacturer has no relationship, and therefore, no duty of care¹⁸³ to consumers of generic drugs.¹⁸⁴

On the other hand, the argument for allowing such suits is simple: since generic drug manufacturers depend on the brand-name drug manufacturers to alter the drug's label, if the brand-name manufacturer does not change its label, generic manufacturers have no duty (and in fact, it would be impossible) to do so on their own.¹⁸⁵ Two courts have adopted this principle to permit suits by generic drug consumers against brand-name manufacturers; both decisions were premised on facts similar to *Mensing*.¹⁸⁶ In *Conte v. Wyeth*, a California appellate court held that Wyeth, the brand-name manufacturer of Reglan,¹⁸⁷ in fact owed a duty of care to all consumers, including users of the generic versions of the drug.¹⁸⁸ As the original manufacturer, Wyeth was the only

182. See, e.g., *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 540 (E.D. Pa. 2006), *vacated*, 129 S. Ct. 1578 (2009) (“[A] review of case-law reveals that every state and federal district court which has confronted the issue of innovator drug-manufacturer liability has either adopted the *Foster* reasoning or cited *Foster* with approval.”).

183. “Duty of reasonable care” is a principle of tort law that states that the manufacturer of a product owes a legal duty of due care to those affected by the use of the product. See *Straley v. Calongne Drayage & Storage, Inc.*, 346 So. 2d 171, 176 (La. 1977). Liability will be imposed where the manufacturer failed to employ reasonable care to eliminate foreseeable dangers and thus subjected the product's user to an unreasonable risk of injury. See *Haglund v. Philip Morris, Inc.*, 847 N.E.2d 315, 322 n.9 (Mass. 2006).

184. *Stoddart*, *supra* note 22, at 1985–86.

185. See *Wyeth v. Levine*, 555 U.S. 555, 570–71 (2009); see also *Kazhdan*, *supra* note 8, at 924.

186. Elizabeth Conte developed tardive dyskinesia upon consumption of the generic version of Wyeth's drug Reglan® (metoclopramide), manufactured by Purepac Pharmaceutical Company, Teva Pharmaceutical USA, Inc., and PLIVA, Inc. *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299, 305 (Cal. Ct. App. 2008). She alleged that the manufacturers, including Wyeth, knew or should have known of the risk of using the drug consecutively for more than one year, and that by not warning physicians of the danger or enhancing the drug's label to reflect the danger, were liable under California's failure-to-warn law. *Id.* Ethel Kellogg also developed tardive dyskinesia after more than four years of using the drug. *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 698 (D. Vt. 2010). She relied solely on information from her physicians regarding the potential side effects of metoclopramide. *Id.*

187. The active ingredient, and generic name of Reglan, is metoclopramide. U.S. FOOD & DRUG ADMIN., MEDICATION GUIDE: REGLAN 4 (June 2009), available at <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM176362.pdf>, archived at <http://perma.cc/D3J6-HHVK>.

188. A decision that the court deemed “rooted in common sense and California

entity able to strengthen its drug's warning label.¹⁸⁹ Furthermore, the court held that Wyeth knew or should have known of the likelihood that a large number of patients would be prescribed generic metoclopramide.¹⁹⁰ Wyeth therefore should have foreseen the risk that would arise from not changing Reglan's label.¹⁹¹ Like the *Conte* court, the court in *Kellogg v. Wyeth* held that a brand-name firm could be responsible for injuries that resulted from the consumption of a generic drug.¹⁹² The *Kellogg* decision was based on the foreseeability of the risk to consumers of *any* version of the drug.¹⁹³

Much criticism of these decisions centers on the idea that extending foreseeability to the brand-name manufacturer "would push the concept of foreseeability too far."¹⁹⁴ Federal and state courts¹⁹⁵ have largely emphasized that products-liability law allows plaintiffs to sue only the producer of the product that allegedly caused the injury.¹⁹⁶ To allow otherwise would be tantamount to forcing one manufacturer to pay for the "sins" of another,¹⁹⁷ when the brand-name manufacturer had no control over the production of the generic manufacturer's drug.¹⁹⁸ *Conte* and *Kellogg* are exceptions,

common law." *Conte*, 168 Cal. App. 4th at 102.

189. See *supra* notes 90–91 and accompanying text.

190. *Conte*, 168 Cal. App. 4th at 107.

191. The *Conte* court applied a standard of foreseeability that states that a duty "extends to any person who, in the course of an activity which is in furtherance of his own interests, undertakes to give information to another, and knows or should realize that the safety of the person or others may depend on the accuracy of the information." *Id.* at 104 (quoting *Garcia v. Superior Ct.*, 50 Cal.3d 728, 735 (Cal. 1990)).

192. *Kellogg*, 762 F. Supp. 2d 708–09.

193. *Id.* at 706. The drug in question was again metoclopramide. *Id.* at 697–98.

194. Stoddart, *supra* note 22, at 1991.

195. See, e.g., *Meade v. Parsley*, No. 2:09-cv-00388, 2009 WL 3806716 (S.D. W. Va. Nov. 13, 2009); *DaCosta v. Novartis AG*, 242 F. Supp. 2d 765 (D. Or. 2002); *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586 XXX MB, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009); *Huck v. Trimark Physicians Grp.*, No. LACV018947, 2009 WL 3760458 (Iowa Dist. Ct. Feb. 27, 2009).

196. Victor E. Schwartz, et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 *FORDHAM L. REV.* 1835, 1860 (2013).

197. *Id.* at 1837 (explaining that, in questioning whether tort law allows for a company to be liable for its competitors' activities, "American tort law has always said, 'No.' Companies are not their competitors' keepers; Peter does not pay for the alleged sins of Paul.").

198. See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) ("There is no legal precedent for using a name brand manufacturer's statements

rather than the rule,¹⁹⁹ and in view of traditional principles of products-liability law,²⁰⁰ the rule makes sense.

This proposal, then, must ultimately fail, because permitting generic manufacturers to be liable for the sin of the brand-name manufacturer's inadequate labeling would contravene the purposes of products-liability law and the general interpretation of these laws at the federal and state level. While this Comment's proposal below argues that, in many circumstances, the brand-name manufacturer ought to be responsible for the injuries to a generic drug consumer, permitting suits by generic drug consumers to go forward *directly* against brand-name manufacturers in all circumstances unacceptably distorts the concepts of duty of care and foreseeability. Such a solution may also discourage brand-name manufacturers from continuing to sell their products in the marketplace after the drugs' patent terms expire, or from creating new drugs and entering the marketplace at all.²⁰¹

C. Allow Generic Manufacturers to Unilaterally Change a Drug's Label

Multiple authors who address this incongruence of results propose that FDA regulations be amended to allow generic manufacturers to use the CBE process independently of FDA approval and without having to follow the brand-name manufacturer.²⁰² Admittedly, permitting generic

about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control.").

199. Schwartz et al., *supra* note 196, at 1837-38.

200. One justification for strict liability law, including products liability, is that the seller assumes a certain responsibility toward consumers of his or her product who are injured while using it: "[P]ublic policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained . . ." *Id.* at 1861. However, strict liability also seeks to limit the scope of its effects to the direct manufacturer of the product. *Id.* at 1860.

201. Schwartz et al., *supra* note 196, at 1970-71. Not only will "the fear of such liability . . . likely drive many brand-name manufacturers from a drug's market once it becomes available in generic form . . . it will become riskier for brand-name manufacturers to dedicate resources to researching and developing potentially life-saving or life-improving medicines . . ." *Id.*

202. See, e.g., Stoddart, *supra* note 22, at 1993; see also Kazhdan, *supra* note 8,

manufacturers to unilaterally strengthen or modify their drug labels would render the *Mensing* holding moot.²⁰³ If this change were instituted, consumers harmed by generic drugs could sue the generic manufacturer for failure to warn, and these claims would likely not be preempted.²⁰⁴ However, an analysis of the legislative intent of Hatch-Waxman reveals that generic use of the CBE process is undesirable as a matter of both FDA oversight and approval.²⁰⁵

Recall that the ANDA process is designed to expedite the entry of generic drugs into the pharmaceutical marketplace in order to provide patients with relatively inexpensive treatment options.²⁰⁶ To meet this goal, an ANDA applicant need only show that its drug mimics the brand-name drug.²⁰⁷ The “federal duty of ‘sameness’” imposed on generic manufacturers is “ongoing,” meaning that it does not end upon FDA approval of the ANDA, but continues after the generic drug enters the pharmaceutical marketplace.²⁰⁸

The agency is tasked with ensuring the continued safety and effectiveness of every marketed drug and device—this responsibility “is . . . squarely and solely [the] FDA’s.”²⁰⁹ The content of the labeling is one part of this responsibility.²¹⁰ The FDA’s position is that its approval of a label establishes both a “floor” and a “ceiling” on liability associated with the label.²¹¹ If state tort laws established other requirements, particularly for generic manufacturers, those laws would “frustrate the agency’s implementation of its statutory mandate.”²¹² Furthermore, a unilateral alteration of a drug’s label without FDA approval does not guarantee that the alteration is

at 919–21.

203. See Stoddart, *supra* note 22, at 1993.

204. *Id.* at 1994.

205. See Requirements on Content and Format Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006); see also Amicus Brief at 25–26; *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-04597) [hereinafter *Thoratec Amicus Brief*].

206. See *supra* Part I.A.

207. See 21 U.S.C. § 355(j)(2)(A)(i)–(v) (2013); see also *Waxman Amicus Brief*, *supra* note 34, at 7.

208. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574–75 (2011) (quoting U.S. Brief 16).

209. 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

210. *Id.* at 3935.

211. *Id.*

212. *Id.* at 3934.

accurate and necessary, or that it improves safety.²¹³ As described above, such guarantees are necessary at the approval stage to allow the ANDA to truly be “abbreviated.” During post-marketing surveillance, these guarantees are no less important, if for no other reason than to further Hatch-Waxman’s purposes by preserving drug substitutions.²¹⁴

Courts are not likely to actively interpret the Hatch-Waxman Amendments and FDA’s labeling regulations in a way that will run contrary to the agency’s judgment on the matter.²¹⁵ The judiciary has often held that its role in administrative law in this context is to defer to an agency’s interpretations of its own regulations.²¹⁶ Allowing generic manufacturers to unilaterally change their labels would undermine both the FDA’s regulatory authority²¹⁷ and the purposes of Hatch-Waxman. Furthermore, it would create an undesirable result. If a generic manufacturer were to unilaterally modify its label without either the brand-name manufacturer’s or the FDA’s approval, physicians could not assure their patients that the new warning was accurate. Many

213. See *id.* at 3935 (“In fact, FDA interprets the [A]ct to establish both a ‘floor’ and a ‘ceiling,’ such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading. Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the [A]ct, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use.”). See 54 Fed. Reg. 28,872, 28,884 (1989) (stating that the intention of 21 U.S.C. § 355(j), governing ANDA submissions, is “to assure the marketing of generic drugs that are *as safe and effective as their brand-name counterparts*”) (emphasis added).

214. See *supra* Part I:C.1.

215. Interestingly, the FDA has made explicit its belief that “FDA approval of labeling . . . preempts conflicting or contrary State law. Indeed, the Department of Justice (DOJ), on behalf of the FDA, has filed a number of amicus briefs making this very point.” 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006).

216. See *supra* note 143 and accompanying text. While it is true that regulations could later change, as could the FDA’s current thinking on the subject, such a change would have the severe consequence of pushing back up the cost of pharmaceuticals, resulting from a decrease in drug substitution. See *infra* note 218 and accompanying text.

217. The FDA believes that state law tort awards to plaintiffs encourage “defensive labeling” by manufacturers who wish to comply with state laws, including the addition of warnings that FDA has not approved or found necessary, or removal of FDA-approved drugs and devices from the market despite the “agency’s expert determination” that the products are safe and effective. Thoratec Amicus Brief, *supra* note 205, at 25–26.

physicians may even block substitution of the generic for the brand-name drug,²¹⁸ meaning the patient must either pay more for the brand-name drug or not have it at all. To paraphrase Justice Clarence Thomas in *Mensing*,²¹⁹ we should not let the decision of whether to maintain lower drug prices turn on the *possibility* that FDA will change its mind.

Deference to the agency's position on labeling requirements should not be read to suggest, however, that generic firms are not responsible for monitoring post-market adverse reactions to the drugs. In fact, Representative Waxman himself relied upon the existence of this responsibility when he argued that generic manufacturers *ought* to be liable under failure-to-warn claims.²²⁰ Still, Representative Waxman was only partially correct. The category of failure-to-warn claims he identifies would be viable only in the limited instance where a generic manufacturer failed to provide vital post-marketing information to the FDA.²²¹ The claim's limited applicability does not cover instances in which a generic manufacturer complied with this duty but was nonetheless unable to strengthen its drug label accordingly due to disagreement or inaction by the FDA or the brand-name firm. Under *Mensing*, it is precisely in these instances that an injured generic drug consumer finds him or herself completely out of luck; he or she cannot sue the generic manufacturer because the Supreme Court determined that it would be impossible for the manufacturer to simultaneously comply with conflicting state and federal laws.

Post-market monitoring must, of course, still be a vital part of a generic manufacturer's responsibilities. However, the existence of this responsibility, without more, does not justify a modification to the regulatory scheme that would give generic manufacturers the unilateral ability to institute moderate label changes. Such a drastic shift would undermine the purposes of requiring "sameness" at *all* stages of a generic drug's lifetime. As this Comment explains, however, this responsibility does form the basis for a less drastic change—the imposition of state

218. Kazhdan, *supra* note 8, at 913–15.

219. *See supra* note 147.

220. *See Waxman Amicus Brief, supra* note 34, at 3–4.

221. *Id.* at 14. ("[I]t is not only possible for a generic manufacturer in possession of important risk information to take steps to notify FDA that a labeling change may be necessary, but it is, in fact, also encouraged and recommended by FDA.")

tort liability on generic manufacturers.²²²

D. Plaintiffs Should Sue Under Theories Other Than Failure-to-Warn

While *Mensing* held only that federal law preempted failure-to-warn claims, it may be the case that “[i]f plaintiffs can advance other theories . . . such as a failure to adequately warn a physician *about* a recent change to the drug’s label,” then a claim may still exist against generic drug manufacturers.²²³ One scholar noted that not *all* failure-to-warn claims levied against generic manufacturers are inherently preempted, only those premised on a duty to change the drug’s label.²²⁴ However, this observation falls flat in light of *Bartlett*.²²⁵ In addition to those failure-to-warn claims premised on a duty to change the drug’s label, *Bartlett* expanded *Mensing*’s rationale to include state law design-defect claims.²²⁶ This is because the “sameness” of a generic drug is not limited to the drug’s label—it also includes the drug’s composition.²²⁷

Furthermore, encouraging plaintiffs to find alternative tort theories on which to premise a claim is not an equitable solution to the problem the dichotomy presents. This is especially so when the plaintiff has no alternative—as in *Mensing*, *Conte*, and *Kellogg*, where the alleged injury was the direct result of the inadequacy of the label.²²⁸ Plaintiffs deserve recovery when they suffer as a result of the statutory regime that precludes a generic manufacturer from improving its labeling when there is information suggesting that the label needs improvement. For one to simply accept that failure-to-warn claims are unavailable does nothing to provide relief for these individuals.

The ideal remedy for consumers who are directly injured

222. See *infra* Part IV.B.1.

223. Jenny, *supra* note 164, at 165.

224. *Id.* at 167.

225. Jenny’s article was written in 2012; the *Bartlett* decision was authored in 2013. See *id.*; *Mut. Pharm. Co. v. Bartlett*, 144 S. Ct. 2466 (2013).

226. *Bartlett*, 144 S. Ct. at 2475.

227. See 21 U.S.C. § 355(j)(2)(A)(ii)–(iv) (2013).

228. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011); *Conte v. Wyeth*, 85 Cal. Rptr. 3d 299, 315 (Cal. Ct. App. 2008); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 701 (D. Vt. 2010).

due to defective labeling is one that does not violate the purposes of Hatch-Waxman, addresses the precise issue at hand, and preserves principles of American tort law. This Comment proposes one statutory change that imposes an assumption of liability on generic manufacturers for faulty labels, and another that permits a defendant generic firm to implead the brand-name firm that pioneered the drug in question, where the drug's label is at issue. The following Part first describes the contours of the impleader rule. Next, it lays the foundation for impleader between the two companies. The final section fully details the proposal, and simultaneously anticipates possible critiques.

IV. A PROCEDURAL SOLUTION: CREATE REGULATIONS THAT PERMIT GENERIC COMPANIES TO IMPLEAD BRAND-NAME COMPANIES

This Comment proposes that a legislative remedy is best suited to improve all consumers injured by generic drugs. While rewriting regulations to allow generic companies to unilaterally change their labels is against the spirit of the Hatch-Waxman Amendments, and bringing suit directly against the brand-name manufacturers is antithetical to American tort law, a combination of these two proposals may yield the necessary change to provide relief for injured generic drug consumers. The following solution is premised on the idea that there is a proper basis to enable the generic firm to implead its brand-name counterpart. However, because generic companies are currently shielded from liability under tort theories that allege defective labeling,²²⁹ they lack any incentive to transfer liability to a third party. No incentive is likely to emerge without a statutory change that eliminates the effects of *Mensing*.

The first proposed step is to amend Hatch-Waxman to subject generic manufacturers to failure-to-warn and design defect claims as a risk of entering the pharmaceutical marketplace. However, to ensure that generic manufacturers are not "paying for the sins"²³⁰ of the brand-name manufacturer, the statutes must be further amended to permit

229. Generic companies are shielded from such liability under *Wyeth, Bartlett*, and *Mensing*. See generally *supra* Part II.

230. See Schwartz et al., *supra* note 196 and accompanying text.

generic companies to implead the brand-name manufacturer of the drug in question. In this way, the injured drug consumer may recover from either the generic or brand-name manufacturer, depending on the particular facts and circumstances of the lawsuit. This ensures the most fair result possible in the face of a difficult and complex legal scenario.

The following section outlines the impleader rule and provide examples of the rule's construction and application. Next, it describes how the rule may be used to hold a brand-name manufacturer liable for injuries suffered by consumers of generic drugs. The final section details how the proposed statutory changes to the Hatch-Waxman Amendments will incentivize generic manufacturers to implead their brand-name counterparts so that plaintiffs are properly compensated for their injuries, and why these changes are desirable as a matter of policy and regulation.

A. *The Impleader Rule: Construction and Application*

The impleader rule, as codified in the Federal Rules of Civil Procedure, authorizes a defendant, "as a third-party plaintiff," to serve a summons and complaint on a non-party, if the defendant believes that the non-party "is or may be liable to it for all or part of the claim against it."²³¹ The purpose of the impleader rule is to consolidate claims of derivative liability, such that when properly used, impleader can "reduce litigation by having one lawsuit do the work of two."²³²

When asserting derivative liability, the impleading party must demonstrate that the liability of the non-party is

231. FED. R. CIV. P. 14(a)(1). All states have adopted some form of the impleader rule, usually containing the same or similar language as the Federal Rule. *See, e.g.*, WIS. STAT. § 812.17 (2014), COLO. R. CIV. P. 14 (2012), VT. R. CIV. P. 14 (2002). However, since most pharmaceutical litigation will meet the diversity requirements of 28 U.S.C. § 1332, federal procedural rules will almost always apply. *See* 28 U.S.C. § 1332 (2012). *Compare* *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938) (holding that federal courts must apply state law) *with* *Guaranty Trust Co. v. York*, 326 U.S. 99 (1945) (holding that despite mandate that federal courts apply state law, in order to avoid litigants' forum shopping, federal procedural rules apply in federal courts). A "claim" is simply "a group of operative facts giving occasion for judicial action." *United States v. Joe Grasso & Son, Inc.*, 380 F.2d 749, 751 (5th Cir. 1967).

232. *Falls Indus., Inc. v. Consol. Chem. Indus., Inc.*, 258 F.2d 277, 283 (5th Cir. 1959).

“dependent upon the outcome of the main claim.”²³³ For example, in *Farmers Production Credit Ass’n of Oneonta v. Whiteman*, the defendant, a local credit association, was permitted to implead the Department of Agriculture (DOA) in a mortgage foreclosure action.²³⁴ The credit association alleged that, but for the DOA’s fraudulent misrepresentations, the credit association would not have entered into the mortgage agreement with the plaintiffs.²³⁵ The trial court agreed, concluding that derivative liability arose from the fact that, had the misrepresentation never occurred, the association would never have been liable to the plaintiffs in the first instance.²³⁶

The impleader rule does not require any relationship between the impleaded party and the original plaintiff. Many defendants mistakenly attempt to implead the third-party defendant on the basis of the third-party defendant’s liability to the *plaintiff*.²³⁷ However, “a third-party defendant may be joined even if the plaintiff could not sue that party directly.”²³⁸ As the following subsection explains, this limitation avoids having to establish a relationship between the impleaded brand-name manufacturer and the injured generic drug consumer.

1. Application of the Impleader Rule to Drug Companies

In view of the requirements of the joinder mechanism and the relationship between generic and brand-name pharmaceutical manufacturers, impleader is a proper means by

233. *Joe Grasso & Son, Inc.*, 380 F.2d at 752.

234. *See Farmers Prod. Credit Ass’n of Oneonta v. Whiteman*, 100 F.R.D. 310, 312 (N.D.N.Y. 1983).

235. *See id.*

236. *See id.* at 313.

237. *See, e.g., Carriere v. Cominco Alaska, Inc.*, 823 F. Supp. 680, 691 (D. Alaska 1993) (holding that impleader not based on admiralty claim may not be based on third-party defendant’s liability to plaintiff); *Frazier v. Harley Davidson Motor Co.*, 109 F.R.D. 293, 294 (W.D. Pa. 1985) (finding impleader improper where there was no allegation that third-party defendant would be liable to any party other than the plaintiff); *Coleman Clinic v. Mass. Mut. Life Ins. Co.*, 698 F. Supp. 740, 747 (C.D. Ill. 1988) (holding that impleader of attorneys who might be liable to plaintiffs was improper).

238. 3 RICHARD D. FREER, *MOORE’S FEDERAL PRACTICE—CIVIL* § 14.04[3][b] (3d ed. 1997).

which a generic manufacturer may join a brand-name manufacturer to the lawsuit. As *Foster* and its progeny have held, a generic drug consumer has no claim against a brand-name drug manufacturer.²³⁹ When impleading, a generic manufacturer does not assert that the brand-name firm is liable to the *plaintiff*. Rather, the brand-name firm will be liable in whole or in part to the generic firm as a result of the plaintiff's claim against the generic firm. The brand-name manufacturer's liability is contingent upon the outcome of the plaintiff's claim against the generic manufacturer. A generic manufacturer will of course argue that, because the brand-name manufacturer did not strengthen or otherwise properly modify the drug's label, the generic manufacturer was precluded from doing so. And under *Mensing*, they would be correct. Some mechanism is therefore needed to initially establish liability from the generic manufacturer to its consumers.²⁴⁰

If and when such liability is established, that liability (even partially) may be transferred to the brand-name company via the impleader. Like the credit union's potential liability for the mortgage default in *Whiteman*,²⁴¹ a generic manufacturer's liability here is a direct result of the brand-name manufacturer's failure to comply with its labeling duties. While in theory this ought to operate as described, plaintiffs face yet another hurdle—the generic manufacturer simply cannot be liable for faulty labeling.

2. No Incentive For Generic Companies to Implead

As we know, the result of *Mensing* and *Bartlett* is that generic companies are shielded from liability on failure-to-warn and defective design claims premised on the inadequacy of a drug's warnings.²⁴² Therefore, certain tort claims brought against them *must* be dismissed. Since any failure-to-warn or defective-design lawsuit will be dismissed, generic manufacturers have no reason to implead a brand-name manufacturer to indemnify any potential liability the former

239. See *supra* notes 178–180 and accompanying text.

240. See *infra* Part IV.B.1.

241. See *supra* notes 234–236 and accompanying text.

242. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577–78 (2011); *Mut. Pharm. Co. v. Bartlett*, 144 S. Ct. 2466, 2470 (2013).

may face, as no such liability could be found.

Mensing thus makes it difficult to propose a solution to the very problems it created. No change in the current state of the law in this area is possible without either judicial reversal, which is unlikely, or a statutory or regulatory amendment. This Comment proposes two modifications to the Hatch-Waxman Amendments that aim to circumvent *Mensing* by first, establishing that generic companies may be liable to their consumers for faulty labeling by virtue of entering the pharmaceutical marketplace, and second, permitting generic companies to implead the brand-name company if the generic company's liability is based on a defective label.

B. Proposal: Creating Generic Manufacturer Liability for Faulty Labeling and Permitting Impleader of the Brand-Name Manufacturer

For a generic manufacturer to feel any pressure to implead the brand-name company, it must first be able to be held liable for defective labeling that causes injury to consumers of its product.²⁴³ Perhaps the simplest way to accomplish this would be judicial reversal. Unfortunately, this is a solution premised more on hope than reality—as *Bartlett* demonstrated, the current composition of this Supreme Court is unlikely to change its mind with respect to the applicability of federal preemption in the area of pharmaceutical regulation.²⁴⁴ Lower courts are even less likely to contravene rulings by the Supreme Court, nor does any principle hold that they may do so.²⁴⁵ Legislatures, on the other hand, may directly overrule or modify the law with respect to a decision with which they disagree.²⁴⁶ Therefore, in order to establish liability, Congress

243. See *supra* note 11. Recall that impleader may only be invoked when there is a basis for liability between the original defendant and the party to be added as a third-party defendant. Liability must exist in the first instance between the plaintiff and the original defendant. See *supra* Part IV.A.

244. See *supra* notes 154–156 and accompanying text.

245. See, e.g., *Rodriguez de Quijas v. Shearson/American Express, Inc.*, 490 U.S. 477, 484 (1989) (“If a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions.”).

246. Lawrence C. Marshall, “*Let Congress Do It: The Case for an Absolute Rule of Statutory Stare Decisis*,” 88 MICH. L. REV. 177, 197 (1989) (“Congress is authorized to overrule statutory precedents with which it is unhappy.”).

must modify the Hatch-Waxman Amendments to warn generic manufacturers that, by filing an ANDA and entering the generic marketplace, they may be subject to state failure-to-warn and design-defect claims, along with other state tort claims.

1. Step One: Generic Manufacturers' Post-Marketing Surveillance Duties Form the Basis for State Tort Liability

While the Supreme Court held that state laws that use drug labeling as the basis for imposing tort liability on generic manufacturers conflict with federal regulations,²⁴⁷ the fact remains that generic manufacturers have a duty to keep track of adverse reactions and any new information regarding the safety or efficacy of their drugs.²⁴⁸ This duty persists even if the generic manufacturers are unable to implement these changes without FDA approval of the change for the brand-name drug.²⁴⁹ The duty also forms the basis for providing that ANDA applicants will be subject to state tort laws imposing liability for failure-to-warn or defective design if their drugs are approved. This is particularly necessary where a generic manufacturer knows of a risk of using the drug, yet fails to inform the FDA or the brand-name manufacturer of this risk. The manufacturer in this situation may nonetheless avoid liability under *Mensing*, since it would have been unable to unilaterally change its label anyway. Under the proposed statute, however, generic manufacturers *will* be liable to injured consumers in this sort of situation.

Strict liability with respect to a manufacturer is appropriate where the consumer can establish a breach of the manufacturer's duty to warn.²⁵⁰ For example, breach of this duty may be established by showing that the manufacturer did not warn of a known danger.²⁵¹ Alternately, a generic manufacturer who becomes aware of potential safety risks can notify physicians and health care providers of those additional risks using Dear Health Care Professional letters, which can be

247. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2577–78 (2011).

248. *See supra* note 63 and accompanying text.

249. *See supra* note 91 and accompanying text.

250. *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969).

251. *Id.*

done in the absence of a proposed label change.²⁵² In the situation described in the previous paragraph, proof that the generic manufacturer knew of a danger, but did not take steps to warn of that danger, may be sufficient to hold the generic manufacturer liable. Under the current scheme, a court in this situation would likely defer to the FDA's strict interpretation²⁵³ of the availability of the CBE process to invoke impossibility preemption.²⁵⁴ However, the addition of statutory language that requires ANDA applicants to be subject to state tort liability provides litigants a means of avoiding this preemptive effect. While this solution would not immediately require the FDA to alter its interpretation or amend its regulations, it may eventually force the agency to take a position on the new statutory requirement.

The doctrine of express preemption strengthens the basis for the statutory imposition of liability.²⁵⁵ As Dean Chemerinsky points out, "preemption analysis is always a question of legislative intent."²⁵⁶ Few would know the intent of the Hatch-Waxman Amendments better than their sponsors. As Representative Henry Waxman unequivocally stated, "Congress . . . did not intend [the] outcome" in *Mensing*.²⁵⁷ Congress can clarify its intent to circumvent *Mensing* by expressly writing that nothing in the Hatch-Waxman Amendments or FDA regulations promulgated thereunder is intended to preempt the imposition of state tort liability on generic manufacturers. Under the doctrine of express preemption, this explicit statement of congressional intent makes the determination of whether federal law preempts state law an easy one.²⁵⁸ A court need look no further than this added provision to hold, definitively, that state laws that impose failure-to-warn, design-defect, or other tort liability on generic manufacturers are *not preempted* by the Hatch-Waxman Amendments or associated federal regulations.

All told, express language that permits the imposition of state tort liability on generic manufacturers will avoid *Mensing's* preemptive effect while adhering to well-established

252. Waxman Amicus Brief, *supra* note 34, at 12–13.

253. See *supra* text accompanying note 211.

254. See *supra* notes 143–144 and accompanying text.

255. See Stabile, *supra* note 102.

256. See Chemerinsky, *supra* note 162.

257. See Waxman Amicus Brief, *supra* note 34, at 9.

258. See Stabile, *supra* note 102.

principles of constitutional and tort law. It also sets the stage for the second of the two proposed statutory amendments.

2. Step Two: Permit Generic Companies to Implead Brand-Name Manufacturers to Appropriately Determine Liability

Taken alone, the amendment proposed in the previous section may lead to unfair results. Recall an earlier example where the brand-name manufacturer did not update its label to match a risk known to the generic manufacturer.²⁵⁹ It is in this type of situation that impleader may be properly employed, for it is highly unfair for the generic manufacturer to be held liable for the “sins” of the brand-name company. The Hatch-Waxman Amendments should contain an added provision that provides generic manufacturers with the option to implead the brand-name manufacturer. In the current version of the Amendments, a similar procedural option already exists. Under Hatch-Waxman, generic manufacturers may file a counterclaim against the brand-name manufacturer to contest the brand-name manufacturer’s allegations of patent infringement.²⁶⁰ This only occurs after the generic manufacturer files a paragraph IV certification and the brand-name manufacturer responds with an infringement suit.²⁶¹ Generic manufacturers utilize the counterclaim to assert that the brand-name manufacturer’s patent information is incorrect in an attempt to defeat a claim of infringement.²⁶²

The existence of this sort of procedural provision supports the addition of a similar provision with respect to impleader of a third-party defendant. This new provision would encourage generic manufacturers to enter the pharmaceutical marketplace despite agreeing to be subject to liability under state tort laws. In particular, generic manufacturers who believe that they are not liable to the injured consumer for a defective label may implead their brand-name counterpart and assert their claim that, if the brand-name manufacturer had

259. See Schwartz, et al., *supra* note 197.

260. 21 U.S.C. § 355(j)(5)(C)(ii)(I).

261. See *supra* note 53.

262. See, e.g., *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1679 (2012) (generic manufacturer could successfully assert statutory counterclaim to petition brand-name manufacturer to change its overbroad “use code.”).

updated its label to warn of a known risk, the generic manufacturer could have (and would have) done the same. This is far preferable to the current state of affairs, where *neither* the brand-name manufacturer *nor* the generic manufacturer may be held responsible for any labeling sin that negatively affects a generic drug consumer. Without these amendments, the consumer who is unlucky enough to suffer adverse effects of using a generic drug must simply absorb the cost of mounting medical bills, an inability to work, and perhaps death—with no chance of recovery.

Under the proposed statutory changes, consumers can rest assured knowing that, regardless of the type of drug they use, state tort laws and federal regulations will not leave them without remedy. Even if the ultimate practical result of these changes is that generic manufacturers always implead, and are always successful in transferring liability, the consumer is still protected from injuries resulting from faulty labeling. However, it is unlikely—if not impossible—that impleader will always be successful. For example, where the generic manufacturer failed in its post-marketing surveillance obligations, it could not successfully transfer liability to the brand-name manufacturer. Thus, these changes place even greater emphasis on each manufacturer's post-marketing responsibilities. These amendments also produce a number of other desirable effects.

3. Statutory Changes Create Desirable Pressures on All Manufacturers

Given the dangers of continuing along the path that *Mensing* has paved, the above-described amendments provide a rational and necessary solution. Critics may lament that this does little to solve the issue of imposing liability where there was no duty from the brand-name manufacturer to the generic drug consumer. However, impleader eliminates precisely this problem by dictating that liability flows from the brand-name manufacturer to its generic counterpart (rather than the consumer) and stems from a failure to strengthen a drug's label despite evidence that a change was necessary.

Furthermore, these statutory changes place *both* manufacturers on unequivocal notice of their post-marketing labeling responsibilities and the consequences that may result from a failure to comply with those responsibilities. This

statutory notice should increase these manufacturers' willingness to stay ahead of developments that could render current drug labels defective or inadequate under the laws of various states. The need to update pharmaceutical labels ought not to be understated: new technologies and improved research demonstrate that a significant percentage of approved drugs require strengthened labeling or risk exile from the marketplace.²⁶³ Since generic manufacturers may not engage in unilateral labeling changes, there must be pressure on the brand-name firm to appropriately respond to new information on a timely basis in order to protect consumer health. Imposing liability by virtue of their entering the marketplace creates an identical pressure on generic manufacturers. Under current law, the fact that both manufacturers are shielded from liability may actually serve as a disincentive to stay abreast of necessary labeling updates. A change to the existing regulatory landscape is therefore undeniably necessary. A change codified within the Hatch-Waxman Amendments that permits the joinder of the brand-name manufacturer as a third-party defendant will impress upon that manufacturer the importance of adequate labeling to consumers of both their drugs and generic drugs, and will further the purposes of the Amendments to speed up the entrance of generic drugs into the pharmaceutical marketplace and lower the cost of drugs for all Americans.

Without a doubt, this proposal represents a significant departure from previous approaches to solving the problems associated with the *Levine-Mensing* dichotomy. But the importance of retaining the low cost of drugs and continuing drug substitutions cannot be overstated. Generic drugs can be 80–85% less expensive than their brand-name counterparts while retaining equivalent safety and efficacy.²⁶⁴ It is not hard to believe that more individuals consume generic drugs than

263. Kazhdan, *supra* note 8, at 913–15 (“A 2002 study published in the Journal of the American Medical Association showed that of drugs approved for sale between 1975 and 1999, 10.2% acquired a new black box warning (the most serious warning the FDA can require) or were withdrawn from the market after entering the market”) (citing Karen E. Lasser et al., *Timing of New Black Box Warnings and Withdrawal for Prescription Medications*, 287 J. AM. MED. ASS’N 2215, 2216 (2002)).

264. *Facts About Generic Drugs*, U.S. FOOD & DRUG ADMIN. (Sept. 19, 2012), http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm#_ftnref3, archived at <http://perma.cc/Z7S6-6TLB>.

brand-name drugs, given their significantly reduced cost—in 2011, “generics . . . represent[ed] 80% of dispensed prescriptions.”²⁶⁵ The magnitude of the risks involved in continuing to allow all drug manufacturers to avoid liability for defective warnings on generic pharmaceuticals therefore warrants a significant departure from the current statutory and regulatory scheme.

CONCLUSION

According to the named sponsors of the Hatch-Waxman Amendments, the legislation aims to serve consumer interests in two ways: first, to create “further incentive for research and development for new, innovative drugs,”²⁶⁶ and second, to reduce the price of drugs.²⁶⁷ To achieve these ends, the Amendments provide for the expedited introduction of generic drugs, produced by competitor manufacturers, into the pharmaceutical marketplace.²⁶⁸ According to Representative Waxman, nothing in the Amendments was designed to preempt state tort remedies premised on a theory that a drug’s label was defective.²⁶⁹ Nonetheless, in *Mensing* and *Bartlett*, the Supreme Court held that state law tort claims against generic drug manufacturers premised on defective labels or designs could not proceed. In both cases, federal law preempted the claims by requiring all aspects of the generic drug to mimic the original and prohibiting the generic manufacturers from unilaterally changing their drugs’ labels after approval.²⁷⁰

As a result, many generic drug consumers face the risk of being injured by generic drugs without any possibility of recovery on a defective labeling theory. To rectify this situation, this Comment proposes that Congress expressly provide that generic manufacturers are subject to state tort

265. IMS INST. FOR HEALTHCARE INFORMATICS, *THE USE OF MEDICINE IN THE UNITED STATES: REVIEW OF 2011 2* (Apr. 2012), available at http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf, archived at <http://perma.cc/TUU7-W7SS>.

266. 130 CONG. REC. 24,430 (Sept. 6, 1984) (statement of Rep. Henry A. Waxman).

267. 130 CONG. REC. 15,847 (June 12, 1984) (statement of Sen. Orrin Hatch).

268. Waxman Amicus Brief, *supra* note 34, at 7.

269. *Id.* at 5–10.

270. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011), *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2475 (2013).

liability, and simultaneously permit these manufacturers to implead their brand-name counterparts. This solution most effectively provides relief to injured generic drug consumers from the appropriate manufacturer. The dichotomy requires a change that is practical in application but creates positive results for the future of the pharmaceutical and healthcare industries, as well as their consumers. This Comment's proposed solution meets both of these important criteria.