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Missing After Mensing: A Remedy for Generic Drug Consumers

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MISSING AFTER *MENSING*: A REMEDY FOR GENERIC DRUG CONSUMERS

Abstract: The U.S. Supreme Court's 2011 decision in *PLIVA v. Mensing* left consumers of generic drugs without a remedy for failure-to-warn claims. The Court held that FDA regulations made it impossible for a generic drug manufacturer unilaterally to enhance its warning label. Because of this impossibility, the Court held that the FDA regulations preempt state failure-to-warn claims. The FDA regulations do not, however, preempt brand name drug consumers' claims against brand name drug manufacturers. Accordingly, consumers stand in starkly different positions depending on whether they consumed a brand name or a generic drug. This Note argues that the FDA should amend its regulations to allow all manufacturers unilaterally to enhance their warning labels. This would allow both generic and brand name consumers to recover from the manufacturer that produced the inadequately-labeled drug that was consumed.

INTRODUCTION

Drug manufacturers spend billions of dollars every year researching and developing new drugs.¹ To recoup the invested money, these companies aggressively market their brand name drugs to doctors and patients directly.² New drugs typically enjoy a twenty-year patent, during which the patent holder has the exclusive right to manufacture and

¹ See Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 166, 166 (2003) (estimating that the fully capitalized total research and development cost of a new drug is \$802 million); *Pharmaceutical Industry Profile 2011*, PHARMACEUTICAL RES. & MANUFACTURERS OF AM., 11 (Apr. 2011), http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf (estimating total biopharmaceutical industry research and development spending at \$67.4 billion in 2010). Consumers also spend billions of dollars to purchase prescription drugs. See *National Health Expenditures 2010 Highlights*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.hhs.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> (last visited Nov. 1, 2012) (estimating that U.S. retail prescription drug spending was \$259.1 billion in 2010).

² See Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. 1123, 1133 (2011) (citing Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PUB. LIBR. SCI. MED. 29, 31–32 (2008) (estimating that in 2004, U.S. pharmaceutical companies spent \$57.5 billion on marketing—almost twice as much as they spent on research and development)).

market their brand name drug.³ After the patent expires, however, competing manufacturers often create generic duplicates of the drugs and sell them at a much lower price.⁴ If a generic drug manufacturer can prove that its drug is effectively identical in substance and labeling to the brand name drug, then the U.S. Food and Drug Administration (FDA)—the sole regulatory body responsible for ensuring the safety and efficacy of pharmaceutical drugs on the market—will allow the generic manufacturer to forego the rigorous clinical testing required of the brand name drug.⁵

Largely due to generic substitution laws, generic drugs account for the vast majority of drugs consumed.⁶ Every state has some form of generic substitution law that allows (and in some instances requires) pharmacists to fill prescriptions with a cheaper generic drug unless the doctor specifically requests the brand name drug.⁷ As a result, even though many doctors prescribe the brand name drug with which they are familiar,⁸ approximately seventy-five percent of prescriptions are filled with generics.⁹

The FDA requires new drugs to undergo extensive clinical testing before they can be marketed.¹⁰ Nonetheless, plaintiffs sometimes bring

³ See 35 U.S.C. § 154(a)(2) (2006); Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 722–23 (2005).

⁴ See Anthony L. Martin, Jr., *California Dreamin'? Generic Drug Users Can Sue Brand Name Drug Manufacturers*, 77 DEF. COUNS. J. 474, 475 (2010).

⁵ See 21 U.S.C. § 355(j)(2)(A) (2006); *PLIVA, Inc. v. Mensing (Mensing III)*, 131 S. Ct. 2567, 2574 (2011).

⁶ See U.S. DEPT. OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS 5 (2010) [hereinafter HHS REPORT], available at <http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.pdf> (“The rate of generic prescribing for all prescriptions reached almost 75 percent in 2009, up from 57 percent in 2004.”).

⁷ See *Mensing III*, 131 S. Ct. at 2583 (Sotomayor, J., dissenting); HHS REPORT, *supra* note 6, at app. A (providing a chart of all fifty states’ generic substitution laws). Fourteen states—Florida, Hawaii, Kentucky, Maine, Massachusetts, Minnesota, Nevada, New Jersey, New York, Rhode Island, Tennessee, Vermont, Washington, and West Virginia—require a pharmacist to substitute a generic drug unless a physician affirmatively indicates otherwise. HHS REPORT, *supra* note 6, at app. A.

⁸ See Thomas L. Hafemeister & Sarah P. Bryan, *Beware Those Bearing Gifts: Physicians’ Fiduciary Duty to Avoid Pharmaceutical Marketing*, 57 U. KAN. L. REV. 491, 506 (2009) (“Despite the fact that over 70% of prescriptions are written for drugs for which both generic and brand name versions are available, fewer than 30% of prescriptions are written for the generic version.”); Judith K. Hellerstein, *The Importance of the Physician in the Generic Versus Trade-Name Prescription Decision*, 29 RAND J. ECON. 108, 108 (1998).

⁹ See *Mensing III*, 131 S. Ct. at 2584 (Sotomayor, J., dissenting). Justice Sonia Sotomayor noted in her dissent in the U.S. Supreme Court’s 2011 *PLIVA, Inc. v. Mensing (Mensing III)* decision that this number rises to ninety percent when a generic version is available. See *id.*

¹⁰ See 21 U.S.C. § 355(b)(1)(A); *How Drugs Are Developed and Approved*, U.S. FOOD & DRUG ADMIN. (last updated Apr. 23, 2010), www.fda.gov/Drugs/DevelopmentApproval

claims that the labeling of a drug provided inadequate warning of the drug's known or foreseeable risks.¹¹ When the plaintiff consumed a brand name drug, that plaintiff successfully can sue the brand name manufacturer who created the drug's warning label.¹² But what happens to the seventy-five percent of prescriptions filled with a generic equivalent—a product manufactured by a different company but using the inadequate warning label created by the brand name manufacturer?¹³

On June 23, 2011, the U.S. Supreme Court held in *PLIVA, Inc. v. Mensing* (*Mensing III*) that FDA regulations preempted state tort law failure-to-warn claims against generic manufacturers.¹⁴ As a result, the decision effectively foreclosed suits against generic manufacturers because the Supreme Court stated that FDA regulations made it impossible for a generic manufacturer to enhance its warning label unilaterally.¹⁵ The Court noted that even if a generic manufacturer notified the FDA of its drug's risks, it could not fulfill its state law duties unless it actually enhanced its label—an action which federal regulations prohibit.¹⁶ Moreover, it is unclear whether these plaintiffs can sue the brand name manufacturers for the inadequate warnings.¹⁷ The majority of courts to address this issue have held that generic consumers cannot successfully sue brand name manufacturers.¹⁸ Consequently,

Process/HowDrugsAreDevelopedandApproved/default.htm (illustrating the process for bringing a new drug to market).

¹¹ See, e.g., *Mensing III*, 131 S. Ct. at 2573 (bringing a claim against a generic manufacturer); *Wyeth v. Levine* (*Levine III*), 555 U.S. 555, 559 (2009) (bringing a claim against a brand name manufacturer).

¹² See *Levine III*, 555 U.S. at 558–59, 581.

¹³ See *Mensing III*, 131 S. Ct. at 2581. *Mensing III* provides the answer: these plaintiffs' claims against generic manufacturers are pre-empted by federal FDA regulations. See *id.*

¹⁴ *Id.* (holding that it is impossible for generic manufacturers to comply with their federal duty to keep the labeling the same as the brand name drug and their state duty to update labeling to ensure it provides an adequate warning); see 21 U.S.C. § 355(j)(4)(G) (stating that a generic drug's label must be the same as the brand name drug's label for approval); 21 C.F.R. § 314.94(a)(8)(iii) (2012) (same); 21 C.F.R. § 314.150(b)(10) (approval may be withdrawn if a generic drug's labeling stops being consistent with the brand name drug's label).

¹⁵ See *Mensing III*, 131 S. Ct. at 2581; see 21 U.S.C. § 355(j)(4)(G); 21 C.F.R. § 314.94(a)(8)(iii); 21 C.F.R. § 314.150(b)(10).

¹⁶ See *Mensing III*, 131 S. Ct. at 2581; see 21 U.S.C. § 355(j)(4)(G); 21 C.F.R. § 314.94(a)(8)(iii); 21 C.F.R. § 314.150(b)(10).

¹⁷ See e.g., *Smith v. Wyeth*, 657 F.3d 420, 424 (6th Cir. 2011) (denying a generic consumer's claim against the brand name manufacturer); *Metz v. Wyeth LLC*, 830 F. Supp. 2d 1291, 1295 (M.D. Fla. 2011).

¹⁸ See, e.g., *Smith*, 657 F.3d at 424; *Hogue v. Pfizer, Inc.*, 2012 WL 4466609, at *5 (S.D. Ohio Sept. 27, 2012); *Baymiller v. Ranbaxy Pharm., Inc.*, 2012 WL 3929768, at *8–9 (D.

patients who consume generic drugs appear to be without a remedy if they are harmed by inadequate warning labels.¹⁹

This Note argues that the FDA should rewrite its regulations to allow all manufacturers unilaterally to enhance their labeling, and thus allow all manufacturers to be subject to state failure-to-warn claims.²⁰ Part I explains the FDA's regulatory scheme and the differences between pre-market and post-market safety risk identification.²¹ Part II examines how two recent Supreme Court cases interpreting FDA regulations have effectively granted a remedy to brand name consumers, but have foreclosed a remedy for generic consumers.²² Finally, Part III argues that to ensure continued drug innovation and to maintain state law tort principles, the FDA should amend its regulations to allow both brand name and generic manufacturers to be subject to state law liability for failing to provide adequate warning labels.²³

I. THE FDA'S REGULATORY SCHEME

This Part explains the FDA's regulatory scheme designed to ensure the safety and efficacy of drugs.²⁴ First, Section A briefly describes the role of the FDA, and then summarizes the process for obtaining approval to market new drugs.²⁵ Next, Section B explains the approval process for generic equivalents of existing drugs.²⁶ Finally, Section C examines the requirements for both brand name and generic manufac-

Nev. Sept. 6, 2012); *Phares v. Actavis-Elizabeth LLC*, 2012 WL 3779227, at *7–11 (S.D. Tex. Aug. 30, 2012); *Lashley v. Pfizer, Inc.*, 2012 WL 2459148, at *11 (S.D. Miss. June 27, 2012); *Phelps v. Wyeth*, 857 F. Supp. 2d 1114, 1130 (D. Or. 2012); *Guarino v. Wyeth LLC*, 2012 WL 1138631, at *2 (M.D. Fla. Apr. 3, 2012); *Metz*, 830 F. Supp. 2d at 1295; *Gross v. Pfizer*, 2011 WL 4005266, at *2 (D. Md. Sept. 7, 2011). *But see Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 709 (D. Vt. 2010); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 114 (Cal. Ct. App. 2008).

¹⁹ *See Metz*, 830 F. Supp. 2d at 1295 (“Tellingly, the Supreme Court in *Mensing* appeared to contemplate that consumers of generic drugs may be without a remedy when it noted ‘the unfortunate hand that federal drug regulation has dealt [consumers of generic drugs].’” (quoting *Mensing III*, 131 S. Ct. at 2581)).

²⁰ *See infra* notes 181–256 and accompanying text. Once such a system is in place, then a consumer will be able to sue whichever manufacturer—brand name or generic—actually manufactured the drug consumed. *See infra* notes 181–256 and accompanying text.

²¹ *See infra* notes 24–73 and accompanying text.

²² *See infra* notes 74–180 and accompanying text.

²³ *See infra* notes 181–256 and accompanying text.

²⁴ *See infra* notes 28–73 and accompanying text.

²⁵ *See infra* notes 28–48 and accompanying text.

²⁶ *See infra* notes 49–59 and accompanying text.

turers to monitor adverse reactions to the drug after its initial approval.²⁷

A. *The Role of the FDA and Pre-Market Approval of New Drugs*

The FDA is responsible for, among other things, ensuring the safety and efficacy of drugs sold in interstate commerce.²⁸ As part of these duties, the FDA evaluates applications for new drugs, regulates the labeling of prescription and over-the-counter drugs, and sets drug manufacturing standards.²⁹ The FDA's role as regulator of food and drugs dates to 1906, when Congress passed the Federal Food and Drugs Act to combat the repulsive conditions in the meat-packing and other food industries.³⁰ In 1938, Congress enacted the Food, Drug, and Cosmetic Act ("FDCA"), which was much more comprehensive than the 1906 Act, and which gave the FDA much of its regulatory authority.³¹ Most significantly, the FDCA added the requirement for premarket approval of new drugs.³²

Today, the FDA has a more important role than ever, as the number of drugs on the market has mushroomed to 11,000.³³ As the sole regulatory body responsible for ensuring the safety and efficacy of drugs sold in the United States, the FDA provides an important barrier to keep unsafe drugs off the shelves.³⁴ Because of the massive number of drugs under the FDA's purview, the onus for testing the safety and

²⁷ See *infra* notes 60–73 and accompanying text.

²⁸ See Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, U.S. FOOD & DRUG ADMIN. (last updated June 18, 2009), <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/default.htm>.

²⁹ See 21 U.S.C. § 355(a)–(e) (2006) (setting forth procedures and requirements for new drug applications to the FDA, including labeling and manufacturing requirements); 21 C.F.R. § 211 (2012) (setting drug manufacturing standards).

³⁰ See Federal Food and Drugs Act, ch. 3915, 38 Stat. 768, 768–72 (1906) (repealed 1938); *FDA History—Part I*, U.S. FOOD & DRUG ADMIN. (last updated June 18, 2009), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054819.htm>; *FDA's Origin*, U.S. FOOD & DRUG ADMIN. (last updated June 18, 2009), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm> (adapted from A HISTORICAL GUIDE TO THE U.S. GOVERNMENT, (George Kurian ed., 1998)).

³¹ See Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040, 1040–59 (1938) (codified as amended at 21 U.S.C. §§ 301–399 (2006 & Supp. IV 2011)); *FDA History—Part II*, U.S. FOOD & DRUG ADMIN. (last updated Sept. 24, 2012), <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm>.

³² *Levine III*, 555 U.S. at 566.

³³ See *id.* at 578.

³⁴ See Meadows, *supra* note 28.

efficacy of drugs falls on the drug's manufacturer, both before and after the product becomes available.³⁵

To protect their significant investment in newly developed drugs, drug originators typically enjoy twenty years of patent protection from competition.³⁶ A patent provides the patent holder with the exclusive right to manufacture the drug for a period of time.³⁷ Because the public values new drug innovations, Congress provided drug patents to incentivize the innovation of new drugs.³⁸ The drug originators generally market their drugs heavily as brand name drugs in order to recoup their investment (and try to earn a profit) during the patent term, while they do not face competition from generic drugs.³⁹

Obtaining FDA approval to market a new drug is costly and time-consuming, reducing the effective patent term to eleven to twelve years on average.⁴⁰ A drug innovator will typically file a patent application as soon as it discovers a new drug that meets the patent statutory requirements of utility, novelty, and non-obviousness.⁴¹ To gain FDA approval, a drug originator must first perform laboratory and

³⁵ See 21 U.S.C. § 355(b) (2006); *Levine III*, 555 U.S. at 578; 21 C.F.R. § 314.70(b) (2012) (describing steps a manufacturer must take to update its labeling based on safety and efficacy changes after the drug becomes available).

³⁶ See 35 U.S.C. § 154(a)(2) (2006). The patent term begins running from the time of the patent application. See *id.*

³⁷ *Id.* § 154(a)(1).

³⁸ See *id.* § 154(a)(2). The Hatch-Waxman Amendments also allow for up to a five-year patent extension. Eisenberg, *supra* note 3, at 723; see 35 U.S.C. § 156.

³⁹ See Gagnon & Lexchin, *supra* note 2, at 31–32; Saami Zain, *Sword or Shield? An Overview and Competitive Analysis of the Marketing of "Authorized Generics,"* 62 FOOD & DRUG L.J. 739, 746 (2007) (discussing how some brand name manufacturers—who lose fifty to eighty percent of their sales once a generic competitor enters the market—attempt to continue reaping profits beyond the patent term by producing “authorized generics”).

⁴⁰ See *Mensing III*, 131 S. Ct. at 2574 (“Meeting [the FDA] requirements involves costly and lengthy clinical testing.”); Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 96–97 (2004) (arguing for increased pharmaceutical intellectual property protection in order to foster innovation and describing the effective patent term as eleven to twelve years on average); *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (last updated May 1, 2012), www.fda.gov/resources/foryou/consumers/ucm143534.htm.

⁴¹ See 35 U.S.C. §§ 101 (utility), 102 (novelty), 103 (non-obviousness); Le-Nhung McLeland, *What Every Chemist Should Know About Patents*, AM. CHEMICAL SOC'Y, 13 (3d ed. 2002), http://portal.acs.org/portal/PublicWebSite/about/governance/committees/WPCP_006903 (listing reasons for drug innovators to file a patent application as soon as practicable). Starting with patent applications filed on or after March 16, 2013, the U.S. patent system will change from the present “first-to-invent” system to a “first-inventor-to-file” system, which will create an additional incentive to file a patent application as soon as practicable. See Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 35 U.S.C.).

animal testing followed by small-sample clinical testing on humans.⁴² There are three stages to the clinical trial schedule, with each stage testing a relatively larger sample of people.⁴³ At the conclusion of the clinical trials, the drug originator can submit a New Drug Application (“NDA”) to the FDA.⁴⁴ In 2009, these clinical trials accounted for approximately fifty-eight percent of total research and development costs among members of the Pharmaceutical Research Manufacturers of America (“PhRMA”).⁴⁵

As part of the NDA, the manufacturer must provide the proposed adequate and accurate labeling of the drug.⁴⁶ This labeling must reflect, among other things, any “reasonable evidence of an association of a serious hazard with a drug,” even if no evidence of a causal relationship between the drug and the hazard exists.⁴⁷ The FDA reviews the NDA and makes a decision as to whether to permit the drug originator to market the drug.⁴⁸

B. Pre-Market Approval of Generic Drugs

To encourage the production of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act (the “Hatch-Waxman Amendments”) in 1984, which allows generic drug manufacturers to bypass the extensive clinical testing required for brand name drugs upon a showing of bioequivalency to the brand name drug.⁴⁹ Thus, when a brand name drug’s patent expires, other manufacturers can produce generic duplicates of the drug without the rigorous testing standards, if they can prove that their drug is the bio-

⁴² See *Development and Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN. (last updated Oct. 15, 2012), <http://www.fda.gov/drugs/developmentapprovalprocess/default.htm>.

⁴³ See *id.*

⁴⁴ See 21 U.S.C. § 355(b)(1)(A) (2006) (requiring that manufacturers seeking FDA approval provide “full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use”); *id.* § 355(d) (requiring “adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use”).

⁴⁵ See *Pharmaceutical Industry Profile 2011*, *supra* note 1, at 45. PhRMA is a pharmaceutical trade group that represents many of the largest pharmaceutical research companies in the United States. *About PhRMA*, PHARMACEUTICAL RES. & MANUFACTURERS OF AM., www.phrma.org/about/phrma (last visited Nov. 2, 2012).

⁴⁶ See 21 U.S.C. § 355(b)(1).

⁴⁷ *Mensing*, 131 S. Ct. at 2576; 21 C.F.R. § 201.80(e) (2012).

⁴⁸ See 21 U.S.C. § 355(d) (listing grounds for refusing an application).

⁴⁹ See 21 U.S.C. § 355(j)(2)(A); *supra* notes 40–48 and accompanying text (describing the extensive process to bring a brand name drug to market).

equivalent of the previously approved, brand name drug.⁵⁰ Congress created this exception for generic manufacturers in 1984 by passing the Hatch-Waxman Amendments, which created the process for abbreviated new drug applications (“ANDAs”).⁵¹ In passing the Hatch-Waxman Amendments, Congress chose to free generic manufacturers from having to duplicate safety and effectiveness data that a brand name manufacturer had already submitted to the FDA.⁵² These amendments allowed generic drugs to be produced more cheaply than when generic manufacturers had to perform the same rigorous clinical tests as the brand name manufacturers.⁵³ In fact, in contrast to the estimated \$802 million in research and development costs to bring a brand name drug to market, today a generic drug costs roughly two million dollars to bring to market.⁵⁴

In addition to proving the bioequivalence of the generic drug to the brand name drug, a generic manufacturer must also use the same labeling as the brand name drug.⁵⁵ The FDA’s definition of “labeling” is broader than simply the label on the drug bottle; it also includes virtually any dissemination of information by the drug manufacturer,

⁵⁰ See *Mensing III*, 131 S. Ct. at 2574. The FDA defines bioequivalence as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.” 21 C.F.R. § 320.1 (e).

⁵¹ See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., 28 U.S.C., and 35 U.S.C.); *Mensing III*, 131 S. Ct. at 2574.

⁵² 21 U.S.C. § 355(j) (setting forth the requirements for generic manufacturer applications); *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S. 2748 Before the S. Comm. on Labor & Human Res.*, 98th Cong. 1 (1984) [hereinafter *Hatch-Waxman Hearing*] (opening statement of Sen. Orrin Hatch, Chairman, S. Comm. on Labor and Human Resources). Prior to the Hatch-Waxman Amendments, the FDA had two sets of rules for the marketing of generic drugs, depending on whether they were approved before or after the 1962 amendments to the FDCA. See H.R. REP. No. 98-857(II), at 4 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2688. For drugs approved before 1962, for which a manufacturer only had to prove safety, but not efficacy, generic manufacturers could simply submit ANDAs. See *id.* For drugs approved after 1962, however, which required a showing of safety and efficacy, the generic substitutes had to duplicate the previously approved tests of the brand name manufacturers. See *id.* As a result, manufacturers had a reduced incentive to create generic substitutes because of the high costs of clinical testing. See *id.*

⁵³ See *Mensing III*, 131 S. Ct. at 2574.

⁵⁴ See Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in SCIENCE AND CENTS: EXPLORING THE ECONOMICS OF BIOTECHNOLOGY 92 (Fed. Reserve Bank of Dall. ed., 2003); *Big Generic Pharma*, ECONOMIST, July 28, 2005, at 58.

⁵⁵ 21 U.S.C. § 355(j)(2)(A)(v) (requiring “information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug”).

packer, or distributor to medical professionals.⁵⁶ The purpose of this requirement is to avoid consumer confusion and to convey to consumers that the generic and brand name drugs are the same.⁵⁷

Since the passage of the Hatch-Waxman Amendments, generic drugs have become an even more important component of the drug market, with approximately 75% of all prescriptions filled with generics, compared with 19% before the Hatch-Waxman Amendments.⁵⁸ The Congressional Budget Office has estimated that generic drugs save consumers between eight and ten billion dollars per year.⁵⁹

C. Post-Market Risk Identification

After the FDA approves a drug, both brand name and generic manufacturers must continue to monitor adverse reactions to the drug and identify new risks.⁶⁰ In addition to the adverse events reported to them directly, manufacturers must also review the scientific literature relating to their drugs.⁶¹ Upon acquiring new information, brand name manufacturers have a state law duty to update their labels to warn consumers of newly-discovered risks.⁶² There are three methods for changing a label, depending on whether the change is “major,” “moderate,” or “minor.”⁶³ Although FDA regulations require both brand name and generic manufacturers to notify the FDA of the post-market risks they have identified, a generic manufacturer cannot use any of the

⁵⁶ See 21 C.F.R. § 202.1(1)(2) (2012).

⁵⁷ Brief of the United States as Amicus Curiae Supporting Respondents at 4, *Mensing III*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501) [hereinafter U.S. *Mensing III* Brief] (quoting FDA, DIVISION OF GENERIC DRUGS, POLICY AND PROCEDURE GUIDE 37 (1989)).

⁵⁸ See *Mensing III*, 131 S. Ct. at 2584 (Sotomayor, J., dissenting).

⁵⁹ CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, at xiii (1998), available at <http://cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf>. In 2009, the average retail price for a prescription generic drug was \$39.73, seventy-six percent less than the \$155.45 average retail price for a prescription brand name drug. U.S. DEPT. OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS 5 (2010), available at <http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.pdf>.

⁶⁰ See 21 C.F.R. § 314.80 (obliging manufacturers to review and report adverse reactions that occur after bringing the drug to market).

⁶¹ *Id.* § 314.80(b), (d).

⁶² See *Levine III*, 555 U.S. at 581. By contrast, in *Mensing III*, the Supreme Court held that FDA regulations preempt state law failure-to-warn claims against generic manufacturers. 131 S. Ct. at 2581.

⁶³ 21 C.F.R. § 314.70(b)–(d).

label-changing procedures except to match a change that the brand name manufacturer has effected.⁶⁴

“Major” changes to labeling require FDA approval before the changes can be implemented.⁶⁵ Changes are considered major as a default, unless they fall into one of the excepted categories.⁶⁶ To effect a major change, a manufacturer must submit a supplemental application detailing the proposed change and providing a description of the studies performed and the data derived from such studies.⁶⁷

“Moderate” changes to labeling can be effected without prior FDA approval through the “changes-being-effected” (“CBE”) process, but the FDA retains the authority to reject the change.⁶⁸ A manufacturer can use the CBE process to strengthen its warning label when it discovers new risks.⁶⁹ Although a manufacturer may effect such a label change unilaterally, the FDA may subsequently reject the change and order the manufacturer to cease distribution of the drug with the new labeling.⁷⁰

Finally, a manufacturer can make “minor” changes to the labeling without FDA oversight.⁷¹ Minor changes include changes in the description of the drug (not involving a change in dosage strength or form) or editorial changes in the labeling.⁷² A manufacturer must document the

⁶⁴ *Id.* § 314.80 (setting forth post-market reporting requirements for brand name manufacturers); *id.* § 314.98 (requiring generic manufacturers to comply with 21 C.F.R. § 314.80); see *Mensing III*, 131 S. Ct. at 2577. In *Mensing III*, the U.S. Supreme Court reiterated that “[t]he FDA’s views are ‘controlling unless plainly erroneous or inconsistent with the regulation[s].’” 131 S. Ct. at 2575. The FDA, in turn, construes its regulations to prohibit a generic manufacturer from using either the major change prior approval process or the moderate-change CBE process (the standard processes that govern major and moderate changes to FDA labels), except to conform its label to a brand name manufacturer’s label change. U.S. *Mensing III* Brief, *supra* note 57, at 15–18. Although the FDA did not address the minor change process in its brief, its reasoning on major and moderate changes likely also extends to prohibit generic manufacturers from making minor changes except to conform to a brand name manufacturer’s label change. See *id.*

⁶⁵ 21 C.F.R. § 314.70(b).

⁶⁶ *Id.* § 314.70(b)(2)(v).

⁶⁷ *Id.* § 314.70(b)(3).

⁶⁸ *Id.* § 314.70(c). For example, a brand name manufacturer should use the CBE process to strengthen its warning label if it becomes aware that a specific method of administering its drug is significantly more dangerous than an alternative method of administration. See *Levine III*, 555 U.S. at 573.

⁶⁹ 21 C.F.R. § 314.70(c)(6)(iii). A contraindication advises against the use of the drug by certain people who, because of a certain characteristic, have a “substantial risk” of being harmed by using the drug. See *id.* § 201.80(d).

⁷⁰ *Id.* § 314.70(c)(7).

⁷¹ *Id.* § 314.70(d).

⁷² *Id.* § 314.70(d)(2)(ix)–(x).

label change in an annual report, but may make the change unilaterally.⁷³

II. DIFFERENT REMEDIES FOR BRAND NAME AND GENERIC CONSUMERS

Two recent U.S. Supreme Court decisions establish that brand name drug consumers may sue brand name manufacturers, but generic drug consumers cannot successfully sue generic manufacturers.⁷⁴ Section A of this Part reviews these two cases, and also examines the U.S. Courts of Appeals' treatment of the issue during the time between the two cases.⁷⁵ Section B then examines the separate yet related question of whether a generic consumer can sue a brand name manufacturer.⁷⁶

A. *Levine III* and *Mensing III* Establish Differences in the Duty to Warn Consumers for Brand Name and Generic Drug Manufacturers

In two recent cases, the Supreme Court has interpreted how the FDA regulations on brand name and generic labeling interact with state tort law duties to provide adequate warnings to customers.⁷⁷ As a result of these two cases, the viability of claims for brand name consumers versus generic consumers is vastly different.⁷⁸ First, in the 2009 case, *Wyeth v. Levine* (*Levine III*), the U.S. Supreme Court held that FDA regulations did not preempt state law failure-to-warn claims against a brand name manufacturer.⁷⁹ Following the reasoning of *Levine III*, lower courts generally held that such claims against generic manufacturers were similarly not preempted.⁸⁰ In 2011, however, the U.S. Supreme Court in *PLIVA v. Mensing* (*Mensing III*) held that FDA regulations preempted such claims against generic manufacturers because—unlike brand name manufac-

⁷³ *Id.* § 314.70(d).

⁷⁴ See *PLIVA, Inc. v. Mensing* (*Mensing III*), 131 S. Ct. 2567, 2581 (2011) (holding that FDA regulations preempt state claims against generic manufacturers); *Wyeth v. Levine* (*Levine III*), 555 U.S. 555, 581 (2009) (holding that FDA regulations do not preempt state claims against brand name manufacturers).

⁷⁵ See *infra* notes 77–148 and accompanying text.

⁷⁶ See *infra* notes 149–180 and accompanying text.

⁷⁷ See *Mensing III*, 131 S. Ct. at 2581; *Levine III*, 555 U.S. at 581.

⁷⁸ See *Mensing III*, 131 S. Ct. at 2581; *Levine III*, 555 U.S. at 581; Erwin Chemerinsky, *Supreme Court Review: A Devastating Decision*, 47 TRIAL 54, 57 (2011) (describing the result of the two decisions as “treat[ing] generic drugs dramatically different from their brand name equivalents”).

⁷⁹ See *Levine III*, 555 U.S. at 581; *infra* notes 82–100 and accompanying text.

⁸⁰ See *Gaeta v. Perrigo Pharm. Co.*, 630 F.3d 1225, 1227 (9th Cir. 2011), *vacated*, 132 S. Ct. 497 (2011); *Demahy v. Actavis, Inc.* (*Demahy II*), 593 F.3d 428, 449 (5th Cir. 2010), *rev'd*, *Mensing III*, 131 S. Ct. 2567; *Mensing v. Wyeth* (*Mensing II*), 588 F.3d 603, 614 (8th Cir. 2009), *rev'd*, *Mensing III*, 131 S. Ct. 2567.

turers—generic manufacturers could not unilaterally update a label and therefore it was impossible to comply with both state and federal obligations.⁸¹

In *Levine III*, the plaintiff consumed a brand name drug and sued the brand name manufacturer.⁸² Wyeth's brand name drug, Phenergan, is used to treat nausea; it can be administered intravenously through either an "IV-push" method directly into a patient's vein, or an "IV-drip" method in which it is introduced into saline solution before slowly entering a patient's vein.⁸³ When the drug enters a patient's artery instead of a vein, it causes irreversible gangrene.⁸⁴ In *Levine III*, the plaintiff, Diana Levine, had to have her forearm amputated because Wyeth's drug entered her artery.⁸⁵ Levine sued Wyeth for failing to provide an adequate warning of the risks of intravenous injection of its drug.⁸⁶

Levine argued that the labeling on Phenergan was defective because it failed to instruct physicians to use the IV-drip method rather than the riskier IV-push method.⁸⁷ Although Wyeth's Phenergan label warned of the risk of the drug entering an artery, it did not alert physicians that the IV-push method created a much higher likelihood of this result.⁸⁸ During Levine's five-day jury trial, the evidence showed that the IV-drip method "almost entirely eliminated" the risk of the drug entering an artery.⁸⁹ The jury entered a verdict for Levine, which the Vermont Supreme Court affirmed.⁹⁰

In affirming the Vermont Supreme Court's decision in favor of Levine, the U.S. Supreme Court first rejected Wyeth's impossibility preemption argument.⁹¹ Specifically, Wyeth had argued that it was impossible for it to comply with both federal regulations prohibiting unilateral changes in labeling and the state-law duties underlying failure-to-

⁸¹ See *Mensing III*, 131 S. Ct. at 2581. Unlike brand name manufacturers, generic manufacturers cannot unilaterally update their warning labels. See *id.*; *supra* notes 64–69 and accompanying text.

⁸² See *Levine III*, 555 U.S. at 559.

⁸³ See *id.* at 559.

⁸⁴ See *id.*

⁸⁵ See *id.* at 559–60.

⁸⁶ See *id.*

⁸⁷ See *id.* at 560.

⁸⁸ See *Levine III*, 555 U.S. at 560.

⁸⁹ See *id.* at 561.

⁹⁰ *Levine v. Wyeth*, 944 A.2d 179, 197 (Vt. 2006) (affirming jury verdict); Jury Verdict, *Levine v. Am. Home Prods., Inc.*, No. 670-12-01, 2004 WL 5388972, at *1 (Vt. Sup. Mar. 12, 2004) (awarding the plaintiff \$7.4 million).

⁹¹ *Levine III*, 555 U.S. at 573. Impossibility preemption occurs "where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce." *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963).

warn claims.⁹² Therefore, Wyeth argued, FDA regulations preempt state failure-to-warn claims.⁹³ The Court rejected this argument, concluding that Wyeth had a duty to provide adequate labeling and that the FDA's "changes-being-effected" ("CBE") regulation enabled Wyeth to comply with this duty.⁹⁴ Notably, the Court held that the CBE regulation permitted Wyeth, as a brand name manufacturer, *unilaterally* to strengthen its warning label.⁹⁵ Accordingly, the Court held that it was not impossible to comply with state duties to provide adequate warnings and federal duties under the Food, Drug, and Cosmetic Act ("FDCA").⁹⁶

The Court in *Levine III* also rejected Wyeth's "purposes and objectives" preemption argument.⁹⁷ Wyeth had contended that Congress's purpose in enacting the FDCA was to allow an expert federal agency to create both the floor and ceiling of drug regulation.⁹⁸ The Court disagreed with this characterization of Congress's purpose.⁹⁹ Instead, it concluded that FDA regulations create merely the floor for drug labeling requirements, and that state failure-to-warn claims complement the regulations by further motivating manufacturers to create adequate labels.¹⁰⁰

⁹² See *Levine III*, 555 U.S. at 563, 568.

⁹³ See *id.*

⁹⁴ See *id.* at 568–73; *supra* notes 68–70 and accompanying text (describing the CBE regulation). Wyeth argued that it could not have employed the CBE regulation because *Levine* did not show that there had been any new analysis in the time between the FDA's 1998 approval of Phenergan's labeling and *Levine*'s injury in 2000. Brief for Petitioner at 10, *Levine III*, 555 U.S. 555. Wyeth referred to language in the CBE regulation that allows changes in labeling only "to reflect newly acquired information." 21 C.F.R. § 314.70(c)(6)(iii) (2012); see Brief for Petitioner, *supra*, at 10. The Court, however, stated that Wyeth could have re-analyzed the accumulating information about the risks of Phenergan since the time Wyeth first notified the FDA in 1967 after the first such incident. *Levine III*, 555 U.S. at 569–70.

⁹⁵ *Levine III*, 555 U.S. at 573. In 2011 in *PLIVA, Inc. v. Mensing (Mensing III)*, the U.S. Supreme Court distinguished brand name manufacturers from generic manufacturers because of the brand name manufacturers' ability to enhance their labels unilaterally. 131 S. Ct. at 2581.

⁹⁶ *Levine III*, 555 U.S. at 573.

⁹⁷ *Id.* at 581. Purposes and objectives preemption occurs when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

⁹⁸ *Levine III*, 555 U.S. at 563–64, 573.

⁹⁹ See *id.* at 563.

¹⁰⁰ See *id.* at 577–78; Keith N. Hylton, *An Economic Perspective on Preemption*, 53 B.C. L. REV. 203, 217, 223 (arguing for a preemption model that predicted that *Levine*'s claims would be preempted because the Court had information available to it that was not available to the FDA). In support of this conclusion, the Court noted that despite a 1976 enactment of an express preemption provision for medical devices, Congress did not enact a similar provision for drugs. See *id.* at 574. The Court also declined to defer to the preamble

Although *Levine III* solely concerned brand name drug labeling, the three circuit courts to address *Levine III*'s subsequent impact on generic labeling all held that FDA regulations do not preempt state law claims against generic manufacturers.¹⁰¹ In all three cases—*Gaeta v. Perigo Pharmaceuticals Co.* in 2011, *Demahy v. Activis (Demahy II)* in 2010, and *Mensing v. Wyeth (Mensing II)* in 2009—the U.S. Courts of Appeals for the Ninth, Fifth, and Eighth Circuit respectively held that it was not impossible for generic manufacturers to comply with both the FDA regulations and their state law duty to warn.¹⁰²

Using the same rationale as *Levine III*, the three circuit courts held that FDA regulations did not preempt failure-to-warn claims against generic manufacturers.¹⁰³ Although the Supreme Court did not distinguish between brand name and generic drugs in its analysis, all three circuit courts recognized that different regulations govern brand name versus generic manufacturers.¹⁰⁴ Specifically, all three courts noted that generic manufacturers have a duty of “sameness”—that is, a duty to use the same labeling as their brand name counterparts.¹⁰⁵ Nonetheless, all three courts held that generic manufacturers were able to comply with FDA regulations in the same manner as brand name manufacturers.¹⁰⁶

of a 2006 FDA regulation that purported to preempt state failure-to-warn claims. *See id.* at 575; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–35 (Jan. 24, 2006) (preamble). The Court noted that the preamble did not go through notice-and-comment rule-making, and that Congress did not authorize the FDA to preempt state law directly. *See Levine III*, 555 U.S. at 577.

¹⁰¹ *See Gaeta*, 630 F.3d at 1227; *Demahy II*, 593 F.3d at 449; *Mensing II*, 588 F.3d at 614.

¹⁰² *See Gaeta*, 630 F.3d at 1227; *Demahy II*, 593 F.3d at 449; *Mensing II*, 588 F.3d at 614.

¹⁰³ *See Levine III*, 555 U.S. at 568–81 (reasoning first that it was possible for brand name manufacturers to comply with federal and state law duties, and second that state law did not stand as an obstacle to the accomplishment of federal law); *Gaeta*, 630 F.3d at 1227; *Demahy II*, 593 F.3d at 449; *Mensing II*, 588 F.3d at 614.

¹⁰⁴ *See Levine III*, 555 U.S. at 570–71 (declining to distinguish between brand name and generic manufacturers in a discussion of a manufacturer's responsibility for the content of its warning label); *Gaeta*, 630 F.3d at 1229 (recognizing that different regulations govern generic and brand name manufacturers' applications to the FDA); *Demahy II*, 593 F.3d at 436 (same); *Mensing II*, 588 F.3d at 606 (same).

¹⁰⁵ *See Gaeta*, 630 F.3d at 1229 (“At any time after a new generic drug is approved, the FDA reserves the right to withdraw approval if it determines that the generic drug's labeling is ‘no longer consistent’ with that of the listed drug.”); *Demahy II*, 593 F.3d at 432 (“ANDA drugs must be the ‘same as’ a name brand drug that has already been approved by the FDA as to . . . conditions of use recommended in the labeling.”); *Mensing II*, 588 F.3d at 606 (“ANDA applicants must show the FDA that . . . their proposed label is in relevant part identical to the name brand drug label.”).

¹⁰⁶ *See Gaeta*, 630 F.3d at 1227; *Demahy II*, 593 F.3d at 449; *Mensing II*, 588 F.3d at 614.

In rejecting the generic manufacturer's impossibility preemption defense, the circuit courts held that generic manufacturers had three possible ways to update their labels.¹⁰⁷ First, under the prior approval process (which is required for "major" changes), generic manufacturers could submit proposed changes to the FDA, which could review the changes and then require "sameness" between the brand name and generic labeling.¹⁰⁸ Second, generic manufacturers could employ the CBE process, which does not distinguish between brand name and generic manufacturers.¹⁰⁹ Finally, generic manufacturers could send "dear doctor" letters directly to physicians warning of the drug's dangers.¹¹⁰ Accordingly, the circuit courts held that it was not impossible to comply with both state and federal law, and that FDA regulations therefore did not preempt state claims against generic manufacturers.¹¹¹

On December 10, 2010, the U.S. Supreme Court granted certiorari for two of these circuit court cases—*Mensing II* and *Demahy II*—consolidating the two cases into *Mensing III*.¹¹² Although the three circuit court cases agreed on the result, there was a split among the district courts that had addressed the issue.¹¹³ *Mensing III* reversed the Fifth and Eighth Circuit's opinions and held that the FDA regulations preempted

¹⁰⁷ See *Gaeta*, 630 F.3d at 1227; *Demahy II*, 593 F.3d at 449; *Mensing II*, 588 F.3d at 614.

¹⁰⁸ See *Demahy II*, 593 F.3d at 444 ("Nor does anything in the FDCA or Hatch-Waxman Amendments explicitly forbid generic manufacturers from proposing a label change through the so-called prior approval process."); 21 C.F.R. § 314.70(b) (2012); *supra* notes 66–67 and accompanying text (describing the prior approval process).

¹⁰⁹ See *Gaeta*, 630 F.3d at 1231; *Demahy II*, 593 F.3d at 440; *Mensing II*, 588 F.3d at 611; 21 C.F.R. § 314.70(c)(6)(iii)(A)–(D); *supra* notes 68–70 and accompanying text (describing the CBE process).

¹¹⁰ See *Gaeta*, 630 F.3d at 1231; *Demahy II*, 593 F.3d at 440; *Mensing II*, 588 F.3d at 611. Manufacturers sometimes send "dear doctor" letters to physicians to warn of dangers of a drug or to alert them to changes in labeling. See 21 C.F.R. 200.5 (setting standards for "dear doctor" letters); U.S. *Mensing III* Brief, *supra* note 57, at 7–8. Although dear doctor letters fall within the FDA's broad definition of labeling and are therefore subject to FDA oversight, the circuit courts noted that "the FDA made clear that the requirements 'do not prohibit a manufacturer from warning health care professionals whenever possibly harmful adverse effects associated with the use of the drug are discovered.'" See, e.g., *Demahy II*, 593 F.3d at 444 (quoting Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,447 (June 26, 1979)).

¹¹¹ *Gaeta*, 630 F.3d at 1227; *Demahy II*, 593 F.3d at 449; *Mensing II*, 588 F.3d at 614.

¹¹² *PLIVA, Inc. v. Mensing*, 131 S. Ct. 817, 817 (2010) (granting certiorari); *Actavis, Inc. v. Demahy*, 131 S. Ct. 817, 817 (2010) (granting certiorari).

¹¹³ See *Gaeta*, 630 F.3d at 1227; *Demahy II*, 593 F.3d at 449; *Demahy II*, 593 F.3d at 431 n.7 (listing numerous district court decisions on each side of the issue); *Mensing II*, 588 F.3d at 614.

the state tort law duties of generic manufacturers.¹¹⁴ In effect, *Mensing III* denies a failure-to-warn remedy to generic consumers.¹¹⁵

The facts in the two consolidated cases that *Mensing III* decided—*Mensing II* and *Demahy II*—were similar.¹¹⁶ In both, the plaintiffs, Gladys Mensing and Julie Demahy, were prescribed Reglan, a brand name version of the drug metoclopramide, which is designed to speed the movement of food through the digestive system.¹¹⁷ Although both plaintiffs were prescribed Reglan, they were given the generic version of metoclopramide by their pharmacists and took the drug for several years.¹¹⁸

Both plaintiffs developed tardive dyskinesia, a neurological disorder resulting in “grotesque involuntary movements of the mouth, tongue, lips, and extremities, involuntary chewing movements, and a general sense of agitation.”¹¹⁹ Since the drug first entered the market in 1980, studies have found that long-term use of metoclopramide can cause tardive dyskinesia.¹²⁰ As a result, the labeling on the drug has been enhanced at least three times.¹²¹

The warning label was first strengthened in 1985, adding that “tardive dyskinesia . . . may develop in patients treated with metoclopramide,” and that because the drug had not been evaluated for use longer than twelve weeks, it could not be recommended for an extensive term of use.¹²² In 2004, the FDA approved a Reglan manufacturer’s request to change the label to add that “[t]herapy should not exceed 12 weeks in duration.”¹²³

¹¹⁴ *Mensing III*, 131 S. Ct. at 2572. In 2011, the U.S. Supreme Court subsequently granted certiorari to the remaining circuit court case, *Gaeta v. Perrigo Pharmaceuticals Co.*, vacating the judgment and remanding the case to the Ninth Circuit for further consideration in light of *Mensing III*. *L. Perrigo Co. v. Gaeta*, 132 S. Ct. 497, 497 (2011).

¹¹⁵ See *Mensing III*, 131 S. Ct. at 2581. The majority opinion recognized that:

[F]rom the perspective of [the plaintiffs], finding pre-emption here but not in *Wyeth* makes little sense. Had [the plaintiffs taken] the brand name drug prescribed by their doctors, *Wyeth* would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted [the generic drug] instead, federal law pre-empts these lawsuits.

Id.

¹¹⁶ *Id.* at 2573.

¹¹⁷ *Id.* at 2572–73.

¹¹⁸ *Id.* at 2572.

¹¹⁹ *Id.* at 2573.

¹²⁰ *Id.* at 2572.

¹²¹ *Mensing III*, 131 S. Ct. at 2572–73.

¹²² *Id.* at 2572.

¹²³ *Id.*

It was not until 2009, approximately two years after the plaintiffs in these actions filed their original suits, that the FDA ordered the labeling to include its strongest warning: a black box warning.¹²⁴ This warning stated that “[t]reatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases.”¹²⁵

In 2007 and 2008, respectively, Mensing and Demahy filed separate suits against the generic manufacturers of metoclopramide, alleging a failure to provide adequate warnings of the risks of long-term use.¹²⁶ Although the two district courts deciding the cases reached divergent conclusions,¹²⁷ on appeal both the Fifth and Eighth Circuits held that FDA regulations did not preempt the plaintiffs’ state law claims.¹²⁸ Therefore, under these circuit court opinions, Mensing and Demahy could successfully sue the generic manufacturers.¹²⁹

It is undisputed that a generic drug’s label must be the same as its brand name counterpart when it is first approved by the FDA.¹³⁰ Whereas a brand name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label, a generic manufacturer simply must show that its label is identical to the brand name drug’s label.¹³¹

The parties disagreed, however, on whether generic manufacturers may change their labels after initial FDA approval.¹³² Without a regulation specifically on point, the parties and the Court had to interpret the collective meaning of several regulations taken together.¹³³ In reversing the Fifth and Eighth Circuits’ decisions, the Supreme Court relied heavily on the FDA’s own interpretation of its regulations, as presented

¹²⁴ *Id.* at 2573.

¹²⁵ *Id.*

¹²⁶ *Demahy v. Wyeth (Demahy I)*, 586 F. Supp. 2d 642, 644 (E.D. La. 2008); *Mensing v. Wyeth (Mensing I)*, 562 F. Supp. 2d 1056, 1057–58 (D. Minn. 2008).

¹²⁷ *Compare Demahy I*, 586 F. Supp. 2d at 662 (holding that FDA regulations do not preempt state law failure-to-warn claims), *with Mensing I*, 562 F. Supp. 2d at 1064–65 (holding that FDA regulations preempt state law failure-to-warn claims).

¹²⁸ *Demahy II*, 593 F.3d at 449; *Mensing II*, 588 F.3d at 614.

¹²⁹ *Demahy II*, 593 F.3d at 449; *Mensing II*, 588 F.3d at 614.

¹³⁰ *See Mensing III*, 131 S. Ct. at 2574.

¹³¹ 21 U.S.C. § 355(j)(2)(A)(v) (2006); *see id.* § 355(j)(4)(G) (declaring that one ground for not approving an ANDA is that “information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the [brand name] drug referred to in the application”); *Mensing III*, 131 S. Ct. at 2574.

¹³² *Mensing III*, 131 S. Ct. at 2574.

¹³³ *See id.* at 2574–75.

in the United States' amicus brief, to show that generic manufacturers could not unilaterally change their labeling.¹³⁴

First, the Court accepted the FDA's seemingly inconsistent interpretation that although the CBE process applied to generic manufacturers, generic manufacturers could not use the CBE process unilaterally to update a warning label as state law would require.¹³⁵ Thus, unlike brand name manufacturers that can unilaterally enhance a warning through the CBE process (subject to the FDA's subsequent approval), generic manufacturers can only use the CBE process to update a label to match a brand name manufacturer's updated label.¹³⁶ The FDA maintained that the CBE process is simply the procedure that a generic manufacturer could use to change a label, but that the content of the label change is governed by the statutes and regulations requiring "sameness" among generic and brand name labels.¹³⁷ Finding that the FDA's interpretation of its own regulations was not "plainly erroneous," the Court deferred to the FDA and concluded that the generic manufacturer could not meet its state law duty through the CBE process.¹³⁸

Second, the Court determined that generic manufacturers could not send "dear doctor" letters to fulfill their state law obligations.¹³⁹ The FDA maintained that sending a letter from only a generic manufacturer—without a comparable letter from the brand name manufacturer—would imply that the two drugs were different in some re-

¹³⁴ See *id.* at 2575–76 (relying on the FDA's own interpretation of its regulations to conclude that the generic manufacturers could not have used the CBE process or sent the sort of "dear doctor" letters the plaintiffs envisioned).

¹³⁵ *Id.* Generic manufacturers are in fact required to use the CBE process under the appropriate circumstances. 21 C.F.R. § 314.97 (2012) (requiring generic manufacturers to comply with 21 C.F.R. § 314.70); see *id.* § 314.70(c) (describing the CBE process).

¹³⁶ *Mensing III*, 131 S. Ct. at 2575.

¹³⁷ U.S. *Mensing III* Brief, *supra* note 57, at 15–16. Specifically, the FDA maintained that even after a generic drug's ANDA has been approved, the substantive regulations and statutes governing the original ANDA continue to govern its supplements, such as those filed through the CBE process. *Id.*; see 21 U.S.C. § 355(j)(4)(G) (2006) (stating that the FDA may deny an ANDA if a generic drug's proposed labeling is not the "same as" the brand name drug); 21 C.F.R. § 314.94(a)(8)(iii) (governing the content of an ANDA and requiring that proposed labeling be the "same as" that of the brand name drug); 21 C.F.R. § 314.150(b)(10) (stating that the FDA may withdraw approval of an ANDA if the labeling of the generic drug is "no longer consistent with" that of the brand name drug).

¹³⁸ *Mensing III*, 131 S. Ct. at 2575–76 (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (setting forth the standard for deferral to an agency's interpretation of its own regulations)).

¹³⁹ *Id.* at 2576.

spect.¹⁴⁰ Because such a difference would be “misleading,” the FDA may withdraw its approval of the generic drug’s ANDA.¹⁴¹ Thus, federal law did not permit the generic manufacturer to fulfill its state law duty through “dear doctor” letters either.¹⁴²

Given that the generic manufacturers could not unilaterally change their labeling, the Court found that it would be impossible for the generic manufacturers simultaneously to comply with state and federal requirements.¹⁴³ The Court found that even if a generic manufacturer had fulfilled its federal duty to notify the FDA of the drug’s risks, it would not have fulfilled its state law duty to provide adequate labeling.¹⁴⁴ To satisfy the requirements of state law, the generic manufacturer would have had to actually change its label—not simply request that the FDA change it—but, according to the Court, it could not have done so without violating its federal duty demanding that its label be the same as the brand name label.¹⁴⁵

As a result of the *Mensing III* decision, consumers cannot sue generic manufacturers for failure to warn.¹⁴⁶ Even the majority’s decision recognized the inanity of this result: “We acknowledge the unfortunate hand that federal drug regulation has dealt *Mensing*, *Demahy*, and others similarly situated.”¹⁴⁷ After *Mensing III*, the question became whether generic consumers could successfully sue the brand name manufacturers instead.¹⁴⁸

¹⁴⁰ *Id.* The FDA did not argue that generic manufacturers could not send “dear doctor” letters as a general matter; they could, but only if the letter conformed to the requirements for a generic drug’s labeling. See U.S. *Mensing III* Brief, *supra* note 57, at 18–19. That is, because “dear doctor” letters qualify as labeling under the FDA’s definition, the labeling must be “consistent with and not contrary to” the brand name drug’s labeling. *Id.* (quoting 21 C.F.R. § 201.100(d)(1)).

¹⁴¹ *Mensing III*, 131 S. Ct. at 2576; 21 C.F.R. § 314.150(b)(3); U.S. *Mensing III* Brief, *supra* note 57, at 19.

¹⁴² *Mensing III*, 131 S. Ct. at 2576.

¹⁴³ *Id.* at 2576–77.

¹⁴⁴ *Id.* at 2577–78. The FDA agreed with the plaintiffs that generic manufacturers do have a duty to report new information about risks to the FDA. Brief for Respondents Gladys *Mensing* and Julie *Demahy* at 15, *Mensing III*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501) [hereinafter *Mensing III* Brief for Respondents]; U.S. *Mensing III* Brief, *supra* note 57, at 15. Nonetheless, the Court did not address the issue, stating that preemption would exist even if such a duty existed. *Mensing III*, 131 S. Ct. at 2577.

¹⁴⁵ See *Mensing III*, 131 S. Ct. at 2578.

¹⁴⁶ See *Chemmerinsky*, *supra* note 78, at 54 (“[I]njured patients now generally must sue on a theory other than failure to warn.”).

¹⁴⁷ See *Mensing III*, 131 S. Ct. at 2581.

¹⁴⁸ See *Metz v. Wyeth*, 830 F. Supp. 2d 1291, 1294–95 (M.D. Fla. 2011) (holding that generic consumers cannot recover from brand name manufacturers and noting that the Court in *Mensing III* appeared to contemplate this outcome).

B. *Generic Consumers' Actions Against Brand Name Manufacturers*

Prior to *Mensing III*, courts were nearly unanimous in denying generic consumers' failure-to-warn claims against brand name manufacturers despite the wide variety of legal theories that plaintiffs argued.¹⁴⁹ The underlying argument in each of the claims was that prescribing physicians rely on the labeling and marketing provided by the brand name manufacturer, regardless of whether the patient actually consumes the brand name or generic version of the drug.¹⁵⁰

In the seminal case on this issue, the 1994 case *Foster v. American Home Products Corp.*, the U.S. Court of Appeals for the Fourth Circuit held that a brand name manufacturer cannot be held liable for injuries resulting from the use of a generic manufacturer's product.¹⁵¹ In that case, six-week-old Brandy Foster died suddenly, allegedly as a result of taking the generic equivalent of the brand name drug Phenergan.¹⁵² The child's parents sued Wyeth—the manufacturer of Phenergan—for negligent misrepresentation.¹⁵³

¹⁴⁹ See, e.g., *Howe v. Wyeth Inc.*, No. 8:09-CV-610-T-17AEP, 2010 WL 1708857, at *3–4 (D. Fla. Apr. 26, 2010) (denying claims for negligence, strict products liability, breach of express and implied warranties of merchantability, negligent misrepresentation and fraudulent concealment, negligence per se, and loss of consortium); *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643, at 645–46 (W.D.N.C. 2010) (denying claims for negligence, breach of undertaking a special duty, misrepresentation by omission, negligent misrepresentation, constructive fraud, fraud by concealment, intentional infliction of emotional distress, negligent infliction of emotional distress, unfair and deceptive trade practices in violation of N.C. Gen. Stat. § 75-1.1, breach of express warranty, and breach of implied warranties).

¹⁵⁰ See, e.g., Brief of Appellants/Cross-Appellees at 37, *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994) (No. 93-1627) (arguing that it was foreseeable to the brand name manufacturer that its conduct would cause harm to generic consumers when prescribing physicians rely on the communications from the brand name manufacturer).

¹⁵¹ 29 F.3d 165, 167 (4th Cir. 1994); see *Metz*, 830 F. Supp. 2d at 1295 (noting that the Fourth Circuit's holding in *Foster* was the seminal case on the issue).

¹⁵² See *Foster*, 29 F.3d at 167.

¹⁵³ See *id.* The original complaint contained four counts: (1) negligence—wrongful death; (2) negligence—survivorship; (3) strict liability; and (4) breach of warranty. See *id.* The district court granted summary judgment on each of these four counts, but allowed the plaintiffs to argue a negligent misrepresentation claim, which the plaintiffs argued was alleged in the original complaint, even though the term was not mentioned. See *id.* at 167 n.1. The plaintiffs also filed suit against a generic manufacturer, Barre-National Corporation, believing that Barre had manufactured the generic promethazine that their child was given. *Id.* at 167. The district court granted Barre's unopposed motion for summary judgment when it was determined that My-K Laboratories, not Barre, manufactured the drug that their child consumed. *Id.*; Brief of Appellee/Cross-Appellant, *supra* note 150, at 3, *Foster*, 29 F.3d 165 (No. 93-1627). The plaintiffs agreed to a dismissal with prejudice of their subsequent suit against My-K Laboratories for reasons not stated in the record. *Foster*, 29 F.3d at 167.

The Fourth Circuit in *Foster* rejected the plaintiffs' negligent misrepresentation claim against the brand name manufacturer for three related reasons.¹⁵⁴ First, the court viewed the negligent misrepresentation claim as an attempt to circumvent Maryland's requirement for products liability claims that the defendant manufactured the product at issue.¹⁵⁵ Second, the court rejected the contention that brand name manufacturers are liable to generic consumers because brand name manufacturers are aware that generic manufacturers copy their labeling.¹⁵⁶ Finally, the court held that brand name manufacturers do not owe a duty to consumers of another manufacturer's product.¹⁵⁷ As a result, *Foster* established the rule that generic consumers had no right of action against brand name manufacturers.¹⁵⁸

With the exception of two cases—*Conte v. Wyeth*, a 2008 California Court of Appeals case, and *Kellogg v. Wyeth*, a 2010 case from the U.S. District Court for the District of Vermont—every court to address the issue has rejected attempts by consumers of generic drugs to sue brand name manufacturers because the courts determined that no duty exists.¹⁵⁹ Nearly all of the cases addressing this issue have cited *Foster* with approval.¹⁶⁰

Arguably, the Supreme Court's 2011 decision in *Mensing III* affected the *Foster* rule because it undermined the notion that generic consumers have a cause of action against generic manufacturers.¹⁶¹

¹⁵⁴ See *Foster*, 29 F.3d at 168–71.

¹⁵⁵ See *id.* at 168.

¹⁵⁶ See *id.* at 170.

¹⁵⁷ See *id.* at 171.

¹⁵⁸ See *id.* at 170.

¹⁵⁹ See *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 709 (D. Vt. 2010) (holding that a brand name manufacturer could be liable to a generic consumer); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 114 (Ct. App. 2008) (same). “In the sixteen years since *Foster* was decided, federal district courts sitting in fifteen states, several state trial courts and one intermediate court of appeal, have . . . dismissed claims against brand name manufacturers by users of the generic form of the drug.” *Kellogg*, 762 F. Supp. 2d at 707.

¹⁶⁰ See *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 540 (E.D. Pa. 2006), *vacated*, 129 S. Ct. 1578 (2009) (“[A] review of caselaw 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.”).

¹⁶¹ See *Mensing III*, 131 S. Ct. at 2574–75; *Foster*, 29 F.3d at 169; See *supra* notes 130–148 and accompanying text (discussing *Mensing III*'s holding that generic consumers' claims against generic manufacturers are preempted by FDA regulations). Specifically, the Fourth Circuit stated that a generic manufacturer has the ability to change its label “[t]o add or strengthen a contraindication, warning, precaution or adverse reaction or [t]o delete false, misleading or unsupported indications for use or claims for effectiveness without prior FDA approval.” *Id.* (internal quotation marks omitted). The Supreme Court's decision in *Mensing III* abrogated this dictum. 131 S. Ct. at 2575.

The court in *Foster* stated, in dicta, that generic consumers had a cause of action against generic manufacturers.¹⁶²

There is little reason to expect a changed outcome, however, on strict liability or breach of warranty claims, because each requires that the defendant actually manufactured the product at issue.¹⁶³ Negligence-based claims, by contrast, do not necessarily have the same relational requirement, despite the vast majority of cases on this subject stating the opposite.¹⁶⁴ Nonetheless, all courts to address this issue since *Mensing III* have refused to abandon *Foster*.¹⁶⁵

With the exception of courts applying California law and following *Conte*, no court has yet seized the opportunity provided by *Mensing III* to revisit the reasoning of *Foster*.¹⁶⁶ Instead, the cases to address these claims have reaffirmed the *Foster* rule.¹⁶⁷

¹⁶² *Foster*, 29 F.3d at 170 (stating that generic manufacturers are able to use the CBE process to strengthen a warning, and, “like all other manufacturers, are responsible for the representations they make regarding their products”).

¹⁶³ See U.C.C. §§ 2-313, 2-314, 2-315 (2012) (stating that liability for breach of warranty can be imposed only on those who sold the product that harmed the plaintiff); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §§ 1, 9 (1998) (stating that strict tort liability applies only to “one who sells” a product); RESTATEMENT (SECOND) OF TORTS §§ 402A(1), 402B (1965); Rostron, *supra* note 2, at 1140.

¹⁶⁴ See Rostron, *supra* note 2, at 1169 (stating that the principle that a product manufacturer owes no duty to a plaintiff who does not use its product “may be [true] for strict liability claims, but . . . [i]n the realm of negligence, it is far less clear that any such principle exists.”); see also DAN B. DOBBS, THE LAW OF TORTS 269 (2000) (Explaining that, in general, the elements of a negligence claim are: (1) duty; (2) breach; (3) cause in fact; (4) proximate cause; and (5) damages).

¹⁶⁵ See *Smith v. Wyeth*, 657 F.3d 420, 423 (6th Cir. 2011) (affirming *Foster*); *Metz*, 830 F. Supp. 2d at 1295; *Gross v. Pfizer, Inc.*, No. 8:10-cv-00110-AW, 2011 WL 4005266, at *2 (D. Md. Sept. 7, 2011).

¹⁶⁶ Compare *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 2012 WL 3842271, at *6–7 (E.D. Ky. Sept. 5, 2012) (following *Conte* in applying California law); with *Smith*, 657 F.3d at 424 (joining the majority of courts following *Foster*). In a related context, however, in 2012 the U.S. Court of Appeals for the First Circuit in *Bartlett v. Mutual Pharmaceutical Co.*, refused to extend *Mensing III*'s preemption of claims against generic manufacturers to the design defect realm. *Bartlett v. Mutual Pharm. Co.*, 678 F.3d 30, 38 (1st Cir. 2012) (holding generic manufacturers responsible for design defect claims). But see *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 484 (E.D.N.Y. 2012) (holding that design defect claims against generic manufacturers are preempted under the *Mensing III* rationale).

¹⁶⁷ See, e.g., *Smith*, 657 F.3d at 423; *Hogue v. Pfizer, Inc.*, 2012 WL 4466609, at *5 (S.D. Ohio Sept. 27, 2012); *Baymiller v. Ranbaxy Pharm., Inc.*, 2012 WL 3929768, at *8–9 (D. Nev. Sept. 6, 2012); *Phares v. Actavis-Elizabeth LLC*, 2012 WL 3779227, at *7–11 (S.D. Tex. Aug. 30, 2012); *Lashley v. Pfizer, Inc.*, 2012 WL 2459148, at *11 (S.D. Miss. June 27, 2012); *Phelps v. Wyeth*, 857 F. Supp. 2d 1114, 1130 (D. Or. 2012); *Guarino v. Wyeth LLC*, 2012 WL 1138631, at *2 (M.D. Fla. Apr. 3, 2012); *Metz*, 830 F. Supp. 2d at 1295; *Gross*, 2011 WL 4005266, at *2.

In one of the first cases to address the issue, in the fall of 2011, the U.S. District Court for the District of Maryland in *Gross v. Pfizer* denied the plaintiff's motion for reconsideration of a grant of summary judgment for the brand name defendants.¹⁶⁸ In *Gross*, the district court had granted summary judgment relying heavily on the Fourth Circuit's holding in *Foster*, which had also been based on Maryland law.¹⁶⁹ On motion for reconsideration, however, the district court determined that "[t]he Supreme Court's holding in *Mensing III* neither created nor abrogated any duty under Maryland law with regard to brand name manufacturers."¹⁷⁰ Therefore, the court decided that *Mensing III* changed the outcome of neither *Foster* nor *Gross*.¹⁷¹

On September 22, 2011, in *Smith v. Wyeth*, the U.S. Court of Appeals for the Sixth Circuit became the first appellate court to examine a state law claim against brand name manufacturers after the *Mensing III* decision.¹⁷² The facts in *Smith* were very similar to those in *Mensing III*: the plaintiffs had taken a generic version of Wyeth's brand name Reglan for a period longer than twelve weeks and had developed tardive dyskinesia as a result.¹⁷³ Relying on *Mensing III*, the Sixth Circuit affirmed the district court's grant of summary judgment to the generic defendants.¹⁷⁴ As to the brand name defendants, the Sixth Circuit did not even mention any possible effect that *Mensing III* may have had on the pre-*Mensing III* case law.¹⁷⁵ Instead, the court simply followed *Foster* and its progeny.¹⁷⁶

Similarly, on November 18, 2011, the U.S. District Court for the Middle District of Florida reaffirmed the holding of *Foster* in *Metz v. Wyeth*.¹⁷⁷ Again, where plaintiffs consumed a generic equivalent of Wyeth's Reglan, the district court granted summary judgment to the brand name defendants.¹⁷⁸ The court rejected the plaintiffs' arguments that *Mensing III* in any way changed the outcome of *Foster*, stating that the proposition in *Foster* that consumers could recover from generic

¹⁶⁸ See *Gross*, 2011 WL 4005266, at *2.

¹⁶⁹ See *id.* at *1–2.

¹⁷⁰ See *id.* at *2.

¹⁷¹ See *id.*

¹⁷² See *Smith*, 657 F.3d at 424; *Sixth Circuit Rejects Brand-Liability Theory Post-Pliva v. Mensing*, MAYER BROWN (Dec. 8, 2011), <http://www.mayerbrown.com/publications/article.asp?id=11949&nid=6>.

¹⁷³ See *Smith*, 657 F.3d at 421–22.

¹⁷⁴ See *id.* at 423.

¹⁷⁵ See *id.* at 423–24.

¹⁷⁶ See *id.* at 424.

¹⁷⁷ See *Metz*, 830 F. Supp. 2d at 1295.

¹⁷⁸ See *id.* at *1, *3.

manufacturers for misrepresentations relating to their products was merely dicta and “was by no means central to the ultimate holding in *Foster*.”¹⁷⁹ Furthermore, the court noted that federal courts sitting in diversity should not adopt innovative theories of state law recovery.¹⁸⁰

III. A SOLUTION: THE FDA SHOULD ALLOW ALL MANUFACTURERS TO USE THE CBE PROCESS

This Part argues for an amendment to the FDA regulations to allow drug consumers to successfully sue the manufacturer of the drug they consumed—regardless of whether the manufacturer was a brand name or generic manufacturer.¹⁸¹ First, Section A explains why courts should not allow consumers who take generic drugs to sue brand name manufacturers.¹⁸² Then, Section B offers a basic outline of how the FDA should amend its regulations to make all manufacturers liable to their consumers.¹⁸³ Finally, Section C analyzes the policy justifications supporting such an amendment.¹⁸⁴

A. *Conte and Kellogg: The Wrong Prescription*

In 2008, in *Conte v. Wyeth*, the California Court of Appeals held that a brand name manufacturer could be held liable for injuries resulting from the use of another manufacturer’s product.¹⁸⁵ The facts of *Conte* were similar to those of *Mensing III*; in *Conte*, the plaintiff, Elizabeth Conte, developed tardive dyskinesia after taking a generic equivalent of Reglan for nearly four years.¹⁸⁶ Conte sued both the brand name manufacturer, Wyeth, as well as the manufacturers of the generic equivalent drug that she actually consumed.¹⁸⁷ Although *Mensing III* superseded the court’s disposition with respect to the generic defendants, it appears that the *Conte* court’s reasoning with respect to the brand name manufacturers is still good law in California.¹⁸⁸

¹⁷⁹ See *id.* at *2.

¹⁸⁰ *Id.*

¹⁸¹ See *infra* notes 185–256 and accompanying text.

¹⁸² See *infra* notes 185–207 and accompanying text.

¹⁸³ See *infra* notes 208–228 and accompanying text.

¹⁸⁴ See *infra* notes 229–256 and accompanying text.

¹⁸⁵ 168 Cal. App. 4th 89, 94–95 (Cal. Ct. App. 2008).

¹⁸⁶ *Id.* at 95; see *PLIVA, Inc. v. Mensing III*, 131 S. Ct. 2567, 2573 (2011).

¹⁸⁷ *Conte*, 168 Cal. App. 4th at 94.

¹⁸⁸ *Id.* at 114; see *Mensing III*, 131 S. Ct. at 2581 (holding that FDA regulations preempt failure-to-warn claims against generic manufacturers). In a 2012 case on unrelated facts, *O’Neil v. Crane Co.*, the Supreme Court of California arguably cut back on the expansive foreseeability inquiry that the court in *Conte* proposed. See *O’Neil v. Crane Co.*, 266 P.3d

To succeed on a negligent misrepresentation claim, California law requires a plaintiff to establish that: (1) the defendant owed the plaintiff a duty; (2) the defendant breached that duty by making a misrepresentation; and (3) the defendant's actual and reasonable reliance on that misrepresentation proximately caused the defendant's injury.¹⁸⁹ The major legal issue in this and similar cases was whether the first element was met; namely, whether a name-brand manufacturer owed a duty to a consumer of a generic equivalent.¹⁹⁰

The *Conte* court held that the brand name manufacturer Wyeth did in fact owe the generic consumer a duty of care.¹⁹¹ Looking to the Restatement Second of Torts, as the California Supreme Court had done in other negligent misrepresentation cases, the court noted 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."¹⁹² The court reasoned that it was "eminently foreseeable" that a physician would rely on the information provided by Wyeth in prescribing the generic equivalent of Reglan.¹⁹³ As a result, the court held that Wyeth owed a duty to consumers of generics, such as Conte.¹⁹⁴

987, 995 (holding that aircraft valve and pump manufacturers "had no duty to warn of risks arising from *other manufacturers'* products"). Nonetheless, the U.S. District Court for the Eastern District of Kentucky, applying California law in its 2012 opinion in *In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, did not view *O'Neil* as limiting the holding in *Conte*. *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 2012 WL 3842271, at *6 n.6 (E.D. Ky. Sept. 5, 2012) ("If the California Supreme Court had wished to overrule *Conte*, it could have done so explicitly. The reason for the *O'Neil* court's complete lack of citation to *Conte* is, therefore, most likely that the court believed the case to be irrelevant to determination of the issue at hand.").

¹⁸⁹ *Garcia v. Superior Court*, 789 P.2d 960, 960, 963 (Cal. 1990); Respondent Wyeth's Brief at 12, *Conte*, 168 Cal. App. 4th 89 (No. A117353).

¹⁹⁰ See *Conte*, 168 Cal. App. 4th at 114.

¹⁹¹ *Id.* at 103–07, 114. The court in *Conte* first distinguished strict products liability cases, which require the plaintiff actually to have used a product produced by the defendant, from negligence-based cases, which do not have such a requirement. See *id.* at 100–02. The court explicitly rejected the notion from *Foster* that the plaintiff was arguing a strict products liability case masquerading as a negligence claim. Compare *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 168 (4th Cir. 1994) (stating that the plaintiffs were attempting "to circumvent" the requirements of strict products liability by bringing a negligent misrepresentation claim), with *Conte*, 168 Cal. App. 4th at 101 (determining that there is "no logical or legal inconsistency between allowing the suit for negligence and disallowing the suit for strict products liability").

¹⁹² See *id.* at 104 (citing *Garcia*, 50 Cal. 3d at 728, 735 (quoting RESTATEMENT (SECOND) OF TORTS § 311, cmt. b, at 106)).

¹⁹³ See *Conte*, 168 Cal. App. 4th at 105.

¹⁹⁴ See *id.* at 114.

Similarly, in the 2010 case, *Kellogg v. Wyeth*, the U.S. District Court for the District of Vermont held that a brand name manufacturer could foresee the injury to generic consumers, and therefore owed those consumers a duty of reasonable care.¹⁹⁵ As in *Conte* and *Mensing III*, the plaintiff's doctor in *Kellogg* prescribed Reglan, which a pharmacist filled with a generic version of metoclopramide.¹⁹⁶ Rejecting the strict liability requirement that the defendant actually sold the product in question to the plaintiff, the court found that it is "entirely foreseeable[] that a physician will prescribe a drug in reliance upon information disseminated by the brand name manufacturer, and that the patient will receive and ingest a generic equivalent."¹⁹⁷

Courts have correctly been reluctant to follow the reasoning of *Conte* and *Kellogg* for two primary reasons.¹⁹⁸ First, federal courts adjudicating state law issues have been reluctant to rewrite state law.¹⁹⁹ Moreover, in some states, courts are bound by the statutes declaring that where a product causes an injury, the claim will be governed by that state's strict products liability rules.²⁰⁰ Thus, courts have generally joined the majority of other states on the issue, viewing *Conte* and *Kellogg* as an aberration.²⁰¹

¹⁹⁵ *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 706 (D. Vt. 2010), 762 F. Supp. 2d at 706.

¹⁹⁶ *See id.* at 697–98.

¹⁹⁷ *See id.* at 706.

¹⁹⁸ *See* *Smith v. Wyeth*, 657 F.3d 420, 424 (6th Cir. 2011) (joining the "majority" of courts disagreeing with *Conte* and *Kellogg*); *infra* notes 199–207 and accompanying text.

¹⁹⁹ *See Foster*, 29 F.3d at 171 (citing *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938) ("As a federal court sitting in diversity, we must apply the applicable state law as it now exists.")).

²⁰⁰ *See, e.g.*, N.J. STAT. ANN. § 2A:58C-1(b)(2) (West 2000) ("Product liability action" means any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim . . ."); *Smith*, 657 F.3d at 423 (holding that Ky. REV. STAT. ANN. § 411.300(1) (West 2010) controls all Kentucky damage claims resulting from the use of products, regardless of the legal theory advanced, and requires that the defendant's product caused the plaintiff's injury); *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114, 1121 (D. Or. 2012) ("Oregon courts have found that ORS § 30.900 [Oregon's product liability statute] includes all theories a plaintiff may bring in an action based on a product defect. Consequently, Oregon product liability law is controlling here, and it does not allow for name-brand manufacturer liability unless Mrs. Phelps can demonstrate that the name-brand manufacturers' products caused her injury.") (internal citations omitted).

²⁰¹ *See, e.g.*, *Fisher v. Pelstring*, No. 09-252, 2010 WL 2998474, at *7 (D.S.C. July 28, 2010) (noting "that *Conte* is in direct conflict with the weight of authority in the courts that have addressed the issue"); *Finnicum v. Wyeth*, 708 F. Supp. 2d 616, 621 (E.D. Tex. 2010); *see also* *Martin*, *supra* note 4, at 475 ("The question now is whether *Conte* will become the leading case on brand name manufacturers' liability to users of generic drugs using a negligent misrepresentation theory, or whether it remains an isolated anomaly.").

Second, most courts have found that to hold brand name manufacturers responsible for generic consumers would push the concept of foreseeability too far.²⁰² Embedded in the foreseeability inquiry, courts have looked at fundamental fairness, finding that it would be unfair to hold a brand name manufacturer liable for a product from which it did not profit.²⁰³

As a policy matter, although drug labeling might improve if brand name manufacturers were held liable to all consumers, it is also likely that fewer drugs would be discovered and marketed.²⁰⁴ Manufacturers would consider lawsuit awards as costs of doing business, but at some point, as costs increase and potential revenue streams decrease, some manufacturers would likely choose not to invest in product development.²⁰⁵ From an economic perspective, this is not necessarily inefficient because firms should consider the true costs of their products when making production decisions.²⁰⁶ Nonetheless, these costs should be borne by each of the manufacturers who created the risks—that is, each manufacturer should be liable only to its own customers.²⁰⁷

B. Amending the FDA Regulations to Allow Generic Manufacturers to Enhance a Warning Through the CBE Process

The FDA should amend its regulations to allow generic manufacturers to strengthen a warning through the “changes-being-effected” (“CBE”) process.²⁰⁸ This would provide generic manufacturers with a means to change a warning label without prior FDA approval.²⁰⁹ Such a

²⁰² See *Foster*, 29 F.3d at 171 (“We think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far.”); *Couick v. Wyeth*, 691 F. Supp. 2d 643, 646 (W.D.N.C. 2010).

²⁰³ See, e.g., *Foster*, 29 F.3d at 170.

²⁰⁴ See *infra* note 205 and accompanying text.

²⁰⁵ See Kip Viscusi & Michael J. Moore, *Industrial Profile of the Links Between Product Liability and Innovation*, in *THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION* 81, 114 (Peter W. Huber & Robert E. Litan eds., 1991) (“Higher levels of liability costs usually increase product-related research and development. However, extremely high levels of liability dampen innovation as firms reduce their focus on new product development.”).

²⁰⁶ See STEVEN SHAPELL, *ECONOMIC ANALYSIS OF ACCIDENT LAW* 127 (1987) (“[I]f liable parties pay for the actual level of losses they cause, they will be led to act optimally under liability rules.”).

²⁰⁷ See *infra* notes 208–256 and accompanying text.

²⁰⁸ See *infra* notes 209–256 and accompanying text.

²⁰⁹ See *Wyeth v. Levine (Levine III)*, 555 U.S. 555, 568 (2009) (describing the CBE process, which currently allows brand name manufacturers unilaterally to update their warning labels to “add or strengthen a contraindication, warning, precaution, or adverse reaction” (quoting 21 C.F.R. § 314.70(c) (6) (iii) (A) (2012))).

change would nullify *Mensing III* and allow generic consumers to sue generic manufacturers for failure to warn.²¹⁰ Allowing generic consumers to sue generic manufacturers incentivizes all manufacturers to strengthen warning labels upon discovering new adverse information, thus increasing safety for consumers.²¹¹

A new FDA regulation should treat brand name and generic manufacturers identically for purposes of post-market risks.²¹² The regulation should do three things: (1) create a database for adverse incident reporting, accessible to *all* manufacturers of a drug, and require all manufacturers to monitor the reports; (2) allow *all* manufacturers to strengthen a warning label unilaterally; and (3) require sameness among *all* manufacturers' labels.²¹³ As a result of such regulation, consumers of generic drugs would be able to sue the generic manufacturers.²¹⁴

The first requirement—to create a common database for adverse incident reporting—would provide all manufacturers with the same information as it is reported.²¹⁵ After the initial approval process, brand name manufacturers do not have a comparative advantage over the generic manufacturers in terms of interpreting new data.²¹⁶ The brand

²¹⁰ See *Mensing III*, 131 S. Ct. at 2577–78. In 2011, the U.S. Supreme Court in *PLIVA, Inc. v. Mensing (Mensing III)* held that the FDA regulations preempted state law failure-to-warn claims against generic manufacturers because it was impossible for generic manufacturers to comply with both their state law duty to change a label and their federal law duty to keep the label the same. *Id.* It was not enough that the generic manufacturers had the ability to request a label change from the FDA as that would not have satisfied their state law duty to provide adequate labeling—the state law duty could only be fulfilled through a unilateral ability to change the label. *Id.*

²¹¹ See *Mensing III* Brief for Respondents, *supra* note 144, at 20 (arguing that “[i]f generic drug manufacturers did not share in responsibility for ensuring the adequacy of drug warnings, there would often be no one left ‘minding the store’”).

²¹² See *infra* notes 215–228 and accompanying text (describing how to achieve such a result); *infra* notes 229–256 and accompanying text (arguing that brand name and generic manufacturers should each be liable to their respective consumers).

²¹³ See *infra* notes 215–228 and accompanying text.

²¹⁴ Cf. *Levine III*, 555 U.S. at 573 (holding that the FDA regulations do not preempt state law failure-to-warn claims because brand name manufacturers could unilaterally strengthen a warning through the CBE regulation).

²¹⁵ See David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 489–90 (2008) (discussing the FDA Amendments Act's attempt to strengthen the FDA's ability to conduct post-approval surveillance). Under the current system, the FDA requires manufacturers to gather adverse reaction reports through its Adverse Event Reporting System (“AERS”). *Id.* at 489.

²¹⁶ See Catherine D. DeAngelis & Phil B. Fontanarosa, *Prescription Drugs, Products Liability, and Preemption of Tort Litigation*, 300 J. AM. MED. ASS'N 1939, 1939 (2008) (stating that the safety and effectiveness profile of a drug may be dramatically different ten years after its initial approval due to the data received from a wider population of patients). The small

name manufacturer has supplied all its relevant data to the FDA in order to gain pre-market approval, and thus any new information could equally be interpreted by a generic manufacturer with the same information.²¹⁷ Currently, the FDA and the brand name manufacturers receive most, if not all, adverse incident reports.²¹⁸ As a result, it is highly unlikely that a generic manufacturer would have the information necessary to implement a label change.²¹⁹ Under the new regulation, however, all manufacturers would see and be required to monitor the same information.²²⁰

Second, in order to override *Mensing III*, a new regulation would need to explicitly state that all manufacturers are allowed to strengthen a warning label unilaterally.²²¹ In holding that FDA regulations preempt failure-to-warn claims against generic manufacturers, the Court in *Mensing III* relied on the FDA's own interpretation of its regulations, stating that generic manufacturers could not unilaterally update a

sample size for pre-market clinical trials “virtually guarantees” that new risks will emerge after initial FDA approval. *See id.* Because such data emerges after the drug's initial application, a generic manufacturer and the original brand name manufacturer are equally able to interpret this new data. *See id.*

²¹⁷ *See id.*

²¹⁸ *See* Oral Argument at 23:31, *Mensing III*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), available at http://www.oyez.org/cases/2010-2019/2010/2010_09_993#argument (describing how brand name manufacturers, not generic manufacturers, typically receive adverse event reports); *Adverse Event Reporting System (AERS)*, U.S. FOOD & DRUG ADMIN. (last updated Sept. 10, 2012), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm> (describing how the FDA utilizes the data it receives through the AERS system to update labeling or restrict use of a drug).

²¹⁹ *See* Oral Argument, *supra* note 218, at 23:31. An attorney for the generic manufacturers in *Mensing III* argued:

[G]enerics rarely even get adverse reports because if a doctor prescribes a drug, the doctor prescribes it as the brand, and then checks off the box that says a generic can be issued. If a patient comes and tells him about an adverse report, the doctor has no idea which generic of the 15 that might be in the market actually was dispensed, so he'll actually tell the brand company. He'll report the adverse event to the brand company.

Id.

²²⁰ *See supra* note 215 and accompanying text.

²²¹ *See Mensing III*, 131 S. Ct. at 2577–79; *supra* notes 91–100 and accompanying text (summarizing *Levine III*'s holding that FDA regulations do not preempt failure-to-warn claims against brand name manufacturers because brand name manufacturers can enhance a warning label unilaterally); *supra* notes 130–148 (summarizing *Mensing III*'s holding that FDA regulations preempt failure-to-warn claims against generic manufacturers because generic manufacturers cannot enhance a warning label unilaterally).

warning label.²²² If, however, generic manufacturers have the same ability unilaterally to change a label as brand name manufacturers, then FDA regulations would not preempt failure-to-warn claims against any manufacturer.²²³

Third, a new regulation must require sameness among all manufacturers' labels to lessen consumer confusion.²²⁴ The FDA currently requires sameness "to preclude a basis for lack of confidence in the equivalency of generic versus brand name products."²²⁵ If, for example, a brand name manufacturer enhanced its warning label but a generic manufacturer did not copy the change, the different labels would impermissibly suggest that the two drugs have different effects.²²⁶ Currently, however, the brand name drug is the leader in making changes, and sameness is only required of the generic manufacturers.²²⁷ If, however, all manufacturers are able to change a label unilaterally, then even brand name manufacturers should be required to match the same label.²²⁸

C. *The Argument for Holding Generic Manufacturers Liable*

The current system, under which generic manufacturers are liable to no one and generic consumers have no remedy, is neither politically nor economically desirable.²²⁹ It is hard to imagine a public policy justi-

²²² See *id.* at 2575 ("The [FDA] interprets the CBE regulation to allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand name label or to follow the FDA's instructions."); *supra* notes 132–142 and accompanying text (describing the U.S. Supreme Court's reliance in *Mensing III* on the FDA's interpretation of its own regulations).

²²³ See *id.* at 2579. The Court in *Mensing III* held that federal regulations preempted state law failure-to-warn claims when a manufacturer could only ask the FDA to change a label, but not when the manufacturer had the unilateral ability to change the label without prior FDA approval. See *id.*

²²⁴ See U.S. *Mensing III* Brief, *supra* note 57, at 4.

²²⁵ *Id.* (quoting U.S. FOOD & DRUG ADMIN., DIVISION OF GENERIC DRUGS, POLICY AND PROCEDURE GUIDE 37 (1989)).

²²⁶ See *id.*

²²⁷ 21 C.F.R. § 314.70(c) (2012) (requiring all manufacturers to update labels through the CBE process); see *Mensing III*, 131 S. Ct. at 2575 (stating that generic manufacturers can only use the CBE process to update a label to match a brand name manufacturer's updated label).

²²⁸ See U.S. *Mensing III* Brief, *supra* note 57, at 4. If a brand name manufacturer were allowed to maintain its original label after a generic manufacturer changed its labeling, then the policy requiring sameness would be undermined. See *id.* (emphasizing the importance of sameness).

²²⁹ See *infra* notes 230–256 and accompanying text. Indeed, U.S. Representative Henry A. Waxman wrote a letter requesting that the Commissioner of the FDA respond to the *Mensing III* decision by "devising a system that both permits consumers injured by the use

fication for forcing injured patients to bear the burden of negligently labeled drugs.²³⁰ Furthermore, without an incentive for all manufacturers to provide adequate warning labels, manufacturers may opt to provide less-than-adequate warnings.²³¹ If so, patients may choose to forego certain medical treatments if they do not trust drug labeling to warn them of dangerous risks associated with the drug.²³² Clearly, this outcome undermines the very basis for drug patent legislation: if patients will not consume the drug, then there is no purpose for the innovation.²³³

The current system of no liability for generic manufacturers is not only unfair to consumers, but may lead to weaker warning labels.²³⁴ Under the current no-liability scheme, generic manufacturers have no incentive to reduce injuries.²³⁵ Generally, the costs of injury avoidance for a drug manufacturer include both the costs of monitoring and reporting of adverse reactions as well as the costs of lost sales to consumers who will not consume the drug because of the stronger warning

of a generic drug to seek a remedy in court and ensures that the labels of generic drugs are the same as those of their brand name counterparts.” Letter from Henry A. Waxman, Ranking Member, U.S. House Comm. on Energy & Commerce, to Margaret Hamburg, Comm’r, The Food & Drug Admin. (Apr. 11, 2012), <http://democrats.energycommerce.house.gov/index.php?q=news/waxman-urges-fda-for-proper-revisions-in-light-of-supreme-court-ruling>.

²³⁰ See Erin Fuchs, *FDA Could Make Generics Liable Amid Push to Undo Mensing*, LAW 360 (Mar. 28, 2012), <http://www.facgrebdc.com/webfiles/FDA%20Could%20Make%20Generics%20Liable%20Amid%20Push%20To%20Undo%20Mensing.pdf> (describing the “recent public outcry” over the Supreme Court’s decision in *Mensing III*, which made this outcome a reality).

²³¹ See *infra* notes 235–238 and accompanying text.

²³² See SHAVELL, *supra* note 206, at 11, 51–54. “[I]njurers will not take care in the absence of liability, and the outcome will therefore generally depart from the optimal. However, because victims will bear their accident losses, they will have a reason to take care.” *Id.* at 11. Thus, patients will “take care” by choosing not to engage in the risky activity—consuming the potentially mislabeled drugs. See *id.*

²³³ See *Hatch-Waxman Hearing*, *supra* note 52, at 1–2 (promoting the Hatch-Waxman Amendments by touting the innovation of beneficial new drugs that would be increased by an extended patent term).

²³⁴ See *infra* notes 235–249 and accompanying text.

²³⁵ See SHAVELL, *supra* note 206, at 53 (stating that, assuming consumers’ knowledge of risk is imperfect, firms will not take care to reduce injuries). Brand name manufacturers, of course, still have an incentive to provide non-negligent labeling. See *Levine III*, 555 U.S. at 581 (holding brand name manufacturers liable to brand name consumers). With generic drugs representing seventy-five percent of the market, however, and brand name manufacturers only liable to their customers, brand name manufacturers have a lower incentive to investigate post-approval reports and update their label. See *Mensing III*, 131 S. Ct. at 2584 (Sotomayor, J., dissenting) (stating that generic drugs represent seventy-five percent of the market); *Smith*, 657 F.3d at 424 (joining “the majority of courts” in denying generic consumers a remedy from brand name manufacturers).

label.²³⁶ Generic drug manufacturers under the current scheme can avoid these costs altogether because they do not have to monitor adverse reactions, nor do they risk losing customers because of strengthened warning labels.²³⁷

The FDA should set up a system of incentives to uncover adverse reaction information and ensure that such information is properly reflected in drug labeling.²³⁸ The tort system can provide such incentives that deter unwanted behavior.²³⁹ The tort system incentivizes manufacturers to strengthen warnings by allowing tort claims against manufacturers when the probability of harm from an inadequate warning is greater than the burden of enhancing the warning—that is, when the manufacturer is negligent.²⁴⁰

If each manufacturer (brand name and generic) were liable to their own customers for inadequate warnings, then each manufacturer would have an incentive to update warning labels so that they adequately warn of risks.²⁴¹ Assuming that the FDA continues to require sameness among brand name and generic drug labeling, either all manufacturers will have an adequate label or all manufacturers will have an inadequate label.²⁴² If all manufacturers have an inadequate label, then each will face an expected liability cost equal to the total damages caused by the inadequate warning multiplied by the manufac-

²³⁶ Cf. James F. Thrasher et al., *Estimating the Impact of Different Cigarette Package Warning Label Policies: The Auction Method*, 32 ADDICTIVE BEHAV. 2916, 2922–23 (2007) (finding that stronger warnings on cigarette packages discourage consumer purchases).

²³⁷ See *Mensing III*, 131 S. Ct. at 2581 (preempting claims against generic manufacturers); SHAVELL, *supra* note 206, at 11 (stating that “injurers will not take care in the absence of liability”).

²³⁸ See *supra* notes 208–228 and accompanying text (describing the framework required for and FDA regulation to achieve this result).

²³⁹ See Gary T. Schwartz, *Reality in the Economic Analysis of Tort Law: Does Tort Law Really Deter?*, 42 UCLA L. REV. 377, 378 (1994) (“[D]eterrence has now assumed the role of a primary rationale for tort liability rules.”).

²⁴⁰ See *United States v. Carroll Towing*, 159 F.2d 169, 173 (2d Cir. 1947); Schwartz, *supra* note 239, at 378. This is a reformulation of Judge Learned Hand’s classic calculus of negligence. See *Carroll Towing*, 159 F.2d at 173 (stating that a behavior is negligent when $B < PL$, where B represents the defendant’s burden, and P represents the probability of the injury, L, occurring). The burden of enhancing a label includes not only the cost of monitoring and reporting adverse reactions, but also the costs of reduced sales to consumers who would have consumed the drug with the lesser warning, but not with the stronger warning. Cf. Thrasher et al., *supra* note 236, at 2922–23 (describing how a stronger warning label on a cigarette package decreases sales).

²⁴¹ See SHAVELL, *supra* note 206, at 8 (stating that under a negligence standard, injurers will want to take due care to avoid liability).

²⁴² See U.S. *Mensing III* Brief, *supra* note 57, at 4 (describing FDA policy favoring sameness).

turer's individual market share.²⁴³ In contrast, if each of the manufacturers has an adequate label, then they will not be liable and will face only the costs of accident avoidance.²⁴⁴ Given that the expected liability cost will always be higher than the costs of accident avoidance, manufacturers will have an incentive to provide adequate warnings.²⁴⁵

Although it would be economically efficient to have only one manufacturer bear the accident avoidance costs, requiring more manufacturers to bear such costs promotes better labeling.²⁴⁶ The current scheme (in which only the brand name manufacturer bears the accident avoidance costs) is more efficient because it requires only one manufacturer to monitor adverse reports and update its label.²⁴⁷ Although less efficient, a system whereby all manufacturers were required to monitor reports and update labels would lessen the likelihood of inadequate warnings.²⁴⁸ With more manufacturers analyzing the data, it is more likely that suboptimal labels will be corrected.²⁴⁹

Furthermore, there is no principled way to determine which manufacturer should be the single manufacturer to bear the monitoring and reporting costs.²⁵⁰ The system could leave the duty solely on the brand name manufacturer, extending that manufacturer's liability to generic consumers, but this would unfairly penalize the brand name

²⁴³ See William M. Landes & Richard A. Posner, *Joint and Multiple Tortfeasors: An Economic Analysis*, 9 J. LEGAL STUD. 517, 522 (1980) (noting that where more than one injurer was negligent, each injurer's expected liability costs are its expected share of damages multiplied by the total damage). Thus, manufacturers with larger market share face higher expected liability costs because they are liable to more consumers. *See id.*

²⁴⁴ *See id.* In this context, accident avoidance costs refer to the costs that a manufacturer incurs in order to provide an adequate label. *See id.* at 521. These costs include the costs of monitoring and analyzing data about risks of the drug and also include the lost sales to consumers who choose not to consume the drug because of the stronger warning label. *See Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1089 (5th Cir. 1973) (reasoning that "the user or consumer is entitled to make his own choice as to whether the product's utility or benefits justify exposing himself to the risk of harm").

²⁴⁵ *See* Landes & Posner, *supra* note 243, at 524. To see why this must be so, consider that if the costs of accident avoidance were higher than the expected harm, the manufacturer would be non-negligent for failing to provide a stronger warning. *See id.*

²⁴⁶ *See id.* at 520 ("If, ex ante, each defendant bears a cost (an expected cost) of liability, each defendant is deterred, even if ex post all but one pay nothing.").

²⁴⁷ *See* Landes & Posner, *supra* note 243, at 526. Specifically, "optimal care requires that only one of the tortfeasors take care—the one whose costs of care are lower." *Id.* In the context of post-market risk identification, however, there is no reason to believe that the costs of accident avoidance to a brand name manufacturer are lower than the costs to a generic manufacturer. *See id.*

²⁴⁸ *See id.*; *supra* notes 234–247 and accompanying text.

²⁴⁹ *See supra* notes 234–247 and accompanying text.

²⁵⁰ *See infra* notes 251–253 and accompanying text.

manufacturer.²⁵¹ There is no evidence that after a drug's initial approval the brand name manufacturer has a comparative advantage over the generic manufacturers in monitoring adverse reactions and requesting label updates.²⁵² Furthermore, if each manufacturer were required to report adverse events to a common database, then each manufacturer would have the same risk information available.²⁵³

Generic manufacturers may be more reluctant to produce generic equivalents of drugs if they are held liable for inadequately labeled drugs.²⁵⁴ Whereas some manufacturers might stop producing generics, others would probably allocate some amount of funding to doing their own monitoring of the drugs and then make label changes when appropriate to avoid state law liability.²⁵⁵ Although this would increase the cost of such generic drugs—an outcome the Hatch-Waxman Amendments were designed to avoid—it would have the salutary effect of enhancing warnings.²⁵⁶

²⁵¹ See *Foster*, 29 F.3d at 170.

Name brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information. Generic manufacturers avoid these expenses by duplicating successful pioneer drugs and their labels. . . . [It] would be especially unfair [to hold a brand name manufacturer liable to a generic consumer] when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising. The premarketing approval scheme Congress established for generic equivalents of previously approved drugs cannot be construed to create liability of a name brand manufacturer when another manufacturer's drug has been consumed.

Id.

²⁵² See David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. 37, 38 (2005) (noting that generic manufacturers, not just brand name manufacturers, must often conduct additional testing before gaining FDA approval); *supra* note 216 and accompanying text. Because generic manufacturers must conduct additional testing before FDA approval, they are often aware of many of the same risks as a brand name manufacturer even before they begin manufacturing the drug. See *id.*

²⁵³ See *supra* notes 215–220 and accompanying text (proposing that the FDA amend its regulations to include a mandatory common database for adverse incident reporting).

²⁵⁴ See Brief of the Generic Pharmaceutical Association as Amicus Curiae in Support of Petitioners, at 3, *Mensing III*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501) (arguing that “exposing generic manufacturers to state tort liability will adversely affect the industry [and] drive up costs for no salutary purpose”).

²⁵⁵ See SHAVELL, *supra* note 206, at 8.

²⁵⁶ See *Hatch-Waxman Hearing*, *supra* note 52, at 1–2; SHAVELL, *supra* note 206, at 8.

CONCLUSION

The FDA should amend its regulations to allow generic manufacturers to enhance warning labels unilaterally, and thus allow state law failure-to-warn claims against generic manufacturers to lie. The current outcome—in which generic consumers ultimately bear the cost of inadequately labeled drugs—is clearly wrong from a policy perspective. Instead, each manufacturer should be liable to its own customers.

The Supreme Court's decisions in *Wyeth v. Levine* and *PLIVA v. Mensing*, however, establish that the current FDA regulations create this disparate treatment for brand name and generic consumers. As a result, the onus should be on the FDA to correct this predicament.

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