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**WARNING: SHIFTING LIABILITY
TO MANUFACTURERS OF BRAND-NAME
MEDICINES WHEN THE HARM WAS
ALLEGEDLY CAUSED BY GENERIC DRUGS
HAS SEVERE SIDE EFFECTS**

Victor E. Schwartz, Phil Goldberg** & Cary Silverman****

Can a product manufacturer be subject to liability for a competitor's product? American tort law has always said, "No." It does not matter if the products are identical. Companies are not to be their competitors' keepers.

Nevertheless, over the past few years, three courts have overturned this fundamental of tort law, holding that a manufacturer of a brand-name prescription drug can be subject to liability even when a plaintiff alleges that he or she was harmed by a generic drug made by the brand-name manufacturer's competitor. Most courts, including four federal courts of appeal and dozens of federal district and state trial courts, have rejected this expansion of tort law.

This debate has intensified since 2011, when the Supreme Court of the United States held that all duty to warn claims against manufacturers of generic drugs are preempted by federal drug. The personal injury bar is

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This Article is dedicated to the memory of Ralph Willard Johnson III, a distinguished Fordham Law Graduate, class of 1993, whose professionalism and kindness were a tribute to his school.

hoping that courts will give competitor liability theories a new look, particularly when courts find that there is no other path for users of generic drugs to sue.

This Article explains the reasons courts should continue resisting any temptation to change state tort law to allow for competitor liability: (1) it is driven by a search for pockets for paying claims in violation of fundamental tort law principles; (2) the overwhelming majority of courts have continued rejecting competitor liability, even since the Supreme Court ruling; and (3) shifting liability to manufacturers of brand-name drugs could have significant adverse legal and health care consequences.

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INTRODUCTION

Can a business be subject to liability for a competitor’s product? Say you own a restaurant and a woman gets ill from eating at a restaurant down the block serving food with the same exact recipe as your own. In fact, they copied your recipe. Can she successfully sue your restaurant for her harm? What if you are a car manufacturer, and a man buys a sports car from a foreign competitor who copied your product? If the car crashes because of an alleged defect in the car, can he successfully sue your company? American tort law has always said, “No.” Companies are not their competitors’ keepers; Peter does not pay for the alleged sins of Paul.

A few years ago, though, a California appellate court¹ followed by a federal district court “*Erie* guessing” at Vermont law² broke with this fundamental principle. They subjected manufacturers of brand-name pharmaceuticals to liability, even though the plaintiffs in those lawsuits were alleging that they were injured by generic versions of those drugs. The courts reasoned that even though the plaintiffs took only generic drugs, the generics were required to use the same warning labels developed for the brand-name drugs.³ These courts also based their conclusions on the assumption that physicians may write prescriptions filled by generic drugs based on the safety and efficacy representations that the brand-name drugs’ manufacturers made about the brand-name drug in the Physicians’ Desk Reference and other materials.⁴

Most courts have rejected this end run around traditional product liability law. These courts now include the Fourth, Fifth, Sixth, and Eighth Circuits, as well as dozens of federal district and state trial courts. They have properly held that a pharmaceutical manufacturer, as with any other company, can be subject to liability only for products it manufactured or sold. As they have explained, brand-name manufacturers, in their materials

1. See *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).
2. See *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010).
3. See *Conte*, 85 Cal. Rptr. 3d at 307.
4. See *id.* at 313; see also *Kellogg*, 762 F. Supp. 2d. at 705.

and labeling, are referencing the safety and efficacy of only their *own* drugs, not the generic forms of their drugs.

Nevertheless, optimism has arisen among innovative personal injury lawyers that competitor liability for brand-name pharmaceutical companies will gain new momentum in light of the tension between two U.S. Supreme Court rulings. In a little noticed 2011 case, the Supreme Court created different liability laws for users of brand-name and generic drugs. In this case, *PLIVA, Inc. v. Mensing*,⁵ the Court determined that federal labeling law for generic drugs preempts a failure-to-warn claim brought by someone claiming that the manufacturer of the generic drug did not adequately disclose the risk of taking its drug.⁶ In 2009, though, the Court ruled in *Wyeth v. Levine*⁷ that individuals can, in most cases, proceed with such failure-to-warn claims against manufacturers of brand-name medications.⁸

The plaintiffs' bar's hope is that judges will succumb to allowing an aggrieved user of generic drugs to sue the brand-name manufacturer when there is no other path for recovery against the generic drug's manufacturer, or as a shortcut to a perceived deep pocket. The initial reaction from the lower courts, including two federal courts of appeal, has largely been the right one: to faithfully apply traditional product liability and tort law, even if doing so leads to results they believe are inequitable for some plaintiffs and defendants in their courtrooms.⁹ The only court to hold otherwise has been the Supreme Court of Alabama.¹⁰

This Article explains the reasons courts should continue resisting any temptation to change their state's tort law to allow for competitor liability, *Mensing* notwithstanding. In *Mensing*, the Supreme Court fully appreciated that "finding pre-emption [in *Mensing*] but not in *Wyeth* makes little [practical] sense,"¹¹ but concluded that altering this system rests solely with the legislative and executive branches, saying that Congress and the Food & Drug Administration (FDA) can "change the law and regulations if they so desire."¹²

This Article discusses the divergent regulatory regimes for brand-name and generic drugs that laid the basis for the Supreme Court rulings and the novel theories at the heart of the three rulings allowing competitor liability. It then explains the reasons courts should not adopt competitor liability under fundamental principles of state tort law, and why they should instead yield to Congress to address any inequities from the Supreme Court cases.

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

6. *Id.* at 2572.

7. 555 U.S. 555 (2009).

8. *See id.* at 581.

9. *See infra* Parts II, III.C.

10. *See Wyeth, Inc. v Weeks*, 2013 WL 135753 (Ala. Jan. 11, 2013).

11. *Mensing*, 131 S. Ct. at 2581 (explaining that 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 [a generic drug] instead, federal law pre-empts these lawsuits").

12. *Id.* at 2582.

I. THE SEPARATE TREATMENT AND THE RISE OF GENERIC DRUGS

In the early twentieth century, consumers had vastly different perceptions of generic and brand-name drugs; they had broad concerns that generic drugs could be counterfeit or have wide variations in quality from their brand-name counterparts.¹³ This view of generic drugs began to change in 1962, when Congress tightened regulatory oversight of prescription drugs and subjected generic drugs to the same lengthy, complex pre-market approval process applicable to brand-name drugs.¹⁴ The legitimacy of generic drugs was enhanced, but few manufacturers developed them given the expense of investing in the type of clinical trials needed for new drug approval.¹⁵ As late as the 1970s, the generic drug market was largely limited to antibiotics.¹⁶

In the early 1980s, only about one-third of top-selling drugs with expired patents—excluding antibiotics and drugs approved before 1962—had generic versions available.¹⁷ When available, the market share for the generic versions of these top-selling drugs averaged just 12.7 percent of prescriptions dispensed through retail pharmacies.¹⁸

A. *Separate Approval Processes for Brand-Name and Generic Drugs*

The modern era for prescription generic drugs began in 1984 when Congress enacted the Drug Price Competition and Patent Term Restoration Act, widely referred to as the Hatch-Waxman Amendments to the Food, Drug and Cosmetic Act (FDCA).¹⁹ This law provided a simpler, less demanding, and faster process for approval of generic drugs that can begin

13. *See infra* Part I.C.

14. *See* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. §§ 301–381 (2006)) (known as the Kefauver-Harris Amendments); *United States v. Generix Drug Corp.*, 460 U.S. 453, 461 (1983) (holding that a generic version of a drug approved after 1962 constituted a new drug under the Federal Food, Drug, and Cosmetics Act).

15. Teresa J. Lechner-Fish, Comment, *The Hatch-Waxman System: Suffering a Plague of Bad Behavior*, 5 HOUSTON BUS. & TAX L.J. 372, 387 (2005) (noting that, by 1984, only fifteen new drug approvals for post-1962 generic products existed in the market for 150 drugs with expired patents (citing Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999))).

16. *See* CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 29 (1998), available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf>.

17. *Id.*

18. *Id.*

19. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) (2006) and 35 U.S.C. §§ 156, 271(e) (2006)); *see also* Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,951 (Apr. 28, 1992) (describing the Hatch-Waxman Amendments). The abbreviated new drug approval (ANDA) process provides applicants with four certification routes when filing an application: (1) that the drug has not been patented; (2) that the patent has expired; (3) the date on which the patent will expire, and that the generic drug will not go on the market until that date passes; and (4) that the patent is not infringed or is invalid. *See* 21 U.S.C. § 355(b)(2)(A)(i)–(iv); 21 C.F.R. § 314.94(a)(12)(i)(A) (2012).

before an innovator drug loses its patent protection.²⁰ It decreased the average time between patent expiration and generic entry from three or four years to less than three months.²¹ In return, the Act extended patent protection for the products of brand-name drug manufacturers to account for the time spent in the FDA's rigorous approval process.²² The goal was to give brand-name drug manufacturers more time to try to recoup their investment in successful drugs, which could compensate for the many other drugs that never reach the market, are not profitable, or are ultimately replaced by generics.

1. New Drug Approval Process for Brand-Name Drugs

The New Drug Approval (NDA) process for brand-name drugs subjects all new prescription drugs to formal review so that the FDA can understand and carefully balance the risks and benefits of each prescription drug. Only drugs whose design, when accompanied with proper warnings, is safe and effective for public use are approved.²³

A manufacturer of a brand-name drug begins the approval process by submitting an "Investigational New Drug" (IND) application to the FDA, which permits clinical (human) testing.²⁴ The FDA uses its considerable scientific expertise to review the application and animal testing conducted with the proposed drug.²⁵ Only after the FDA approves the IND can a company use the drug in tightly controlled tests with patients, who agree to participate in the experimental drug program, so that it can gather data on the drug's clinical safety and efficacy.²⁶ The manufacturer then works with physicians to put the brand-name drug through trial phases with varying controls, supervision, patient populations, and goals.²⁷

20. See CONG. BUDGET OFFICE, *supra* note 16, at 3–4.

21. See *id.* at 28; Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999) (observing that Hatch-Waxman was not a "good deal [for the research-based pharmaceutical industry], unless one believed that FDA was going to go forward with its plans to implement abbreviated new drug applications (ANDAs) through regulation").

22. See Mossinghoff, *supra* note 21, at 188–89 (discussing the legislative history of the Act). The patent term of drugs manufactured in the United States is the greater of twenty years from the time of filing or seventeen years from the grant of the patent. 35 U.S.C. § 154. Hatch-Waxman allows manufacturers to obtain an extension equal to one-half the investigational new drug (IND) period, described *infra*, plus the period of new drug approval (NDA) review, but the extension can be no greater than five years and total market exclusivity cannot be more than fourteen years. See *id.* § 156. The Act generally guarantees five years of exclusivity to NDA holders, as the FDA will not approve an ANDA application for a generic drug during that period. See 21 U.S.C. § 355(j)(5); 21 C.F.R. § 314.108(b)(2).

23. See generally 21 C.F.R. § 314.

24. See *id.* § 312.

25. See *id.* § 312.22.

26. See 21 U.S.C. § 355(b)(1); 21 C.F.R. §§ 312.20, 312.21; see also Charles J. Walsh & Alyssa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 905–07 (1996) (discussing the three phases of human trials).

27. See 21 C.F.R. § 312.21 (describing Phase 1, 2, and 3 trials).

Upon conclusion of those tests, the manufacturer files an NDA, detailing the chemistry of the drug, clinical data and patient information, its use by children, reports of adverse reactions, proposed packaging and labeling, as well as any other pertinent manufacturing information.²⁸ An NDA often spans thousands of pages and describes the impact of the drug on several hundred to several thousand patients.²⁹

NDA approval requires that the product's warnings accurately portray the drug's safety profile so that healthcare practitioners can prescribe drugs in ways that maximize effectiveness and minimize risk.³⁰ The label must include basic information, such as a description of the drug, identity of its manufacturer, statement of ingredients, and an expiration date.³¹ It also must provide directions for its intended use in the treatment, prevention, or diagnosis of a disease or condition; this information includes any necessary preparation, dosage (recommended, usual, and maximum dosage), frequency, and duration of use.³² And, it must include a description of any situation in which the drug should not be used because the risk would clearly outweigh the benefit.³³ This may include precautionary information regarding any special care needed, such as its use during pregnancy or by children.³⁴

The FDA also requires that prescription drug labels break down information about the potential side effects of taking a drug into three categories: (1) "contraindications," where a patient would be under severe risk for taking the drug and should be discouraged from taking it; (2) "warnings," which are serious risks known to occur in some patients; and (3) "precautions," which are risks that arise less frequently.³⁵ The manufacturer must provide steps that can be taken in the event of an adverse reaction, as well as any dependency concerns, signs and symptoms of an overdose, and potential treatments.³⁶ Unless the FDA grants a specific waiver, every element of these extensive disclosures must be included in a drug's labeling.³⁷

In 2006, the FDA amended its regulations to add a new requirement that drug labels highlight the most important prescribing information, including concise summaries of the most significant contraindications, warnings, and

28. See 21 U.S.C. § 355(b); 21 C.F.R. § 314.50 (providing the required content and format of an NDA); *id.* § 314.55 (requiring an assessment of safety and effectiveness in pediatric subpopulations).

29. See *Grundberg v. Upjohn Co.*, 813 P.2d 89, 96 (Utah 1991) (describing the NDA process).

30. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified at 21 C.F.R. §§ 201, 314, and 601).

31. See 21 C.F.R. §§ 201.1, 201.10, 201.17, 201.50, 201.51.

32. See *id.* §§ 201.5, 201.55, 201.57.

33. See *id.* § 201.57.

34. See *id.*

35. *Id.* § 201.57(a)(5)–(6).

36. *Id.* § 201.57.

37. *Id.* § 201.58.

precautions, and the most frequently occurring adverse reactions.³⁸ To approve a new drug, the FDA must find “that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling.”³⁹ For successful drugs, the NDA process is completed when the Division or Office Director signs an approval action letter allowing the manufacturer to market the drug.⁴⁰

All told, the average process for successfully bringing a drug to market takes more than a decade.⁴¹ The industry association representing manufacturers of brand-name drugs estimates the R&D cost of bringing a single new drug to market at \$1.2 billion.⁴² Most drug products are never approved for patient use, resulting in significant sunk investment costs. In fact, less than one-in-ten products submitted to the agency receive approval and enter the marketplace.⁴³ Researchers also abandon development of many other potential medicines before filing with the FDA.⁴⁴ The considerable time and expense of bringing a drug to market, from development to approval, is the reason for extended patent exclusivity and a major factor in the pricing of brand-name drugs.

2. Abbreviated New Drug Application Process for Generic Drugs

The generic drug application process, called the Abbreviated New Drug Application (ANDA), is completely different. Unlike the innovator manufacturer, generic drug manufacturers are no longer required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness.⁴⁵ The FDA only requires a generic drug applicant that uses

38. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified at 21 C.F.R. §§ 201, 314, and 601).

39. 21 C.F.R. § 314.105(c).

40. The FDA must approve or reject an NDA within 180 days of filing. 21 U.S.C. § 355(c)(1) (2006); 21 C.F.R. § 314.100(a). Products that treat life threatening conditions may be eligible for accelerated approval. See 21 C.F.R. § 314.500.

41. Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003). The estimated median approval time for standard and priority applications in fiscal year 2010 were 10.1 months and 7.9 months, respectively, approximately half the length of a decade ago. FDA, FY 2011 PERFORMANCE REPORT TO THE PRESIDENT AND CONGRESS FOR THE PROSCRIPTION DRUG USER FEE ACT 4 (2011), available at <http://www.FDA.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/UCM294101.pdf>. In practice, these time frames are much longer because the FDA does not consider an application “filed” until it includes all the information sought by regulators. See *id.* at A-14.

42. PhRMA, NEW DRUG APPROVALS IN 2010, at 12 (2011), available at <http://www.phrma.org/sites/default/files/422/newdrugapprovals2010.pdf>.

43. See Lester M. Crawford, Acting Comm’r of FDA, Speech Before the Mayo Alliance for Clinical Trials Conference (Aug. 26, 2004), available at <http://www.FDA.gov/NewsEvents/Speeches/ucm053373.htm> (noting an 8 percent success rate for candidate drugs entering Phase 1 trials and a 50 percent failure rate among products in late-stage Phase 3 trials).

44. See generally DiMasi et al., *supra* note 41.

45. See 21 U.S.C. § 355(i)(1)(A).

the ANDA process to scientifically demonstrate that its product is “equivalent” to the pioneer drug.⁴⁶

It is often believed that a generic drug is the exact same as its brand-name counterpart, but this is not necessarily the case. The standard for a generic drug is to be “therapeutically equivalent” to the brand-name drug, meaning that it is both a pharmaceutical equivalent and bioequivalent of the original product.⁴⁷ Pharmaceutical equivalence requires “sameness” in the generic drug’s active ingredients, route of administration, dosage, form, and strength.⁴⁸ The FDA allows manufacturers of generic drugs, though, to use different “inert” or “inactive” ingredients, such as release mechanisms, binders, and preservatives.⁴⁹

Manufacturers of generic drugs demonstrate bioequivalence through testing a generic drug on a small sample of patients to show that there are no significant differences from the already-approved brand-name drug in the rate and extent that the active ingredients are absorbed into the bloodstream.⁵⁰ Often, such tests may involve as few as twenty-four to thirty-six individuals.⁵¹ To be approved, a generic drug applicant must show that its version of the drug is bioequivalent to the brand-name drug—namely, that it has a rate and extent of absorption that is 80 percent to 125 percent of the rate and extent of absorption of the brand-name drug.⁵² Because they are bioequivalent, generic drugs generally, but not always, induce reactions in patients that are similar to the brand-name innovators.⁵³

Manufacturers of brand-name drugs also do not have separate responsibilities for writing labeling information for their drug. Federal law mandates that generic drugs carry labeling that is “the same as” the brand-name version.⁵⁴

46. *See id.* § 355(j).

47. *See id.*

48. *See id.* § 355(j)(2)(A)(iii), (v).

49. *See* 21 CFR 320.1(c) (2012); *see also* *Drugs@FDA Glossary of Terms*, FDA, <http://www.FDA.gov/Drugs/informationondrugs/ucm079436.htm#G> (last updated Feb. 2, 2012) (defining pharmaceutical equivalents).

50. 21 U.S.C. § 355(j)(2)(A)(iv), (j)(8).

51. *Abbreviated New Drug Application (ANDA): Generics*, FDA, <http://www.FDA.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm> (last updated Jan. 4, 2013).

52. *See* FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS ix (32d ed. 2012), available at <http://www.FDA.gov/ucm/groups/FDAgov-public/@FDAgov-drugs-gen/documents/document/ucm071436.pdf>.

53. *See* Lisa Zamosky, *The New Deal with Lipitor; Patients Could Now Get a Generic—or Stay on the Name-Brand for Less*, L.A. TIMES, Jan. 16, 2012, at E1 (citing pharmacologist Joe Graedon, cocreator of the consumer health column, the People’s Pharmacy). *But see* *Review of Therapeutic Equivalence Generic Bupropion XL 300 mg and Wellbutrin XL 300 mg*, FDA, <http://www.FDA.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm153270.htm> (last updated Oct. 3, 2012).

54. *See* 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8)(iii)–(iv), 314.127(a)(7).

B. Differences in Postmarket Safety Obligations of Brand-Name and Generic Drug Manufacturers

Federal law also places different postmarket monitoring and safety labeling obligations on manufacturers of brand-name and generic prescription drugs. Common to all manufacturers is the obligation to report adverse drug reactions, regardless of whether the company or attending physician believes that the adverse event is related to the drug.⁵⁵ Manufacturers must report “serious and unexpected” adverse drug events within fifteen days; lesser suspected harms must be reported quarterly or annually, depending on the time since the initial approval.⁵⁶

1. Responsibilities of Brand-Name Manufacturers

The post-approval responsibilities for brand-name manufacturers (NDA holders), as with the initial approval process, focus on the need to learn about and adjust the drugs that are new to the market.⁵⁷ NDA holders must submit reports on any new developments in scientific knowledge on the drug, which they gain through extensive postmarketing reports, studies in scientific literature, and experiences with the drug in the United States and other countries.⁵⁸

Each year, NDA holders file summary reports with the FDA highlighting any “significant new information . . . that might affect the safety, effectiveness, or labeling of the drug product” and describes the actions that the manufacturer has taken or intends to take as a result of the new information.⁵⁹ Should the situation arise, the FDA can require NDA holders to undertake further clinical studies to better understand the adverse events that may not have been fully anticipated.⁶⁰

Should the NDA holder learn of any “clinically significant hazard,” it must revise a drug’s labeling to include appropriate warnings for that hazard “as soon as there is reasonable evidence of a causal association with a drug.”⁶¹ There are two processes for NDA holders to add or strengthen a contraindication, warning, precaution, adverse reaction, or safety-related dosing and administration instruction. The manufacturer may seek prior approval from the FDA or use the “changes being effected” (CBE) procedure through which the manufacturer immediately makes the change and provides notification to the FDA.⁶²

55. See 21 C.F.R. § 314.80(b).

56. *Id.* § 314.80(c).

57. See *id.* § 314.80(b).

58. See *id.*

59. See *id.* § 314.81(b)(2)(i).

60. 21 U.S.C. § 355(o)(3) (known as a postmarketing requirement, a type of Phase IV study); see also U.S. DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., FDA’S MONITORING OF POSTMARKETING STUDY COMMITMENTS ii (2006), available at <http://oig.hhs.gov/oei/reports/oei-01-04-00390.pdf> (finding that 48 percent of NDAs approved between 1990 and 2004 involved at least one postmarketing study commitment).

61. 21 C.F.R. § 201.57(c)(6)(i).

62. See *id.* § 314.70.

All of these monitoring, reporting, and labeling requirements continue after the patent for a drug expires and one or more generic versions of the product become available.⁶³

2. Limited Reporting Obligations of Generic Drug Manufacturers

The postmarket obligations placed on generic drug manufacturers, by contrast, are solely to maintain adequate records and to submit to the FDA reports of adverse events.⁶⁴ The FDA does not require generic manufacturers to affirmatively monitor scientific literature or report scientific developments to the agency.⁶⁵ Most of the adverse effects are known by the time generics enter the market.

Should a generic manufacturer “believe[] that new safety information should be added” to its drug’s labeling, it must “provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drug should be revised.”⁶⁶ Unlike with brand-name drugs, the FDA has stated that the CBE process does not apply to manufacturers of generic drugs.⁶⁷ Accordingly, all generic drug manufacturers must obtain prior FDA approval before making any safety changes to their drug’s labeling.⁶⁸

This, in part, is because of the requirement discussed earlier that generic drug manufacturers have “the same” labeling as their brand-name counterparts.⁶⁹ If the generic drug’s manufacturer were to change its product’s labeling, it would be inconsistent with that of the branded drug.⁷⁰ In such a circumstance, the FDA could charge the manufacturer with misbranding or even withdraw the manufacturer’s ANDA.⁷¹

This postmarket safety system remains intact even when a brand-name manufacturer stops selling a drug and withdraws its NDA. The FDA moves the brand-name drug to the “Discontinued Drug Product List,” presuming it

63. *See id.* §§ 314.3(b), 314.70(c), 314.71(a).

64. *Id.* § 314.98 (limiting postmarketing obligations of generic manufacturers to the “reporting and record-keeping” subsections of 21 C.F.R. § 314.80, which governs branded manufacturers).

65. *Id.* § 314.80(b). While the postmarketing surveillance regulation refers to the obligations of an “applicant,” such applicants are those covered by 21 C.F.R. §§ 314.50 or 505(b), which apply only to NDA applicants.

66. Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992).

67. *See* Brief for the United States As Amicus Curiae Supporting Respondents at 15, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (No. 09-1039).

68. Abbreviated New Drug Application Regulations, 57 Fed. Reg. at 17,950.

69. *See* 21 U.S.C. § 355(j)(4)(G) (2006); 21 C.F.R. § 314.94(a)(8)(iii).

70. 21 C.F.R. § 314.150(b)(10).

71. *See* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011) (stating that the FDA’s position is “if generic drug manufacturers, but not the brand-name manufacturer, sent [Dear Health Care Provider] letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly ‘misleading’”).

was not removed from the market for reasons of safety or effectiveness,⁷² and designates one of the generic drugs as the “reference listed drug” (RLD).⁷³ This generic drug becomes the vehicle for future bioequivalence studies,⁷⁴ and its label becomes the model that others in the industry must follow. The RLD holder, though, still cannot change its label without prior FDA approval.⁷⁵ When this happens, the FDA takes the central role of determining when a labeling change is needed and advises ANDA applicants accordingly.⁷⁶

Thus, the regulatory regime for generic drugs, as compared with brand-name drugs, provides for lower barriers of entry and reduced postmarketing obligations. These dynamics have allowed generic drugs to be priced much lower than brand-name drugs, which has given their manufacturers a competitive advantage over their brand-name counterparts.

C. State Generic Substitution Laws and the Dramatic Increased Use of Generic Drugs

The other significant legal change facilitating the rise in generic drugs is the widespread adoption of state substitution laws requiring pharmacists to substitute available generic drugs when filling prescriptions. Every state has now enacted these laws, which became popular because, given the lower price of generic drugs, they help reduce health care costs for state-run Medicaid programs.

State substitution laws represent a complete reversal in public policy. In the 1950s, the American Pharmaceutical Association (APhA), now known as the American Pharmacists Association, passed resolutions recommending that pharmacists dispense only the brand-name drug prescribed unless a physician specifically prescribed a generic drug.⁷⁷ By 1972, every jurisdiction except the District of Columbia had enacted some form of *antisubstitution* law.⁷⁸

72. See FDA Notice, Determination That DECA-DURABOLIN (Nandrolone Decanoate) Injection, 200 Milligrams/Milliliter, 1 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 75 Fed. Reg. 48,351, 48,352 (Aug. 10, 2010).

73. See Julie A. Steinberg, *Preempted: Reference Drug Designation Doesn't Save Generic Drug Suit*, 40 PRODUCT SAFETY & LIABILITY REP. 67 (2012).

74. See Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,958 (Apr. 28, 1992).

75. See Steinberg, *supra* note 73 (discussing *Moore v. Mylan Inc.*, No. 11-3037 (N.D. Ga., Jan. 5, 2012), in which the court rejected the plaintiff's argument that the FDA's designation of a generic seizure medication as the RLD conferred brand-name status on the manufacturer, eliminating its preemption defense under *Mensing*, discussed *infra* Part II).

76. See FDA Notice, Determination That DECA-DURABOLIN (Nandrolone Decanoate) Injection, 200 Milligrams/Milliliter, 1 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 75 Fed. Reg. at 48,352.

77. See Frank J. Ascione et al., *Historical Overview of Generic Medication Policy*, 41 J. AM. PHARMACEUTICALS ASS'N 567 (2001).

78. See BUREAU OF CONSUMER PROTECTION, DRUG PRODUCT SELECTION, STAFF REPORT TO THE FTC 150 (1979).

This legal environment changed in the 1970s, eventually flipping 180 degrees. Generic drugs became accepted as “safe alternatives” to most brand-name drugs, and APhA reversed its position, calling for the repeal of ant substitution laws.⁷⁹ In 1979, the Federal Trade Commission (FTC) and the FDA worked together to publish a model Drug Product Selection Act.⁸⁰ In adopting generic drug substitution laws, many states relied on an FDA publication known as the “Orange Book,” which provides guidance on the therapeutic equivalence of drugs but does not dictate which drugs may be substituted for one another.⁸¹

While there are variations among state substitution laws, most of them allow a pharmacist to fill a prescription with a generic drug, regardless of whether the doctor wrote the name of the brand-name drug on the prescription.⁸² More than a dozen states *require* pharmacists to substitute a generic drug, when available, unless the physician has explicitly indicated that the pharmacist is to “dispense as written” or indicated “no substitution.”⁸³ Estimates suggest that physicians mark prescriptions in this manner only between 5 and 15 percent of the time.⁸⁴

Most state substitution laws, but not all, also require the pharmacist to provide notice to the patient, and some states affirmatively require the patient’s consent when making a substitution. A recent study found that requiring pharmacists to obtain consent from their patients before substituting a generic product for the prescribed brand-name drug led to a 25 percent reduction in generic substitution.⁸⁵ For this reason, some have

79. *See id.* at 153.

80. *See id.* at 273. The major provisions of the model act included: (1) allowing pharmacists to select a lower cost generic drug from a positive formulary, listing drugs that are therapeutically equivalent according to the FDA; (2) permitting physicians to prohibit substitution; (3) sharing savings from generic substitution among pharmacists and consumers (an incentive for pharmacists to use generic drugs); (4) allowing patients to choose whether or not they want less-expensive generic drugs; and (5) an optional provision assuring pharmacists that there is no greater liability for using generic drugs instead of brand-names. *Id.* at 274–88.

81. *See generally* FDA, *supra* note 52.

82. States with permissive generic substitution laws include Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maryland, Michigan, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Texas, Utah, Virginia, Wisconsin, and Wyoming. *See* DEP’T OF HEALTH & HUMAN SERVS., ASPE ISSUE BRIEF, EXPANDING THE USE OF GENERIC DRUGS app. A (2010), *available at* <http://aspe.hhs.gov/sp/reports/2010/GenericDrugs/ib.pdf>.

83. Florida, Hawaii (anticonvulsants only), Kentucky, Maine, Massachusetts, Minnesota, Nevada, New Jersey, New York, Rhode Island, Tennessee, Vermont, Washington, and West Virginia mandate substitution of generic drugs for brand drugs. *Id.*

84. *See, e.g.*, FTC, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES xi (2005), *available at* <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitpt.pdf>.

85. *See* William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFF. 1383, 1388 (2010), *available at* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3103121/pdf/nihms290401.pdf> (examining Medicaid data for generic simvastatin and brand-name Zocor, a cholesterol-reducing drug).

advocated for eliminating patient choice as an additional cost-saving measure.⁸⁶

These laws, coupled with the wide availability of generic drugs, have significantly increased generic drug use. In 1996, the market share of generic drugs increased to 43 percent,⁸⁷ rising to 63 percent in 2006, and 78 percent of all prescriptions dispensed in 2010.⁸⁸ Now, the generic version of a drug, on average, seizes 80 percent of brand-name drug sales within six months of the loss of patent protection.⁸⁹ Further, in 2011 alone, the FDA approved more than 400 generic drugs,⁹⁰ including ninety-three products that were the first-approved alternatives to their branded-drugs counterparts.⁹¹ The Generic Pharmaceuticals Association boasts that, over the past two decades, the generic drug industry grew from \$1 billion to \$63 billion in annual U.S. revenues.⁹² The distinctions in the regulatory regimes, therefore, have allowed generic drugs to dominate the post-patent marketplace, which is expected to continue.⁹³

II. LIABILITY AND THE DIFFERENT REGULATORY STRUCTURES FOR BRAND-NAME AND GENERIC DRUGS

The differences between brand-name and generic drugs, particularly with respect to the regulatory regimes that govern them, have led to divergent, and sometimes novel, liability theories and results.

86. *See id.*

87. CONG. BUDGET OFFICE, *supra* note 16, at 27 (basing estimate on drugs that come in easily countable units, such as tablets and capsules, and not including injectable drugs and prescription drugs dispensed in liquid form); PhRMA, 2011 PROFILE PHARMACEUTICAL INDUSTRY, KEY FACTS (2011), *available at* http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf (citing the IMS National Prescription Audit from February 2011).

88. IMF INST. FOR HEALTHCARE INFORMATICS, THE USE OF MEDICINES IN THE UNITED STATES: REVIEW OF 2010, at 22 (2011), *available at* http://www.imshealth.com/deployedfiles/imshealth/Global/Content/IMS%20Institute/Static%20File/IHII_UseOfMed_report.pdf.

89. *Id.* at 21; *see also* MEDCO HEALTH SOLUTIONS, 2009 DRUG TREND REPORT 22 (2009), *available at* <http://medco.mediaroom.com/index.php?s=17885&cat=1561> (estimating that the typical market share for a branded drug falls to 6 percent for mail-order pharmacy prescriptions and 16 percent at retail within a month of the introduction of a generic version).

90. *See Drug Approval Reports*, FDA, <http://www.accessdata.FDA.gov/scripts/cder/drugsatFDA/index.cfm?fuseaction=Reports.ReportsMenu> (last visited Feb. 15, 2013).

91. *See ANDA (Generic) Drug Approvals*, FDA, <http://www.FDA.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/default.htm> (last updated Jan. 4, 2013).

92. *See About GPhA, The Industry*, GENERIC PHARM. ASS'N, <http://www.gphaonline.org/about/the-industry/> (last visited Feb. 15, 2013).

93. *See* Katie Moisse, *10 Top-Selling Drugs Coming Off Patent*, ABC NEWS (July 25, 2011), <http://abcnews.go.com/Health/Drugs/prescription-drug-prices-plummet/story?id=14152014> (reporting that Plavix, Lipitor, Seroquel, Actos, Enbrel, Singulair, Levaquin, Zyprexa, Concerta, and Protonix lost patent protection in 2011 or will come off patent in 2012). The best-selling drug ever, Lipitor, went off patent in December 2011, allowing patients to obtain the generic version, called atorvastatin, or continue to purchase the brand drug at generic-level prices. *See* Zamosky, *supra* note 53; *see also* *Sales of Lipitor Are Leveling Off*, N.Y. TIMES, Jan. 13, 2012, at B4.

A. *The Advent of Novel Competitor Liability Theories for Shifting Generic Drug Liability to Manufacturers of Brand-Name Drugs*

Starting in the early 1990s, when brand-name pharmaceutical manufacturers maintained significant market share after a drug's patent expiration, some creative plaintiffs' lawyers developed a legal theory to try to subject brand-name manufacturers, who were perceived to have deep pockets, to liability even if plaintiffs took only generic forms of their drugs. They argued that the federal regulatory regime for prescription drugs, which links the generic's design and labeling to its brand-name counterpart, creates the requisite connection to establish tort liability between the manufacturer of the brand-name drug and consumers of its generic competitors.⁹⁴ In the individual cases, they would allege that the brand-name drug manufacturers, either in labeling or promoting its own drug, misrepresented certain safety or efficacy information that led the consumer to end up taking the generic equivalent and becoming injured.⁹⁵

In 1994, the Fourth Circuit issued the first appellate decision on competitor liability for the pharmaceutical industry in *Foster v. American Home Products Corp.*,⁹⁶ which involved a generic drug, Phenergan.⁹⁷ The court held that a woman whose daughter died after taking the generic drug could not recover from the brand-name manufacturer, Wyeth.⁹⁸ The Fourth Circuit, applying Maryland law, appreciated that the claims were "an effort to recover for injuries caused by a product without meeting the requirements the law imposes in products liability actions."⁹⁹ It held that plaintiffs could not creatively plead their claims, here in negligence misrepresentation or fraud, to get around product liability law.¹⁰⁰ The plaintiff would still have to demonstrate that the defendant manufactured the product alleged to have caused the injury at issue.¹⁰¹ The federal law requirement that a generic drug's label be a copy of the one used by the brand-name manufacturer did not change the state's fundamental product liability law.¹⁰²

Until 2008, dozens of courts also rejected this theory.¹⁰³ But, that year, a California appellate court in *Conte v. Wyeth, Inc.*¹⁰⁴ broke with the others and allowed plaintiffs to state a claim against brand-name manufacturers for

94. See Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. 1123, 1173 (2011) ("The prescription drug scenario is therefore unlike situations in which one manufacturer unilaterally decides to imitate another manufacturer's design and no other link connects the two companies.").

95. See, e.g., *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 167–68 (4th Cir. 1994).

96. 29 F.3d 165 (4th Cir. 1994) (applying Maryland law).

97. *Id.* at 167.

98. *Id.* at 172.

99. *Id.* at 168.

100. *Id.*

101. *Id.*

102. *Id.* at 169.

103. See *infra* Part III.A.

104. 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).

harms resulting from generic drugs.¹⁰⁵ In 2010, a federal district court, “interpreting” or guessing at what Vermont law might be, echoed this ruling in *Kellogg v. Wyeth, Inc.*¹⁰⁶ In both cases, the courts sidestepped products liability law and the well-defined rights and responsibilities of warning and design defect to approve novel tort-based claims, including negligent misrepresentation and fraud.¹⁰⁷

Elizabeth Conte and Ethel Kellogg, the plaintiffs in the California and Vermont cases respectively, exclusively took generic metoclopramide—not the brand-name drug Reglan.¹⁰⁸ They did so for several years in the early 2000s.¹⁰⁹ In lawsuits filed against Wyeth and the generic manufacturers of metoclopramide, Conte and Kellogg claimed that their physicians were not adequately warned of the seriousness of the potential consequences of long-term use.¹¹⁰ The FDA-approved label for Reglan and generic metoclopramide indicated it for “short-term (4 to 12 weeks) therapy for adults with symptomatic, documented esophageal reflux who fail to respond to conventional therapy.”¹¹¹ In 2009, the FDA found that chronic use of the drug had been linked to tardive dyskinesia, a severe neurological condition.¹¹² Later that year, the FDA required all makers of metoclopramide to have a “black box” warning highlighting this risk.¹¹³

Although Conte and Kellogg had not taken the brand-name drug, they both named Wyeth as a defendant. They alleged that the drug’s initial manufacturer, A.H. Robins Company, which sold Reglan to Wyeth in 1989, aggressively promoted long-term use of Reglan before and soon after its approval in the mid-1970s through the mid-1980s for “vague gastrointestinal complaints.”¹¹⁴ It was during this time and upon this information, they allege, that physicians’ knowledge of the drug was shaped.¹¹⁵ It was of no consequence that for much of the time the plaintiffs took generic metoclopramide, Wyeth no longer made Reglan; Wyeth sold the rights to the Reglan name to another company in December 2001.¹¹⁶

In *Conte*, the California court subjected Wyeth to potential liability under the torts of negligent misrepresentation and fraud.¹¹⁷ Under either tort, a plaintiff would have to show that the defendant made a false or misleading statement about the actual product at issue.¹¹⁸ Here, though, the court did

105. *See id.* at 304–05.

106. *See Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010).

107. *See Conte*, 85 Cal. Rptr. 3d at 317–18; *see also Kellogg*, 762 F. Supp. 2d at 706–10.

108. *See Conte*, 85 Cal. Rptr. 3d at 305; *see also Kellogg*, 762 F. Supp. 2d at 697–98.

109. *See Conte*, 85 Cal. Rptr. 3d at 305; *see also Kellogg*, 762 F. Supp. 2d at 698.

110. *See Conte*, 85 Cal. Rptr. 3d at 305; *see also Kellogg*, 762 F. Supp. 2d at 699.

111. *Kellogg*, 762 F. Supp. 2d at 697 (quoting PHYSICIANS’ DESK REFERENCE 2604 (54th ed. 2000)).

112. *See id.* at 698–99.

113. *See id.* at 699.

114. *Id.* at 697; *see also Conte*, 85 Cal. Rptr. 3d at 305.

115. *See Kellogg*, 762 F. Supp. 2d at 697.

116. *Id.*

117. *Conte*, 85 Cal. Rptr. 3d at 305, 320–21.

118. *See id.* at 307.

not find that Wyeth and A.H. Robins made such a statement about generic metoclopramide. The reason the court allowed liability was that Conte's prescribing physician did not read or rely upon warnings that came with the generic drug¹¹⁹ or even Wyeth's labeling during the time he prescribed the drug to Conte.¹²⁰ Rather, he testified in his deposition that he "probably" learned about the drug by reading the monograph on Reglan in the Physicians' Desk Reference "during his residency training," which was many years earlier.¹²¹

The court, seizing on this statement, held that Wyeth had a common law duty to users of generic metoclopramide because it was "eminently foreseeable that a physician might prescribe generic metoclopramide in reliance on Wyeth's representations about Reglan."¹²² The court said:

[A] defendant that authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury, even though the defendant would not be liable in strict products liability because it did not manufacture or sell the product.¹²³

Because California law authorizes pharmacists to fill prescriptions for brand-name drugs with their generic equivalents unless the prescribing physician expressly forbids such a substitution, such substitutions are foreseeable.¹²⁴ Wyeth appealed, but the Supreme Court of California declined to review the case.

In 2010, a federal district court in *Kellogg* issued a similar opinion, "Erie guessing" at what might be Vermont law.¹²⁵ *Kellogg's* doctors also recalled reading a past version of the Physicians' Desk Reference prior to prescribing the generic drug to her,¹²⁶ and the court similarly found that "[u]sually the prescriber will not know which generic version will be dispensed by the pharmacy."¹²⁷ Citing *Levine*, the court found that brand-

119. *Id.* at 318 ("[n]o evidence suggests that [the prescriber] relied on" generic warnings).

120. *Id.* at 308.

121. *Id.*

122. *Id.* at 313; *see also id.* at 315 ("[W]e find the conclusion inescapable that Wyeth knows or should know that a significant number of patients whose doctors rely on its product information for Reglan are likely to have generic metoclopramide prescribed or dispensed to them.").

123. *Id.* at 311.

124. The trial court found that federal law preempted the plaintiff's failure-to-warn claims against the manufacturers of generic metoclopramide. *See id.* at 305–06. The appellate court declined to address the preemption argument, finding consideration of the constitutional issue unnecessary since the plaintiff could not prove her claim against any of the generic manufacturers because she conceded that she could not show her doctor relied on representations by any of the generic manufacturers. *See id.* at 320.

125. *Kellogg*, 762 F. Supp. 2d at 694. The federal judge may well have been wrong as to how the Supreme Court of Vermont would rule on this issue; the state's high court has adhered to traditional principles of tort law in sympathetic cases in the past. *See, e.g.,* *Goodby v. Vetpharm, Inc.*, 974 A.2d 1269 (Vt. 2009).

126. *Kellogg*, 762 F. Supp. 2d at 701.

127. *Id.* at 705.

name manufacturers are responsible for updating their label and the Physicians' Desk Reference to reflect new risks and that

it is reasonably foreseeable that a physician will rely upon a brand name manufacturer's representations—or the absence of representations—about the risk of side effects of its drug, when deciding to prescribe the drug for a patient, regardless of whether the pharmacist fills the prescription with a generic form of the drug.¹²⁸

Therefore, “[a] reasonable jury could conclude that inadequate, misleading and inaccurate information provided by the Defendants was a proximate cause of Kellogg’s injury.”¹²⁹

While competitor liability theories have been asserted in dozens of cases, the idea of shifting liability from generic drugs to their brand-name counterparts has not generated much support; more than sixty courts have rejected such liability.¹³⁰

B. The Supreme Court’s Rulings Creating Different Liability Rules for Generic Drug Manufacturers than for Makers of Brand-Name Drugs

Speculation has arisen, though, that competitor liability theories could gain new traction as a byproduct of two recent Supreme Court rulings on the viability of state failure-to-warn claims against manufacturers of prescription drugs. In the first case, the Court held that federal drug law does not preempt state failure-to-warn claims with respect to brand-name drugs;¹³¹ in the second case, it ruled that federal law does preempt failure-to-warn claims stemming from the use of generic products.¹³² As a result, the Court allowed users of brand-name drugs to potentially have an avenue for recovery not available to users of generic drugs.

The brand-name ruling came from the 2009 case *Wyeth, Inc. v. Levine*. The Court considered whether a plaintiff who had been administered brand-name Phenergan, an antihistamine used to treat nausea, could claim that its manufacturer, Wyeth, inadequately warned of the risk of developing gangrene when the drug is injected into a patient’s vein rather than administered through an IV drip.¹³³ The FDA had first approved injectable Phenergan in 1955,¹³⁴ and the drug has long been available in generic form.

In allowing the claim against Wyeth, the brand-name manufacturer, to go forward, a 6–3 majority of the Court reasoned it was not impossible for

128. *See id.* at 702, 709.

129. *Id.* at 702.

130. *See Scorecard: Non-Manufacturer, Brand-name Defendants in Generic Drug Cases*, DRUG & DEVICE L. (Nov. 12, 2009), <http://druganddevicelaw.blogspot.com/2009/11/scorecard-non-manufacturer-name-brand.html> (citing sixty-nine court decisions as of September 2012 that have refused to impose liability on a brand name drug manufacturers for injuries caused by its competitors’ generic drugs).

131. *See Wyeth, Inc. v. Levine*, 555 U.S. 555, 558–59 (2009).

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

133. *Levine*, 555 U.S. at 558.

134. *Id.* at 561.

Wyeth to comply with both federal labeling law and any state law warning requirements that would be derived if the litigation deemed its warnings inadequate.¹³⁵ The majority opinion explained that Wyeth could have used the CBE process to add the safety information required by the jury's determination and then seek FDA approval for that change.¹³⁶ In order to demonstrate that FDA labeling law preempts a state failure-to-warn claim against a brand-name manufacturer, the manufacturer must show "clear evidence that the FDA would not have approved a change to [the drug's] label."¹³⁷ While Wyeth showed that the FDA had approved Phenergan's label and worked with the company to update the label several times, the Court said it did not show that the FDA would have prohibited the change required if the warning was deemed inadequate under a state's tort law.¹³⁸ As a result, plaintiffs who take brand-name drugs can generally move forward with state failure-to-warn claims against the drug's manufacturer.

Two years later, in *PLIVA, Inc. v. Mensing*, the Supreme Court faced the preemption issue, but this time with respect to generic drugs. In *Mensing*, two individuals who developed tardive dyskinesia claimed that the drug's manufacturer failed to adequately warn of this risk.¹³⁹ Here, as is often the situation, the plaintiffs' doctors wrote the brand-name version of the drug, Reglan, on the prescriptions.¹⁴⁰ Pursuant to state substitution laws, the pharmacists filled the prescriptions with generic metoclopramide manufactured by PLIVA,¹⁴¹ a Croatian pharmaceutical company.¹⁴²

As in *Levine*, the Court applied the forward looking "impossibility preemption" test. Here, though, a 5–4 majority of the Court found that it would be impossible for PLIVA, as a manufacturer of generic drugs, to adhere to both its federal labeling requirements to use the "same" warning approved for the brand-name drug and to change those warnings to cure any defect a jury in a state failure-to-warn suit determines to exist.¹⁴³ Unlike the manufacturer of the brand-name drug, a generic drug maker cannot use the CBE process to change its labels; it can only request the FDA to make such a change.¹⁴⁴ This process for approving changes to warnings

135. *Id.* at 573.

136. *Id.*

137. *Id.* at 571. Some defendants have met this standard. *See, e.g.*, *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1277 (W.D. Okla. 2011) (finding a failure-to-warn claim preempted where the regulatory history of Effexor presented "clear evidence" that, had the defendant submitted a stronger warning about adult suicide to the FDA, the FDA would have rejected it).

138. *Levine*, 555 U.S. at 568–73; *see supra* Part I.B.1 (discussing the CBE process).

139. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572–73 (2011).

140. *Id.* at 2573.

141. *Id.*

142. *Company Info*, PLIVA, <http://www.pliva.com/pliva/company-info> (last visited Feb. 15, 2013).

143. *Mensing*, 131 S. Ct. at 2579.

144. *Id.*

suggested by manufacturers of generic drugs, the Court continued, does not turn impossibility into possibility.¹⁴⁵

Thus, the distinction between the *Levine* and *Mensing* preemption rulings seem to hinge on the old adage about asking for forgiveness or permission. Brand-name manufacturers can change the label first and ask for permission second, while generics must ask for permission first and can only make a change once the FDA has agreed with the request. Neither the process through which the warning was established nor the content of the warning is relevant to this preemption analysis. The sole issue is whether the manufacturer had the ability to implement new labeling requirements demanded by a court decision finding that the product's warning is inadequate. The Court held that brand-name manufacturers could do so, while generic manufacturers could not.¹⁴⁶

The Court fully appreciated the potential tension its two rulings created for makers and users of prescription drugs:

We recognize that from the perspective of [plaintiffs], finding preemption here but not in [*Levine*] makes little sense. Had [plaintiffs] taken Reglan, the brand-name drug prescribed by their doctors, [*Levine*] would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits.¹⁴⁷

Importantly, the Justices also indicated that they understood their ruling ended the ability of users of generic drugs to recover at all based on the content of a drug's labeling. The majority wrote, "We acknowledge the unfortunate hand that federal drug regulation has dealt [these plaintiffs], and others similarly situated."¹⁴⁸ The dissenters emphasized this point in explaining their opposition to the holding, stating, "As a result of today's decision, whether a consumer harmed by inadequate warnings *can obtain relief* turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug."¹⁴⁹ In this instance, "she now has *no right to sue*."¹⁵⁰

The ruling, therefore, did not lay the groundwork for creating new ways for users of generic drugs to sue, including against the manufacturer of the brand name drug at issue. Rather, the majority stated clearly that if these divergent liability rules for users and makers of generic and brand-name drugs did not represent the right public policy, Congress and the FDA could change the law and regulations to equalize the liability rules.¹⁵¹ Congress or the FDA could either revoke the preemption afforded to manufacturers of

145. *See id.*

146. *Id.* at 2581.

147. *Id.*

148. *Id.*

149. *Id.* at 2583 (Sotomayor, J., joined by Ginsburg, Breyer, & Kagan, JJ., dissenting) (emphasis added).

150. *Id.* at 2592 (emphasis added).

151. *Id.* at 2582.

generic drugs or affirmatively give brand-name drug manufacturers a comparable preemption defense.

C. Attempts To Circumvent Mensing Have Generated Novel Theories for Creating State Product and Tort Liability Notwithstanding the Purpose and Operation of Federal Drug Law

Despite the Supreme Court's understanding of *Mensing*'s impact on users of generic drugs, and of which arms of government have the authority to address the Court's disparate preemption rulings, there have been creative litigation attempts to find alternative means for users of generic drugs to recover for injuries allegedly caused by inadequate warnings.

Some post-*Mensing* attempts have focused on keeping manufacturers of generic drugs in the litigation, asserting for example, that manufacturers of generic drugs should still be subject to liability for "wrongful marketing" or not sending "dear doctor" letters to highlight a particular side effect associated with a drug.¹⁵² As a federal district judge in Tennessee explained in dismissing all such claims, "*Mensing* means what it says: all failure to warn claims against generic drug manufacturers are preempted if generic manufacturers cannot independently alter their warning labels."¹⁵³ Most courts have followed *Mensing* faithfully in this regard.¹⁵⁴

The First Circuit, however, created a stir when it allowed a case to proceed against a manufacturer of generic drugs on a design defect theory for simply selling the drug. The First Circuit stated that "while the generic maker has no choice as to label[,] the decision to make the drug and market it . . . is wholly its own."¹⁵⁵ The court suggested that a jury should be able to "second-guess[] the FDA"¹⁵⁶ and determine that the drug's "risks

152. See, e.g., *Looking for Loopholes in Pliva v. Mensing*, LAW360 (Nov. 21, 2011), <http://www.law360.com/articles/283282/looking-for-loopholes-in-pliva-v-mensing>. Most courts have rejected "wrongful marketing" claims that argue that while a generic drug manufacturer could not change the FDA-approved label, it had a duty to withdraw its dangerously designed drug from the market. See, e.g., *Cooper v. Wyeth, Inc.*, No. 09-929-JJB, 2012 WL 733846, at *6 (M.D. La. Mar. 6, 2012); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 718618, at *2 (E.D. Ky. Mar. 5, 2012); *Moretti v. Mut. Pharm. Co.*, 852 F. Supp. 2d 1114, 1118–19 (D. Minn. 2012).

153. See *Strayhorn v. Wyeth, Inc.*, No. 11-2058-STA-cgc, 2012 WL 3261377, at *10 (W.D. Tenn. Aug. 8, 2012) (Order Granting Generic Defendants' Motion to Dismiss). The court rejected various theories asserted by the plaintiffs to avoid *Mensing* preemption. *Id.* at *14 ("At bottom, regardless of their packaging, Plaintiffs' claims against the Generic Defendants 'relate to the sufficiency of the [metoclopramide] warnings.'").

154. See Katie Thomas, *Generic Drugs Proving Resistant to Damage Suits*, N.Y. TIMES, Mar. 21, 2012, at A1. *But see* Nate Raymond, *Moss Sides with Plaintiffs in Reglan Mass Tort*, LEGAL INTELLIGENCER (Nov. 21, 2011), <http://www.law.com/jsp/pa/PubArticlePA.jsp?id=1202533034673>; Julie A. Steinberg, *Failure To Update Warning a Colorable Claim; Court Joins Others Allowing Such Claims*, BNA PRODUCT SAFETY & LIABILITY REP., Feb. 6, 2012.

155. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 38 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012).

156. *Id.* The trial would presumably consider whether all versions of sulindac, including the innovator drug, are defective in design, even though the FDA approved the brand-name

outweighed its benefits making it unreasonably dangerous to consumers, despite [the FDA] having never withdrawn its statutory ‘safe and effective’ designation.”¹⁵⁷

The First Circuit fully acknowledged that, historically, courts have not been willing to determine through the judiciary whether a prescription drug is defective in design.¹⁵⁸ The *Restatement (Second) of Torts* § 402A explains in comment k that applying strict liability with regard to design defects in the pharmaceutical arena is improper because prescription drugs are “incapable of being made safe for their intended and ordinary use.”¹⁵⁹ The *Restatement* includes the example of the Pasteur treatment of rabies, which can lead to serious and damaging effects.¹⁶⁰ It states that because the disease is deadly, the vaccine is justified even though it comes with an unavoidably high degree of risk.¹⁶¹ For each prescription drug, the manufacturers and the FDA try to explain the known risks in the labeling, and doctors and patients determine which risks are worth taking based on the benefit the drug can provide.¹⁶² The *Restatement Third, Torts: Products Liability*, based on this concept, makes it almost impossible to sue a drug company under a product liability design theory, stating that the standard for design defect is when a reasonable physician would not prescribe the drug for *any* class of patients.¹⁶³

As a result, courts have used a fault-based liability system based on the adequacy of warnings accompanying the drugs. This is because, as the *Restatement* further explains, while prescription drugs are unavoidably unsafe, they are not *unreasonably* dangerous when accompanied by proper directions and warning.¹⁶⁴ If a drug manufacturer meets the standard of care for labeling, the product is not defective and the manufacturer has not committed a tort. The First Circuit panel conceded this point, stating that the defendant “could still have avoided liability by proving that [the drug] was unavoidably unsafe but was highly useful and had an adequate safety warning . . . [but it] abandoned that defense.”¹⁶⁵

drug’s specific design and warnings—not any ways in which the generic drug’s design may have differed from the innovator drug.

157. *Id.* at 34.

158. *Id.* at 35 (stating “courts ‘traditionally have refused to review the reasonableness of the designs of prescription drugs’” (quoting RESTATEMENT THIRD, TORTS: PRODUCTS LIABILITY § 6 cmt. f, at 156 (1998))).

159. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k, at 353–54 (1965). Dean Prosser, reporter for the *Restatement (Second)*, chose to handle prescription drug liability in a comment rather than a separate section. See *Brown v. Abbott Labs*, 751 P.2d 470, 475 (Cal. 1988).

160. RESTATEMENT (SECOND) OF TORTS, § 402A cmt. k, at 353–54.

161. *Id.* at 353.

162. *Id.*

163. See RESTATEMENT THIRD, TORTS: PRODUCTS LIABILITY § 6(c) (1998) (emphasis added).

164. *Id.* § 6(a)–(d).

165. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30, 36 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012).

The court's reason for this ruling, though, was clear. The judges on the panel stated that they were willing to redefine the relationship between state liability law and federal drug laws because they did not believe a plaintiff should lose the right to recover "by the mere chance of her drug store's selection of a generic."¹⁶⁶ They then urged the Supreme Court to take the case and review its novel design-defect theory, noting that "the Supreme Court has yet to decide" it but that it "needs a decisive answer from the only court that can supply it."¹⁶⁷ In this regard, the First Circuit panel seemed more interested in registering its objection to *Mensing* than setting precedent. The ruling has generally not been followed,¹⁶⁸ with the exception being a federal district court in Ohio.¹⁶⁹ The Supreme Court has granted certiorari and should rule on the case this year.¹⁷⁰

The practice of creating new liability theories to find pockets for paying claims has been discredited and remains unjustified. If a jury, looking in isolation at the injury to a single individual, second guesses the FDA and determines the drug's design to be defective, the drug's manufacturers may have to pull the drug from the market, just as if the FDA had withdrawn its approval. As a result, the many individuals benefiting from the drug might be deprived of a successful treatment. The temptation to solve the *Levine-Mensing* dichotomy when a user of a generic drug appears in a courtroom and claims he or she would not have been injured but for the inadequacy of the information provided to his or her doctor is understandable. But, courts should not change fundamental product liability and tort law in any such ends-justifies-the-means or deep pocket jurisprudence rulings.

III. IRRESPECTIVE OF *MENSING*, COMPETITOR LIABILITY THEORIES VIOLATE FUNDAMENTAL PRINCIPLES OF AMERICAN TORT LAW

Since the Supreme Court decided *Mensing* in June 2011, plaintiffs' lawyers have also increased their decades-long effort to use the interplay in the federal regulations between brand-name and generic drugs to create competitor liability for brand-name manufacturers. Nevertheless, during these two years, courts have wisely continued to reject these efforts, emphasizing two key points: competitor liability is still not supported by American tort or product liability law, and there is no intersection between *Mensing* and competitor liability.

As a threshold matter, *Mensing* does not provide an invitation to give competitor liability a renewed look. Here, case history provides important

166. *Id.* at 38.

167. *Id.* at 36, 38.

168. *See, e.g., In re Darvocet, Darvon and Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012) ("This argument—which failed to persuade either the Supreme Court or the Eighth Circuit on remand in *Mensing*, and the Sixth Circuit in *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011)—is no more availing now.").

169. *Arters v. Sandoz, Inc.*, No. 2:10-cv-142, 2013 WL 308768 (S.D. Ohio Jan. 25, 2013).

170. *Mut. Pharm. Co., Inc. v. Bartlett*, 133 S. Ct. 694 (2012).

context. Earlier in their case, the *Mensing* plaintiffs had included claims against the manufacturers of brand-name Reglan even though the plaintiffs had taken only generic metoclopramide.¹⁷¹ The Court of Appeals for the Eighth Circuit dismissed those claims, echoing other rulings that “holding name brand manufacturers liable for harm caused by generic manufacturers ‘stretch[es] [the law] too far.’”¹⁷² The Supreme Court did not disturb this earlier determination that a person who never ingested a brand-name drug cannot bring common law tort claims against a brand-name manufacturer or signal that it would consider such a claim if it were before the Court.¹⁷³ Indeed, the Eighth Circuit on remand endorsed the view that the Supreme Court’s ruling in *Mensing* did not alter its earlier ruling that state tort law principles do not support competitor liability.¹⁷⁴

This hostile reception for allowing plaintiffs’ attorneys to search for a different pocket from which to pay users of generic drugs has persisted since *Mensing* was decided. Most prominently, in the fall of 2011, the Sixth Circuit affirmed the dismissal of a generic drug user’s claims for state-law fraud, fraudulent concealment, and negligent misrepresentation against a brand-name drug manufacturer.¹⁷⁵ Here, the court, applying Kentucky’s products liability law, stated that the findings of the Fourth Circuit in *Foster* still govern and competitor liability is not permitted:

[A]dopting [plaintiff’s] theory of liability would require the court to attribute any deficiency in a name-brand manufacturer’s labeling and marketing of its products to products manufactured by its generic competitors. Such a theory, however, fails to satisfy the threshold requirement of a products-liability action—that the *defendant’s* product have injured the plaintiff. As the district court stated, “Just because a company is in the same business as a tortfeasor, the company is not automatically liable for the harm caused by the tortfeasor’s product.”¹⁷⁶

171. See *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 605 (8th Cir. 2009), *aff’d in pertinent part and vacated in part on other grounds*, 658 F.3d 867 (8th Cir. 2011).

172. See *id.* at 613.

173. Justice Ginsburg has discussed the importance of looking at the case history upon receiving a case, saying, “[People] think we pick their brilliant briefs first. We don’t. We read the opinions of the trial court and the court of appeals and then we turn to the lawyers briefs.” Lisa Snedeker, *Italian, Austrian and Wake Forest Law Students Have Opportunity To Study with U.S. Supreme Court Justice Ruth Bader Ginsburg in Venice and Vienna*, WAKE FOREST U. SCH. L. (Aug. 27, 2012), <http://news.law.wfu.edu/2012/08/italian-austrian-and-wake-forest-law-students-have-opportunity-to-study-with-u-s-supreme-court-justice-ruth-bader-ginsburg-in-venice-and-vienna/>; see also *Interview of Ruth Bader Ginsburg*, 13 SCRIBES J. LEGAL WRITING 133, 137 (2010) (“The first thing we read is the decision we’re reviewing.”).

174. In response to the Supreme Court’s ruling in *Mensing*, the Eighth Circuit mistakenly vacated its entire judgment, not just the part affected by the high court’s decision. In response to a motion from the brand-name manufacturers to reinstate the part of its earlier ruling against competitor liability, the Eighth Circuit reinstated that part of the opinion. See *Mensing v. Wyeth, Inc.*, 658 F.3d 867 (8th Cir. 2011).

175. *Smith v. Wyeth, Inc.*, 657 F.3d. 420, 422 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012) (applying Kentucky law).

176. *Id.* at 423.

In October 2012, the Fifth Circuit similarly held that under Louisiana law, brand-name manufacturers cannot be subject to competitor liability theories because the manufacturer did not produce the product at issue.¹⁷⁷

The only court to use *Mensing* as a game changer for allowing competitor liability has been the Supreme Court of Alabama in *Wyeth, Inc., v. Weeks*.¹⁷⁸ The issue arose as a certified question from the Middle District of Alabama. As in *Conte* and *Kellogg*, Weeks ingested only generic metoclopramide, but sued the brand-name manufacturer for misrepresentation and fraud, claiming his physician was not adequately warned of the potential consequences of long-term use when the drug was marketed and sold by the brand-name manufacturer.¹⁷⁹ In allowing the case to proceed, the Alabama high court discounted the scores of pre-*Mensing* rulings striking down competitor liability, stating that those decisions were based on the premise that the generic drugs' manufacturers could be subject to liability if the warnings were not sufficient.¹⁸⁰ It also set aside the many post-*Mensing* cases uniformly holding that whether or not federal law preempts warning-based claims against generic drug manufacturers has no impact whatsoever on whether state tort claims can be made out against makers of brand-name drugs.

The Alabama court also contradicted long-standing product liability law, particularly with respect to pharmaceuticals. Specifically, it stated that “a warning label is not part of the manufacturing process” and that while a manufacturer “will not be held liable for another manufacturer’s production, design, or manufacturing defect,” it could be subject to liability “when the plaintiff is arguing that he or she was injured by a failure to warn.”¹⁸¹ For more than fifty years, though, the premise for product liability with respect to pharmaceuticals and other products with inherent risks is that a product’s design and warnings are inextricably intertwined. The product’s design cannot eliminate its inherent risks, so warnings are required to make the product nondefective or no longer unreasonably dangerous.¹⁸² As discussed above, this is the core issue before the Supreme Court in the *Mutual Pharmaceutical Co. v. Bartlett* design-defect case.¹⁸³ In briefing

177. *Demahy v. Schwarz Pharma, Inc.*, No. 11-31073, 2012 WL 6698692, at *3–4 (5th Cir. Oct. 25, 2012).

178. 2013 WL 135753 (Ala. Jan. 11, 2013).

179. *Id.* at *2–3.

180. *See, e.g., id.* at *9 (“Reliance upon the reasoning in *Mosley* that a generic manufacturer is responsible for its own warning labels and revisions of those labels is unsound.”); *id.* at *10 (“*Overton* was issued before the Supreme Court decided *PLIVA*.”); *id.* at *11 (“*Simpson* was issued before *PLIVA* was decided.”).

181. *Id.* at *15.

182. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k, at 353–354 (1965) (stating that it is “especially common in the field of drugs” for products to be “incapable of being made safe for their intended and ordinary use” and “[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably dangerous*.”); RESTATEMENT THIRD, TORTS: PRODUCTS LIABILITY §§ 1–2 (1998).

183. *Bartlett v. Mut. Pharm. Co.*, 678 F.3d 30 (1st Cir. 2012), *cert. granted*, 133 S. Ct. 694 (2012).

the Court, Solicitor General Donald Verrilli explained that “[a] defective-drug-design claim often overlaps with a failure-to-warn claim.”¹⁸⁴

Overall, nearly two dozen courts have assessed competitor liability theories since *Mensing* was decided. Other than the Supreme Court of Alabama, all have held that *Mensing* does not alter state law principles that brand-name drug manufacturers cannot be liable for harms caused by their generic competitors.¹⁸⁵ Courts that rule otherwise risk being perceived as being willing to subvert the law in an effort to find a pocket for paying claims. Mississippi plaintiffs’ lawyer Dickie Scruggs famously commented on this tactic in the asbestos litigation context, saying that once the traditional defendants were no longer available to be sued, the litigation turned into “the endless search for a solvent bystander” to pay plaintiffs’ claims.¹⁸⁶ As discussed below, there is no legal foundation supporting this tactic, either generally or particularly in pharmaceutical litigation. The federal regulatory regime for brand-name and generic drugs does not somehow support subjecting one to state tort liability for harms caused by a competitor’s product.¹⁸⁷

A. Competitor Liability Violates Fundamental Principles of Product Liability Law

As federal and state courts have explained, under product liability law, when a plaintiff is injured by a product and seeks to hold a manufacturer liable for her injuries, she can sue only the manufacturer of the product that caused the injury.¹⁸⁸ Product liability law is based on the rationale that a seller is accountable for the risks internal to its operations, namely the manufacture, design, and warnings of the goods that it makes, distributes, or sells.¹⁸⁹ It was decided long ago that manufacturers are not general insurers of their products.¹⁹⁰

184. Brief of the United States As Amicus Curiae, *Mutual Pharm. Co., v. Bartlett*, No. 12-142, *17 (U.S. Jan. 22, 2013).

185. The Drug and Device Law blog maintains a list of cases in which competitor liability theories arise in pharmaceutical litigation. See *Scorecard*, *supra* note 130.

186. ‘*Medical Monitoring and Asbestos Litigation*’—A Discussion with Richard Scruggs and Victor Schwartz, MEALEY’S LITIG. REP.: ASBESTOS, Mar. 1, 2002, at 5 (quoting Richard Scruggs).

187. *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) (“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.”).

188. See *infra* note 214 and accompanying text.

189. RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (1965) (emphasis added).

190. John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 828 (1973) (“Strict liability for products is clearly not that of an insurer. If it were, a plaintiff would only need to prove that the product was a factual cause in producing his injury. Thus, the manufacturer of a match would be liable for anything burned by a fire started by a match produced by him, an automobile manufacturer would be liable for all damages produced by the car, a gun maker would be liable to anyone shot by the gun, [and] anyone cut by a knife could sue the maker . . .”); see also *Buonanno v. Colmar Belting Co.*, 733 A.2d 712, 719 (R.I. 1999) (“A component part supplier . . . should not be required to act

As explained in the *Restatement (Second) of Torts*:

[T]he justification for the strict liability has been said to be that *the seller*, by marketing *his product* for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon *the seller*, that reputable sellers will stand behind *their goods*; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon *those who market them*, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and *the proper persons to afford it are those who market the products*.¹⁹¹

Whether in the field of lawn mowers, pharmaceuticals, or cars, this foundation is absent when the plaintiff sues a manufacturer of a product he or she never used. Manufacturers do not have any special responsibility to those who use a competitor's product; they have no moral or legal obligation to stand behind the goods of another, and they are not in a position to incorporate the costs of liability into their prices when the liability is associated with products they did not make or sell. They also are not insurers of their competitors' products.

This legal conclusion is abundantly clear in the twenty-five states that have statutory product liability laws.¹⁹² Most of these statutes were enacted in the 1980s and 1990s along the lines of the Uniform Product Liability Act (UPLA)¹⁹³ or other model acts.¹⁹⁴ These acts, like the UPLA, typically provide a single body of law for injuries stemming from products, providing manufacturers, product sellers, and consumers with needed clarity and predictability.¹⁹⁵ Many of these laws define "product liability

as insurer for any and all accidents that may arise after that component part leaves the supplier's hands."); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 782 (R.I. 1988) (manufacturers cannot be "insurers of their products").

191. RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (emphasis added).

192. States with statutory product liability laws include Alabama, Arizona, Arkansas, Colorado, Connecticut, Idaho, Indiana, Kansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Nebraska, New Jersey, North Carolina, North Dakota, Ohio, Oregon, South Carolina, Tennessee, Texas, Utah, Washington, and Wisconsin (independent survey on file with author).

193. See Model Uniform Product Liability Act, § 103(a), 44 Fed. Reg. 62,714 (Oct. 31, 1979).

194. See, e.g., MODEL PRODUCT LIABILITY ACT (Am. Legislative Exch. Council 1995).

195. See Model Uniform Product Liability Act, § 103(a), 44 Fed. Reg. at 62,720 (providing that "[t]his Act is in lieu of and preempts all existing law governing matters within its coverage" and explaining that "[t]he Act consolidates all product liability recovery theories into one. . . . While some have argued that for trial tactics purposes, it is useful to retain the negligence and breach of warranty causes of action as distinct from strict tort liability, a claimant's attorney can retain the essence of this utility by showing the basic wrongfulness of the product seller's conduct."); see also *Patton v. Hutchinson Wil-Rich Mfg. Co.*, 861 P.2d 1299, 1311 (Kan. 1993) ("The [Kansas Product Liability Act] is based on the Model Uniform Product Liability Act. . . . The purpose of the Model Act was to consolidate all product liability actions, regardless of theory into one theory of legal

action” as including any action for personal injury or death caused by warnings, instructions, marketing, packaging, or labeling of a product regardless of the substantive legal theory or theories upon which the action is brought.¹⁹⁶ This includes injuries allegedly caused by generic drugs.

Importantly, courts in many states with product liability acts have recognized that these acts provide the *exclusive* avenue through which plaintiffs can seek recompense for product-based injuries.¹⁹⁷ Plaintiffs cannot, through creative pleadings such as in *Conte*, *Kellogg*, and *Weeks*, circumvent a state product liability act and create new common law theories of liability for harms caused by products in those states.¹⁹⁸ As a federal district court explained,

a “product liability action” is defined not by the substantive legal theory under which the plaintiff proceeds, but rather by the factual scenario that gives rise to the plaintiff’s claim and injury that results from the conduct of the defendant. The term encompasses “all” actions that otherwise meet the strictures of its definition.¹⁹⁹

Thus, an individual alleging injury from a generic drug can sue successfully only when she can establish the elements of a product liability action against that defendant.

In the dozens of state and federal rulings on this issue, it has become clear that competitor liability theories cannot exist under product liability law, whether that law is based in statute or common law.²⁰⁰ Product

liability. . . . [Kan. Stat. Ann. § 60-3302(c)] provides that all legal theories of . . . negligence, strict liability, and failure to warn, are to be merged into one legal theory called a ‘product liability claim.’”).

196. *See, e.g.*, ARIZ. REV. STAT. ANN. § 12-681(5) (2003); ARK. CODE ANN. § 16-116-102(5) (2006); COLO. REV. STAT. § 13-21-401(2) (2012); CONN. GEN. STAT. § 52-572m(b) (West 2007); IND. CODE ANN. § 34-20-1-1 (West 2008); KAN. STAT. ANN. § 60-3302(c) (1994); KY. REV. STAT. ANN. § 411.300(1) (LexisNexis 2005); LA. REV. STAT. ANN. § 9:2800.52 (2009); MISS. CODE ANN. § 11-1-63(c)(i) (West 2008); N.J. STAT. ANN. § 2A:58C-8 (West 2000); N.C. GEN. STAT. § 99B-1(3) (2011); N.D. CENT. CODE § 28-01.3-01(2) (2006); OHIO REV. CODE ANN. § 2307.71(13) (LexisNexis 2010); TENN. CODE ANN. § 29-28-106(6) (2012); TEX. CIV. PRAC. & REM. CODE ANN. § 82.001(2) (West 2011); WASH. REV. CODE § 7.72.010(4) (West 2007).

197. *See, e.g.*, *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 633 (E.D. N.C. 2009) (noting that North Carolina’s product liability statute defines “product liability action to include *any action* brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formulation . . . warning, instructing, marketing, selling, advertising, packaging or labeling of any product” (internal quotation marks omitted)); *Winslow v. Lewis-Shepard, Inc.*, 562 A.2d 517, 521 (Conn. 1989); *Patton*, 861 P.2d at 1311; *Monsanto Co. v. Westinghouse Elec. Corp.*, 950 S.W.2d 811, 814 (Ky. 1997).

198. *See, e.g.*, *Winslow*, 562 A.2d at 521; *Patton*, 861 P.2d at 1311; *Monsanto Co.*, 950 S.W.2d at 814; *Wash. State Physicians Ins. Exch. & Ass’n v. Fisons Corp.*, 858 P.2d 1054, 1066 (Wash. 1993).

199. *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056, 1059 (W.D. Ark. 2009).

200. *See, e.g.*, *Bell v. Pfizer, Inc.*, No. 5:10CV00101, 2011 WL 904161, at *2–3 (E.D. Ark. Mar. 16, 2011); *Cooper v. Wyeth Inc.*, No. 09-CV-929, 2010 WL 4318816, at *3 (M.D. La. Oct. 26, 2010); *Neal v. Teva Pharm. USA, Inc.*, No. 09-CV-1027, 2010 WL 2640170, at *2 (W.D. Ark. July 1, 2010); *Phelps v. Wyeth, Inc.*, No. 09-6168-TC, 2010 WL 2553619, at *3 (D. Or. May 28, 2010), *adopted by* 2010 WL 2553614 (D. Or. June 21, 2010); *Fields*, 613

identification and causation are fundamental requirements under all product liability law,²⁰¹ meaning that when harm arises out of a product, a cause of action exists only against the manufacturer of the product in question. As indicated earlier, the Sixth Circuit cited Kentucky's product liability act in rejecting claims against brand-name drug manufacturers brought by users of generic drugs.²⁰² Even the *Conte* court recognized that California's product liability law cannot be contorted to extend a manufacturer's liability to products that it did not make, distribute, or sell.²⁰³

Of the trial court decisions since *Mensing* on this point, the one authored by Judge Carol Higbee of the New Jersey Superior Court has received particular attention because she presides over New Jersey's mass tort pharmaceutical docket. In June 2012, in a case involving users of generic metoclopramide, she held that the New Jersey Product Liability Act (NJPLA) precluded claims against the makers of brand-name Reglan.²⁰⁴

There were three important parts to Judge Higbee's ruling. First, she concluded that, regardless of how the claims were pled, they fell squarely under the NJPLA; the NJPLA governs "any claim or action brought by a claimant for a harm caused by a product, irrespective of the theory underlying the claim."²⁰⁵ Second, she held that under this product liability law, the claims failed because the defendant did not manufacture the product that allegedly harmed the plaintiff.²⁰⁶ Third, she stated unequivocally that *Mensing* had no impact on this analysis.²⁰⁷ *Mensing* may harm a plaintiff's ability to recover from the manufacturers of the

F. Supp. 2d at 1058; *Morris v. Wyeth, Inc.*, No. 09-0854, 2009 WL 40464103, at *5 (W.D. La. Nov. 23, 2009); *Burke v. Wyeth Inc.*, No. G-09-82, 2009 WL 3698480, at *2 n.4 (S.D. Tex. Oct. 29, 2009); *Stoddard*, 630 F. Supp. 2d at 633; *Smith v. Wyeth, Inc.*, No. 5:07-CV-18-R, 2008 WL 2677051, at *4 (W.D. Ky. June 30, 2008), *aff'd*, 657 F.3d 420 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012); *Wilson v. Wyeth, Inc.*, No. 3:07-CV-178-R, 2008 WL 2677049, at *2 (W.D. Ky. June 30, 2008); *Morris v. Wyeth, Inc.*, No. 1:07-CV-176-R, 2008 WL 2677048, at *4 (W.D. Ky. June 30, 2008); *Sheeks v. Am. Home Prods. Corp.*, No. 02CV337, 2004 WL 4056060, at *2 (Colo. Dist. Ct. Oct. 15, 2004); *Condouris v. Wyeth*, 2012 WL 2401776, at *7 (N.J. Super. Ct. June 26, 2012); *Westerlund v. Wyeth, Inc.*, No. MID-2174-05, 2008 WL 5592753, at *3 (N.J. Super. Ct. Law Div. Oct. 20, 2008); *Sloan v. Wyeth Inc.*, No. MRS-L-1183-04, 2004 WL 5767103, at *9 (N.J. Super. Ct. Oct. 13, 2004).

201. *Fields*, 613 F. Supp. 2d at 1060 ("A basic requirement of products liability actions . . . is product identification, i.e. that the actual product manufactured or distributed by the defendant caused injury to the plaintiff.").

202. *See Smith v. Wyeth, Inc.*, 657 F.3d 420, 423–24 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012) (applying Kentucky law).

203. *See Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 311 (Cal. Ct. App. 2008). ("We are not marking out new territory by recognizing that a defendant that authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury, even though the defendant would not be liable in strict products liability because it did not manufacture or sell the product." (emphasis added)).

204. *Condouris*, 2012 WL 2401776.

205. *Id.* at *4 (emphasis in original) (quoting N.J. STAT. ANN. § 2A:58C-1(b)(3)).

206. *Id.* at *5.

207. *Id.* at *6.

generic drugs used, she wrote, but it does not change state law, including the “essential element of a plaintiff’s prima facie products liability action [that he or she show] . . . proof that the manufacturer actually produced the product which gave rise to the plaintiff’s injury.”²⁰⁸

Soon after Judge Higbee’s ruling, U.S. District Judge S. Thomas Anderson arrived at the same conclusion under the Tennessee Product Liability Act²⁰⁹ (TPLA), finding that plaintiffs’ claims against the brand-name drug manufacturers were “easily capture[d]” within the TPLA’s definition of a products liability action.²¹⁰ He stated that this was the majority approach and that “[p]laintiffs’ theory of liability as to brand name pharmaceutical manufacturers is not only an extreme minority position but also would mark a ‘fundamental policy innovation’ under Tennessee law.”²¹¹ Judge Anderson also concluded that, notwithstanding the TPLA, the claims also did not satisfy the traditional common law elements of products liability law.²¹² Finally, he held, for the reasons discussed in the next section, that the common law torts of misrepresentation, fraud, and warranty claims apply only to the seller of goods which allegedly caused the injury.²¹³

Courts around the country have applied similar reasoning in rejecting competitor liability claims under statutory and common law products liability law, both before and after *Mensing*.²¹⁴

B. There Is No Tort Duty Between Manufacturers of Brand-Name Drugs and Users of Generic Drugs

In an effort to circumvent product liability law, plaintiffs’ lawyers seeking to subject brand-name manufacturers to liability for harms caused by generic drugs have tried to recast their claims under other common law tort theories, usually negligent misrepresentation and fraud. These common law tort theories, they argue, are distinct from products liability law and are not bound by product identification or other product liability requirements.

208. *Id.* at *7.

209. TENN. CODE ANN. § 29-28-102 (2012).

210. *Strayhorn v. Wyeth, Inc.*, No. 11-2058-STA-cgc, 2012 WL 3217672, at *6 (W.D. Tenn. Aug. 8, 2012) (Order Granting Brand Name Defendants’ Motion for Summary Judgment). The plaintiffs’ claims, which the court found fell within the TPLA, included strict liability in tort; negligence; breach of express or implied warranty; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; constructive fraud; unfair and deceptive trade practices; conspiracy; unjust enrichment; and civil conspiracy. *Id.*

211. *Id.* at *8.

212. *See id.* at *7.

213. *See id.* at *8.

214. *See, e.g.*, *Meade v. Parsley*, No. 2:09-cv-00388, 2009 WL 3806716 (S.D. W. Va. Nov. 13, 2009); *DaCosta v. Novartis AG*, No. CV 01-800-BR, 2002 WL 31957424, at *8–9 (D. Or. Mar. 1, 2002); *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586 XXX MB, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009); *Huck v. Trimark Physicians Grp.*, No. LACV018947, 2009 WL 3760458 (Iowa Dist. Ct. Feb. 27, 2009).

Courts by and large have rejected these creative pleadings.²¹⁵ Regardless of the tort, manufacturers of brand-name drugs have no common law duty to the users of another's products and, therefore, cannot be subject to liability for harms caused by their generic competitors.²¹⁶

All torts, including negligent misrepresentation and fraud, require a plaintiff to show that each defendant owed her a duty, which is a legal, not factual determination.²¹⁷ As discussed above, the *Conte*, *Kellogg*, and *Weeks* courts concluded that a tort duty can be established between the manufacturer of the brand-name drug and the users of generic drugs solely because these manufacturers can “foresee” that statements made in labeling or promoting its drugs could, even years later, cause a patient to be prescribed and take a generic version of that drug. They argue that the requirement that generic drugs have the “same” labeling as the brand-name drug and the operation of state generic substitution laws bolster this foreseeability argument.²¹⁸

The “foreseeability fallacy” in these rulings, though, is that the alleged harm is not a foreseeable result of the brand-name manufacturer's conduct, but of laws over which the brand-name manufacturers have no control. Congress made the public policy decisions to lower barriers of entry for generic drugs, as have state legislatures in enacting laws to require certain prescriptions be filled with available generics. Other courts have held that using these laws as a basis for supplying the duty element stretches foreseeability too far. As one Florida court held, “[n]o federal statute or FDA regulation imposes a duty or suggests that a name brand manufacturer is responsible for the labeling of competing generic products.”²¹⁹

The other shortcoming in this analysis is that foreseeability alone does not determine duty in tort law. While based in part on foreseeability, courts must also always consider public policy and basic fairness, including whether the defendant had control over the risk allegedly harming the

215. See, e.g., *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340, 1348 (S.D. Ala. 2010); *Phelps v. Wyeth, Inc.*, No. 09-6168-TC, 2010 WL 2553619, at *3 (D. Or. May 28, 2010), *adopted by* 2010 WL 2553614 (D. Or. June 21, 2010); *Moretti v. Wyeth, Inc.*, No. 2:08-CV-00396-JCM-(GWF), 2009 WL 749532, at *3-4 (D. Nev. Mar. 20, 2009); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 540-41 (E.D. Pa. 2006), *aff'd in pertinent part*, 521 F.3d 253 (3d Cir. 2008), *vacated and remanded on other grounds*, 129 S. Ct. 1578 (2009); *Beutella v. A.H. Robins Co.*, No. 980502372, 2001 WL 35669202, at *2-3 (D. Utah Dec. 10, 2001); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 350 (Minn. Ct. App. 2001).

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

217. See generally RESTATEMENT (SECOND) OF TORTS (1965).

218. See, e.g., *Foster*, 29 F.3d at 171 (“The Fosters contend that a duty exists in this case because it was foreseeable to Wyeth that misrepresentations regarding Phenergan could result in personal injury to users of Phenergan's generic equivalents.”).

219. *Dietrich*, 2009 WL 4924722, at *7. A study issued in 2012 by the Regenstrief Institute at Indiana University School of Medicine supports this point, finding that more than two-thirds of generic drug labeling showed discrepancies between the safety information on their labels from their brand-name counterparts. See Jon Duke et al., *Consistency in the Safety Labeling of Bioequivalent Medications*, PHARMACOEPIDEMOLOGY & DRUG SAFETY (forthcoming 2013), available at http://pubcit.typepad.com/files/consistency-in-the-safety-labeling-of-bioequivalent-medications_duke_pds.pdf.

plaintiff and the relationship between the parties.²²⁰ Other courts have appreciated this basic principle of tort law and have followed *Foster's* ruling that imposing a duty must be based on more than mere foreseeability.²²¹ With respect to the tort of negligent misrepresentation specifically, a duty arises only “when there is ‘such a relation that one party has the right to rely for information upon the other, and the other giving the information owes a duty to give it with care.’”²²² In these cases, there is no qualifying relationship between the parties because the plaintiff is injured by a product that the brand-name manufacturer did not manufacture, nor did the brand-name manufacturer make any representations about that generic’s safety or efficacy.²²³ Other courts have held that brand-name manufacturers cannot reasonably expect consumers to rely on information about its medications when taking another company’s drug.²²⁴

In their duty analyses, courts have also expressed concern over other public policy implications for establishing a duty between a brand-name drug manufacturer and consumers of generic competitors.²²⁵ For the most part, courts have pointed to

unfair consequences [that] would result if we were to impose a duty upon [the brand-name manufacturer], when it obtained no benefit from the sale of [the] generic equivalent and had no control over the manufacturing or labeling of [the generic], yet it bore the expense of developing [the drug] from which [the generic manufacturer] materially benefits.²²⁶

This situation, the courts have stated, “would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand

220. *See, e.g.,* *Levine v. Wyeth*, 684 F. Supp. 2d 1338, 1345–48 (M.D. Fla. 2010) (applying Florida law). Duty is “an expression of the sum total of those considerations of policy which lead the law to say that the plaintiff is entitled to protection.” W. PAGE KEETON, PROSSER & KEETON ON TORTS 358 (5th ed. 1984). Moreover, it has been stated that “the existence of a duty is determined by a number of factors, including (1) the nature of the defendant’s activity; (2) the relationship between the parties; and (3) the type of injury or harm threatened.” *Overton v. Wyeth, Inc.*, No. CA-10-0491-KD-C, 2011 WL 1343392, at *6 (S.D. Ala. March 15, 2011) (quoting Alabama law).

221. *Levine*, 684 F. Supp. 2d at 1344 (citing *Swett v. United States*, No. 04-40278, 2007 WL 1017644, at *3 (M.D. Fla. 2007)).

222. *Foster*, 29 F.3d at 171 (quoting *Weisman v. Connors*, 540 A.2d 783, 790 (Md. 1988)).

223. *Id.*

224. *Bell v. Pfizer Inc.*, No. 5:10CV00101 BSM, 2011 WL 904161, at *3 (E.D. Ark. Mar. 16, 2011) (applying Arkansas law) (“Although foreseeability is an important consideration in determining whether an actor owes a duty to another, it is not the end of the duty analysis. Rather, the inquiry turns on reasonableness.”); *Colacicco v. Apotex Inc.*, 432 F. Supp. 2d 514, 541 (E.D. Pa. 2006), *aff’d in part*, 521 F.3d 253 (3d Cir. 2008), *cert. granted, judgment vacated*, 129 S. Ct. 1578 (2009).

225. *See, e.g.,* *Sheeks v. Am. Home Prods. Corp.*, No. 02CV337, 2004 WL 4056060, at *2 (D. Colo. Oct. 15, 2004) (applying *Foster* and considering “the social utility of Defendant’s activity, the magnitude of the burden of guarding against the harm, the consequences of placing that burden [on] the Defendant, and the individual and social interests implicated by the conduct. . . . I find that Wyeth owed no duty to Plaintiffs to warn of a drug that it did not manufacture or supply”).

226. *Colacicco*, 432 F. Supp. 2d at 541.

manufacturer's statements by copying its labels and riding on the coattails of its advertising."²²⁷ In addition, allowing such liability would require a brand-name manufacturer to become insurers of the whole industry. As discussed above, requiring manufacturers to be insurers of even their own products has been widely and wisely rejected.²²⁸

Given the fact that brand-name manufacturers have only a small percentage of the post-patent market, the economics of this imbalance would lead to a host of other public policy concerns, which are discussed in detail later in this Article.

C. The Above Rulings To Maintain a Rational Boundary on Tort Law Duties Are Consistent with American Jurisprudence

American courts, overall, have carefully controlled the situations when someone owed a tort law duty to another. Over the course of American jurisprudence, there have been similar attempts to extend traditional tort or product liability duties where sympathetic plaintiffs may not otherwise have a viable or deep-pocket from which to recover.

In the pharmaceutical context, Maryland's highest court held that a plaintiff injured in a car accident by a diabetic who suffered an adverse reaction from an insulin product could not sue the manufacturer of the insulin because she had not used the drug herself.²²⁹ The plaintiff, as in *Conte*, argued that the law should recognize such a suit because it is "foreseeable" that if a manufacturer fails to adequately warn a patient about the risks from taking its drug, the patient will injure someone else when that risk manifests itself.²³⁰ But, as indicated above, foreseeability alone does not define the extent of a duty in tort law. As the Maryland Court of Appeals explained in a unanimous ruling, under long-standing, fundamental tort law principles, there is no "duty to the world."²³¹ If there is no contact between the drug's manufacturer and the plaintiff, there is no tort law duty.

Similar efforts to expand tort law duties have arisen in other contexts, as plaintiffs' lawyers regularly look to expand the pool of defendants that can

227. *Foster*, 29 F.3d at 170 (continuing that "[t]he 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").

228. As Dean John Wade explained in the 1970s, it would be impossible for manufacturers to police customers to ensure that products are not used or neglected in ways that cause injury: "Strict liability for products is clearly not that of an insurer." See Wade, *supra* note 190, at 828; see also *Buonanno v. Colmar Belting Co.*, 733 A.2d 712, 719 (R.I. 1999) ("A component part supplier . . . should not be required to act as insurer for any and all accidents that may arise after that component part leaves the supplier's hands."); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 782 (R.I. 1988) (stating that manufacturers cannot be "insurers of their products").

229. *Gourdine v. Crews*, 955 A.2d 769 (Md. 2008).

230. *Id.* at 772.

231. *Id.* at 786.

be sued for a given injury.²³² Courts, though, have consistently declined invitations to stray from the core principle of product liability law that only a company in the chain of distribution of the product that allegedly caused the plaintiff's injury is subject to liability.²³³

The California Supreme Court, in a decision with potential repercussions for *Conte's* continued viability in that state, denied such an extension of duty in the *O'Neil v. Crane Co.*²³⁴ asbestos case. The case involved a mesothelioma plaintiff allegedly exposed to asbestos in the late 1960s as a result of supervising individuals who repaired equipment in the engine and boiler rooms of a World War II-era naval ship.²³⁵ While the defendants did not sell products containing the asbestos to which the plaintiffs were allegedly exposed, plaintiffs argued that the defendants had a duty to warn them of the hazards of asbestos because their injuries were allegedly caused by adjacent products or replacement parts made by others that the defendants knew or could foresee would be used in conjunction with their products.²³⁶ The court found that while "manufacturers, distributors, and retailers have a duty to ensure the safety of their products . . . we have never held that these responsibilities extend to preventing injuries caused by *other* products that might foreseeably be used in conjunction with a defendant's product."²³⁷

The California Supreme Court reasoned that requiring manufacturers to warn about the dangerous propensities of products they did not design, make, or sell is contrary to the purposes of both product liability and common law tort duty. In strict liability, "the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market" or who are in the chain of commerce for that

232. See Mark A. Behrens, *What's New in Asbestos Litigation?*, 28 REV. LITIG. 501, 542 (2009); see, e.g., *Conner v. Alfa Laval, Inc.*, 842 F. Supp. 2d 791, 794 n.4, 801 (E.D. Pa. 2012) (holding that "consistent with the development of products-liability law based on strict liability and negligence, relevant state case law, the leading federal decisions, and important policy considerations regarding the issue," a manufacturer "is not liable for harm caused by, and owes no duty to warn of the hazards inherent in, asbestos products that the manufacturer did not manufacture or distribute"); *Surre v. Foster Wheeler LLC*, 831 F. Supp. 2d 797, 802 (S.D.N.Y. 2011) (recognizing that "a duty to warn against the dangers of a third party's product does not arise from foreseeability alone"); *Braaten v. Saberhagen Holdings*, 198 P.3d 493, 495-96 (Wash. 2008) (holding that since the valve and pump manufacturers had not placed the asbestos-containing parts to which the plaintiff was exposed in the stream of commerce, they had no duty to warn him of the risks of the products of others); *Simonetta v. Viad Corp.*, 197 P.3d 127, 134 (Wash. 2008) (holding that a fireman and machinist who performed maintenance aboard a Navy vessel on a seawater evaporator that was insulated with asbestos mud and cloth could not recover from the evaporator manufacturer because it did not manufacture, sell, or supply the hazardous asbestos insulation).

233. See RESTATEMENT (SECOND) OF TORTS § 402A (1965); RESTATEMENT THIRD, TORTS: PRODUCTS LIABILITY §§ 1-2 (1998).

234. 266 P.3d 987 (Cal. 2012).

235. *Id.* at 993.

236. *Id.*

237. *Id.* at 991.

product.²³⁸ With respect to tort duties, “foreseeability alone is not sufficient to create an independent tort duty” and thus there is no liability where a defendant’s product did not cause the plaintiff’s harm.²³⁹ It concluded that “[t]he same policy considerations that militate against imposing strict liability in this situation apply with equal force in the context of negligence.”²⁴⁰

Pharmaceutical liability is no different.²⁴¹ A physician may have been influenced in prescribing a drug by what the makers of brand-name drugs have said about their products, but the same can be said for any number of products. Consider the example of a mother purchasing a minivan and learning about side curtain airbags at a Chrysler dealership while looking at a Town & Country. Now suppose she decides to buy a Toyota Sienna, and based on the knowledge she gained at the Chrysler dealership, insists that her Sienna come with side curtain airbags. If the Sienna airbags are defective or cause injury to her children, she has no claim against Chrysler. This is true regardless of whether Toyota’s side curtain airbags work the same way as Chrysler’s, are made to the same standards, or were even made by the same part supplier. Chrysler, as with the brand-name drug manufacturer, did not make any statements about and did not profit from the sale of its competitor’s product. There are no falsely gained profits.²⁴²

Indeed, there is no principle limiting competitor liability to prescription drugs. What if a foreign company over which U.S. courts do not have jurisdiction reverse engineers an American manufacturer’s lawnmower and sells it with identical packaging, instructions, and warnings? What if, instead of FDA law creating the connection between the innovator and the subsequent generic product, federal patent law is used to link the two? Should anyone who files a patent and divulges the design of a product foresee that a consumer will be injured by a competitor’s product that builds off their technology? Competitor liability does not make sense in

238. *Id.* at 995 (quoting *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963)).

239. *Id.* at 1005 (quoting *Erlich v. Menezes*, 981 P.2d 978, 983 (Cal.1999)).

240. *Id.* at 1007. A federal district court sitting in Kentucky has stated that it did not interpret *O’Neil* as limiting the holding of *Conte* with respect to California plaintiffs. See *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 3842271, at *6 n.6 (E.D. Ky. Sept. 5, 2012).

241. See *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 351 (Minn. Ct. App. 2001) (observing that Minnesota courts have “expressly declined to recognize the tort of negligent misrepresentation involving the risk of physical harm. Accordingly, the district court did not err as a matter of law by granting summary judgment to respondents on this claim” (citation omitted)).

242. As the *Restatement (Second) of Torts* recognizes:

One who, in the course of his business, profession or employment, or in any other transaction in which he has a *pecuniary interest*, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

See RESTATEMENT (SECOND) OF TORTS § 552(1) (1965) (emphasis added).

these other contexts, and it does not make sense in the pharmaceutical industry either.

D. Expanding Liability for a Competitor's Product Is Not Sound Health Policy

As courts have recognized, often in the public policy part of their duty analyses, shifting liability to brand-name drug manufacturers for injuries allegedly stemming from products of their generic competitors has significant downsides.²⁴³ As a primary matter, the economics of the pharmaceutical industry do not support competitor liability. Saddling 10 percent of a market with 100 percent of its liability is certain to create new and significant financial pressures on brand-name drugs, the effects of which would harm health care consumers. Consider the following three concerns.

First, consumers would likely have to pay higher prices for brand-name drugs during the period of exclusivity so that the drugs' manufacturers could amass resources for anticipated competitor liability claims. As discussed earlier, once generics become available, the brand-name manufacturer's share of the market now shrinks to a fraction of its size within a few months.²⁴⁴ Accordingly, their ability to afford competitor liability claims after their period of exclusivity ends will be more quickly and more greatly diminished than in years past.

Second, the fear of such liability would likely drive many brand-name manufacturers from a drug's market once it becomes available in generic form. Ironically, some plaintiffs have argued that manufacturers of brand-name drugs can never escape competitor liability, even by withdrawing from the market, saying that the basis for liability can be the representations made when educating physicians about their drugs during the period of exclusivity. Even the judge authoring the *Kellogg* opinion has rejected this argument, subsequently holding that the any duty he held that a manufacturer of brand-name drugs has to users of their generic competitors is extinguished once the brand-name manufacturer leaves the market and no longer has a duty to warn about the potential risks of a drug.²⁴⁵ Should the brand-name manufacturer prematurely withdraw from the market over liability, consumers will have lost the company most familiar with a medicine and the one that likely has the greatest infrastructure and

243. *Kelly v. Wyeth*, No. Civ.A.MICV200303314B, 2005 WL 4056740 (Mass. Super. Ct. May 6, 2005) (dismissing claims against Wyeth stemming from generic metoclopramide).

244. *See* MEDCO HEALTH SOLUTIONS, *supra* note 89, at 22 (using the brand name drug Fosamax as an example, which lost 94 percent of its market share at mail and 84 percent of its market share at retail within thirty days of its generic equivalent becoming available).

245. *See* Lyman v. Pfizer, Inc., No. 2:09-cv-262, 2012 WL 2970627, at *16 (D. Vt. July 20, 2012) (stating when Wyeth transferred its rights and responsibilities for Reglan® to Schwarz, "Wyeth lost any ability to change the design of Reglan or its label"); *see also In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-2226-DCR, 2012 WL 3109424, at *3 (E.D. Ky. July 31, 2012) (concluding that Lilly could not change its drug's label once it left the market).

resources to facilitate postmarket research and analysis into any late developing safety issues with a drug.²⁴⁶

Third, it will become riskier for brand-name manufacturers to dedicate resources to researching and developing potentially life-saving or life-improving medicines, particularly when those medicines have greater health risks or are for small communities of people that will not drive large revenues.²⁴⁷ As discussed in detail above, on the average, it takes ten to fifteen years and \$1.2 billion to bring a new drug to market, with the FDA only approving a tenth of the new drug applications it receives.²⁴⁸ Drugs with high litigation risk will be avoided in favor of safer blockbusters that can make up for these costs.

In addition, the underpinning of competitor liability, namely, that the risks are the same for generic and brand-name drugs, is not always true. Brand-name and generic drugs are biologically equivalent, but not necessarily identical.²⁴⁹ For instance, there are certain drugs known to have a narrow therapeutic index (NTI), meaning that small variations in the dosage or release method can have a critical effect.²⁵⁰ Such minor differences, for example, can have a significant impact on the treatment of epilepsy, hypothyroidism, and immunosuppressive therapy required to prevent transplant rejection.²⁵¹ Similarly, many doctors are reluctant to substitute generic warfarin for the brand-name anticoagulant Coumadin

246. See Letter from Jerome D. Jabbour, Senior Vice President & Head of Legal Affairs, Morton Grove Pharm., Inc., to Div. of Dockets Mgmt., FDA (HFA-305) (Sept. 30, 2011), available at <http://www.hpm.com/pdf/blog/MGP%20Comments%20to%20PC%20CP.pdf>.

247. See Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1153–54 (1987) (“If in the aggregate the net gains [to consumers and pharmaceutical companies] are wiped out by the liability costs, then the product will no longer be made. If some net gains survive, then fewer units will be produced to reflect the changes in rules and some marginal consumers must do without.”); W. Kip Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976–1989*, 24 SETON HALL L. REV. 1418, 1419 (1994) (“[T]he net effect of the surge in liability costs had been to discourage innovation in the pharmaceutical industry.”).

248. PhRMA, *supra* note 42, at 1.

249. See *supra* Part I.A.2.

250. See Tina Zerilli et al., *To Substitute or Not To Substitute: That Is the Question*, PHARMACY TIMES (Mar. 14, 2011), <http://www.pharmacytimes.com/publications/issue/2011/March2011/GenericFeature-0311>.

251. See, e.g., Rita R. Alloway et al., *Report of the American Society of Transplantation Conference on Immunosuppressive Drugs and the Use of Generic Immunosuppressants*, 3 AM. J. TRANSPLANTATION 1211 (2003); K. Liow et al., *Position Statement on the Coverage of Anticonvulsant Drugs for the Treatment of Epilepsy*, 68 NEUROLOGY 1249 (2007) (position of the American Academy of Neurology); *Report of the American Society of Transplantation Conference on Immunosuppressant Drugs and the Use of Generic Immunosuppressants*, 3 AM. J. TRANSPLANTATION 1211 (2003); Am. Thyroid Ass’n, The Endocrine Soc’y, Am. Ass’n of Clinical Endocrinologists, *Joint Statement on the U.S. Food and Drug Administration’s Decision Regarding Bioequivalence of Levothyroxine Sodium*, ENDOCRINE SOC’Y, http://www.endo-society.org/advocacy/legislative/upload/Joint_Statement_Levothyroxine-Thyroxine.pdf (last visited Feb. 15, 2013).

when their patients have been stabilized on Coumadin.²⁵² Indeed, it is not unusual for individuals switching drugs in a variety of contexts to report that the change in drugs either led to side effects not present with the original or did not result in the same effective treatment.²⁵³

Finally, additional litigation against brand-name manufacturers is not needed to create a deterrence effect. If labeling or marketing practices overstate benefits or downplay risks of a drug, brand-name manufacturers can be subject to significant liability, as well as substantial civil fines from the U.S. Department of Justice and state attorneys general.²⁵⁴

By contrast, the only rationale for liability here is to find a pocket for compensating someone alleging that they have been unfairly injured. Compensation alone, though, is not a sufficient reason for establishing tort liability.²⁵⁵ Deep-pocket jurisprudence is law without principle. As one federal judge explained, “I cannot find that a decision to hold a manufacturer liable for injury caused by its competitor’s product is rooted in common sense.”²⁵⁶

E. Creative Pleadings and Arguments Cannot Overcome the Innate Deficiencies in Competitor Liability

Throughout the two-decade effort to create competitor liability on manufacturers of brand-name drugs, plaintiffs’ attorneys have developed several creative theories for circumventing the solid, growing body of case law against them. The core deficiencies inherent to competitor liability, though, are not cured by creative pleadings and arguments.

252. See John Gever, Kristina Fiore & Todd Neale, *Generic Versus Brands: How It Plays Out in Practice*, MEDPAGE TODAY (Aug. 24, 2009), <http://www.medpagetoday.com/ProductAlert/Prescriptions/15665>.

253. See, e.g., Robyn Shelton, *Rx for Trouble? Generics Don’t Always Work As Well As Brand Names, Critics Say. FDA Disagrees. We Take a Look.*, ORLANDO SENTINEL (Aug. 10, 2008), http://articles.orlandosentinel.com/2008-08-10/news/generic10_1_generics-drug-brand/ (reporting on patient experiences finding that generic drugs for treatment of high blood pressure, epilepsy, and depression did not work as well as the brand-name drug or found variations in effectiveness among generic versions of a drug); *Defending Generic Drugs*, PEOPLE’S PHARMACY (Dec. 19, 2011), <http://www.peoplespharmacy.com/2011/12/19/defending-generic-drugs/> (providing comments from numerous individuals who reacted adversely after they switched from brand to generic drugs used to treat a wide range of conditions, including epilepsy, hypothyroidism, migraines, sleeplessness, depression, and osteoporosis as well as substitution of warfarin for Coumadin).

254. See, e.g., Katie Thomas, *J. & J. Fined \$1.2 Billion in Drug Case*, N.Y. TIMES, Apr. 12, 2012, at B1 (discussing \$1.2 billion fine against Johnson & Johnson related to its marketing of the drug, Risperdal, and noting civil penalties against Janssen Pharmaceuticals of \$158 million in Texas, \$327 million in South Carolina, and \$258 million in Louisiana).

255. See Sarah C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 VAND. J. ENT. & TECH. L. 185 (2010) (suggesting the creation of a federal trust fund, similar to the Vaccine Injury Compensation Trust Fund, to compensate plaintiffs who prove deficiencies in generic drug labels).

256. *Phelps v. Wyeth, Inc.*, No. 09-6168-TC, 2010 WL 2553619, at *2 (D. Or. May 28, 2010).

For example, plaintiffs have recently argued that the *Restatement (Second) of Torts* § 324A authorizes competitor liability because the brand-name manufacturers *voluntarily* accepted such liability.²⁵⁷ This is a twist on the foreseeability argument. Its premise is that because brand-name manufacturers know that the representations and labeling associated with their drugs will become the basis for the use of generic versions of their drugs, they voluntarily assumed responsibility for harms caused by those generic drugs. To demonstrate this point, they mention that brand-name manufacturers maintain control over the information and labels for generic versions of their drug; by changing their own labeling, they automatically trigger a change in the generic's label.²⁵⁸ Therefore, by not changing their labeling, they voluntarily undertook a responsibility, but then failed to intervene to avoid the plaintiffs' harm.

Restatement (Second) of Torts § 324A, which provides the "good Samaritan" rule, in no way authorizes such liability. The provision applies only when someone "undertakes, gratuitously or for consideration, to render services to another."²⁵⁹ Manufacturers of brand-named drugs, in selling and marketing their own drugs, are not "rendering" services to the generic drug manufacturers or their customers.²⁶⁰ Their operations are focused solely on selling their own products. Accordingly, they are only "responsible for the accuracy and adequacy of *its* label,"²⁶¹ not anyone else's products.

Some plaintiffs have also alleged that brand-name manufacturers can be subject to competitor liability under fraud and conspiracy charges. They allege that the brand-name companies, by not changing their labeling, suppress material health effects of both their drugs and the generic versions of their drugs. In fraud terms, the brand-name manufacturers, they say, knowingly mislead doctors and patients who relied on the false statements, and those patients sustained injuries as a result of this concealment. These theories, in particular, have been tried in Florida and are based on market share and tobacco litigation rulings in that state.²⁶²

257. Swicegood v. Pliva, Inc., 543 F. Supp. 2d 1351, 1356 (N.D. Ga. 2008).

258. *Id.* at 1354.

259. RESTATEMENT (SECOND) OF TORTS § 324A (1965).

260. *See, e.g.,* Mosley v. Wyeth, Inc., 719 F. Supp. 2d 1340, 1347–48 (S.D. Ala. 2010); Schrock v. Wyeth, Inc., 601 F. Supp. 2d 1262, 1266 (W.D. Okla. 2009); Smith v. Wyeth, Inc., No. 5:07-CV-18-R, 2008 WL 2677051, at *4 (W.D. Ky. June 30, 2008), *aff'd*, 657 F.3d 420 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012); Wilson v. Wyeth, Inc., Civ. No. 3:07-CV-378-R, 2008 WL 2677049, at *4 (W.D. Ky. June 30, 2008), *aff'd*, 657 F.3d 420 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012); Morris v. Wyeth, Inc., Civ. No. 1:07-CV-176-R, 2008 WL 2677048, at *4 (W.D. Ky. June 30, 2008), *aff'd*, 657 F.3d 420 (6th Cir. 2011), *cert. denied*, 132 S. Ct. 2103 (2012).

261. PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2574 (2011) (emphasis added).

262. *See, e.g.,* Engle v. Liggett Grp., Inc., 945 So. 2d 1246 (Fla. 2006); Conley v. Boyle Drug Co., 570 So. 2d 275 (Fla. 1990) (establishing market share theory in DES drug case); Rey v. Phillip Morris, Inc., 75 So. 3d 378, 383 (Fla. Dist. Ct. App. 2011) (stating that "[t]he law of civil conspiracy is striking in its extension of liability to a co-conspirator which may not have caused any direct injury to the claimant").

As Florida courts have maintained, though, any such broad interpretation of fraud-based claims would “render virtually any manufacturer liable for the defective products of an entire industry, even if it could be demonstrated that the product which caused the injury was not made by the defendant.”²⁶³ It is hornbook tort law that in fraud and misrepresentation cases, “the defendant is not liable if the plaintiff relies on the information in a type of transaction the defendant does not intend to influence.”²⁶⁴ Branded manufacturers, in marketing and selling drugs, are seeking to facilitate a market for their own products. They are not seeking to induce anyone to purchase a competitor’s product. The same is true for businesses in other industries.

Other, more creative theories have surfaced. For example, some have suggested that manufacturers could be subject to liability under component part liability, which would require the warning labels to be categorized as a component part of the generic drug,²⁶⁵ or pursuant to vicarious liability theories.²⁶⁶ In New York, a plaintiff invoked the state’s consumer fraud statute, but the federal district court explained that the consumer fraud claim fails because it too requires the element of causation and because the brand-name manufacturer did not produce the drugs at issue, the causation element is interrupted.²⁶⁷ Others have theorized that if generic manufacturers are unavailable for liability, through preemption or other means, then the brand-name manufacturer should have “secondary liability.”²⁶⁸ Yet others, including the Supreme Court of Alabama, have tried to go back and undermine the seminal case of *Foster* and its progeny, suggesting that they rejected competitor liability only under the premise

263. *Rey*, 75 So.3d at 382 (quoting *Conley v. Boyle Drug Co.*, 477 So.2d 600, 603 (Fla. Dist. Ct. App. 1985)); *see also* *Pulte Home Corp. v. Ply Gem Indus.*, 804 F. Supp. 1471, 1484–85 (M.D. Fla. 1992) (“It is well established under Florida law and elsewhere that identification of the product that caused the harm as the one sold or manufactured by the defendant is an essential element of traditional tort law.”).

264. DAN B. DOBBS, *THE LAW OF TORTS* 1372 (2000).

265. *See generally* *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586 XXX MB, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009); Beatrice Skye Resendes, Note, *The Extinct Distinction of Privity: When a Generic Drug Label Fails To Warn, the Drug’s Pioneer Should Be Liable As Component Part Supplier of the Warning Label*, 32 T. JEFFERSON L. REV. 95 (2009).

266. Vicarious liability permits one party to be liable for the tortious conduct of another in highly limited circumstances. *See* KEETON, *supra* note 220, § 69, at 500. The brand-name manufacturer has no control over another manufacturer that copies its product. There is typically no agreement, contract or otherwise, between brand-name and generic manufacturers that qualify their relationship as a joint venture. Perhaps most significantly, in regard to the fundamental basis for vicarious liability, the brand-name manufacturer does not profit from sales of a competitor’s products. *See id.* (noting in the employment context, the “modern justification for vicarious liability” to place the loss on the employer for the torts of employees because the employer “sought to profit” from actions in pursuit of its enterprise).

267. *See* *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436, at *8 (N.D.N.Y. July 19, 2006).

268. *Rostron*, *supra* note 94, at 1129.

that the generic's manufacturer could be subject for failure-to-warn liability.²⁶⁹

Regardless of the creativity of one's arguments or pleadings, all of these theories falter on the same principles: the brand-name manufacturer did not say or do anything related to its competitors' products, and neither the operation of federal drug law nor the availability of the generic drug's manufacturer for liability impacts whether state tort or product liability theories can be established against the manufacturers of brand-name drugs.²⁷⁰

IV. CONGRESS IS THE BRANCH OF GOVERNMENT FOR DECIDING WHETHER FEDERAL DRUG LAW CAN BE USED TO CREATE LIABILITY

As the Supreme Court appreciated in *Mensing*, if liability stemming from federal drug law needs to be changed, Congress and the FDA, acting pursuant to congressional authority, are the appropriate arms of government for making these decisions in the context of fashioning the best health care policy for the country. With regard to *Mensing*, these discussions are already taking place, ranging from a decentralized system where each drug manufacturer has responsibility over its own labeling to an FDA-centric system where the FDA makes all labeling decisions for a drug once its patent expires and it becomes available from multiple sources.

The decentralized approach was first put forth two months after the *Mensing* decision. Public Citizen filed a petition with the FDA requesting that the agency change the rights and responsibilities of generic drug manufacturers so that they can independently change their labeling and be subject to liability for their labels' content.²⁷¹ The FDA is actively

269. In *Foster*, the court explained that there were two separate issues: (1) whether the plaintiff was able to recover from the generic drug's manufacturer and (2) whether the defendant Wyeth could be held responsible for the patient's injuries. See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169 (4th Cir. 1994). While the court held that the generic drug's manufacturer could be subject to liability, which has now been overturned by *Mensing*, that decision was not a predicate for its holding denying liability against the brand-name manufacturer. See *id.* at 170 (stating unequivocally that it "also reject[s] the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug.").

270. See *id.* at 170 ("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.").

271. See *Citizen Petition*, PUB. CITIZEN (AUG. 29, 2011), <http://www.citizen.org/documents/Citizen-Petition-8-26.pdf> (filed with the FDA) (Docket No. FDA-2011-P-0675-0001). On March 9, 2012, the FDA provided Public Citizen with an "interim response" indicating that the FDA had been "unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials." Letter from Jane A. Axelrad, Assoc. Dir. for Policy, Ctr. for Drug Evaluation & Research, to Sidney M. Wolfe & Brian Wolfman (Mar. 9, 2012), available at <http://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0675-0006>. As of publication, the petition remains pending before the FDA. Public Citizen explained that amending the regulations to allow generics to change their safety labeling unilaterally "would undo th[e] impossibility" preemption in *Mensing* and "eliminate the absurd inconsistency in common-law." *Citizen Petition*, *supra*, at 8.

considering this approach.²⁷² In April 2012, Senator Patrick Leahy and Representative Chris Van Hollen introduced legislation, the Patient Safety and Generic Labeling Improvement Act,²⁷³ that takes a similar approach through amending the Food, Drug & Cosmetic Act. These proposals have been supported by the nation's trial bar for "reinstat[ing] the ability of the public to bring state tort law based claims."²⁷⁴

These proposals seek to reverse *Mensing* by creating an exception to the traditional principle that generic drugs have the "same" labeling as their brand-name counterparts by allowing manufacturers of generic drugs to use the CBE process to alter their labeling prior to FDA approval.²⁷⁵ While this approach may provide uniformity in liability, questions have been raised about the potential impact of not requiring uniformity where it has traditionally mattered most: safety labeling. The drug approval system, particularly the same-labeling requirement, is designed to assure patients and health care professionals that generic drug products are equivalent to their branded counterparts.²⁷⁶

Issues that would need to be fleshed out include whether allowing each generic manufacturer to add its own product warnings would create multiple and contradictory versions of safety labeling information for drugs deemed to be bioequivalent. Patients and health care professionals, under such a scenario, would have to consider which, if any, of the product labels are accurate. They also may have to consider whether a new warning included with a generic drug pertains to all versions of a drug or is a signal that there is a bioequivalence problem for that specific generic drug. If the latter, the new labeling could raise into question whether the ANDA for that generic drug, which is based on bioequivalence, is still in effect. The burden would likely fall to the FDA to assess the situation and provide guidance.²⁷⁷

272. Brief of the United States As Amicus Curiae at 15 n.2, *Mutual Pharm. Co., v. Bartlett*, No. 12-142 (U.S. Jan. 22, 2013) ("This office has been informed that FDA is considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances.").

273. S. 2295, 112th Cong. (2012); H.R. 4384, 112th Cong. (2012).

274. See Press Release, Am. Ass'n for Justice, Congressional Proposal Would Expand Generic Drug Manufacturers' Duty to Warn (Apr. 18, 2012), available at <http://www.justice.org/cps/rde/justice/hs.xml/18218.htm>; Letter from Gary M. Paul, President, Am. Ass'n for Justice, to Div. of Dockets Mgmt., FDA (Mar. 2, 2012), available at [http://www.justice.org/cps/rde/xbcr/justice/FDA_\(Comments_Supporting_Public_Citizen_Petition_Generic_Drugs\)_Feb_12.pdf](http://www.justice.org/cps/rde/xbcr/justice/FDA_(Comments_Supporting_Public_Citizen_Petition_Generic_Drugs)_Feb_12.pdf).

275. 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(4)(G) (2006); 21 C.F.R. § 314.94(a)(8)(iii) (2012).

276. The "FDA 'places a very high priority [on] assuring consistency in labeling,' so as 'to minimize any cause for confusion among health care professionals and consumers as well as to preclude a basis for lack of confidence in the equivalency of generic versus brand name products.'" Brief for the United States As Amicus Curiae Supporting Respondents at 4, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039 and 09-1501) (alterations in original) (quoting DIV. OF GENERIC DRUGS, FDA, POLICY AND PROCEDURE GUIDE 37 (1989)) (citing 57 Fed. Reg. 17,961 (1992)).

277. Congress and the FDA are working on a regulatory approval process for biosimilars, and confusion caused by any differences in labeling between innovator biologics and generic

In addition, some have speculated that there could be an incentive for manufacturers of generic drugs to overwarn against potential side effects in order to guard against failure-to-warn liability.²⁷⁸ A ripple effect could be created where the other manufacturers of the drug, including the brand-name drug's manufacturer, adopt the same overwarnings, regardless of their accuracy, to similarly avoid liability. Overwarning, just like underwarning, should be avoided because overwarning deters doctors and patients from trusting medicines that provide needed benefits. Policymakers will have to examine the impact of this proposal on the purpose of warnings, which is to carefully recognize a drug's benefits and risks and indicate how a drug can be used in ways that maximize safety and effectiveness. They also will have to assess the impact on the FDA, which could find itself in the crossfire, trying to sort through the various warnings.

Creating an FDA-centric system was the subject of an article in the *New England Journal of Medicine*.²⁷⁹ Doctors Aaron Kesselheim, Jerry Avorn, and Jeremy Greene write that a "better solution" is to create a "central repository of information on adverse drug events" for studying "late-arising side effects and to assess the need for changes to drug labels."²⁸⁰ This way, the brand-name and generic manufacturers of a drug could pool their collective knowledge about a drug's adverse effects.²⁸¹ Presumably, then, the FDA, which would be in a better position than any individual company to determine appropriate labeling, would be charged with approving all labeling changes.²⁸²

This approach was also supported by the authors of a Regenstrief study for resolving discrepancies between brand-name and generic labeling. In the press release accompanying the study, Dr. John Duke stated, "The solution to the problem of labeling inconsistency may be a centralized listing of drug side-effects, maintained independently of individual manufacturer labels. Drug labels would simply reference this common repository" ²⁸³ The FDA already takes on this type of role when a

biosimilar drugs is of particular concern. The FDA is the only entity that can make the needed judgment as to which types of safety differences trigger a meaningful difference to the patient, and therefore disqualify the product from being a biosimilar.

278. There may be little reason for generic drug manufacturers *not* to adopt such an approach, as doctors frequently do not review generic drug labels. Instead, they often prescribe the branded drug based on the product labeling and their own experience, and the generic is substituted for the branded version at the pharmacy.

279. Aaron S. Kesselheim et al., *Risk, Responsibility, and Generic Drugs*, 367 *NEW ENG. J. MED.* 1679 (2012).

280. *Id.* at 1680.

281. Additionally, the authors propose a compensation system similar to the Vaccine Injury Compensation Program for providing compensation to those harmed by drugs. *See id.* at 1680–81.

282. This result could be achieved by amending 21 C.F.R. § 314.70(c)(6)(iii) to eliminate the ability of an NDA holder to make labeling changes through the CBE process once an ANDA had been approved.

283. *Regenstrief Study Finds that Generic Drugs Often Have Incorrect Safety Labeling*, *IND. U. SCH. MED.* (Dec. 13, 2012), <http://communications.medicine.iu.edu/newsroom/stories/2012/regenstrief-study-finds-that-generic-drugs-often-have-incorrect-/>.

brand-name manufacturer leaves the market and withdraws its NDA.²⁸⁴ Reforms seeking to achieve these goals should also include measures to assure that the FDA is not improperly burdened by this responsibility.

In exploring this approach, consideration should be given to whether the current emphasis on the NDA holder's safety labeling obligations still reflects the way safety information is typically discovered, collected, or evaluated once generics enter the market, as well as the overwhelming command generic drugs have over the market. The reliance on the NDA holder and the CBE process was designed for the first few years after a drug had been approved, where safety information is accumulated primarily through clinical studies or other controlled postmarketing research performed by the NDA holder.²⁸⁵ These dynamics change once a drug has been on the market for several years and becomes multisourced. As the FDA has observed, "new information about drugs in long use (as generic drugs typically are) appears infrequently."²⁸⁶ Also, safety information comes largely from spontaneous adverse event reports from each manufacturer, which can require extensive evaluation before drawing safety conclusions.

Highly regarded product liability lawyer, Jim Beck, has suggested a hybrid system, where the FDA governs a centralized system for labeling multisourced drugs, but both the brand-name and generic drug manufacturers have the authority to unilaterally change product labeling through the CBE process when a manufacturer becomes aware that there is a heightened risk of permanent physical injury or death.²⁸⁷

None of these ideas would impact a brand-name manufacturer's obligations during the period in which it is the sole provider of a drug.²⁸⁸ They all, however, deserve careful evaluation. Rewriting the federal regulatory regime for prescription drugs is a serious undertaking that will have a significant impact on America's health care.

284. See *supra* notes 75–78 and accompanying text. Under current law, brand-name manufacturers sometimes have an incentive to withdraw their NDAs to limit their failure-to-warn liability. These reforms could change the dynamics and encourage companies that invent drugs to continue safety monitoring after generic manufacturers dominate the drug's market.

285. See *supra* note 58 and accompanying text.

286. See Brief for the United States As Amicus Curiae Supporting Respondents at 35, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039 and 09-1501).

287. See James M. Beck, *One Shoe Drops*, *DRUG & DEVICE L.* (Sept. 2, 2011), <http://druganddevicelaw.blogspot.com/2011/09/one-shoe-drops.html>.

288. An area where these theories can be further developed and tested is with biosimilars, which are generic versions of biologic drugs. See *Biosimilars*, FDA, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm> (last updated July 10, 2012). The laws and regulations for testing and marketing biosimilars are currently being established, and these concepts can add some certainty.

CONCLUSION

It is a bedrock principle of product liability and tort law that a product manufacturer is subject to liability only for harms caused by its products.²⁸⁹ The federal regulatory regime for prescription drugs does not change this basic truth. The fact that federal law allows a company that makes generic drugs to use an innovator's product and labeling to compete against that innovator does not mean that the innovator must also assume its generic competitor's liability. In this regard, manufacturers of prescription drugs are no differently situated than any other business competitors, whether in the restaurant, auto, or other industries. As detailed in this Article, there are two decades of cases from all around the country rejecting competitor liability theories for prescription drugs and reinforcing these fundamental principles of law.

The Supreme Court's decision in *Mensing* that federal drug law preempts state failure-to-warn claims against manufacturers of generic drugs has no impact on competitor liability. The issues are completely separate. Courts may be frustrated by the disparate liability treatment for users of brand-name and generic drugs, but they should not be tempted to radically alter tort law in search of defendants that users of generic drugs can sue. As the Supreme Court stated in *Mensing*, Congress and the FDA are the appropriate arms of government for fashioning a response to *Mensing*, should they decide reform is needed.²⁹⁰ This debate is well under way.

289. See, e.g., *supra* note 130.

290. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2582 (2011).