PICKING UP THE TAB FOR YOUR COMPETITORS: INNOVATOR LIABILITY AFTER *PLIVA, INC. V. MENSING*

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INTRODUCTION

Pharmaceutical adverse effects are a leading cause of death and injury in America.[1] Many of these side effects are caused by generic drugs, which make up 75 percent of the U.S. prescription drug market.[2] Under state tort law, plaintiffs injured by unwarned-of side effects could traditionally recover for their injuries in failure-to-warn actions if they could prove that the failure to warn made the drug defective and unreasonably dangerous and that the drug would not have been prescribed had an adequate warning been provided.[3] However, after the recent Supreme Court decision, *PLIVA, Inc. v. Mensing*,[4] these failure-to-warn claims against generic drugs are preempted by federal drug regulations.[5] As the *Mensing* dissent notes, a patient's ability to receive compensation for his or her injury now depends on an arbitrary distinction—whether the injuring drug was brand name or

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[1] *See* Barbara Starfield, *Is US Health Really the Best in the World?*, 284 JAMA 483, 484 (2000) (noting that 106,000 deaths per year in America result from "nonerror, adverse effects of medications").

[2] PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2584 (Sotomayor, J., dissenting) (citing OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, U.S. DEP'T OF HEALTH & HUMAN SERVS., ASPE ISSUE BRIEF: EXPANDING THE USE OF GENERIC DRUGS 2 (2010)).

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

> The elements of the tort of negligent misrepresentation under Maryland law are: "(1) the defendant, *owing a duty of care to the plaintiff*, negligently asserts a false statement; (2) the defendant intends that his statement will be acted on by the plaintiff; (3) the defendant has knowledge that the plaintiff will probably rely on the statement which, if erroneous, will cause loss or injury; (4) the plaintiff, justifiably, takes action in reliance on the statement; and (5) the plaintiff suffers damage proximately caused by the defendant's negligence."

Id. (quoting Martens Chevrolet, Inc. v. Seney, 439 A.2d 534, 539 (Md. 1982)); Oppenheimer v. Sterling Drug, Inc., 219 N.E.2d 54, 58 (Ohio Ct. App. 1964) (holding that no causation existed because the plaintiff's doctor did not rely on the existent warnings of the drug manufacturer when prescribing the drug to the plaintiff but instead relied on his own experience and other sources); RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) (1998) (a product "is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings").

[4] 131 S. Ct. 2567 (2011).

[5] *Id.* at 2572.

generic.[6] This decision leaves plaintiffs injured by generic drugs with inadequate warnings without recourse against the drug's manufacturers.

Plaintiffs faced with this situation will likely attempt to recover from brand-name drug manufacturers for the injury caused by the generic versions of their drugs[7] as failure-to-warn claims against these manufacturers are not preempted.[8] While these so-called innovator liability[9] suits have generally been unsuccessful in the past,[10] the *Mensing* decision undermines a large part of the rationale for not allowing these suits.[11] Prior to *Mensing*, many courts assumed that a generic drug manufacturer could alter or supplement the warnings it provided with its drugs.[12] However, in reaching its preemption decision, the *Mensing* Court held that a generic drug manufac-

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6 *Id.* at 2592 (Sotomayor, J., dissenting).

> [A] drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth*. If, however, she takes a generic drug, as occurs 75 percent of the time, she now has no right to sue. The majority offers no reason to think—apart from its new articulation of the impossibility standard—that Congress would have intended such an arbitrary distinction.

Id.

7 In the first Court of Appeals case to be decided after *PLIVA, Inc. v. Mensing*, the plaintiffs attempted to recover from the brand-name manufacturer as their claims against the generic manufacturer were preempted; the Sixth Circuit rejected this form of liability. Smith v. Wyeth, Inc., 657 F.3d 420, 424 (6th Cir. 2011).

8 Wyeth v. Levine, 555 U.S. 555, 573 (2009); *see also* Stephanie M. Rippee & Ceejaye S. Peters, *What Does the Future Hold for Generic Pharmaceutical Manufacturers?: Implied Conflict Preemption Defense*, FOR THE DEF., Aug. 2011, at 35, 36 (stating that *Wyeth* "greatly limited branded drug manufacturers' ability to successfully assert th[e preemption] defense").

9 Innovator liability is a term that has been used to refer to failure-to-warn liability imposed on a brand-name drug manufacturer when the plaintiff took a generic version of the drug. *See* Bartlett v. Mut. Pharm. Co., 659 F. Supp. 2d 279, 308 n.40 (D.N.H. 2009) ("The vast majority of courts have rejected the notion that the manufacturer of the brand-name drug may be liable for defects in its generic equivalent on a theory of 'innovator liability.'"). This Comment will use the term innovator liability throughout to refer to these suits.

10 *See, e.g.*, Foster v. Am. Home Prods. Corp., 29 F.3d 165, 167 (4th Cir. 1994); Fullington v. Pfizer, Inc., No. 4:10CV00236 JLH, 2010 WL 3632747, at *2 (E.D. Ark. Sept. 17, 2010); Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056, 1058 (W.D. Ark. 2009). *But see* Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 304-05 (Cal. Ct. App. 2008).

11 *See Mensing*, 131 S. Ct. at 2575 (holding that makers of generic drugs were not able to unilaterally change their warning labels to comply with their duties under state tort law). Previous courts denying innovator liability cases relied partly on their interpretation that makers of generic drugs were free to supplement their warnings. *See, e.g.*, *Foster*, 29 F.3d at 170. The question of *Mensing*'s impact on innovator liability suits was first raised on the FDA Law Blog. *See* Kurt R. Karst, *Supreme Court Issues Decision on Generic Drug Preemption; To Borrow from Harry Caray—"Holy Cow! Generics Win! Generics Win!"*, FDA LAW BLOG (June 23, 2011), http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/06/supreme-court-issues-decision-on-generic-drug-preemption-to-borrow-from-harry-caray-holy-cow-generic.html.

12 *See, e.g.*, *Foster*, 29 F.3d at 170; *Fullington*, 2010 WL 3632747, at *2; *Fields*, 613 F. Supp. 2d at 1061. *But see Conte*, 85 Cal. Rptr. 3d at 307.

turer must use a warning identical to the warning used by the brand-name manufacturer and cannot supplement this warning in any way.[13]

This Comment argues that because of their sole ability to determine warning labels, brand-name drug manufacturers do, in fact, have a duty to provide adequate warnings to patients who take the generic version of their drugs. This Comment further argues that because the brand-name manufacturer's chosen warning is the warning on which all patients—including those taking a generic drug—rely, a brand-name drug manufacturer's inadequate warning is the proximate cause of failure-to-warn injuries resulting from a generic version of a drug. Therefore, the brand-name manufacturer should be liable for harm caused by generic drugs in failure-to-warn cases.

This outcome is far from ideal. The brand-name manufacturer invests resources to produce helpful pharmaceuticals, and under innovator liability, it would be liable for harm caused by its competitors' drugs. As this reduces the profitability of creating new drugs, it could provide drug developers with a negative incentive, reducing the number of beneficial drugs developed in this country. Meanwhile, generic drug manufacturers are insulated from failure-to-warn lawsuits by the preemption recognized in *Mensing*. This result illustrates the need for the U.S. Food and Drug Administration ("FDA") or Congress to amend the drug approval laws. Generic manufacturers should have the ability to modify and supplement their warnings unilaterally through the Changes-Being-Effected process and by sending "Dear Doctor Letters."[14] This proposal returns the responsibility for warning patients of side effects to each individual drug manufacturer. It would remove generic manufacturers' preemption defense, making them liable for the harms caused by the drugs they produce. This sensible action would provide plaintiffs and drug manufacturers with a clear, consistent, and coherent legal framework and would restore responsibility for failure to warn to all drug manufacturers.

Part I of this Comment discusses the background of failure-to-warn claims, the generic drug approval process, the history of previous innovator liability cases, and the *Mensing* case. Part II argues that brand-name drug manufacturers should be liable for the harm caused by their generic counterparts because the brand-name manufacturers have a duty to generic patients, and their inadequate warnings are the proximate cause of those patients' injuries. Part III argues that generic drug manufacturers should be allowed to unilaterally choose and supplement their own warnings as this

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

14 Dear Doctor Letters are memoranda sent to doctors informing them of newly discovered risks or side effects for a particular drug. *See* CTR. FOR DRUG EVALUATION & RESEARCH, U.S. FOOD & DRUG ADMIN., NDAS: "DEAR HEALTH CARE PROFESSIONAL" LETTERS 1-3 (2003), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/ucm082012.pdf. "Changes being effected" is a process where a drug manufacturer unilaterally changes its warning label without prior approval from the FDA. *Mensing*, 131 S. Ct. at 2575.

would allow them to comply with their duty to warn and would avoid the preemption of state tort law.[15]

I. BACKGROUND

This background section describes the current state of the law regarding innovator liability. This Part first discusses the history of generic drugs and the Hatch-Waxman Amendments. It next presents an overview of failure-to-warn claims against drug manufacturers. It then addresses the history of failure-to-warn claims against brand-name drug manufacturers prior to *PLIVA, Inc. v. Mensing*. Finally, it provides an overview of the *Mensing* decision and the prior history of the case in the lower courts.

A. *Generic Drugs and the Hatch-Waxman Amendments*

Developers of new drugs receive a patent protecting their drug from competition for a certain amount of time.[16] After the patent on a new drug expires, other drug manufacturers can apply for FDA approval to sell non-brand-name versions of that drug, popularly known as generics.[17] These generic drugs are chemically identical to the brand-name drug and thus theoretically[18] have the same efficacy, safety, and risks.[19] When a doctor

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15 This Comment assumes that it is desirable to avoid the preemption by federal law of areas traditionally governed by state law. However, scholars such as Professor Richard Epstein have argued that federal drug regulation should preempt state tort claims against drug manufacturers as a matter of law and of normative policy preferences. *See* Richard A. Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of* Chevron *Deference and a Response to Richard Nagareda*, 1 J. TORT L. 1 (2006).

> Where the use of [a] drug has a positive expected value to all class members, imposing tort liability can only muddy the waters. The higher cost of running a liability system, with its deadweight administrative costs and high rates of error[,] will reduce the distribution of the drug and increase its costs. Every false positive that wins in litigation is an unfair tax that hurts all successful drug users. What possible reason is there not to preempt litigation which on balance is worse than useless?

Id. at 25 (footnote omitted). *But see* Lesley A. Stout, Note, *Making Changes: Generic Drug Labeling and the Case Against Federal Preemption*, 98 KY. L.J. 623, 625 (2010). The issue of the normative value of preemption is beyond the scope of this Comment.

16 35 U.S.C. § 154 grants new patents for a term of twenty years. However, pharmaceutical patents are entitled to extension of this period to compensate for the long time it takes for a drug company to gain FDA approval for a new drug. *See* 35 U.S.C. § 156 (2006) (allowing a patent term extension when a "product has been subject to a regulatory review period before its commercial marketing or use").

17 21 U.S.C. § 355(j)(2)(A)(i) (2006).

18 Generic drugs could, in reality, present risks not present in the brand-name drug. For example, generic drug manufacturers may use different inactive ingredients or fillers from the brand-name manufacturer, which could cause new side effects for some people. A generic manufacturer could potentially

prescribes a brand-name drug, the patient's pharmacist has the option of filling the prescription with the generic version of the drug unless the prescribing doctor specifies that substitution is not allowed.[20] Generics typically cost significantly less than the identical brand-name drug,[21] providing an affordable option to many people and improving access to needed pharmaceuticals.[22]

Prior to 1984, to gain approval to market a generic drug through the New Drug Application ("NDA") process, generic drug manufacturers were required by law to conduct the same safety and efficacy tests as brand-name manufacturers.[23] Because of the high cost of this process and the low profit margin on generic drugs, very few generic drugs were introduced to the market under this legal regime.[24] In order to increase drug competition, lower prices, and improve patient access to pharmaceuticals, the 1984 Congress passed the Drug Price Competition and Patent Term Restoration Act,[25] commonly known as the "Hatch-Waxman Amendments."[26] The Hatch-Waxman Amendments created an easier and less expensive procedure for the approval of generic drugs called the Abbreviated New Drug Application ("ANDA").[27] The ANDA allows drug companies to gain approval for a generic drug by showing only that it is bioequivalent to the

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have less rigorous quality controls in its manufacturing process. These differences, however, do not relate to the risks caused by the active ingredient, which are the risks typically warned against.

19 21 U.S.C. § 355(j)(2)(A)(ii)-(v).

20 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2583 (2011) (Sotomayor, J., dissenting) (noting that all fifty states have some form of generic substitution laws that allow pharmacists to fill prescriptions made for brand-name drugs with a generic version, if available).

21 WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL31379, THE "HATCH-WAXMAN" ACT: SELECTED PATENT-RELATED ISSUES 3 (2002) [hereinafter SELECTED PATENT-RELATED ISSUES] ("Generics generally are rapidly available after patent expiration [of the brand-name drug] and at lower prices."). Additionally, after a generic version of a particular drug is introduced into the market, the price of the brand-name drug sometimes increases even as its market share declines due to the price insensitivity of loyal customers. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL30756, PATENT LAW AND ITS APPLICATION TO THE PHARMACEUTICAL INDUSTRY: AN EXAMINATION OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 ("THE HATCH-WAXMAN ACT") 32-33 (2005) [hereinafter THE HATCH-WAXMAN ACT].

22 *See* SELECTED PATENT-RELATED ISSUES, *supra* note 21, at 3.

23 *Id.* at 3-4 & n.4.

24 *See Mensing*, 131 S. Ct. at 2584 (Sotomayor, J., dissenting) ("It is estimated that in 1984, when the Hatch-Waxman Amendments were enacted, generic drugs constituted 19 percent of drugs sold in this country.") (citing CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 27 (1998)).

25 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code); *see* H.R. REP. NO. 98-857, pt. 1, at 14 (1984) (explaining that the purpose of the act was to "make available more low cost generic drugs by establishing a generic drug approval procedure").

26 *Mensing*, 131 S. Ct. at 2574.

27 21 U.S.C. § 355(j) (2006).

already approved brand-name drug.[28] Under the ANDA process, the generic drug manufacturer does not need to repeat the expensive safety and efficacy tests required for brand-name drug manufacturers applying with an NDA.[29]

The Hatch-Waxman Amendments made other significant changes to pharmaceutical law. They created financial incentives for companies to challenge the validity of patents.[30] For example, the first company to successfully challenge a pharmaceutical patent now receives a 180-day exclusive right to market the generic version of the drug whose patent it challenged.[31] The Amendments also recognized the need for financial incentives to innovate new drugs and extended the term of brand-name patents.[32]

The overall effect of the Amendments has been a dramatic increase in the number of generic drugs available with no discernible adverse effect on drug innovation.[33] Seventy percent of all prescriptions are now filled with generic drugs.[34] Looking at only the drugs with an available generic version, the numbers are even more dramatic—a full ninety percent of those prescriptions are filled with a generic.[35] This is not a surprising result given the Amendment's framework and the fact that many insurance companies and government benefit programs now require prescriptions to be filled with generics if possible.[36]

Since the adoption of the Hatch-Waxman Amendments, the FDA has formulated regulations for generic drug approval and post-approval responsibilities.[37] For example, the FDA requires drug manufacturers to inform the FDA of any newly discovered risks of their drugs.[38] The FDA contends that, in the case of new risks, generic manufacturers as well as brand-name man-

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28 21 U.S.C. § 355(j)(2)(A)(iv); THE HATCH-WAXMAN ACT, *supra* note 21, at 23.

29 *See* 21 U.S.C. § 355(j).

30 THE HATCH-WAXMAN ACT, *supra* note 21, at 26-27.

31 *Id.* at 27.

32 *Id.* at 28.

33 *Id.* at 31-32.

34 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2584 (2011) (Sotomayor, J., dissenting) (citing ASPE ISSUE BRIEF, *supra* note 2, at 2).

35 *Id.*

36 *Id.* at 2584 n.2. In addition, many insurance plans are structured to promote generic use. *See* CONG. BUDGET OFFICE, EFFECTS OF USING GENERIC DRUGS ON MEDICARE'S PRESCRIPTION DRUG SPENDING 9 (2010), *available at* http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/118xx/doc11838/09-15-prescriptiondrugs.pdf. State Medicaid programs similarly promote generic use. *See* JEFFREY S. CROWLEY ET AL., THE HENRY J. KAISER FAMILY FOUND., STATE MEDICAID OUTPATIENT PRESCRIPTION DRUG POLICIES: FINDING FROM A NATIONAL SURVEY, 2005 UPDATE 10 (2005), *available at* www.kff.org/medicaid/upload/state-medicaid-outpatient-prescription-drug-policies-findings-from-a-national-survey-2005-update-report.pdf.

37 *See, e.g.*, 21 C.F.R. § 314.70 (1993).

38 *Id.*

ufacturers must petition the agency to require all manufacturers of that drug to update their warnings.[39]

Moreover, the FDA has interpreted the Hatch-Waxman Amendments as requiring generic drugs to have identical warning labels as their brand-name counterparts; FDA approval can be withdrawn if this continuing "sameness" requirement is not met.[40] This means that unlike brand-name drugs, generic drug manufacturers cannot unilaterally change their warning labels.[41] The FDA has used a similar interpretation to decide that generic manufacturers may not use "Dear Doctor Letters."[42] Dear Doctor Letters are letters drug manufacturers send to doctors, informing them of newly discovered risks or side effects.[43] Generic manufacturers are prevented from using Dear Doctor Letters because the FDA considers the letters to be "labeling," and they provide information inconsistent with or supplemental to the brand-name warning label.[44] This interpretation creates a potential conflict with state law when a generic drug manufacturer discovers a post-FDA approval risk that it has a duty to warn against under state tort law.[45] This duty to warn is discussed in the next Section.

B. *Failure-to-Warn Claims Against Drug Manufacturers*

State law imposes liability for failure to warn[46] or "informational defects" when a product injures a person in a way that should have been

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39 Brief for the United States as Amicus Curiae Supporting Respondents at 20, *Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, & 09-1501) [hereinafter Amicus Brief] (citing Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992)) (arguing that generic drug manufacturers are "obligated . . . to seek to revise their labeling and provide FDA with supporting information about risks").

40 *See id.* at 16-17; 21 C.F.R. § 314.94 (1993).

41 *Mensing*, 131 S. Ct. at 2575; Amicus Brief, *supra* note 39, at 15.

42 *See infra* notes 43-45 and accompanying text.

43 CTR. FOR DRUG EVALUATION & RESEARCH, *supra* note 14, at 2 (defining Dear Doctor Letters as "[c]orrespondence mailed by a [pharmaceutical] manufacturer and/or distributor to physicians and/or other health care professionals to convey important information about drugs. [Dear Doctor L]etters are considered promotional labeling. These letters can be requested by FDA or initiated by the applicant.").

44 *Mensing*, 131 S. Ct. at 2576; Amicus Brief, *supra* note 39, at 18-19.

45 This was the situation in *Mensing*. While the FDA maintains that generic drug companies faced with this situation must report these adverse effects, the generic drug company does not have the ability to unilaterally change its warning label to comply with its state tort law duties.

46 Plaintiffs variously bring actions for failure to warn, marketing defects, negligent misrepresentation, breach of implied warranty, and fraud, among others. While these actions are conceptually distinct, this Comment refers to them as "failure to warn" and treats them as the same action. This is justified because courts treat them as essentially the same cause of action because of plaintiffs' practice of alleging every possible theory of recovery. *See, e.g.*, Goldych v. Eli Lilly & Co., No. 5:04-CV-1477, 2006 WL 2038436, at *1, *6 (N.D.N.Y. July 19, 2006). The court in *Goldych* stated:

> Goldych filed a state court complaint asserting seven causes of action: *Count I*-Negligence and/or Recklessness; *Count II*-Fraud; *Count III*-Fraudulent Concealment; *Count IV*-

warned against.[47] A manufacturer of any product has a general duty to provide warnings about risks if the product would be unreasonably dangerous without the warnings.[48] In other words, a manufacturer has a duty to warn if it would be negligent not to do so.[49] The calculus of negligence in pharmaceutical cases must consider the fact that excessive warnings will discourage patients from taking beneficial drugs because they overemphasize the risk of rare events.[50] Moreover, if a manufacturer warns against a litany of rare risks, the significant risks may be lost to patients in the noise.[51]

To recover for a failure to warn, the plaintiff must also prove causation.[52] This means that the plaintiff must prove that he or she would not have used the product, or would have used the product differently (in a way

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> Negligent Misrepresentation; *Count V*-Deceptive Business Acts and Practices in Violation of Sections 349 and 350 of New York's General Business Law; *Count VI*-Loss of Consortium; and *Count VII*-Wrongful Death. . . . Since Eli Lilly has no duty to the users of other manufacturers' products, Goldych's claims for negligence, fraud, fraudulent concealment, and negligent misrepresentation cannot be maintained on the facts of this case. The court adopts the rationale articulated in *Foster* and *Colaccio*, and holds that a brand name manufacturer cannot be held liable to a plaintiff allegedly injured by another company's generic bioequivalent. Accordingly, Goldych's first, second, third, and fourth causes of action are dismissed.

Id.

47 MICHAEL I. KRAUSS, PRINCIPLES OF PRODUCTS LIABILITY 104-08 (2011).

48 *See* RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 10 (1998).

49 *See id.* § 10 cmt. b ("The standard governing the liability of the seller is objective: whether a reasonable person in the seller's position would provide a warning. This is the standard traditionally applied in determining negligence.").

50 Consider the warnings given during a typical television drug advertisement. The manufacturer discloses many rare risks to protect itself from liability. Customers are likely to finish watching the advertisement with the impression that the drug is much riskier than it is. *See also* Epstein, *supra* note 15, at 22 ("But surely on any view of this question, the warning issue remains troublesome because, even in the absence of cognitive deficits, an excessive warning from an authoritative source is likely to drive off potential users who might profit from the drug."). If this causes one of these customers to forego taking a helpful drug, it causes a social loss that must be considered in the calculus of whether to include the warning. *See id.* at 24-25.

51 KRAUSS, *supra* note 47, at 116 ("Over-warnings . . . 'crowd out' more important warnings. As one court pointed out, '[E]xcessive warnings on product labels may be counterproductive, causing 'sensory overload' which literally drowns crucial information in a sea of mind-numbing detail.'" (quoting Aetna Cas. & Sur. Co. v. Ralph Wilson Plastics Co., 509 N.W.2d 520, 523 (Mich. Ct. App. 1993))); *see also* Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. 1123, 1191 (2011) ("Overwarning about every imaginable risk may drive doctors and patients to overlook truly significant precautionary information, deter doctors from prescribing worthwhile drugs, or scare patients out of taking drugs that would benefit them. These risks are real."). Consider again the case of television drug advertisements. If the viewer is not scared away from taking the drug by the lengthy warning, there is a good chance that the viewer will ignore the warnings completely because they are long and the viewer understands that they are overinclusive to protect against liability.

52 *See* Moore v. Ford Motor Co., 332 S.W.3d 749, 762 (Mo. 2011).

that would have prevented the injury), if he or she had been properly warned.[53]

Liability for drug manufacturers differs in some key respects from liability for other products. Many pharmaceuticals are what the Second Restatement of Torts describes as "unavoidably unsafe products."[54] This exempts most pharmaceuticals from ordinary principles of strict liability used for other products.[55] For example, a drug manufacturer is not liable if its product causes a known side effect because the benefits outweigh the risk of harm. Drug companies, however, still have a duty to warn of the risks created by their product.[56] While manufacturers of ordinary products may be required to warn of risks discovered post-sale, there is generally no common-law duty to continue testing a product for risks post-sale.[57] Drug manufacturers, however, have a continuing duty to warn of risks they discover and to monitor the safety of their products.[58] This continuing duty gives rise to liability when a risk is discovered after FDA approval and is not communicated to patients though their doctors.[59]

Failure-to-warn claims against pharmaceutical manufacturers also differ from other failure-to-warn actions because the prescribing physician must receive the warning, not the patient.[60] This is known as the learned intermediary doctrine.[61] Thus a plaintiff suing a drug manufacturer for failure to warn must show that the physician, not the patient, was inadequately warned.[62] Some states, however, grant a rebuttable presumption of causation when the plaintiff successfully demonstrates a failure to warn, meaning the plaintiff does not need to actively prove that the warning would have changed his or her doctor's decision to prescribe.[63]

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53 *Id.* ("To do this, 'plaintiffs must show that a warning would have altered the behavior of the individuals.'" (quoting Arnold v. Ingersoll-Rand Co., 834 S.W.2d 192, 194 (Mo. 1992))).

54 RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) ("There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs.").

55 *Id.*

56 *Id.*

57 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 11 cmt. a (1998).

58 *Id.* at § 10 cmt. c.

59 *See e.g.*, Mensing v. Wyeth, Inc., 588 F.3d 603, 614 (8th Cir. 2009), *rev'd sub nom.* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

60 KRAUSS, *supra* note 47 , at 122-23.

61 *Id.*

62 *See* Hurley v. Heart Physicians, P.C., 898 A.2d 777, 779 (Conn. 2006); Oppenheimer v. Sterling Drug, Inc., 219 N.E.2d 54, 58 (Ohio Ct. App. 1964) (holding that no causation existed because the plaintiff's doctor did not rely on the warnings provided by the drug manufacturer when prescribing the drug to the plaintiff but instead relied on his own experience and other sources).

63 *See e.g.*, Kellogg v. Wyeth, 762 F. Supp. 2d 694, 701 (D. Vt. 2010) ("[P]roximate cause in a failure to warn case 'is typically shown by means of a presumption. If a plaintiff can demonstrate that the manufacturer had a duty to warn and failed to provide an adequate warning, a causal presumption arises that had an adequate warning been provided, the user would have read and heeded the warning.'"

The learned intermediary doctrine is based on the reality that in the context of medicine, the patient does not have the background knowledge and training necessary to comprehend drug manufacturers' warnings and make sound decisions based on them.[64] Instead, most patients rely on their doctors to stay abreast of the relevant information regarding their medical condition and the drugs used to treat it, assimilate and translate this information to the patient, and recommend a course of action, such as to take a certain drug.[65] In reaching this recommendation, a doctor will weigh the risks of harm from the drug against the benefits the drug will provide to the patient.[66] Because of this unique relationship, a drug manufacturer's duty to warn is satisfied by directing its warnings to doctors.

C. *Previous Innovator Liability Cases Have Been Generally Unsuccessful.*

Most courts have refused to allow innovator liability suits, partly on the grounds that the manufacturer of the generic drug could have modified its warning.[67] If generic drug manufacturers were free to unilaterally modify

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(quoting Town of Bridport v. Sterling Clark Lurton Corp., 693 A.2d 701, 704 (Vt. 1997))). *But see* Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996) ("In the event that a warning is inadequate, proximate cause is not presumed." (citing Mazur v. Merck & Co., 742 F. Supp. 239, 262 (E.D. Pa. 1990))). Although these cases discuss proximate cause rather than cause-in-fact, the principle is the same.

64 *See Hurley*, 898 A.2d at 779 (noting that the learned intermediary doctrine is "based on the principle that prescribing physicians act as learned intermediaries between a manufacturer and the consumer and, therefore, stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment, [and the doctrine] provides, in general terms, that, adequate warnings to prescribing physicians obviate the need for manufacturers . . . to warn ultimate consumers directly." (quoting Vitanza v. Upjohn Co., 778 A.2d 829, 836 (Conn. 2001)) (internal quotation marks omitted)).

65 *Id.*

66 *Id.*

67 *See, e.g.*, Foster v. Am. Home Prods. Corp., 29 F.3d 165, 168 (4th Cir. 1994); Fullington v. Pfizer, Inc., No. 4:10CV00236 JLH, 2010 WL 3632747, at *2 (E.D. Ark. Sept. 17, 2010); Fields v. Wyeth, Inc., 613 F. Supp. 2d 1056, 1058 (W.D. Ark. 2009); *see also* Gaeta v. Perrigo Pharm. Co., 630 F.3d 1225, 1233 (9th Cir. 2011) (citing *Foster*, 29 F.3d at 170) (finding in the context of a preemption defense that generic drugs are able under federal law to use the changes being effected process to unilaterally change their warnings), *vacated sub nom.* L. Perrigo Co. v. Gaeta, 132 S. Ct. 497 (2011); Demahy v. Actavis, Inc., 593 F.3d 428, 438-41 (5th Cir. 2010) (holding that generic drug manufacturers can use both the changes being effected process and Dear Doctor Letters to change their warnings and comply with state-imposed tort duties), *rev'd sub nom.* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011); Dorsett v. Sandoz, Inc., 699 F. Supp. 2d 1142, 1160-62 (C.D. Cal. 2010) ("[Plaintiff] makes another argument . . . FDA regulations prohibited it from making *any* changes to Fluoxetine labeling that would deviate from that of the 'innovator' (or 'listed') drug— *i.e.*, Prozac—because generic drug manufacturers may not make any change in a warning label without prior FDA approval. This contention was not addressed in *Wyeth*. It lacks merit."); Munroe v. Barr Labs., Inc., 670 F. Supp. 2d 1299, 1302 (N.D. Fla. 2009)

their warnings, any decision to keep using a brand-name manufacturer's inadequate warning after discovering a new risk would be an independent voluntary act defeating proximate cause.[68] Only if generic manufacturers can modify their warnings does this conclusion hold.[69] However, after the *Mensing* decision, discussed *infra*, courts adjudicating one of these innovator liability suits will have to confront the fact that the Supreme Court has endorsed the FDA's position that a generic drug manufacturer has no ability to unilaterally change the warnings on its drugs.[70]

The most prominent case on point pre-*Mensing* is *Foster v. American Home Products Corp.*[71] *Foster* is important because subsequent cases have generally followed its reasoning in rejecting innovator liability.[72] In *Foster*,

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(citing *Foster*, 29 F.3d at 170) ("[Plaintiff's] assertion that it is impossible for a generic-drug manufacturer to comply with both the federal law requiring an FDA-approved label and any state law requiring an additional warning is incorrect. Under 21 C.F.R. §§ 314.70, .97, a drug manufacturer may strengthen its label while seeking FDA approval of the change. As noted in *Bartlett* and other cases, this procedure is not limited to brand manufacturers; a generic manufacturer can invoke the procedure, too."); Bartlett v. Mut. Pharm. Co., 659 F. Supp. 2d 279, 296-304, 308 n.40 (D.N.H. 2009) (holding that generic drugs are free to use the changes being effected process and noting that *Foster* would likely be followed in New Hampshire); Stacel v. Teva Pharm., USA, 620 F. Supp. 2d 899, 905 (N.D. Ill. 2009) (holding that a claim against a generic drug was not preempted because generic manufacturers could unilaterally change their warning labels); Goldych v. Eli Lilly & Co., No. 5:04-CV-1477, 2006 WL 2038436, at *3 (N.D.N.Y. July 19, 2006) (citing *Foster*, 29 F.3d at 169) (noting that generic drugs are able to change their warning labels under federal law).

68 *See, e.g.*, Pittsburg Reduction Co. v. Horton, 113 S.W. 647, 648 (Ark. 1908); Coleman v. Rudisill, 508 S.E.2d 297, 300 (N.C. Ct. App. 1998). Courts also use intervening choice to decide that a manufacturer owes no duty, though this is better addressed as part of proximate cause. For example, in *Blackmon v. American Home Products Corp.*, a court held that the designer of the chemical thimerosal had no duty to customers exposed to competitors' themirosal that was copied without the defendants' permission. 346 F. Supp. 2d 907, 916 (S.D. Tex. 2004). Contrast *Blackmon*'s finding of no liability with *Alm v. Aluminum Co. of America*, where Alcoa was held liable for harm caused by a manufacturer who used Alcoa's bottle cap design under a royalty-paying license from Alcoa. 717 S.W.2d 588, 591 (Tex. 1986).

69 *See, e.g.*, *Horton*, 113 S.W. at 648; *Coleman*, 508 S.E.2d at 300; Sarah C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 VAND. J. ENT. & TECH. L. 185, 206 (2010).

70 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2575-76 (2011).

71 29 F.3d 165 (4th Cir. 1994).

72 *See e.g.*, Mensing v. Wyeth, Inc., 588 F.3d 603, 613 (8th Cir. 2009), *rev'd sub nom.* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011); *Bartlett*, 659 F. Supp. 2d at 308 n.40 (noting that *Foster* would likely be followed by a New Hampshire court); Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 540-41 (E.D. Pa. 2006), *aff'd in part, rev'd in part*, 521 F.3d 253 (3d Cir. 2008), *vacated*, 129 S. Ct. 1578 (2009); *Goldych*, 2006 WL 2038436, at *6 (explicitly adopting *Foster* and *Colaccio*, finding no liability against the manufacturer of Prozac for negligent misrepresentation when the patient took the generic, fluoxetine, because the brand name manufacturer did not manufacture the product that allegedly caused the plaintiff to commit suicide and did not owe a "duty to the users of other manufacturers' products"); Tarver v. Wyeth, Inc., No. Civ.A.3-04-2036, 2005 WL 4052382, at *2 (W.D. La. June 7, 2005) (rejecting liability for Wyeth, the manufacturer of Reglan, when the plaintiff took the generic, metoclopramide, because Wyeth did not manufacture the product that injured the plaintiff); Block v. Wyeth,

the Fosters sued Wyeth,[73] the manufacturer of the brand-name drug Phenergan Syrup, for negligent misrepresentation.[74] The Fosters' doctor had prescribed Phenergan Syrup for their daughter, but their pharmacist substituted the generic version of Phenergan, promethazine syrup,[75] which is not manufactured by Wyeth.[76] After taking the generic promethazine syrup, the Fosters' daughter died.[77] The Fosters argued that their negligent misrepresentation claim against Wyeth should prevail despite the fact that their daughter had taken a generic version of promethazine syrup because they contended that the harm caused by the generic drug was foreseeable to Wyeth.[78]

The Court of Appeals for the Fourth Circuit rejected the Fosters' arguments.[79] The court based its decision in part on its supposition that the generic drug manufacturer was fully capable under federal law of unilaterally providing stronger warnings and, in fact, was required to do so.[80] The court specifically commented that federal drug laws

> simply do[] not evidence Congressional intent to insulate generic drug manufacturers from liability for misrepresentations made regarding their products, or to otherwise alter state products liability law. Manufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products.[81]

Inc., No. Civ.A. 3:02-CV-1077, 2003 WL 203067, at *1-3 (N.D. Tex. Jan. 28, 2003) (holding that Wyeth did not have a duty to warn patients of the dangers of taking the generic, metoclopramide, which it did not manufacture, because Texas products liability law is strict liability); DaCosta v. Novartis AG, No. CV 01-800-BR, 2002 WL 31957424, at *9 (D. Or. Mar. 1, 2002) (applying *Foster* to disallow liability when the plaintiff took a product with the same active ingredient as in the defendant's product with an allegedly insufficient warning); Christian v. Minn. Mining & Mfg. Co., 126 F. Supp. 2d 951, 958 (D. Md. 2001) (applying the rule from *Foster* in a case involving harm caused by a breast implant); *see also* Sheeks v. Am. Home Prods. Corp., No. 02CV337, 2004 WL 4056060, at *2 (Colo. Dist. Ct.Oct. 15, 2004); Sharp v. Leichus, No. 2004-CA-0643, 2006 WL 515532, at *4-5 (Fla. Cir. Ct. Feb.17, 2006); Kelly v. Wyeth, No. Civ.A.MICV200303314B, 2005 WL 4056740, at *4 (Mass. Super. Ct. May 6, 2005); Sloan v. Wyeth, No. MRS-L-1183-04, 2004 WL 5767103 (N.J. Super. Ct. Oct. 13, 2004); Beutella v. A.H. Robins Co., No. 980502372, 2001 WL 35669202 (Utah Dist. Ct. Dec. 10, 2001).

73 American Home Products Corporation/Wyeth-Ayerst ("Wyeth") is commonly called Wyeth.

74 *Foster*, 29 F.3d at 166-67.

75 This drug is an antihistamine indicated for a wide variety of conditions including allergies and motion sickness. *Phenergan*, DRUGS.COM (Apr. 12, 2009, 4:38 PM), http://www.drugs.com/phenergan.html.

76 *Foster*, 29 F.3d at 167.

77 *Id.*

78 *Id.* at 169.

79 *Id.* at 170.

80 *Id.* at 169-70 ("Although generic manufacturers must include the same labeling information as the equivalent name brand drug, they are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval.") (citing 21 C.F.R. § 314.70 (1993)).

81 *Id.* at 170.

The court also relied on economic reasoning, noting that brand-name manufacturers expend substantial resources in developing drugs.[82] Although acknowledging that in Maryland, where the Fosters resided, there is generally no direct duty requirement when a plaintiff has suffered personal injury and not just economic harm,[83] the court held that the lack of a direct duty here prevented liability.[84] The court stated that "to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far."[85]

While courts have generally followed *Foster*,[86] California has uniquely broken with this trend and allowed liability against a brand-name manufacturer for generic-caused harm.[87] In *Conte v. Wyeth, Inc.*,[88] a division of the California Court of Appeals held that Wyeth's duty to warn extended to patients taking the generic version of its drug Reglan, [89] metoclopramide.[90] Although Wyeth argued that the case was one of strict liability and, therefore, it could not be liable for harm caused by a product it did not manufacture, the court rejected this reasoning because failure to warn sounds in negligence.[91] The court decided as a matter of law that Wyeth's inadequate warnings were the proximate cause of the plaintiff's harm because it was foreseeable that a pharmacist would fill a prescription for Reglan with the generic metoclopramide.[92] Thus, Wyeth could be liable for injuries caused by drugs it did not manufacture.[93]

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82 *Foster*, 29 F.3d at 170.

83 *Id.* at 171 (citing Jacques v. First Nat'l Bank, 515 A.2d 756, 759-60 (Md. 1986)).

84 *Id.*

85 *Id.*

86 See cases cited *supra*, note 72.

87 *See* Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 304-05 (Cal. Ct. App. 2008).

88 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).

89 Incidentally, Reglan is the same drug that was at issue in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

90 *Conte*, 85 Cal. Rptr. 3d at 315.

91 *Id.* at 309-10. It is interesting that California is the only state to correctly evaluate failure-to-warn innovator liability cases as sounding in negligence rather than strict liability since California is the birthplace of the strict liability products liability revolution. *See* Greenman v. Yuba Power Prods., Inc., 377 P.2d 897, 900 (Cal. 1963); Escola v. Coca-Cola Bottling Co., 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring).

92 The court also considered a variety of California-specific policy considerations know as the "Rowland Factors," from the case *Rowland v. Christian*, 443 P.2d 561, 564 (Cal. 1968). The factors are:

> [T]he foreseeability of harm to the plaintiff; the degree of certainty that the plaintiff suffered injury; the closeness of the connection between the defendant's conduct and the plaintiff's injury; the moral blame attached to the defendant's conduct; the policy goal of preventing future harm; the burden to the defendant and consequences to the community of imposing a duty of care; and broader consequences including the availability, cost, and prevalence of insurance for the risk involved.

Conte, 85 Cal. Rptr. 3d at 313 (citing Randi W. v. Muroc Joint Unified Sch. Dist., 929 P.2d 582, 588 (Cal. 1997)).

93 *Id.* at 315.

D. PLIVA, Inc. v. Mensing

In *PLIVA, Inc. v. Mensing*, the Supreme Court held that state failure-to-warn claims against generic drug manufacturers are preempted by federal law.[94] Plaintiff Gladys Mensing's[95] doctor prescribed Reglan to treat her gastroparesis.[96] And just as in *Conte v. Wyeth, Inc.*, her pharmacist filled the prescription with the generic version of Reglan, metoclopramide.[97] Because of this, Mensing never took Reglan, the brand-name drug.[98]

Mensing took metoclopramide for four years.[99] The drug caused Mensing to develop tardive dyskinesia,[100] and she sued the drug's manufacturers, alleging that they failed to provide a sufficient warning[101] of the known risk of tardive dyskinesia from long-term metoclopramide use.[102] Mensing sued the generic manufacturers, but she also sued the brand-name manufacturer, Wyeth, on a theory of innovator liability.[103] The Eighth Circuit held that Mensing's claims against the generic metoclopramide manufacturers were not preempted because the generic manufacturers could have proposed new warning labels to the FDA and therefore failed to show that complying with both state and federal law was impossible.[104] As a result, the court did not decide whether the generic manufacturers were able to unilaterally change

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

95 *Mensing* is a consolidated case. Julie Demahy, another plaintiff, was also prescribed Reglan but received the generic metoclopramide from her pharmacist and developed tardive dyskinesia after taking the medicine for four years. *Mensing*, 131 S. Ct. at 2573; *see generally* Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010), *rev'd sub nom.* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

96 Brief for Respondents Gladys Mensing and Julie Demahy at 4, *Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, & 09-1501). Gastroparesis involves delayed stomach emptying caused by a partial paralysis of the stomach and sometimes parts of the small intestines. This results in various complications as food remains in the stomach for longer than normal. GASTROPARESIS: PATHOPHYSIOLOGY, PRESENTATION AND TREATMENT 11-12 (Henry P. Parkman & Richard W. McCallum eds., 2012).

97 *Mensing*, 131 S. Ct. at 2573.

98 Mensing v. Wyeth, Inc., 588 F.3d 603, 612 (8th Cir. 2009), *rev'd sub nom.* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

99 Brief for Respondents, *supra* note 96, at 4.

100 Tardive dyskinesia is a medical condition that usually involves involuntary movement in the patient's face but sometimes involves involuntary movement in the trunk and limbs as well. TASK FORCE ON TARDIVE DYSKINESIA, AM. PSYCHIATRIC ASS'N, TARDIVE DYSKINESIA: A TASK FORCE REPORT OF THE AMERICAN PSYCHIATRIC ASSOCIATION 35 (1992).

101 At the time Mensing was prescribed metoclopramide, its warning did alert doctors to the risk of tardive dyskinesia from metoclopramide usage. Brief for Respondents, *supra* note 96, at 9 & n.11. Mensing argued, however, that this warning was inadequate because it did not reveal the increased risk of long-term metoclopramide usage. *Id.* at 10.

102 *Mensing*, 131 S. Ct. at 2573.

103 *Mensing*, 588 F.3d at 604.

104 *Id.* at 608.

their labeling under FDA regulation.[105] The court also noted that even if the generic drug manufacturers were unable to change their warning labels, they could always decide to stop selling their products rather than continue to provide a product with an inadequate warning.[106]

In the Eighth Circuit, Mensing also argued that in the event that the generic manufacturers were found not liable, Wyeth should be held liable because it created the inadequate warning that caused her injuries.[107] Mensing further argued for Wyeth's liability on the grounds that her doctor relied on Wyeth's inadequate warning when he prescribed the brand-name drug, Reglan.[108] Citing *Foster v. American Home Products Corp.*, the Eighth Circuit rejected this argument, agreeing with the Fourth Circuit that Wyeth owed no duty to Mensing and that allowing liability in this case would "'stretch[] the concept of foreseeability too far.'"[109]

In the Supreme Court,[110] the plaintiffs maintained that generic drug manufacturers are able to supplement their warnings in order to comply with their duty to warn under state tort law.[111] The plaintiffs argued that two options were available to the generic drug manufacturers to supplement their warnings: (1) Changes-Being-Effected (unilaterally providing a stronger warning label); and (2) Dear Doctor Letters.[112] The Changes-Being-Effected process allows a manufacturer to supplement its warning label without approval from the FDA.[113] This option is available to brand-name drug manufacturers, which is why the Court has held that failure-to-warn claims against brand-name manufacturers are not preempted by federal drug regulations.[114] Dear Doctor Letters also satisfy the manufacturer's

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105 *Id.*

106 *Id.* at 611.

107 *Id.* at 612.

108 *Id.* at 605.

109 *Mensing*, 588 F.3d at 612-14 (quoting Foster v. Am. Home Prods. Corp., 29 F.3d 165, 171 (4th Cir. 1994)).

110 The Supreme Court did not address the innovator liability issue; the Court only considered the preemption issue. The generic drug manufacturers were the parties seeking certiorari and their petitions did not mention this issue as it did not pertain to them. *See* Brief of the Generic Pharmaceutical Ass'n as Amicus Curiae in Support of Petitioners, PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, & 09-1501); Respondents' Petition for Rehearing, *Mensing*, 131 S. Ct. 2567 (Nos. 09-993, 09-1039, & 09-1501). However, Respondents Gladys Mensing and Julie Demahy did brief this issue to the Supreme Court. Brief for Respondents, *supra* note 96, at 46-53. The Court, however, did not address the issue and remanded the case to the Eighth Circuit. *Mensing*, 131 S. Ct. at 2582. On remand, the Eighth Circuit affirmed its decision to deny liability to the brand-name drug manufacturers and denied Mensing's motion to submit a supplemental brief. Mensing v. Wyeth, Inc., 658 F.3d 867, 867 (8th Cir. 2011).

111 *Mensing*, 131 S. Ct. at 2574-75.

112 *Id.* at 2575-76.

113 *Id.* at 2575.

114 Wyeth v. Levine, 555 U.S. 555, 568-73, 580-82 (2009) (holding that 73 Fed. Reg. 49,609 did not preempt sate tort actions for failure to warn against brand-name drug manufacturers and that the FDA's interpretation was not due any deference).

duty to warn because the learned intermediary doctrine holds that a drug manufacturer has to warn physicians, not patients.[115]

The Court held that neither option is available to generic drug manufacturers because FDA regulations require a generic drug to use identical warnings to the brand-name drug.[116] In the case of Dear Doctor Letters, the Court determined that this option was unavailable to generic manufacturers because the FDA considers these letters to be labeling.[117] This finding was contrary to the position of most United States courts that generic drug manufacturers could unilaterally change their warnings consistent with federal law.[118] Because the Court found that a generic manufacturer cannot simultaneously comply with both the federal requirement to have identical warnings as the brand-name drug and the state tort law duty to provide adequate warnings, state failure-to-warn claims against generic drug manufacturers are preempted under conflict preemption.[119] As a generic manufacturer cannot independently change its warning labels, the Court rejected the Eighth Circuit's argument that a generic manufacturer's ability to propose label changes defeats preemption.[120]

This decision provoked a dissent from four justices, who agreed with the Eighth Circuit that a generic manufacturer's ability to propose label changes is enough to avoid preempting state law.[121] Notably, however, the dissent agreed with the majority's conclusion that federal drug laws do not allow generic drug manufacturers to update their warning labels through

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115 *See* Hurley v. Heart Physicians, P.C., 898 A.2d 777, 779 (Conn. 2006).

116 *Mensing*, 131 S. Ct. at 2574-75 ("'[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval'" (quoting Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992)).

117 *Mensing*, 131 S. Ct. at 2576.

118 *See supra* Part I.C.

119 Conflict preemption occurs when a person cannot comply with both federal and state law at the same time. *See Mensing*, 131 S. Ct. at 2579-82.

120 *Id.* at 2578 ("The federal duty to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this [preemption] analysis. Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.").

121 *Id.* at 2587-88 (Sotomayor, J., dissenting) ("The [generic] Manufacturers contend that it was impossible for them to provide additional warnings to respondents Mensing and Demahy because federal law prohibited them from changing their labels unilaterally. They concede, however, that they could have asked the FDA to initiate a label change. If the FDA agreed that a label change was required, it could have asked, and indeed pressured, the brand-name manufacturer to change its label, triggering a corresponding change to the Manufacturers' generic labels. Thus, had the Manufacturers invoked the available mechanism for initiating label changes, they may well have been able to change their labels in sufficient time to warn respondents. Having failed to do so, the Manufacturers cannot sustain their burden (at least not without further factual development) to demonstrate that it was impossible for them to comply with both federal and state law. At most, they have demonstrated only 'a hypothetical or potential conflict.'" (footnotes omitted) (quoting Rice v. Norman Williams Co., 458 U.S. 654, 659 (1982)).

either the Changes-Being-Effected process or Dear Doctor Letters.[122] The dissent argued that the 75 percent of drug patients who take generic drugs are now left without recourse when they are injured by inadequate warnings.[123] This Comment argues that this is not the case; these patients should be able to recover from the manufacturer of the relevant brand-name drug under commonly accepted principles of tort law.[124] The Court's recognition that federal law requires generic drugs to conform their warnings to those of the brand-name drug supports this conclusion by undermining the rationale of previous cases declining to extend liability to brand-name manufacturers for harm caused by generic drugs.[125]

II. ANALYSIS: BRAND-NAME DRUG COMPANIES SHOULD BE LIABLE FOR FAILURE TO WARN IN INNOVATOR LIABILITY SUITS.

Innovator liability[126] has received little support among courts or commentators.[127] But this seems to be based more on a perception that innovator liability is unfair or wrong than on a judgment of the legal merits of its underlying rationale.[128] For example, one commentator argues that, to the extent that innovator liability makes sense within the traditional framework of the failure-to-warn doctrine, it only illustrates that the failure-to-warn doctrine is fundamentally flawed.[129] But failure to warn is simply an application of straightforward negligence doctrine in a particularized context,[130] and negligence is a sound and coherent basis for tort liability.

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122 *Id.* at 2585.

123 *Id.* at 2592. This lack of recourse has been used as a reason by earlier courts to find that there has been no preemption. *See* Bartlett v. Mut. Pharm. Co., 659 F. Supp. 2d 279, 308-09 (D.N.H. 2009).

124 Failure-to-warn claims against brand-name manufacturers are not preempted. Wyeth v. Levine, 555 U.S. 555, 568-73, 580-82 (2009).

125 *See Mensing*, 131 S. Ct. at 2574-76.

126 *See supra* note 9.

127 *See, e.g.*, Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 TORT TRIAL & INS. PRAC. L.J. 673, 674, 694-95 (2010) (finding that although *Conte v. Wyeth*, the California case allowing innovator liability, offers "a plausible rationale" under tort law principles, its conclusion is "ultimately dubious").

128 *See, e.g*, Foster v. Am. Home Prods. Corp., 29 F.3d 165, 171 (4th Cir. 1994) ("We think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far."); Noah, *supra* note 127, at 694-95; Duncan, *supra* note 69, at 215 (agreeing with plaintiffs in recognizing "the injustice" of innovator liability); *see also* Martin A. Ramey, Conte V. Wyeth*: Caveat Innovator and the Case for Perpetual Liability in Drug Labeling*, 4 PITT. J. ENVTL. PUB. HEALTH L. 73, 113 (2010) ("*Foster* . . . seem[s] to exhibit more a distaste for the position of the generic manufacturer, suggesting that the generic manufacturer is a type of plagiarist.").

129 Noah, *supra* note 127, at 694-95.

130 *See* Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 310 (Cal. Ct. App. 2008) ("Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about.").

To recover in a negligence action, such as failure to warn, the plaintiff must prove the familiar elements of duty, breach, and causation.[131] This Part first argues that a brand-name drug manufacturer's duty to warn extends to generic drug patients. It next argues that in the case of injury from an inadequate warning, the creator of the warning should be considered the proximate cause of the plaintiff's injury. This Part concludes by examining some of the implications of innovator liability.

A. *Brand-Name Manufacturers Owe a Duty of Care to All Patients Who Will Foreseeably Rely on Their Warnings, Including Patients Taking Generic Versions of Their Drugs.*

Courts have been reluctant to impose innovator liability on brand-name drug manufacturers for failure to warn on the grounds that a brand-name manufacturer owes no duty to persons taking the generic version of their drugs, as they did not manufacture them.[132] This view fundamentally misunderstands the nature of products liability law in particular and of tort law in general. Failure to warn is not an action for a manufacturing defect, in which case liability would indeed be limited to harm caused by items actually manufactured by the company being sued.[133] Instead, failure to warn usually sounds in negligence.[134] This means that a drug company has a duty to prevent any foreseeable harm to those persons who reasonably rely on its warnings.[135] The standard of care is that of a reasonable person.[136] In

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131 McGuire v. Hodges, 639 S.E.2d 284, 288 (Va. 2007). A breach of the duty to warn is caused by a failure to warn against a risk that a reasonable person would have warned against given the circumstances. Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 591 (Tex. 1986). This Comment does not discuss breach of duty as it is not an obstacle to innovator liability.

132 *See, e.g.*, *Foster*, 29 F.3d at 172.

133 *See Conte*, 85 Cal. Rptr. 3d at 309-10.

134 RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) (1998) (a product "is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings"). The Restatement's emphasis on reasonability in failure-to-warn cases firmly grounds it within a negligence framework. *See* KRAUSS, *supra* note 47, at 107-08 (comparing the scopes of liability under negligence and strict liability principles). The Second Restatement of Torts makes it clear that the negligence framework is appropriate for drug cases: "There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965); *see also* KRAUSS, *supra* note 47, at 107-08 (noting that courts have generally considered failure to warn to be negligence-based).

135 Under the learned intermediary doctrine, the relevant reliance is that of the patient's doctor. See discussion of the learned intermediary doctrine, *supra* notes 61-66 and accompanying text.

other words, would a reasonably prudent individual in the position of the manufacturer have found it necessary to warn of the particular risk?[137] Because of its general nature, this duty should extend even to those people who relied on the brand-name manufacturer's warning but took another manufacturer's generic version of the drug.[138] This liability should only be defeated if the generic manufacturer has the ability to choose its own warning, which after *Mensing* it does not.[139]

The case for the recognition of a brand-name manufacturer's duty to generic drug patients has been convincingly made by Professor Allen Rostron in his article "Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers."[140] Rostron notes that "[e]veryone has a general duty to exercise the care of a reasonable person under the circumstances, in order to avoid causing harm to others."[141] Negligence actions generally do not require privity or a direct duty,[142] except in the case of recovery for emotional harm[143] or pure economic harm.[144] The ordinary starting point for most negligence actions is that everyone owes a duty of care to others.[145] In the case of brand-name drug manufac-

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136 Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 591 (Tex. 1986) ("The issue in a negligent failure to warn case is simply whether a reasonably prudent person in the position of the designer would warn of hazards associated with the designed product. [The defendant] had a duty to warn of the hazards associated with its closure technology if a reasonably prudent person in the same position would have warned of the hazards.").

137 *Id.*

138 The plaintiffs in *Foster* made this argument by citing *Jacques v. First National Bank*, 515 A.2d 756, 759-60 (Md. 1986) ("Where the failure to exercise due care creates a risk of economic loss only, courts have generally required an intimate nexus between the parties as a condition to the imposition of tort liability. This intimate nexus is satisfied by contractual privity or its equivalent. By contrast, where the risk created is one of personal injury, no such direct relationship need be shown, and the principal determinant of duty becomes foreseeability." (footnote omitted)). The *Foster* court, however, dismissed this argument, stating: "We think to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far." Foster v. Am. Home Prods. Corp., 29 F.3d 165, 171 (4th Cir. 1994).

139 Even if the generic manufacturer can choose its own warning, the brand-name manufacturer may still be liable for harm caused by the generic if the patient's doctor only relied on the brand-name warning. This possibility is discussed *infra* Part II.B.

140 Rostron, *supra* note 51, at 1165.

141 *Id.*

142 This is subject to some debate, most notably between Justice Cardozo (then Chief Judge) and Judge Andrews in the famous *Palsgraf* decision. Palsgraf v. Long Island R.R. Co., 162 N.E. 99 (N.Y. 1928). The author agrees with Judge Andrews's conception of negligence. *Id.* at 101-05 (Andrews, J., dissenting). This Comment, however, argues that brand-name drug manufacturers owe a duty to generic patients even under the narrower understanding of negligence.

143 *See* Marlene F. v. Affiliated Psychiatric Med. Clinic, Inc., 770 P.2d 278, 282 (Cal. 1989); Martinez v. Long Island Jewish Hillside Med. Ctr., 512 N.E.2d 538, 539 (N.Y. 1987).

144 *See* Robins Dry Dock & Repair Co. v. Flint, 275 U.S. 303, 308-09 (1927); Jacques v. First Nat'l Bank, 515 A.2d 756, 759-60 (Md. 1986).

145 *See* Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 591 (Tex. 1986).

turers, under ordinary principles of negligence, they owe a duty to avoid harming others that should extend to generic drug patients.[146]

However, under a narrower conception of duty, a plaintiff must show that a defendant owed a particular duty to him or her—specifically, that the harm to that particular plaintiff was foreseeable.[147] Thus, a brand-name manufacturer's duty of care should extend at a minimum to all foreseeable third parties, such as those taking the generic versions of their drugs.[148] The court in *Foster* acknowledged this as the general rule but disregarded it because "impos[ing] a duty in the circumstances of this case would be to stretch the concept of foreseeability too far."[149] But why should this be the case? The *Mensing* decision establishes that under federal law, generic drug companies must use a warning identical to the brand-name drugs.[150] Because of this, it is easily foreseeable that generic drug patients will rely on the warnings drafted by brand-name manufacturers.

Furthermore, as was the case in *Foster*, a patient's doctor may prescribe a brand-name drug and rely on its warning, but the patient's pharmacist may fill the prescription with a generic.[151] As these substitutions are a common practice allowed in all fifty states,[152] it does not stretch the concept of foreseeability to conclude that a brand-name manufacturer could reasonably foresee that patients taking the generic version of its drug would rely on its warning.

Additionally, before recognizing that the defendant owes a duty to a third party, some courts require that the defendant possess the ability to control the actions of the party directly causing the injury to the third par-

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146 As innovator liability is imposed under the standard negligence framework, it is not necessary to create a new cause of action, and it is appropriate for the courts rather than the legislature to allow for innovator liability as "[t]he determination of the scope of the common law doctrine of negligence is within the province of the judiciary." Naccash v. Burger, 290 S.E.2d 825, 829 (Va. 1982) (quoting Gildiner v. Thomas Jefferson Univ. Hosp., 451 F. Supp. 692, 696 (E.D. Pa. 1978)). In *Naccash v. Burger*, the Supreme Court of Virginia recognized a novel negligence action for wrongful birth. *Id.* Virginia law provides that the common law of England at the time of American independence is the rule of decision alterable only by the state legislature. VA. CODE ANN. § 1-200 (2011). Thus, the court could only allow the wrongful birth action because it was simply an application of negligence doctrine rather than the creation of a new cause of action. *See Naccash*, 290 S.E.2d at 829. Courts may similarly allow for innovator liability because it is just a form of negligence.

147 This narrow conception of duty is the view expressed in Justice Cardozo's majority opinion in *Palsgraf*. 162 N.E. at 99.

148 While the general duty of care to third parties does not extend to pure economic losses, it does extend at the least to foreseeable physical harms, such as inadequately warned-of side-effects caused by a generic drug. *See Robins Dry Dock & Repair Co*, 275 U.S. at 308-09; *Jacques*, 515 A.2d at 759-60 ("[W]here the risk created is one of personal injury, no . . . direct relationship need be shown, and the principal determinant of duty becomes foreseeability.").

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

150 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2576 (2011).

151 *Foster*, 29 F.3d at 167, 169.

152 *Mensing*, 131 S. Ct. at 2583-84 (Sotomayor, J., dissenting).

ty.[153] The *Mensing* decision's recognition that generic drug manufacturers must adopt the brand-name manufacturer's warning establishes that a generic manufacturer's choice of warning is subject to the control of the brand-name manufacturer.[154] This requirement should be sufficient to overcome this particular barrier to innovator liability.

As pointed out by Rostron, the *Foster* court made several other mistakes, including confusing the plaintiff's innovator liability theory with unidentified tortfeasor theories, such as market share liability; since Maryland has rejected unidentified tortfeasor theories, the *Foster* court rejected the plaintiff's claim.[155] But the *Foster* plaintiffs did identify their tortfeasor, the brand-name drug manufacturer.[156] Their claim was one of innovator liability.[157] They argued that the brand-name drug manufacturer *was* the tortfeasor because it was responsible for the inadequate warning that killed their child.[158] As Rostron also notes, the courts following *Foster* have repeated this same mistake.[159]

The *Foster* court also reasoned that the generic drug manufacturer assumed the risk that the pioneer drug was dangerous and its warning inadequate.[160] But this is inconsistent. Failure to warn is a negligence-based action and therefore the generic manufacturer is only liable for adopting the brand-name manufacturer's warning label if doing so was negligent.[161] Given the rigorous testing required for FDA approval and the time the drug spends on the market before competitors can introduce generics,[162] it is a good assumption on the part of the generic manufacturer that the drug is safe and the warning is adequate. Additionally, generic manufacturers are

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153 Conboy v. Mogeloff, 172 A.D.2d 912, 913, (N.Y. App. Div. 1991) ("As a general rule, a defendant has no legal duty to control the conduct of third persons so as to prevent them from harming others. However, certain relationships may give rise to such a duty, but then only when the defendant has the ability and authority to control the third persons' conduct." (citations omitted)).

154 *See Mensing*, 131 S. Ct. at 2576.

155 Rostron, *supra* note 51, at 1163-64.

156 *Foster*, 29 F.3d at 167.

157 *See id.* at 168 ("The Fosters insist, however, that the fact that Wyeth did not manufacture the promethazine should not shield Wyeth from an action for negligent misrepresentation.").

158 *Id.* at 166-68.

159 Rostron, *supra* note 51, at 1164.

160 *Foster*, 29 F.3d at 169 ("When a generic manufacturer adopts a name brand manufacturer's warnings and representations without independent investigation, it does so at the risk that such warnings and representations may be flawed.").

161 *See, e.g.*, Hammons v. Icon Health & Fitness, 616 F. Supp. 2d 674, 682 (E.D. Mich. 2009) (laying out the elements for a failure-to-warn claim including proving failure to exercise reasonable care).

162 *FDA's Drug Review Process: Continued*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm289601.htm (last updated Mar. 13, 2012) (outlining the process for a drug to obtain FDA approval); *Greater Access to Generic Drugs*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143545.htm (last updated Aug. 12, 2011) (detailing when a generic drug is allowed to enter the market).

not permitted to view brand-name manufacturer's safety and efficacy testing.[163] Thus, it is generally not negligent to adopt the warning label of the brand-name drug, and in fact, generic manufacturers are legally required to do so.[164] Finally, assumption of risk is a plaintiff-side consideration that is raised as a defense to negligence; it cannot be applied to hold a defendant liable when its actions were not independently negligent.[165]

While this Comment's analysis has proceeded under a negligence framework, courts like *Foster* have incorporated elements of strict liability into their analysis of duty, rejecting innovator liability because the defendant did not make the product in question (a strict liability concern).[166] The move to further extend strict liability should be especially resisted in the case of failure to warn because the two doctrines are conceptually incompatible, and it leads to strange results.[167]

For example, one student commentator, Beatrice Skye Resendes, has argued that all drug suits, including failure to warn, should be governed by strict liability.[168] She further argues that innovator liability should be allowed under this strict liability scheme because brand-name manufacturers should be viewed as component manufacturers[169] since they "produce" the warning label on the generic drug.[170] She also argues that brand-name manufacturers "owe a duty of care to generic drug consumers because they are intimately connected to the generic industry, and can control generic manufacturers."[171] While this argument correctly allows for innovator liability, it does so on questionable theoretical grounds. Failure to warn is grounded in

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163 Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585, 587 (2003).

164 *See* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2576-77 (2011).

165 *See, e.g.*, Sheehan v. The N. Am. Mktg. Corp., 610 F.3d 144, 151 (1st Cir. 2010).

166 Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170-71 (4th Cir. 1994).

167 Failure to warn is based on the wrongful act of providing an inadequate warning. If strict liability were adopted for failure to warn, the manufacturer would be liable for all harm caused by the product that was not specifically warned against. This defeats the purpose of the carve-out provided by comment (k) of the Second Restatement of Torts. RESTATEMENT (SECOND) OF TORTS. § 402A cmt. k (1965). Under the framework of comment (k), a drug manufacturer is specifically exempted from the strict liability rule of ordinary products liability, and can only be liable when negligent.

168 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, 105-108 (2009).

169 Component manufacturers produce a product or raw material that is incorporated into the final product. A component manufacturer can be held liable for injury caused by the component they produced if "(1) . . . the component itself was defective when it left the component manufacturer's factory, and (2) . . . these defects caused injury." Taylor v. Elliott Turbomachinery Co., 90 Cal. Rptr. 3d 414, 430 (Cal. Ct. App. 2009).

170 Resendes, *supra* note 168, at 101 (arguing that pioneer-drug manufacturers should be held liable in innovator liability claims because "[p]ioneers are component part manufacturers of generic drugs because they supply the warning labels generics must, by law, carry").

171 *Id.* at 95, 101.

negligence, not strict liability.[172] And determining the existence of a duty only makes sense within a negligence framework.[173]

Because Resendes's analysis is based on strict liability, it uses the fiction that a warning label is a component part of the generic drug and the pioneer manufacturer is therefore a component manufacturer.[174] But a warning is not a product of manufacture[175] as it is not produced. Rather, it is drafted and repeatedly copied. Further, it is not the physical warning label that injures the plaintiff in a failure-to-warn case. Instead, it is the lack of disclosed information.[176] This is notably distinct from liability for a manufactured product. If Resendes were correct that a brand-name manufacturer can be held strictly liable for a warning label, then it would not matter if the warning is adequate or not. Under strict liability, all the plaintiff must prove is proximate cause.[177] Further, the warning label's creator would be liable if the correctly disclosed information caused a prospective patient to forego needed medication even if the warning was needed to protect normal patients.[178] While these hypotheticals cast doubt on the use of strict liability in any tort case, they particularly demonstrate why failure to warn must be understood as a form of negligence.

The existence of an innovator liability duty is a straightforward determination. All manufacturers owe a general duty of care to those who foreseeably rely on their warnings.[179] After *Mensing*, it is foreseeable to brand-name manufacturers that generic drug patients will often rely on their warnings.[180] Therefore, brand-name manufacturers owe a duty of reasonable care

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172 *See* KRAUSS, *supra* note 47, at 107-08.

173 This is because under a strict-liability regime, a defendant is liable to anyone injured by its product—whether the defendant owes a plaintiff a duty is irrelevant. *See id.*

174 Resendes, *supra* note 168, at 101.

175 Admittedly, courts have occasionally found information to be a product, as Resendes notes. *See id.*at 127 n.215 (citing Brocklesby v. United States, 767 F.2d 1288, 1294-95 (9th Cir. 1985)). In *Brocklesby*, the Ninth Circuit held that airplane navigational charts could be considered "products," which allowed the plaintiff to hold the manufacturer strictly liable for an accident caused by inaccurate information. *Brocklesby*, 767 F.2d at 1294-95. While this decision is suspect, a drug warning would not be considered a "product" even under this rationale. *See* Saloomey v. Jeppesen & Co., 707 F.2d 671, 676-77 (2d Cir. 1983); Fluor Corp. v. Jeppesen & Co., 170 Cal. App.3d 468, 475 (1985).

176 Or an insufficient emphasis on a disclosed risk, as was the case in *Mensing*. *See* Brief for Respondents, *supra* note 96, at 9 & n.11.

177 This is because duty and breach are elements of negligence. A plaintiff does not have to prove wrongdoing to succeed in a strict-liability suit. *See* KRAUSS, *supra* note 47, at 107-08.

178 For example, nitroglycerine may cause headaches, nausea, and vomiting. *See Occupational Safety and Health Guideline for Nitroglycerin*, OCCUPATIONAL SAFETY & HEALTH ADMIN., http://www.osha.gov/SLTC/healthguidelines/nitroglycerin/recognition.html (last visited July 21, 2012). If a doctor recommended nitroglycerine to a patient but the patient refused to take it because of the risk of a headache and then suffered a heart attack, the drug manufacturer would be liable for the heart attack under a theory of strict liability. This is not a desirable outcome.

179 *See* Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 591 (Tex. 1986).

180 *See generally* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

to those patients taking the generic versions of their drugs who rely on their warnings.

B. *A Brand-Name Drug Manufacturer's Failure to Warn Is the Proximate Cause of a Generic Drug Patient's Injuries*.

Courts and commentators have focused mostly on the duty element in evaluating innovator liability—most finding no duty to patients who take a competitor's product.[181] This conclusion is incorrect for the reasons discussed in the previous Part of this Comment. The more interesting—and rarely discussed—issue is proximate cause. If brand-name manufacturers owe a duty to generic patients, proximate cause is the grounds where innovator liability will be tested.

While it may seem inequitable that the brand-name manufacturer must pay for the harm caused by its competitor,[182] this concern misunderstands the nature of failure-to-warn liability. The harm recovered for in a failure-to-warn case is caused by the inadequate warning, not by the drug itself.[183] Cause in fact in failure-to-warn cases is based on the argument that if it were not for the defendant's inadequate warning, the plaintiff would not have been harmed (either by not using the product or by taking appropriate precautions).[184] Even in a case where the plaintiff was harmed by a brand-name drug, causation is grounded in the inadequate warning, not in the manufacturing of the drug.

The brand-name drug's warning is also the proximate cause of the generic-caused injury under either a foreseeability or a directness theory of proximate cause. As a result of *Mensing*, when a brand-name manufacturer chooses a particular warning for its drug, it is foreseeable that the generic drug will use the same label. Because *Mensing* held that generic drugs are required by law to use the brand-name drug's label,[185] the generic manufacturer's failure to warn follows mechanically from the brand-name manufacturer's failure to warn. Any defect in the original warning will extend to the generic's warning, foreseeably causing harm to the generic drug patients. Causation is direct as well because the generic drug manufacturer does not

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181 *See generally* Foster v. Am. Home Prods. Corp., 29 F.3d 165 (4th Cir. 1994); Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008); Noah, *supra* note 127; Ramey, *supra* note 128; Rostron, *supra* note 51; Duncan, *supra* note 69; Resendes, *supra* note 168.

182 *See, e.g*, *Foster*, 29 F.3d at 171; Noah, *supra* note 127, at 674, 694 (finding that, although *Conte* offers "a plausible rationale" under tort law principles, its conclusion is "ultimately dubious"); Duncan, *supra* note 69, at 215 (agreeing with plaintiffs in recognizing "the injustice" of pioneer liability); *see also* Ramey, *supra* note 128, at 113 ("*Foster* . . . seem[s] to exhibit more a distaste for the position of the generic manufacturer, suggesting that the generic manufacturer is a type of plagiarist.").

183 This is because it is the inadequate warning that is the negligent act.

184 *See supra* note 63.

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

have any voluntary choice in choosing its warning label.[186] Although the generic drug manufacturer has the option of either declining to produce the inadequately warned drug or informing the FDA that the warning needs to be changed, these failures are not actions and should therefore not be seen as superseding causes.

Even before *Mensing*, brand-name warnings should have been considered the proximate cause of harm to plaintiffs who took generics in cases like *Foster*. Finding causation in those cases is consistent with and required by the learned intermediary doctrine. The learned intermediary doctrine establishes that a drug manufacturer's duty to warn is met by warning the doctor, not the plaintiff.[187] In fact, when a doctor prescribes a medicine without relying on the manufacturer's inadequate warning, there is no proximate cause.[188] In the case of *Foster*, the Fosters' doctor prescribed their daughter the brand-name drug Phenergan.[189] At that point, the Fosters' doctor relied on only the brand-name drug's inadequate warning when prescribing the medicine. The fact that the pharmacist chose to fill the prescription with the generic version of Phenergan should not matter because the Fosters' doctor relied on Phenergan's warning.

In contrast, Roston's "Prescription for Fairness" article argues that when the plaintiff's doctor relied on a brand-name manufacturer's inadequate warning but the plaintiff took the generic version of the drug, both the brand-name and the generic manufacturers should be held liable.[190] This inappropriately reintroduces the concept of strict liability into failure to warn. If the generic drug did not create the warning that caused the plaintiff's injury, there is no wrongdoing to hold it liable for—the only liability that courts could impose on the generic manufacturer in this case would be a form of strict liability for manufacturing the product. This undermines the article's argument that failure to warn must be evaluated using standard negligence principles. Under a negligence rule, the generic manufacturer would not be liable for the harm caused by the warning it did not create.[191]

"Prescription for Fairness" sets up a liability scheme it labels "primary-secondary liability," based in part on vicarious liability principles: "Whichever manufacturer actually made the drug that a plaintiff received should be primarily liable; the other manufacturer, which generated the information on which the plaintiff's doctor relied, should be obligated to

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186 *Id.* at 2576 (citing Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992)).

187 KRAUSS, *supra* note 47, at 121-23.

188 Oppenheimer v. Sterling Drug, Inc., 219 N.E.2d 54, 58 (Ohio Ct. App. 1964).

189 Foster v. Am. Home Prods. Corp., 29 F.3d 165, 167 (4th Cir. 1994).

190 Rostron, *supra* note 51, at 1189.

191 "Prescription for Fairness" also considers holding generics liable in the case where a brand-name manufacturer created the warning the doctor relied on, and the patient took the brand-name drug, not the generic, but ultimately rejects this case on policy grounds because "[l]ines must be drawn somewhere." *Id.* at 1188.

pay damages only if the primarily liable manufacturer turns out to be insolvent or otherwise unable to pay."[192] This is not liability for failure to warn; this is a hybrid negligence-vicarious liability scheme. If the brand-name drug manufacturer's negligent act caused the plaintiff's harm, then it should be liable. It does not matter if the generic manufacturer can afford to pay the damages—the brand-name manufacturer's wrongdoing caused the plaintiff's injury, and it should correct this wrong. Further, if the generic manufacturer non-negligently uses the brand-name drug's warning label (as it must post-*Mensing*), then there is no negligence making it liable.[193] Ultimately, the issue with the "Prescription for Fairness" primary-secondary liability proposal is that it is overly concerned with policy and incentives instead of allowing established principles of tort law to be determinate of liability.[194]

The article also argues that if a generic manufacturer carelessly repeats an inadequate warning, both the generic and brand-name manufacturers should be held liable.[195] But this is not right. They are not joint tortfeasors. If the patient's physician prescribed the brand-name drug while relying on its warning but the pharmacist filled the prescription with a generic, only the brand-name manufacturer would be liable, even if the generic manufacturer negligently copied the original warning. In this scenario, there is no cause in fact connecting the generic manufacturer's negligence to the patient's harm as the doctor relied only on the brand-name warning. In contrast, if the physician relies on the generic manufacturer's negligently copied warning, this may arguably break the causal connection that establishes the brand-name manufacturer's liability. In that case, the generic manufacturer alone would be responsible for the harm caused by its warning.

This proximate cause analysis may be criticized as unfair—that innovator liability is an unjust form of vicarious liability.[196] Innovator liability, however, is not an attempt to impose vicarious liability on brand-name manufacturers. An action for vicarious liability would fail here because there is no agency relationship between the brand-name manufacturer and the generic manufacturer. The liability proposed by this Comment, however, is not vicarious. Vicarious liability occurs when holding a person or

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192 *Id.* at 1189.

193 That is, unless it is negligent to continue to market the defectively warned-of drug as the respondents argued in *Mensing*. Respondents' Petition for Rehearing, *supra* note 110, at 2. This argument is addressed *infra* notes 206-210 and accompanying text.

194 Rostron, *supra* note 51, at 1191 ("Tort law provides vital incentives for drug makers to act with appropriate care. Courts should apply tort law in a manner that encourages drug companies to continue producing innovative products but also to act reasonably to ensure that their products are safe and accompanied by adequate warnings and accurate information.").

195 *Id.* at 1189.

196 For example, Rostron's proposal uses vicarious liability to support his argument for adopting innovator liability. *Id.* at 1189-90.

company responsible for the acts of another.[197] A vicariously liable defendant did not actually do anything wrong.[198] In contrast, innovator liability is imposed not for the acts of generic drug manufacturers (i.e., manufacturing generic drugs with inadequate warnings), but rather for the brand-name manufacturer's wrongful act of providing an inadequate warning for its drug knowing that patients would rely on this warning when deciding whether to take the generic version of the brand-name manufacturer's drug.

This analysis is not new to tort law. For example, in negligent hiring, retention, and supervision suits, the defendant is held liable when a third party's action directly caused the plaintiff's harm.[199] However, liability in these cases is direct—it is not imposed for the harmful acts of employees but for the employer's negligent act in hiring, retaining, or failing to supervise the employee who injured the plaintiff.[200] In a negligent hiring suit, for example, an employer can be held liable for hiring a dangerous worker.[201] Innovator liability suits are potentially distinguishable from negligent hiring cases, however, on the grounds that the brand-name manufacturer had no direct duty to patients using its competitor's products.[202]

Similarly, negligent entrustment suits allow liability for harm caused by the act of a third party but do not rely on vicarious liability.[203] In a negligent entrustment suit, the plaintiff sues the owner of a dangerous instrumentality that the defendant negligently entrusted to a third party, who used the instrumentality in a way that caused harm.[204] For example, a person entrusts his car to a third party whom he knows to be an extremely reckless driver. This third party then recklessly drives the car, causing a collision that injures the plaintiff. The owner of the car would be liable to the plaintiff. Similar to the negligent hiring situation, liability for negligent entrustment is not vicarious liability but rather direct liability; the defendant in a negli-

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197 Moore v. Shawmut Woodworking & Supply, Inc., 788 F. Supp. 2d 821, 825 (S.D. Ind. 2011) (vicarious liability occurs when "'a party is legally responsible for the negligence of another, not because the party did anything wrong but rather because of the party's relationship to the wrongdoer.'" (quoting Hunt Const. Grp., Inc. v. Garrett, 938 N.E.2d 794, 799 (Ind. Ct. App. 2010))).

198 *Id.*

199 *See* Interim Pers. of Cent. Va., Inc. v. Messer, 559 S.E.2d 704, 704 (Va. 2002); Waffle House, Inc. v. Williams, 314 S.W.3d 1, 8 (Tex. App. 2007), *rev'd on other grounds*, 313 S.W.3d 796 (Tex. 2010).

200 *Waffle House*, 314 S.W.3d at 8.

201 *Id.* at 9.

202 This argument is addressed *supra* notes 140-152 and accompanying text.

203 *See* Matheny v. Tenn. Valley Auth., 523 F. Supp. 2d 697, 726 (M.D. Tenn. 2007), *rev'd on other grounds*, 557 F.3d 311 (6th Cir. 2009).

204 *See id.* ("Negligent entrustment requires a showing that 'a chattel was entrusted to one incompetent to use it with knowledge of the incompetence, and that its use was the proximate cause of injury or damage to another.'" (quoting Watrous v. Johnson, No. W2007-00814-COA-R3-CV, 2007 WL 4146289, at *3 (Tenn. Ct. App. Nov. 21, 2007))); Corrie v. Caterpillar, Inc., 403 F. Supp. 2d 1019, 1031 (W.D. Wash. 2005) ("Negligent entrustment requires the following: (1) a negligent entrustment, and (2) incompetence of the entrustee that is a proximate cause of the injury.").

gent entrustment case is held liable for his voluntary act of entrusting an instrumentality to a person that created a risk such that it was negligent to do so.[205] Similarly, innovator liability is imposed on brand-name drug manufacturers for their failure to warn, not for the generic manufacturer's act of producing the harmful drug.

Comparably, liability can be imposed on an attorney if he or she gives a legal opinion with the knowledge and intent that a third party, who is not the attorney's client, will rely on the information.[206] For example, if an attorney writes an opinion letter for his or her client, he can still be held liable for negligent misrepresentation by third parties whom the attorney knew would rely on the opinion letter.[207] This is true even though the attorney and the third party are not in an attorney-client relationship.[208] Similarly, a brand-name drug manufacturer knows that patients taking generic versions of its drug will rely upon its representations and warnings. This is especially true after *Mensing* because the Court has acknowledged that federal law requires generic drug manufacturers to use the same warning as the corresponding brand-name drug.[209] Since the reliance of generic patients on the brand-name manufacturer's warning is easily foreseeable, there should be liability.

Even though generic manufacturers must use the same warning as the brand-name manufacturer, one could argue, as did the *Mensing* respondents and the Eighth Circuit, that a generic drug manufacturer still had a voluntary choice—they could have simply decided not to sell the drug.[210] This fact, however, does not defeat proximate cause because of the nature of the failure-to-warn claim. A failure-to-warn claim is not a products liability claim and liability does not attach to the decision to sell the product.

Instead, failure-to-warn liability is imposed on drug manufacturers for the production of a warning label that does not adequately warn of the risks

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205 *See Corrie*, 403 F. Supp. 2d at 1031.

206 *See, e.g.*, Molecular Tech. Corp. v. Valentine, 925 F.2d 910, 919 (6th Cir. 1991) (rejecting an attorney's argument that he should not be held liable for a negligent misrepresentation, the court held that "negligent misrepresentation . . . imposes a duty in favor of all those third parties who defendant knows and should reasonably foresee will rely on the information in question"); Horizon Fin., F.A. v. Hansen, 791 F. Supp. 1561, 1573-74 (N.D. Ga.1992) ("Defendants' argument ignores the fact that, by giving the opinion letters for plaintiff's benefit, they assumed a duty to plaintiff independent of their relationship to their clients."). *But see* Greycas, Inc. v. Proud, 826 F.2d 1560, 1563 (7th Cir. 1987); Mehaffy, Rider, Windholz & Wilson v. Cent. Bank Denver, N.A., 892 P.2d 230, 240 (Colo. 1995) ("Because attorneys do not owe a duty of reasonable care to non-clients, attorney malpractice cannot extend to non-clients. Attorney malpractice is a particular type of negligence that is confined to situations in which an attorney-client relationship exists between a plaintiff and a defendant.").

207 *See Greycas*, 826 F.2d at 1563; *see also Valentine*, 925 F.2d at 919; *Horizon Fin.*, 791 F. Supp. at 1573-74. *But see Mehaffy, Rider, Windholz & Wilson*, 892 P.2d at 240.

208 *See supra* note 208.

209 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2576 (2011) (citing Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992)).

210 Respondents' Petition for Rehearing, *supra* note 110, at 1.

of their product. After *Mensing*, the generic drug manufacturer is not involved in producing the warning label that is the source of liability.[211] It has effectively been removed from the equation. The generic drug manufacturer's decision to continue selling a drug is not related to the inadequate warning. If the generic drug manufacturer had the ability to choose its own warning and negligently copied the brand-name manufacturer's warning, its action would supersede the brand-name manufacturer's negligence. But that is not the case here.

Moreover, one manufacturer's generic leaving the market is unlikely to prevent the harm to the patient from occurring. If a particular manufacturer's drug is unavailable, pharmacists will use other manufacturers' generics to fill prescriptions instead, relying on the same negligent warning. If the particular manufacturer is the only provider of generics for a particular drug, patients can still use the brand-name drug. While this may prevent some plaintiffs from being harmed due to the higher price, others may be harmed by the lack of needed drugs.

Further, even if correct, this argument would only apply to generic drug manufacturers that knew of the unwarned-of risk. If the generic manufacturer did not know of the risk, there is no reason it should have decided not to sell its product. In this situation, there would be no voluntary choice to supersede the connection between brand-name manufacturer's negligent warning and the generic patient's harm. Moreover, generic drug manufacturers do not always have access to the same information regarding the risk of potential side effects as the brand-name drug manufacturers, making this hypothetical situation likely.[212] For example, brand-name manufacturers are not required to share with generic manufacturers the results of the safety and efficacy testing they conduct before gaining FDA approval.[213] This information may be necessary for the generic manufacturer to determine whether a risk requires a warning. Similarly, reports of new or more prevalent side effects may be directed at the brand-name manufacturer, leaving the generic manufacturer without the information necessary to evaluate a drug's potential harm. And because failure-to-warn claims against generic manufacturers are preempted,[214] they are less likely to monitor the safety of their drugs as closely as the brand-name manufacturers as they have less incentive to do so. Because generic drug manufacturers possess inferior access to information compared to brand-name manufacturers regarding the safety of their drugs, their actions should not be a superseding cause.

Finally, the fact that failure-to-warn claims against generic drugs are now preempted post-*Mensing* undermines the argument that a generic drug

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211 Rostron, *supra* note 51, at 1189-90.

212 *See* Stotland Weiswasser & Danzis, *supra* note 163, at 587.

213 *See id.* As generic manufacturers are the brand-name manufacturer's competitors, it is unlikely that this information is shared voluntarily either.

214 *See Mensing*, 131 S. Ct. at 2577.

manufacturer's failure to remove its drugs from the market supersedes the brand-name manufacturer's negligence. Generic drug manufacturers are now removed from the state tort law failure-to-warn framework. The Supreme Court has held that they have no duty to warn.[215] Given this, their actions should not be considered superseding causes.

According to the FDA, generic drug manufacturers have the ability and the duty to propose labeling changes to the FDA when they believe a stronger warning is needed.[216] In *Mensing*, the Court held that this does not prevent the preemption of state tort law because the generic drug manufacturer's ability to improve their warnings is not unilateral.[217] A generic drug manufacturer's ability to propose labeling changes should not defeat proximate cause in an innovator liability suit for the same reason it did not defeat preemption—a generic drug manufacturer's ability to improve warnings is not unilateral but rather requires the agreement of the FDA. The Court rejected the argument that an ability to propose labeling changes defeats preemption by likening it to a requirement that generic drug manufacturers lobby to have the restrictive law changed, which would be absurd.[218] Similarly, a generic drug manufacturer's use of a brand-name warning does not break a causal relationship between the brand-name manufacturer and the patient unless the generic manufacturer could have prevented the harm independently, without the cooperation of a government agency.[219] The generic drug manufacturer's use of the brand-name warning is easily foreseeable post-*Mensing*. Thus, the brand-name manufacturer's inadequate warning should be considered the proximate cause of harm ostensibly caused by the generic drug.

C. *The Implications of Recognizing Innovator Liability*

Imposing innovator liability in failure-to-warn cases naturally raises the question of what happens when the pioneer drug is withdrawn from the market.[220] Holding a manufacturer liable for harm caused by competitors' products even after it no longer sells the product seems particularly unfair.[221] Even so, if courts accept innovator liability as a viable theory for

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215 *See generally* PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011).

216 Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992); *see also* Amicus Brief, *supra* note 39, at 6-7.

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

218 *Id.* at 2579.

219 *See id.* at 2578.

220 *See* Noah, *supra* note 127, at 692 (noting that innovator liability would create problematic situations in the event that the brand-name manufacturer stops selling the drug, but generic manufacturers continue to sell the drug, relying on the brand-name manufacturer's warning).

221 *See, e.g*, Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994) ("[Imposing innovator liability] would be especially unfair when, as here, the generic manufacturer reaps the benefits of

recovery, the brand-name manufacturer should still be held liable for the harm caused by its warning even if it no longer sells the product. This is because the brand-name manufacturer's negligent act was creating the warning, not manufacturing the drug, and as the creator of the warning, the brand-name manufacturer had a duty to all people who might foreseeably rely on it. A negligent manufacturer violates this duty when it creates the negligent warning; discontinuing sales of the product should not insulate it from liability when generic drug patients are still relying on the warning. This being said, however, it may be possible to limit the reach of innovator liability if the passage of time makes the harm unforeseeable. This could be done through judicial limitation or through legislative acknowledgment of the unforeseeability of far-off harm by creating a statute of repose for warnings.[222] Further, in the event that a brand-name drug withdraws from the market, the FDA can designate a generic drug as the de facto brand-name drug, responsible for updating warnings.[223] This solution is suboptimal; it would be preferable to impose a duty on all generic drug manufacturers to keep the warnings of their drugs up to date though the use of Dear Doctor Letters. This solution avoids arbitrarily assigning responsibility for warnings to a generic drug manufacturer that does not necessarily have any better ability to adequately warn customers on new risks than does its competitors, and it incentivizes all manufactures to continually monitor the adequacy of their warnings.

After *PLIVA, Inc. v. Mensing*, brand-name drug manufacturers are amenable to failure-to-warn suits, but generic drug manufacturers are not due to preemption.[224] If innovator liability suits are allowed, it could potentially distort incentives for both the brand-name and the generic drug manufacturers. This could potentially lead to a reduction in pharmaceutical innovation if drug developers are less willing to invest in developing new drugs

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the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising."); Noah, *supra* note 127, at 674, 694 (finding that although *Conte* offers "a plausible rationale" under tort law principles, its conclusion is "ultimately dubious"); Duncan, *supra* note 69, at 215 (agreeing with plaintiffs in recognizing "the injustice" of pioneer liability).

222 This is also an acknowledgement that a warning is based on the information of the present and may need to be updated from time to time. However, these purposes are best accomplished on a case-by-case basis within the standard negligence framework. If the warning is old enough to be outdated, there should be no liability on proximate cause grounds—the doctor improperly relied on an outdated warning.

223 *See* Reply Brief of Petitioners PLIVA, Inc.; Teva Pharms. USA, Inc.; & UDL Labs, Inc. at 12-13, *Mensing*, 131 S. Ct. 2567 (2011) (Nos. 09-993, 09-1039, & 09-1501) (citing Determination that Brethine (Terbutaline Sulfate) Injection Was Not Withdrawn from Sale for Reasons of Safety or Effectiveness, 72 Fed. Reg. 39,629, 39,630 (July 19, 2007) (FDA notice)) (noting that while the FDA will designate a drug as the new reference drug, the FDA retains responsibility for the warning label's content).

224 *See* discussion of *Mensing*, *supra* Part I.D.

due to increased liability exposure.[225] This would be a substantial loss for society.

Conversely, post-*Mensing*, generic drug manufacturers will no longer internalize the costs of harm caused by inadequate warnings on the drugs they produce. This creates the incentive to sell drugs at a lower than optimal price that does not reflect the true cost to society. In the event of an inadequate warning, more harm would be caused since more patients would purchase the drug at the lower price. If brand-name drug manufacturers are liable for this harm, it will raise the cost of developing a new drug as there is always a risk that a jury will find a particular warning inadequate.[226] If the brand-name manufacturer bears the entire cost of an inadequate warning but receives only part of the benefit, the brand-name manufacturer will underinvest in research and development from a social welfare maximizing perspective. Warnings can always be stronger and more risks can always be included. On the margin, this will result in less investment in developing new drugs.

From a corrective justice conception of tort law, it is appropriate for brand-name drug manufacturers to be liable for the harm caused by their inadequate warnings even if the plaintiff took a generic. This is because their negligent warnings caused the plaintiffs injury, and it is only right that they correct it through compensation. Similarly, it is appropriate for generic drug manufacturers not to be liable when they have no voluntary choice in what warnings they give to consumers, as is currently the case after *Mensing*.

It is suggested, however, that this is an unfair result because brand-name manufacturers do not profit from the sale of their competitors' drugs but instead lose business.[227] But why should profit matter? It is no less neg-

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225 *See* Bridget M. Ahmann & Erin M. Verneris, *Name Brand Exposure for Generic Drug Use: Prescription for Liability*, 32 HAMLINE L. REV. 767, 790 (2009).

226 Even a non-negligent drug developer may be found liable by a jury. It is debatable whether the warning at issue in *Mensing* was actually negligent. The drug manufacturers had warned against the exact condition the plaintiff developed, but the argument was that the warning should have been stronger. Warnings can always be made stronger, but as noted *supra* note 51, the more a drug manufacturer warns against numerous potential side effects, the less effective the warnings, paradoxically, become. *See also* Epstein, *supra* note 15, at 23 ("[T]here is nothing at all that prevents each and every jury from concluding that a particular drug is 'a' proximate cause of the injury.").

227 *See e.g.*, Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994) ("This would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising."); Rostron, *supra* note 51, at 1189 ("[Primary-secondary liability] would alleviate at least some of the unfairness that brand-name manufacturers see in being held liable when generic manufacturers profited by copying the brand-name product and riding the coattails of the brand-name manufacturers' research efforts and discoveries."); Duncan, *supra* note 69, at 215 (noting "the injustice of holding a brand-name manufacturer liable for failing to warn a patient who, as in *Conte*, never consumed that manufacturer's product").

ligent for a nonprofit drug manufacturer[228] to inadequately warn a patient than it is for a for-profit manufacturer of the same drug. If anything, it could be argued that the introduction of profit increases the burden of care required of for-profit manufacturers since warning of certain risks may impose a cost of foregone sales. However, this is not the correct approach. Instead, once a duty to warn is established, all that matters is whether the warning was adequate under regular negligence principles. When a brand-name manufacturer violates this duty, there is nothing unfair in making the manufacturer correct the harm it has wrongfully inflicted on others.

III. RECOMMENDATION: CONGRESS SHOULD ALLOW GENERIC DRUG MANUFACTURERS THE FREEDOM TO UNILATERALLY CHANGE THEIR WARNING LABELS AND TO SUPPLEMENT THEIR WARNINGS THROUGH THE USE OF DEAR DOCTOR LETTERS.

Having preemption for generic manufacturers but not brand-name manufacturers results in a strange liability regime, which, as the *Mensing* majority noted, "makes little sense."[229] The current system has the potential to reduce pharmaceutical innovation. Congress should change the laws governing generic drugs to allow generic manufacturers to unilaterally supplement their warnings through label changes and Dear Doctor Letters. While this would result in different warnings for products that are chemically identical, it would allow generic manufacturers to make their own decisions about what warnings are appropriate. Manufacturers selling a drug in a particular state could conform their warnings to the law of that state. State courts or legislatures would have to decide whether pharmacists dispensing a generic drug when the brand-name drug is prescribed could be held liable for failing to communicate any difference in warnings.

It has been argued that allowing generics to have different warning labels would confuse doctors.[230] Yet, why should this be? Doctors spend four years in medical school, pass rigorous tests, and complete a residency before practicing medicine unsupervised.[231] Given their extensive education and experience, there is no reason doctors would be unable to evaluate different manufacturers' claims of the safety and risks for the same drug. In fact, the entire rationale for the learned intermediary doctrine is that doctors are ideally positioned to evaluate medical information for their patients.[232] If

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228 This is a hypothetical as it is unlikely that many nonprofit drug manufacturers exist.

229 PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2581 (2011).

230 Duncan, *supra* note 69, at 209.

231 *See, e.g.*, ALA. CODE § 34-24-70 (LexisNexis 2011); ALASKA STAT. § 08.64.200-210 (2010); ARIZ. REV. STAT. ANN. § 32-1422 (2011); ARK. CODE ANN. § 17-95-403 (2011); CAL. BUS. & PROF. CODE § 2089-2099.5 (West 2003); MINN. STAT. ANN. § 147.02 (2011); N.Y. EDUC. § 6524 (McKinney 2010); N.C. GEN. STAT. ANN. § 90-9.1 (2011); VA. CODE ANN. § 54.1-2930 (2009).

232 *See* Hurley v. Heart Physicians, P.C., 898 A.2d 777, 779 (Conn. 2006).

doctors were incapable of evaluating the merits of different manufacturers' warnings, there would be little reason to trust their ability to weigh the risks disclosed by a single warning against the potential benefits in the context of a particular patient's situation. Further, ordinary consumers successfully evaluate conflicting information for similar products all the time. There is no reason why doctors would be unable to do the same within their sphere of expertise.

Restoring voluntary choice to generic manufacturers' warning decisions will result in an improved legal framework: the generic manufacturers will lose the special privilege of preemption recognized by *PLIVA, Inc. v. Mensing*, but this will restore a proper federalism balance to this area of the law as well as Congress's intent not to supplant state tort law.

CONCLUSION

After *PLIVA, Inc. v. Mensing*, the majority of patients injured by inadequate warnings have no recourse despite being injured by the wrongdoing of others. As the dissent in *Mensing* points out, the ability of such a patient to recover for their harm is now dependent on the decision of a pharmacist to fill his or her prescription with either the brand-name or the generic drug. Congress did not intend this result when it passed the Hatch-Waxman Amendments, and it should be corrected.

Generic drug manufacturers should be given the ability to inform doctors of newly discovered drug risks. Then, when a patient is injured by an inadequate warning, he or she can recover from the manufacturer that should have known of the risk but failed to warn doctors. If the generic manufacturer was unaware of the risk but the brand-name manufacturer was aware and failed to warn, the plaintiff should be able to recover from the brand-name manufacturer under a theory of innovator liability.

Despite its unpopular status in court decisions, innovator liability stems from the particularized application of straightforward negligence principles. Everyone owes a duty of ordinary care to those they could foreseeably injure. A brand-name manufacturer's negligent warnings will foreseeably injure generic drug patients, particularly after the *Mensing* decision. The brand-name manufacturer's inadequate warning is the proximate cause of the plaintiff's harm because the generic drug manufacturer does not have the ability to unilaterally change its warnings. If generic drug manufacturers were given this ability, their inaction could potentially supersede the brand-name manufacturer's negligence if they should have known of the new risks and failed to warn of them. If the generic manufacturer could not have known of the risk then there is no superseding cause, and innovator liability should still attach to the brand-name manufacturer.

First, because the *Mensing* decision leaves plaintiffs without recourse and upsets the proper federalism balance between federal and state law, it should be corrected by allowing generic drug manufacturers the ability to

unilaterally amend their warning labels and to supplement them through the Dear Doctor Letter process. And second, courts should recognize innovator liability. These two actions will restore individual responsibility and corrective justice to a system of federal drug laws and state tort law that has created unwanted and unwarranted results.