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AM I MY COMPETITOR'S KEEPER? INNOVATOR
LIABILITY IN THE FIFTY STATES

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I. INTRODUCTION

Imagine that a company has invested billions of dollars to develop a drug for heartburn and indigestion that has widely acknowledged health benefits—so widely acknowledged that generic companies copy and market the formula for themselves. Physicians become aware of the drug’s health benefits and subsequently use information in the drug company’s advertisements and Physicians’ Desk Reference to prescribe it to their patients. Yet, when patients go to the pharmacy, they often receive not the branded drug they were prescribed, but a generic copy. Now, imagine that due to taking the generic drug for a prolonged period, one patient develops debilitating side effects that cause permanent neurological damage. Then, when the patient tries to sue the generic drug manufacturer, the patient is barred from bringing suit. Instead, the suit must be brought against the branded drug manufacturer. In front of a sympathetic judge and jury, the patient receives significant damages from the innovator company. Meanwhile, the generic drug company is not legally responsible for any negative repercussions.

This is exactly what happened in the case of *Conte v. Wyeth*. A patient who developed tardive dyskinesia legally prevailed against the branded company for an injury caused by a generic drug.¹ The *Conte* case made legal headlines and generated consternation within the pharmaceutical industry.² It also highlighted the problematic effects of two Supreme Court cases that gave rise to this doctrine. In the first case, *Wyeth v. Levine*, the Court held that state tort claims against branded drug companies were not preempted by Food and Drug Administration (FDA) approval of the drug’s design and labeling.³ In the second case, *PLIVA, Inc. v. Mensing*, the Court found that product liability claims against *generic* drugs *were* preempted by FDA rules due to the generic drugs’ “duty of sameness,” which dictates that their design and labeling must mirror aspects of the brand-name drug.⁴ After *Mensing* granted generic manufacturers immunity from suit, some states began to adopt the doctrine of innovator liability—which holds a branded drug company responsible for defective designs and warnings when the company’s

1. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Ct. App. 2008).

2. See 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 (2010).

3. *Wyeth v. Levine*, 555 U.S. 555, 577 (2009).

4. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 604 (2011).

generic competitors harm a patient—to allow patients some legal remedy against drug manufacturers.⁵

However, this theory of recovery holds that an innovating company, which has spent billions of dollars in the research and development of a drug and has undergone a lengthy FDA approval process, must pay damages to consumers of a competing company whose drug did not go through the same process.⁶ The doctrine of innovator liability supposes that imposing liability on innovator companies is an adequate and just substitute for making generic companies liable to their injured consumers.⁷ Currently, only a minority of states have formally adopted innovator liability whereas many states have formally rejected the doctrine.⁸ However, numerous states have remained silent on innovator liability.⁹

This Note argues that continued adoption of innovator liability would be harmful and that generic manufacturers should not be immune from suit. It further contends that the FDA should update the Federal Food Drug and Cosmetic Act (FDCA) to commit generic pharmaceutical companies to state tort law obligations to update their designs and labels according to the most recent research. Imposing these obligations would allow consumers to sue generic companies directly instead of relying on suits against branded manufacturers.

Part I of this Note introduces the history and current state of innovator liability. It first explores the statutory background that led up to the doctrine and then conducts the first comprehensive survey of innovator liability case law in the fifty states and the District of Columbia. The survey addresses whether and to what extent the states have adopted or rejected innovator liability. Moreover, it explores the state product liability and preemption laws that impact innovator liability. The states are grouped into four categories based on whether they have adopted, rejected, would likely adopt, or would likely reject the doctrine of innovator liability. Part II discusses the legal, policy, and moral concerns implicated by innovator liability, including detriment to public health, distortion of tort laws, and unfairness to branded manufacturers. Part III provides a normative recommendation for how the federal government should address innovator liability, ultimately urging the FDA to update the FDCA to allow generic companies to update

5. See Ramey, *supra* note 2, at 76.

6. See Ramey, *supra* note 2, at 83 (“[W]hy should a manufacturer of one product be liable for injuries caused by another?”).

7. See generally Wesley E. Weeks, Comment, *Picking Up the Tab for Your Competitors: Innovator Liability After Pliva, Inc. v. Mensing*, 19 GEO. MASON L. REV. 1257 (2012) (observing that innovator liability requires an innovator company to pay for its competitors).

8. See *infra* Sections I.C.1-C.2.

9. See *infra* Sections I.C.3-C.4.

their labels independent of branded companies, thereby imposing a state tort duty to warn.

II. BACKGROUND AND LAW OF THE FIFTY STATES

Innovator liability is currently a controversial doctrine within the fifty states. No scholarly article thus far has comprehensively surveyed how all fifty states have reacted to this doctrine. This Part includes an induction to the innovator liability doctrine and its background, a description of the statutes that inform liability, and a survey of the case law relevant to innovator liability from all fifty states and the District of Columbia. Section I.A introduces the concept of innovator liability and cases leading up to the doctrine's adoption. Section I.B discusses the legislative history and intent behind the passing of the FDCA and introduces the current state of the FDCA, the Hatch-Waxman Act, and generic substitution laws. Section I.C lists and describes the case law related to innovator liability in the fifty states and District of Columbia. The states are categorized in four subsections, based on whether they have accepted or rejected innovator liability, or if they are likely to accept or reject the doctrine. Section I.D summarizes innovator liability, the statutes that inform it, and how the doctrine has been treated in the fifty states and the District of Columbia. This summary sets up a discussion in Part II, which considers how increasing adoption of innovator liability would be detrimental to healthcare and tort law.

A. Background

Innovator liability describes a theory of tort liability where a manufacturer of a branded drug can be held responsible for injuries suffered by consumers of its generic counterpart.¹⁰ The issue was first raised after the Supreme Court decided in *Mensing* that consumers of generic drugs could not recover for deficient warnings from the generic manufacturer due to preemption by FDA labeling laws.¹¹ Believing that generic consumers should still be able to recover for their injuries, some courts have circumvented traditional tort principles by holding the branded company responsible.¹² The principle behind this theory of recovery is that since the FDA requires generic drug labels be copies of the branded label, the branded manufacturer could be held responsible to generic consumers for labeling defects.¹³ Innovator companies are even more likely to be targets for liability after the Supreme Court ruled

^{10.} See generally Ramey, *supra* note 2.

^{11.} See *Mensing*, 564 U.S. at 604.

^{12.} See, e.g., *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 304 (Ct. App. 2008).

^{13.} See *id.* at 320-21.

in *Levine* that warning defect claims against branded manufacturers were not preempted by FDA approval.¹⁴ Since *Mensing* and *Levine*, many state, district, and circuit courts have ruled differently on the issue of innovator liability, leading to inconsistent doctrines across the fifty states and the District of Columbia.¹⁵ The Supreme Court has yet to reconcile the differences by determinatively ruling on the issue of innovator liability.

1. Statutes

a. Federal Food Drug and Cosmetic Act (FDCA)

In 1938, in response to a proliferation of misbranded and deceiving drugs and consumer products, Congress passed the Federal Food Drug and Cosmetic Act (FDCA).¹⁶ To safeguard the health of consumers, the FDCA required drug manufacturers to provide evidence of the safety of their products before they entered the market.¹⁷ Over time, Congress passed several amendments to the FDCA that required drug manufacturers to comply with increasingly stringent standards.¹⁸

Currently, the FDA requires drug manufacturers to undergo an extensive approval process.¹⁹ Once the pharmaceutical company's clinical data shows that the drug is safe and effective on human subjects, it can file an application with the FDA to market the drug.²⁰ The FDA continues to monitor the drug's safety once it

14. *Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

15. *See infra* Section I.C.

16. 21 U.S.C.S. §§ 321 et seq.; Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C.S. § 301-399f (2015)); *Laws Enforced by FDA*, U.S. FOOD & DRUG ADMIN. (Mar. 29, 2018), <https://www.fda.gov/Regulatory-Information/laws-enforced-fda>.

17. *See Laws Enforced by FDA*, *supra* note 16.

18. An example of this is the Kefauver-Harris Amendments of 1962 which replaced the notification structure of new drug applications (NDAs) to an approval process. With this amendment, the drug manufacturer could not simply sell a drug sixty days after filing an NDA; the FDA had to accept the safety and effectiveness of the drug formally. *See* Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1762, 1764-68 (1996).

19. This includes discovery and development of the molecular compounds, pre-clinical research which involves *in vitro* (outside of a living organism) or *in vivo* (occurring within a living organism) studies, and clinical research that tests the effectiveness of the drug on human on human participants. 21 U.S.C.S. § 355.

20. *Id.* The application requires the drug manufacturer to submit information regarding clinical results, labeling information, safety information, drug abuse potential, patient information, and directions for use. After the application is submitted, the FDA can take ten months to make a decision; throughout this time, the drug manufacturer may have to constantly submit and resubmit research and data. *Frequently Asked Questions about the FDA Drug Approval Process*, U.S. FOOD & DRUG ADMIN. (Feb. 7, 2017),

reaches the marketplace.²¹ Even if a pharmaceutical company proceeds through the entire research, development, and application process, the FDA may still not allow the drug to go to market.²² The rigor of the FDA approval process means that only 11.8% of drugs initially submitted for clinical trials ultimately enter the market.²³ Considering that the average cost of manufacturing a successful new drug is 2.5 billion dollars, drug companies will likely only invest in the research and development of a drug if they are confident in its success.²⁴

b. The Hatch-Waxman Act

Congress passed the Hatch-Waxman Act in 1984 to encourage the manufacture of generic drugs. The approval process for generic drugs differs greatly from that for branded drugs.²⁵ Generic manufacturers must submit a new drug application (NDA) demonstrating their drugs are safe.²⁶ Furthermore, the FDA allows generic manufacturers to rely on published scientific literature to prove the safety and efficacy of their drugs; this literature is often taken directly from the branded manufacturer instead of the generic company's own clinical trials.²⁷ With the expedited process, generic manufacturers can save significant amounts of money by avoiding research and development costs, such as the millions of dollars spent on recruiting human subjects for clinical trials.²⁸

<https://www.fda.gov/drugs/special-features/frequently-asked-questions-about-fda-drug-approval-process> [hereinafter DRUG APPROVAL FAQ].

^{21.} See DRUG APPROVAL FAQ, *supra* note 20.

^{22.} If the pharmaceutical company wants to alter the formulation, use, or labeling of the drug, it must re-apply these changes with the FDA. *Id.*

^{23.} Joseph A. DiMasi, et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 23 (2016).

^{24.} *Id.* at 28.

^{25.} See 21 U.S.C. § 355(j); see also *What Is the Approval Process for Generic Drugs?*, U.S. FOOD & DRUG ADMIN. (Aug. 31, 2017), <https://www.fda.gov/drugs/generic-drugs/what-approval-process-generic-drugs>.

^{26.} See Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 419 (2011). The Act further specifies that “(1) the generic drug is ‘bioequivalent’ to the pioneer drug; (2) its active ingredients, route of administration, strength and dosage form are ‘the same as’ those of the pioneer drug; and (3) the inactive ingredients are not ‘unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug.’” *Zeneca, Inc. v. Shalala*, 213 F.3d 161, 164 (4th Cir. 2000) (quoting 21 U.S.C.S. § 355(j)(4)(C), (D), (H)).

^{27.} See DRUG APPROVAL FAQ, *supra* note 20.

^{28.} Without the need to conduct their own clinical trials, generic drugs accrue only the minimum of manufacturing costs. See Prabir Basu et al., *Analysis of Manufacturing Costs in Pharmaceutical Companies*, 3 J. PHARMACEUTICAL INNOVATION 30, 34 (2008) (finding that R&D expenditures as a percentage of

2. Generic Substitution Laws

All states have enacted some form of generic substitution law as a means of cost control in the healthcare industry.²⁹ These laws require that pharmacists dispense generic versions of the drugs unless a physician has specifically ordered the brand-name drug.³⁰ In some states, the law explicitly demands that the pharmacist dispense the lowest-cost version of the generic.³¹ Several state laws also dictate that the pharmacist does not need to notify the patient when the generic drug is being substituted.³²

c. Survey of the States

The states are divided in their approach to innovator liability, which has confused legal practitioners.³³ This section seeks to clarify how the doctrine operates by conducting a survey of case law and statutory law in the fifty states and classifying the states according to whether they have explicitly accepted, explicitly rejected, would likely accept, or would likely reject innovator liability. Section I.B.1 addresses the laws of the five states that have explicitly accepted the doctrine of innovator liability, delving into the case law of these states and highlighting critical reasoning from cases and statutes. Section I.B.2 addresses the laws of the twenty states that have explicitly rejected innovator liability, also highlighting crucial reasoning. Sections I.B.3 and I.B.4 delve into the case law and statutes of states that have not directly addressed innovator liability, examining their laws related to either product liability or federal preemption as to how they would likely inform innovator liability. Each subsection includes an initial summary of the states' laws followed by selected examples that illustrate the

sales have gradually increased for brand-name companies between 1994 and 2006, but have remained substantially flat for generics over the same time-span).

^{29.} See U.S. DEPT. OF HEALTH & HUMAN SERVS., EXPANDING THE USE OF GENERIC DRUGS 5 (2010) [hereinafter HHS REPORT], available at <http://aspe.hhs.gov/sp/reports/2010/genericdrugs/ib.pdf> (providing a chart of all fifty states' generic substitution laws).

^{30.} *Id.*

^{31.} *Id.*

^{32.} See Samantha Koopman, Comment, *Hidden Risks of Taking Generic Drugs over Brand Name: The Impact of Drug Labeling Regulations on Injured Consumers and the Pharmaceutical Industry*, 34 J. NAT'L ASS'N ADMIN. L. JUDICIARY 112, 122 n.55 (2014).

^{33.} David L. Ferrera & Michael J. Leard, *5 Things to Know About Innovator Liability*, Risk Management (Sep. 4, 2014), <http://www.rmmagazine.com/2018/09/04/5-things-to-know-about-innovator-liability/>; James M. Beck, *Innovator Liability—A Word to the Wise*, Drug and Device Law Blog (Dec. 11, 2017), <https://www.druganddevicelawblog.com/2017/12/innovator-liability-a-word-to-the-wise.html>.

regimes in each category, chosen either because they were the first decided, the most recent, or most representative of the group of states. A table that details each state's stance on innovator liability, crucial cases, and applicable statutes is included in Appendix A.

3. Innovator Liability States

Thus far, Alabama, California, Massachusetts, Pennsylvania, and Vermont are the only states that have explicitly adopted the doctrine of innovator liability.³⁴ These states assert that innovator liability does not break down traditional tort rules of proximate cause.³⁵ They maintain that any detrimental impact of the generic drug can also be attributed to the branded drug due to the duty of sameness and that it is therefore fair to punish the branded manufacturer.³⁶

California was the first state to adopt the doctrine, with the California Supreme Court's ruling in the 2008 case *Conte v. Wyeth*, a case in which the patient had developed a neurological disease from taking the generic of Reglan.³⁷ The *Conte* court found that Wyeth's production of Reglan was the cause-in-fact of the patient's injury because Wyeth had crafted the warnings for its drug that the physician could have relied on, and that therefore the harm to Conte was foreseeable. Notwithstanding the physician's testimony that he did not rely on Wyeth's warnings, the court found that because the physician did not *unequivocally* assert he had not relied on information

³⁴. In Alabama, California, Massachusetts, and Pennsylvania, the Supreme Courts of the states have ruled on the subject, making it binding authority within the state. In Vermont, a federal district rather than state court affirmed the doctrine. Massachusetts and Vermont both also respectively have statutes related to product liability and federal preemption that indirectly address innovator liability. *See infra* APPENDIX A.

³⁵. *See infra* Section I.C.1.

³⁶. *See infra* Section I.C.1.

³⁷. *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 305 (Ct. App. 2008). The plaintiff Elizabeth Conte suffered from gastroesophageal reflux disease and was prescribed Reglan, a drug manufactured by defendant company Wyeth. Instead of Reglan, she was given the generic metoclopramide manufactured by the companies Purepac, Teva, and Pliva. After taking metoclopramide for a long period of time, she developed tardive dyskinesia, a neurological disease that resulted in involuntary movements. She sued the three generic drug companies as well as the brand-name manufacturer. The Supreme Court of California ultimately dismissed the case against the generic companies but found Wyeth liable. The court reasoned that the doctor that had prescribed Reglan for Conte had done so because he had "read Wyeth's monograph on Reglan in the [Physicians' Desk Reference (PDR)] during his residency training; that the PDR was one of the source he generally refers to in his clinical practice when he considers prescribing Reglan for his patients; and that he believed the information it contained was accurate." *Id.* at 308.

from Reglan to make his decision, there was a genuine issue of material fact and summary judgment was inappropriate.³⁸

The California Supreme Court affirmed *Conte* with its ruling in the 2017 case *T.H. v. Novartis*.³⁹ In order to determine whether Novartis had any duty to the plaintiffs, the court considered the foreseeability of the harm, the certainty of the injury, and the closeness of connection between the plaintiff and defendant.⁴⁰ Citing the precedent established by *Conte*, the court found that a brand-name drug manufacturer has a duty under California law to warn of risks of which it knew or reasonably should have known.⁴¹

The dissent in *T.H. v. Novartis* accepted the majority's holding that a branded manufacturer's duty to warn extends to consumers of the generic drug,⁴² but argued that a drug manufacturer no longer has a duty to warn after the sale of its product line to another company.⁴³ The dissent concluded that "[e]xposing drug manufacturers to broad liability with no predictable end point has the clear potential to destabilize the pharmaceutical industry and chill innovation."⁴⁴

Alabama and Vermont have applied the same rationale as California for adopting innovator liability. The Alabama Supreme Court ruled in *Wyeth v. Weeks* that a brand-name manufacturer could be liable for fraud or misrepresentation in its warning label towards

^{38.} *Id.* at 309. The court ruled there was enough evidence to support causation despite the doctor's insistence that "at no time did [he] rely in any way on representations made in the PDR monograph, package insert, labeling materials or other information from Wyeth regarding the medication Reglan in order to formulate [his] course of care and treatment." *Id.* at 308.

^{39.} *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 29 (Cal. 2017). In this case, minors whose mother had used the generic terbutaline, a medicine to suppress premature labor, brought suit against the branded manufacturer Novartis. During that time the plaintiffs' mother had used terbutaline, Novartis had already ceased to sell its branded drug Brethine and had divested its manufacturing rights to another drug manufacturer. *Id.* at 18.

^{40.} *Id.* at 28 (citing *Rowland v. Christian*, 443 P.2d 561, 567 (Cal. 1968)).

^{41.} *Id.* at 29 ("Only a handful of courts have followed *Conte* . . . But our careful review of the federal regulatory scheme and analysis of all the *Rowland* factors persuades us that a brand-name drug manufacturer has the duty under California law to warn of the risks about which it knew or reasonably should have known, regardless of whether the consumer is prescribed the brand-name drug or its generic bioequivalent.") (internal quotes and citations omitted).

^{42.} *Id.*

^{43.} *Id.* at 48. Judge Corrigan opined that when the drug line is divested to a new company, that second company—instead of the original manufacturer—assumes a duty to warn consumers by updating the product label. He argued that holding the original manufacturer liable would mean recognizing that a predecessor company had control over its successor's warning labels, even though this responsibility would be impossible to discharge.

^{44.} *Id.* at 52.

a consumer of its generic equivalent.⁴⁵ In defending its decision, the court specified that “the FDA traditionally regarded state law as a complementary form of drug regulation.”⁴⁶ The Supreme Court of Vermont has yet to address innovator liability directly, but the United States District Court of Vermont ruled in *Kellogg v. Wyeth* that a name-brand manufacturer has a duty to use due care in disseminating information about the drug and is responsible to consumers of the generic drug.⁴⁷

Massachusetts, another state that has adopted innovator liability, has applied a recklessness rather than negligence standard.⁴⁸ In *Rafferty v. Merck*, in which a patient of a generic drug brought an action for failure to warn against the branded company, Merck, the court decided that Merck had a duty towards customers of its generic counterpart.⁴⁹ However, the plaintiff had to prove that Merck acted with intentionality.⁵⁰ Therefore, Merck was liable only if it *intentionally* failed to update its label to warn of risks that it knew about.⁵¹

In *Lance v. Wyeth*, the Supreme Court of Pennsylvania found the plaintiff had a sufficient case in a design defect claim against a branded pharmaceutical company.⁵² Deciding to hold pharmaceutical companies to a high degree of care, the court held that Wyeth had a duty to Lance under Pennsylvania common law. In its decision, the court ignored the failure of the plaintiff to offer

^{45.} *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676 (Ala. 2014), *superseded by statute*, ALA. CODE § 6-5-530 (2015).

^{46.} *Id.* at 676 (quoting *Wyeth v. Levine*, 555 U.S. 555, 578-79 (2009)).

^{47.} *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 704-09 (D. Vt. 2010). Applying a Vermont statute, the court found that fraudulent misrepresentation comprises the elements of (1) a false representation (2) concerning a material fact (3) relied upon by the plaintiff (4) who was damaged as a proximate result. Thus, because the consumer relied on the labeling of the generic drug which was identical to that of the branded medicine, the court found the brand-name company was proximately responsible towards the consumer even though it did not manufacture the drug that the plaintiff ingested. *Id.*

^{48.} *Rafferty v. Merck & Co.*, 92 N.E.3d 1205 (Mass. 2018).

^{49.} *Id.* at 1219.

^{50.} *Id.* at 1220 (“Under this standard, a brand-name manufacturer that intentionally fails to update the label on its drug to warn of an unreasonable risk of death or grave bodily injury, where the manufacturer knows of this risk or knows of facts that would disclose this risk to any reasonable person, will be held responsible for the resulting harm.”).

^{51.} *Id.* Ultimately, despite assuming a duty, since the plaintiff only alleged negligent failure to warn and therefore failed to prove recklessness, the case was remanded to the Massachusetts Superior Court.

^{52.} *Lance v. Wyeth*, 85 A.3d 434, 458 (Pa. 2014). The estate of a patient who had died from taking the generic version of a prescription diet drug sued the branded manufacturer Wyeth, alleging that the drug was “so unreasonably dangerous and defective in design.” In response, Wyeth argued that the FDA had approved its drug as safe and effective for patient use and that drugs were unavoidably unsafe by nature. *Id.* at 437-38.

an alternative feasible design and his failure to recognize that a drug was an unavoidably unsafe product.⁵³ Furthermore, the court ruled that the drug contained a design defect because it caused pulmonary problems, despite the warning label indicating that such side effects could occur.⁵⁴

The partial dissent in *Lance* explicitly cautioned against creating a new class of actions *sua sponte*—“negligent design defect”—against pharmaceutical companies.⁵⁵ Justice Eakin indicated that the plaintiff did not bring a design defect claim against Wyeth, only citing “negligent marketing” and “failure to withdraw.”⁵⁶ He was also apprehensive that the Superior Court manufactured the design defect claim *sua sponte*, thereby not giving Wyeth a fair opportunity to address and develop its defense against the design defect claim directly.⁵⁷

4. Rejected Innovator Liability

Most states that have ruled directly on innovator liability have rejected the doctrine. There are twenty states whose courts have rejected innovator liability outright: Colorado, Florida, Georgia, Iowa, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Texas, Utah, and West Virginia.⁵⁸ These courts emphasize that companies cannot be responsible for products they were not directly involved in manufacturing.⁵⁹ Some courts have also emphasized the role of duty in their determination—finding that generic pharmaceutical

^{53.} *Id.* at 458-59.

^{54.} *Id.* at 439.

^{55.} *Id.* at 462.

^{56.} *Id.*

^{57.} *Id.* at 465-66. Ultimately, because a “negligent design defect” claim for prescription drugs would have significant public policy implications, the dissent opined that the court should have waited for a fully developed case that considered thoughtful advocacy on both sides before imposing such a doctrine. *Id.* at 466.

^{58.} In Iowa and West Virginia, the state Supreme Courts have rejected the doctrine and thus created binding doctrine across the state. In New Jersey, Georgia, and Florida, lower state courts have decided on innovator liability. In Colorado, Kansas, Minnesota, Missouri, Ohio, Oregon, and Utah, federal district courts have ruled on the doctrine. New York law has been established by both state and district courts. Various Circuit Courts of Appeal have also ruled on the doctrine of innovator liability. The Fifth Circuit has applied Louisiana, Mississippi, and Texas law in separate cases rejecting innovator liability. The Fourth Circuit has interpreted Maryland and North Carolina law to reject innovator liability. The Ninth Circuit and the Tenth Circuit have interpreted Nevada and Oklahoma law respectively.

^{59.} See *infra* Section I.C.2.

companies had duties to their customers that could not be avoided by copying the branded manufacturer.⁶⁰

The earliest case rejecting innovator liability was *Foster v. American Home Products*, a Fourth Circuit case applying Maryland law that predates *Mensing*.⁶¹ The Fourth Circuit found that Maryland law requires “a plaintiff seeking to recover for an injury by a product to demonstrate that the defendant manufactured the product at issue.”⁶² In rejecting innovator liability, the Fourth Circuit indicated that it denied “the assertion that a generic manufacturer is not responsible for negligent misrepresentations on its product labels if it did not initially formulate the warnings and representations itself.”⁶³ Instead, when a generic adopts a name brand’s warnings and representations “without independent investigation,” it assumes the risk that the representations are flawed.⁶⁴ Furthermore, all drug manufacturers—even generic manufacturers—are responsible for keeping abreast of the most recent scientific and medical discoveries regarding the medicine they sell.⁶⁵ This opinion was later overruled when *Mensing* created the “duty of sameness,” according to which generic drugs only needed to copy the warnings of the branded drug.⁶⁶

Although *Foster v. American Home Products* was decided in 1994, more than a decade before California formally adopted innovator liability in the 2008 case *Conte v. Wyeth*, there have been a plethora of cases since *Conte* from various states that continue to reject innovator liability. In 2016, the Fourth Circuit affirmed its decision in *Foster* by holding in *Perdue v. Teva* that a branded manufacturer is not liable for a generic manufacturer’s negligence.⁶⁷ The Fourth

^{60.} See *infra* Section I.C.2.

^{61.} *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994). In this case, the Fosters originally sued Wyeth under a negligent representation claim in a Maryland District Court when their daughter died from consuming the generic equivalent of Wyeth’s name-brand drug. Wyeth submitted evidence that the prescribing physician had employed his own medical knowledge towards the prescription and had not relied on representations made by Wyeth. Ultimately, the Fourth Circuit argued because the Fosters were not injured by a drug that Wyeth manufactured there was no relationship between them, and therefore Wyeth did not owe a duty to the Fosters. *Id.*

^{62.} *Id.* at 168.

^{63.} *Id.* at 169.

^{64.} *Id.*

^{65.} *Id.* at 170.

^{66.} See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011).

^{67.} *Perdue v. Wyeth Pharm., Inc.*, 209 F. Supp. 3d 847, 854 (E.D.N.C. 2016), appeal dismissed sub nom. *Perdue v. Teva Pharm. USA, Inc.*, No. 16-1947, 2018 WL 994177 at*1 (4th Cir. Feb. 8, 2018). In *Perdue*, the plaintiff was prescribed an off-label use of the generic medication amiodarone; when she picked up her medicine, she was not given the medication guide which generic drug manufacturers are supposed to give to pharmacists. Eventually, the plaintiff began experiencing side effects associated with usage of amiodarone that were outlined in the guide. Although the plaintiff sued the generic drug company that

Circuit dismissed the plaintiff's claim against Wyeth, asserting that under North Carolina law, "a defendant may not be held liable for injuries allegedly caused by the use of another's product."⁶⁸

The Fourth Circuit addressed the doctrine of innovator liability most recently in a West Virginia case *McNair v. Johnson & Johnson*.⁶⁹ The court cited *Foster* as precedent for rejecting the contention that a brand name manufacturer could be liable for injuries sustained by consumers of the generic drug.⁷⁰ However, the dissent discussed several more recent cases that all accepted the doctrine of innovator liability.⁷¹

The Fifth Circuit has rejected innovator liability on several occasions.⁷² In *Demahy v. Schwarz*, a Louisiana District Court had dismissed the plaintiff's claim against the branded pharmaceutical manufacturer, allowing only the claim against the generic manufacturer to proceed.⁷³ The Fifth Circuit reviewed the issues of the dismissal *de novo*, ultimately concluding that the District Court was correct in dismissing the claims against the branded manufacturer because a Louisiana statute—the Louisiana Products Liability Act (LPLA)—provided that "recovery is not available against a manufacturer if the manufacturer did not produce the offending product."⁷⁴ The court rejected the notion that the ruling in *Mensing* meant that plaintiffs who could not recover from generic defendants must be able to recover from branded manufacturers and held that *Mensing* had no impact on Louisiana law. In *Johnson v. Teva*, the Fifth Circuit reached the same conclusion, declining to impose liability on branded manufacturers, and affirming that the LPLA was the governing law for product liability in Louisiana.⁷⁵

Oklahoma is another state with a statute applicable to innovator liability, which specifies that "there is a rebuttable presumption that the product manufacturer or seller is not liable for

manufactured amiodarone, she also asserted a case against the branded manufacturer Wyeth. *Id.*

^{68.} *Id.* at 853.

^{69.} *McNair v. Johnson & Johnson*, 694 F. App'x 115 (4th Cir. 2017), certified question answered, 241 W. Va. 26, 818 S.E.2d 852 (2018). In this case, consumers of a generic antibiotic drug who developed acute respiratory distress syndrome (ARDS) sued the brand-name drug manufacturer alleging that the branded manufacturer failed to include the risk of developing ARDS in the warning information. Ultimately, the Fourth Circuit remanded the case to the Supreme Court of Appeals of West Virginia. *Id.*

^{70.} *Id.* at 864.

^{71.} *Id.* at 869; *see, e.g.*, *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Ct. App. 2008); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014), *superseded by statute*, ALA. CODE § 6-5-530 (2015).

^{72.} *See Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605 (5th Cir. 2014); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177 (5th Cir. 2012).

^{73.} *Demahy*, 702 F.3d at 180.

^{74.} *Id.* at 182.

^{75.} *Johnson*, 758 F.3d at 615.

any injury to a claimant . . . [if] the product was subject to premarket licensing or approval by the federal government.”⁷⁶ The Tenth Circuit, interpreting this Oklahoma law, determined that brand-name manufacturers do not owe a duty to consumers of generic drugs.⁷⁷ Ultimately, it opined that “only a handful of courts—and no federal courts of appeals—have held that brand-name manufacturers can be held liable for injuries caused by their generic counterpart” and predicted that “the Oklahoma Supreme Court would not recognize this novel theory of liability.”⁷⁸ Having denied the plaintiff recovery from both branded and generic drug manufacturers, the Tenth Circuit acknowledged the injustice of preventing the consumer from obtaining relief against any party.⁷⁹ However, the court expressed that it had to follow the statutory regime implemented by Congress and affirmed by *Mensing* that denied relief for consumers of generic drugs.⁸⁰

Texas has a plethora of case law in which District Courts have directly rejected innovator liability.⁸¹ The Fifth Circuit has also ruled on two Texas cases involving innovator liability and rejected the doctrine in each case.⁸² In *Lashley v. Pfizer, Inc.*, the court granted summary judgment for the branded manufacturers, citing Texas Supreme Court precedents that entities are “manufacturers . . . only with respect to their own products” and that “[a] fundamental principle of traditional products liability law is that the plaintiff must prove that the defendants supplied the product which caused the injury.”⁸³ The Fifth Circuit also indicated that “[u]nder Texas law, a drug manufacturer enjoys a rebuttable presumption that it is not liable for failure to warn if the FDA has approved . . . the product

^{76.} OKLA. STAT. tit. 76, § 57.2 (2019). This statute would require that FDA-approved products hold a rebuttable presumption against liability.

^{77.} *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1281-82 (10th Cir. 2013) (noting that Oklahoma law established that for a consumer to sue a manufacturer, there must be a relationship between the two parties).

^{78.} *Id.* at 1285-86.

^{79.} *Id.* at 1290.

^{80.} *Id.*

^{81.} *Del Valle v. Pliva, Inc.*, No. B-11-113, 2012 WL 4747259, at *1 (S.D. Tex. Sept. 12, 2012); *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2008 WL 1314902, at *2 (N.D. Tex. Apr. 3, 2008); *Wells v. Wyeth Pharm., Inc.*, 233 F. Supp. 3d 534, 538 (W.D. Tex. 2017); *Burke v. Wyeth, Inc.*, No. G-09-82, 2009 WL 3698480, at *2 (S.D. Tex. Oct. 29, 2009); *Willis v. Schwarz-Pharma, Inc.*, 62 F. Supp. 3d 560, 566 (E.D. Tex. 2014); *Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616, 622 (E.D. Tex. 2010).

^{82.} *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475 (5th Cir. 2014). In *Lashley v. Pfizer*, consumers of the generic drug metoclopramide brought suit against both the generic and branded manufacturers. *Id.* at 472-73.

^{83.} *Id.* at 477 (citation omitted); *Owens & Minor, Inc. v. Ansell Healthcare Prods., Inc.*, 251 S.W.3d 481, 485 (Tex. 2008); *Gaulding v. Celotex Corp.*, 772 S.W.2d 66, 68 (Tex. 1989).

alleged to have harmed the plaintiff.”⁸⁴ The court affirmed *Lashley* in *Eckhardt v. Qualitest Pharm., Inc.*⁸⁵

In *Moretti v. Wyeth*, the Ninth Circuit emphasized the element of duty in innovator liability.⁸⁶ The Ninth Circuit, interpreting Nevada law, indicated that “a misrepresentation by omission is actionable only if the defendant was under a duty to disclose the relevant information” and that there was a duty only if there was a relationship between the parties.⁸⁷ However, since the branded manufacturers were not involved in the direct transaction and the defendant in this case did not undertake to render “testing, advisory, laboratory and personnel services” that would indicate it held continued control over the development of the drug, the duty element was not met.⁸⁸

The Iowa Supreme Court is the only state supreme court that that has directly rejected innovator liability, finding that a branded defendant owes no duty to consumers of generic drugs.⁸⁹ Although the court observed *Mensing’s* duty of sameness, it found the generic manufacturer owed a duty to its consumers to faithfully adopt the warnings that were used by the branded manufacturer.⁹⁰ Furthermore, the court failed to impose a new duty on branded manufacturers, opining that it “decline[d] to change Iowa law to impose a new duty on manufacturers to those who never used their products and were instead harmed by use of a competitor’s product.”⁹¹

5. Likely to Adopt

Alaska, Indiana, New Mexico, Rhode Island, and Wyoming do not have case law or statutes that directly address innovator liability. Nevertheless, laws in these states addressing federal preemption of pharmaceuticals or causation in product liability suggest that their courts would likely rule in favor of innovator liability.⁹²

^{84.} *Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 374 (5th Cir. 2012).

^{85.} *Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 680 (5th Cir. 2014) (indicating that “[a] prior panel of this court held that Texas products liability law does not impose liability in this exact factual situation . . . We are bound by this determination.”).

^{86.} *Moretti v. Wyeth, Inc.*, 579 F. App’x 563, 564 (9th Cir. 2014). In this case, the plaintiff sued both generic and brand-name drug manufacturers after sustaining injury from the generic drug metoclopramide. *Id.*

^{87.} *Id.* at 564.

^{88.} *Id.* at 565.

^{89.} *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 380 (Iowa 2014).

^{90.} *Id.* at 364.

^{91.} *Id.* at 369.

^{92.} Alaska and Wyoming both have laws directly related to design and warning defect claims brought against pharmaceutical companies. Rhode Island

In Wyoming, for example, the State Legislature passed a statute regarding the responsibilities of drug companies.⁹³ As support, the statute cites *Thom v. Bristol-Myers Squibb*, in which the Tenth Circuit found a genuine issue of material fact and overruled summary judgment in favor of the injured plaintiff even though the company had warned the plaintiff's physician of the specific injury.⁹⁴ Thus, even though there was an intervening factor in this case—the physician's failure to warn—the court found that the drug's labeling could still be a substantial factor in the harm.⁹⁵ The statute's citation to *Thom* indicates that Wyoming would likely rule that a branded pharmaceutical company was a substantial factor in a generic consumer's injury.

Indiana has both case law and a statute that would seem to cut in favor of innovator liability. Both a state court and a district court in Indiana have ruled that a consumer's state law claim against a pharmaceutical company is not expressly preempted by the FDCA or indication of FDA approval.⁹⁶ Furthermore, Indiana Code § 34-20-2-2, the authority on product liability in Indiana, cites *Wyeth v. Levine* as informative of its statute.⁹⁷ Similarly, the Court of Appeals of New Mexico has ruled on the issue of FDA preemption and found that compliance with the FDCA does not signify that a drug company is free of negligence.⁹⁸ These authorities seem to indicate

has law addressing causation in product liability actions. Finally, Indiana and New Mexico courts have ruled on the issue of federal preemption for branded drugs.

^{93.} WYO. STAT. ANN. § 1-1-109 (2019). Under the statute, “the test for proximate cause in a pharmaceutical failure to warn case is whether the defendant's inadequate warning could be found to be a *substantial cause* of the plaintiff's ingestion of the drug.” (emphasis added). With this interpretation of proximate cause, a plaintiff would not need to prove that they had a direct relationship with the pharmaceutical company, that the pharmaceutical company owed them a duty, or that there was privity between the plaintiff and manufacturer. Instead, the inadequate warning only need to be a “substantial cause” of the plaintiff's injuries. *Id.*

^{94.} *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 857-58 (10th Cir. 2003).

^{95.} *Id.* at 856.

^{96.} *Bell v. Lollar*, 791 N.E.2d 849 (Ind. Ct. App. 2003); *Warren v. Boehringer Ingleheim Pharm. Inc.*, No. 1:16-cv-01326-SEB-DML, 2017 WL 3970666, at *15 (S.D. Ind. Sept. 8, 2017). In *Warren v. Boehringer*, the South District of Indiana rejected the affirmative defense of preemption because while “[m]ajor changes require FDA approval before distributing the changed drug . . . moderate changes may be distributed first subject to later approval.” *Id.* at *14.

^{97.} IND. CODE § 34-20-2-2 (2019); *Wyeth v. Levine*, 555 U.S. 555 (2009). As mentioned before, the Supreme Court held in *Levine* that adherence to FDA standards does not preempt state tort actions against branded pharmaceutical companies. *Id.*

^{98.} *Michael v. Warner/Chilcott*, 579 P.2d 183 (N.M. Ct. App. 1978). The court indicated that “[s]tatutes and regulations of these agencies merely set minimum standards” and that “a warning adopted verbatim from a regulation

that these states hold branded drug companies as responsible for meeting more stringent manufacturing criteria under state tort laws that exceed FDA standards of safety, and at the very least reflect these states' preference to have their own tort law enforced over federal administrative judgments. Thus, Indiana and New Mexico would likely allow an innovator liability suit against a branded pharmaceutical company to proceed to the jury.

6. Likely to Reject

Arizona, Arkansas, Connecticut, Delaware, Hawaii, Idaho, Illinois, Kentucky, Maine, Michigan, Montana, Nebraska, New Hampshire, North Dakota, South Carolina, South Dakota, Tennessee, Virginia, Wisconsin, Washington, and Washington D.C. do not have case law directly addressing innovator liability, but they do have laws related to federal preemption of pharmaceuticals or product liability causation that indicate they would likely reject innovator liability.⁹⁹

Arizona, Connecticut, North Dakota, and Tennessee's statutes directly address federal preemption of products. For example, Arizona and Connecticut have product liability statutes expressing that "[s]tate-law design-defect claims that turn on adequacy of prescription drug's warnings are preempted by federal law."¹⁰⁰ North Dakota has a similar statutory provision, indicating that "[t]here is a *rebuttable presumption* that a product is free from any defect or defective condition if the plans, designs, warnings, or instructions for the product . . . were in conformity with government standards established for that industry."¹⁰¹ Tennessee's statute is similar to North Dakota's.¹⁰² Though the strength of preemption is

promulgated by a federal or state agency does not constitute an adequate warning as a matter of law." *Id.* at 186.

^{99.} Arizona, Connecticut, North Dakota, and Tennessee's law on product liability for branded pharmaceutical manufacturers turn mostly on statutes. The likelihood of adopting innovator liability in Arkansas, Delaware, Hawaii, Kentucky, Montana, South Carolina, South Dakota, Wisconsin, and Washington D.C. is informed primarily by case law. Finally, Idaho, Illinois, Maine, Michigan, Nebraska, New Hampshire, Virginia, and Washington's interpretation of the doctrine would likely be informed by *both* case law and statutes.

^{100.} See ARIZ. REV. STAT. § 12-682 (2019); CONN. GEN. STAT. § 52-572n (2019).

^{101.} N.D. CENT. CODE ANN. § 28-01.3-09 (2019) (emphasis added). This is similar to Texas's statute which also acknowledged a rebuttable presumption of safety when a product complies with government standards. As mentioned before, Texas has rejected innovator liability.

^{102.} TENN. CODE ANN. § 29-28-104 (2019). Dictating that "[c]ompliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or

less in North Dakota and Tennessee than in Arizona and Connecticut—the preemption is a rebuttable presumption instead of automatic—the inference of preemption remains. Thus, it is likely that a branded pharmaceutical company that complies with FDA regulatory guidelines and whose design and warning label was approved by the FDA would not be liable for state tort claims in the aforementioned states.

Delaware and Kentucky’s case law discuss causation in product liability cases, especially within the context of asbestos litigation. The District Court of Delaware held that to establish causation in an asbestos case, the plaintiff must show exposure to the defendant’s product was the cause of the injury.¹⁰³ Similarly, the Kentucky Court of Appeals ruled that a plaintiff alleging mesothelioma from asbestos must prove that he was exposed to the defendant’s product.¹⁰⁴ The court opined that every defendant is “entitled to have a causative link proven between the defendant’s specific asbestos-containing product and the plaintiff’s disease or injuries.”¹⁰⁵ These rulings indicate that Delaware and Kentucky courts would likely also find that a plaintiff needs to show that branded drug manufacturer’s product specifically caused his or her injury.

In Arkansas, Hawaii, Montana, South Carolina, South Dakota, Wisconsin, and Washington D.C., courts have also established that plaintiffs must show the manufacturer’s own product caused the injury to hold a manufacturer liable. In *Kelley v. Eli Lilly*, brought before the U.S. District Court in Washington, D.C., a plaintiff sued a diethylstilbestrol (DES) manufacturer for injuries sustained by her mother’s ingestion of the drug during pregnancy.¹⁰⁶ The court rejected the plaintiff’s allegation of alternative liability and ruled that “[i]dentification of the party responsible for causing injury to another is a longstanding prerequisite to a successful negligence action.”¹⁰⁷ The U.S. District Court in South Carolina ruled similarly in another case involving a

instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition”

^{103.} *Evans v. Flowserve U.S. Inc.*, 239 F. Supp. 3d 838 (D. Del. 2017). In this case, the plaintiff was exposed to asbestos through his work as a fireman and boiler tender and sued a number of manufacturers of asbestos-containing products. The court granted summary judgment to the defendants because the plaintiff failed to prove he was exposed to products specifically manufactured by the defendants. *Id.* at 844.

^{104.} *Mannahan v. Eaton Corp.*, No. 2013-CA-002005-MR, 2016 WL 3887037 at *1 (Ky. Ct. App. July 15, 2016).

^{105.} *Id.* at *9.

^{106.} *Kelley v. Eli Lilly & Co.*, 517 F. Supp. 2d 99 (D.D.C. 2007).

^{107.} *Id.* at 104.

DES company.¹⁰⁸ In Montana¹⁰⁹, South Dakota¹¹⁰, and Hawaii¹¹¹, the case law on causation in product liability cases does not derive from DES litigation but from other products.¹¹²

Idaho, Illinois, Maine, Michigan, Nebraska, New Hampshire, Virginia, and Washington's law regarding product liability derives from both case law and statutes. Idaho courts, for instance, have ruled in cases regarding causation in product liability, while the Idaho Legislature has passed law informing federal preemption.¹¹³ New Hampshire law also addresses both causation

^{108.} *Ryan v. Eli Lilly & Co.*, 514 F. Supp. 1004 (D.S.C. 1981). The plaintiff's mother had ingested DES and sued a variety of manufacturers. The court indicated that the defendants sold their products at different times, in different forms, with different prices, with vastly different marketing mechanisms. Furthermore, the court found the prescribing physician did not rely on information provided by the company but rather medical literature from other leading physicians. Thus, the court ultimately held a judgment for the plaintiff would be "a total departure from all previous rules of causation and liability" *Id.* at 1018.

^{109.} *Schelske v. Creative Nail Design, Inc.*, 933 P.2d 799 (Mont. 1997). A plaintiff in Montana brought a suit against various cosmetic manufacturers alleging she was exposed to toxic chemicals from their products in her work as a beautician. Although the plaintiff asserted that she used "each and every product on a daily basis," the court found that some of the products were discontinued while she was working. *Id.* at 803. The Montana Supreme Court ultimately ruled against causation, finding that "the record in this case does not provide evidence that any specific substance caused specific harm" *Id.* at 806.

^{110.} *Bradley v. Firestone Tire & Rubber Co.*, 590 F. Supp. 1177, 1179 (D.S.D. 1984). In South Dakota, a plaintiff brought a case against various tire manufacturing companies when he was unable to identify the manufacturer of the specific wheel that caused his accident. *Id.* at 1178. The District Court of South Dakota rejected the plaintiff's arguments of alternative liability and market-share liability, ruling that "[i]t is a fundamental principle that a plaintiff must prove, as an essential element of his case, that the defendant manufacturer actually made the particular product in question" (citation omitted). *Id.* at 1179.

^{111.} *Smith v. Cutter Biological, Inc.*, 823 P.2d 717, 719 (Haw. 1991). Hawaiian case law also establishes a causal nexus requirement. *Id.* In this case a hemophiliac who contracted AIDS from donated blood sued manufacturers of the blood product without identifying the specific manufacturer of the product that harmed him. *Id.* at 722. The Supreme Court of Hawaii ruled that "Hawaii does not recognize the applicability of any non-identification theory of causation to this case." *Id.* at 738.

^{112.} Based on the following rulings in Montana, South Dakota, and Hawaii, courts in these states would likely reject a plaintiff's claim against a branded manufacturer when the plaintiff did not ingest the branded drug.

^{113.} *J.M.F. Trucking, Inc. v. Carburetor & Elec. of Lewiston, Inc.*, 748 P.2d 381 (Idaho 1987). In this case, a purchaser of a truck brought an action in Idaho against the manufacturer for strict product liability when he was injured. *Id.* at 382. The Supreme Court of Idaho delved into the intensive fact-finding presented by both sides, eventually ruling that a finding of causation is imperative to product liability, and it must be proved that the defect which is the subject of litigation caused the injury or damage. *Id.* The Idaho Code also refers to the issue of product liability. Idaho Code Ann. § 6-1401. While the statute itself addresses only product liability in general, its notes of decision reference "[p]roducts liability,

and preemption for product liability claims.¹¹⁴ Nebraska case law favors requiring proof of direct causation to recover for a product liability action as well.¹¹⁵

B. Summary

Since the Supreme Court's decision in *Pliva v. Mensing*, which declared generics pre-empted from state tort suits under FDCA labeling rules, some states have found that innovator companies can be liable in tort suit for injuries sustained by consumers of its generic counterpart. Statutes and regulations, such as the FDCA, the Hatch-Waxman Act, and state generic substitution laws, further perpetuate the doctrine of innovator liability by prescribing

drugs, state law failure to warn claims, federal preemption, Food and Drug Administration approval of drug labeling, see *Wyeth v. Levine*, 2009, 129 S.Ct. 1187, 555 U.S. 555, 173 L.Ed.2d 51." *Id.* As the *Wyeth v. Levine* decision opposed FDA preemption for pharmaceuticals, Idaho state tort laws would likely not defer to FDA approval. Thus, Idaho courts endorse direct causation for product liability actions and its statutes indicate tort law would not be preempted by federal law.

^{114.} *Univ. Sys. of N.H. v. U.S. Gypsum Co.*, 756 F. Supp. 640 (D.N.H. 1991). The District Court of New Hampshire ruled here that the theory of alternative liability would not apply to asbestos manufacturers. Instead, the court opined that "alternative liability is not a complete substitute for defendant-product identification." *Id.* at 654. Thus, New Hampshire law would seem to favor proving direct causation to assert liability. New Hampshire statutes would seem to uphold this ruling, as they indicate that *Wyeth v. Levine* is guiding doctrine in New Hampshire. N.H. Rev. Stat. Ann. tit. LII, Ch. 507-D, Refs & Annos. Thus, the State Legislature would also uphold that FDA approval does not preempt state product liability claims. Ultimately, since New Hampshire law requires finding a causal nexus and denies preemption for generic pharmaceutical companies, state courts would likely reject innovator liability.

^{115.} *Menne v. Celotex Corp.*, 861 F.2d 1453 (10th Cir. 1988). In this case, a plaintiff brought actions against several asbestos manufacturers to recover for injuries from exposure while working in a shipyard. However, the plaintiff "could not identify any particular asbestos products to which he was exposed during his time at the Shipyard." *Id.* at 1458. Thus, the Tenth Circuit applying Nebraska law held that the evidence "did not and could not prove causation either under a pure substantial factor test or under Nebraska's but-for and substantial factor standard." *Id.* at 1461. Ultimately, *Menne* opined Nebraska courts require a but-for and substantial factor test that would implicate the direct manufacturer. *See id.* Furthermore, the Nebraska Legislature passed a statute which says "[n]o product liability action based on the doctrine of strict liability in tort shall be commenced or maintained against any seller or lessor of a product which is alleged to contain or possess a defective condition unreasonably dangerous to the buyer, user, or consumer unless the seller or lessor is also the manufacturer of the product or the part thereof claimed to be defective." NEB. REV. STAT. § 25-21, 181 (2019). This statute indicates that in Nebraska a product liability claim can only be brought against the direct manufacturer of a product. *Id.* Thus, both case law and statutes in Nebraska would cut against innovator liability.

extensive compliance standards for branded but not generic pharmaceutical manufacturers.

States are divided over whether they have adopted, rejected, or are likely to adopt or reject innovator liability. Thus far, five states have explicitly accepted innovator liability and five states are likely to accept it. The rationale that these states generally rely on is that the detrimental impact of the generic drug can be attributed to the branded drug due to the generic's duty of sameness; therefore, the branded manufacturer can be seen as a proximate cause of the generic consumers' injuries. On the other hand, twenty states have explicitly rejected innovator liability and another twenty states and D.C. are likely to reject innovator liability. These states generally believe that companies cannot be responsible for products they did not directly manufacture and have emphasized that branded manufacturers owe no duty to generic consumers.

Section I introduced the lack of uniformity associated with the doctrine of innovator liability and the justifications states have used both in accepting and rejecting it. Section II details the issues with adopting a wider regime of innovator liability and ultimately argues, both with empirical evidence and court-produced reasoning, that adopting the doctrine would be detrimental to public health, tort laws, and principles of justice.

III. PROBLEMS WITH INNOVATOR LIABILITY

This Part introduces the problems inherent in generic immunity and innovator liability, concluding that innovator liability harms consumers and pharmaceutical companies. It then recommends eliminating immunity for generic drugs. Section II.A discusses how innovator liability negatively impacts public health, including decreasing innovation, increasing costs of medicine, lowering uptake of medicine among sick consumers, creating over-warning problems, and generating disparate impacts between states. Section II.B discusses how allowing generic consumers to sue branded drug companies distorts tort laws by circumventing traditional principles of duty and causation. Section II.C discusses the inherent unfairness in forcing branded companies to pay for the damages of their generic competitors. This discussion of the issues associated with innovator liability provides context for the solution presented in Part III, which introduces why the FDA should explicitly amend the FDCA to allow generic manufacturers to update their drug labels and to impose upon them a duty to follow the most recent research regarding their drugs.

A. Public Health

Shifting responsibility from generic drug manufacturers to branded manufacturers decreases the pace of innovation.¹¹⁶ Innovator liability forces the branded company to bear the costs of liability when such liability is divorced from the products it manufactures. The liability includes not only the costs of litigation and settlement with multiple plaintiffs alleging harm from any number of generic drugs that have copied their company's formula, but also the costs of reformulating the drug's warning label and sending updates regarding the drug to physicians and consumers.¹¹⁷ Historically, increased liability has discouraged innovation in the pharmaceutical industry.¹¹⁸ When the average cost of developing a new pharmaceutical product is \$2.5 billion dollars,¹¹⁹ and pharmaceutical companies face uncertainty over whether they will make a return on their profits, companies will be cautious when the opportunity to create a new product arises.¹²⁰ The impact, and even apprehension, of incurring such cost would make pharmaceutical companies wary of investing in novel and potentially life-saving medicines.¹²¹

The impact of decreased research would be felt primarily by small communities afflicted with rare or extremely life-threatening illnesses.¹²² Smaller patient communities, such as those with orphan

^{116.} Alberto Galasso & Hong Luo, *How Does Product Liability Risk Affect Innovation? Evidence from Medical Implants 4* (July 2, 2018) (unpublished manuscript) (“[M]edical implant patenting decreased by 36 percent relative to patenting in other medical device technologies after the increase in liability risk.”).

^{117.} See, e.g., Victor E. Schwartz, Phil Goldberg & Cary Silverman, *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 *FORDHAM L. R.* 1835, 1870-72 (2013) [hereinafter Schwartz et al., *Warning*] (arguing that saddling branded pharmaceutical companies with liability for their generic counterparts will cause them to accrue many costs, including litigation costs, that they would not have otherwise); Richard L. Manning, *Product Liability and Prescription Drug Prices in Canada and the United States*, 61 *J. L. & ECON.* 203, 217-34 (2018) (comparing the differences in product prices between different regions due to the differential risks of liability towards litigation).

^{118.} W. Kip Viscusi et al., *Detering Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 *SETON HALL L. REV.* 1437, 1454 (1994) (suggesting that overt tort liability can result in over-deterrence of pharmaceutical companies, causing them to creating a least a drug lag).

^{119.} Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds \$2.5B*, *Chemical & Engineering News* (Nov. 24, 2014), <https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/>.

^{120.} See Schwartz et al., *Warning*, *supra* note 117, at 1871 (observing that when it is riskier for brand-name manufacturers to develop their medicine, they may cease to produce the medicine).

^{121.} See *id.* As the fear of liability increases, the incentive for innovation decreases and causes the company to release less products.

^{122.} See Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 *CARDOZO L. REV.* 1139,

diseases—conditions that affect fewer than 200,000 people nationwide yet have profound impacts on health—have less potential for driving high revenue, making it likely that drug developers will not pursue pertinent research because of the cost-benefit analysis.¹²³ Pharmaceutical companies, worried about whether they can profit from their research and development investment due to potential liability from consumers of generics, will then deliberately target a broader segment of the population to the exclusion of orphan drugs. This broad targeting will aggravate the issue of companies creating safe blockbusters instead of truly innovative medicine that improves the health of the sickest individuals.¹²⁴

Ultimately, decisions affirming innovator liability will have a detrimental impact on consumers. Pharmaceutical companies, hoping to recoup their investment in the face of potential high litigation costs, will shift the costs to buyers.¹²⁵ Consumers of brand-name medications may have to pay more for branded drugs during the period of exclusivity, when the branded company is attempting to recover its profits, so that the manufacturer can accrue resources in anticipation of future liability claims.¹²⁶

Findings from courts that a drug company is liable for misrepresentation or failure to warn may cause the pharmaceutical company to change its drug label to appease the judge or jury and avoid future liability.¹²⁷ Companies will add information to the label based on singular instances of harm, that the FDA may have deemed unnecessary. Unnecessary labeling may give rise to over-warning

1153 (1987) (“If in the aggregate the net gains [to consumers and pharmaceutical companies] are wiped out by the liability costs, then the product will no longer be made. If some net gains survive, then fewer units will be produced to reflect the changes in rules and some marginal consumers must do without.”).

^{123.} See Schwartz et al., *Warning*, *supra* note 117, at 1871 (“[I]t will become riskier for brand-name manufacturers to dedicate resources to researching and developing potentially life-saving or life-improving medicines, particularly when those medicines have greater health risks or are for small communities of people that will not drive large revenues.”). The same risk applies to high-risk communities with severe medical conditions, where pharmaceutical companies are at greater danger of becoming exposed to litigation if the drug produces adverse side-effects that are more likely to be life-threatening or if the patient suffers from negative health conditions unrelated to the drug but believes the drug responsible.

^{124.} *Id.* (“Drugs with high litigation risk will be avoided in favor of safer blockbusters that can make up for these costs.”).

^{125.} *Id.* at 1870 (observing that drug companies will charge consumers more for their branded products when faced with the risk of litigation).

^{126.} *Id.* (“[C]onsumers would likely have to pay higher prices for brand-name drugs during the period of exclusivity so that the drugs’ manufacturers could amass resources for anticipated competitor liability claims.”).

^{127.} See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 581 (2009) (asserting that a brand-name manufacturer should comply with both state and federal law obligations, including compliance with labeling standards).

on drug labels.¹²⁸ Multiple studies have shown that too many warnings affixed to a drug decrease the effectiveness of each warning, lead to information overload for patients, and discourage patients from using an otherwise beneficial drug.¹²⁹ For example, after litigation over whether Effexor should have affixed more warnings regarding suicidality, the court ruled that adopting additional labeling would “encourage manufacturers to adopt ‘defensive labeling’ that might ‘overwarn’ doctors and patients of potential adverse effects.”¹³⁰ Over-warning may also result in information clutter—important information about researched side effects may be lost in the label among the other miscellaneous warnings, leading to negative information costs.¹³¹ Consumers may ignore the product labels due to being overwhelmed with information, or they may choose to not use a beneficial drug because they judge the risk of the side effects to be too significant, though the risk is truly minor.¹³²

The branded drug company may also cease to produce the drug at all once the generic form enters the market.¹³³ Branded companies are driven to exit by fear of liability for generic consumers. This exit deprives consumers of the version of the medicine created by the company with the most knowledge and research on the drug and the most infrastructure to continue to produce it.¹³⁴ Drugs may even be taken off the market entirely

^{128.} See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 FED. REG. 3922,01 (Jan. 24, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) [hereinafter Labeling Requirements] (asserting that tort claims alleging inadequate labels encourage pharmaceutical company to overwarn).

^{129.} See, e.g., Jon Duke et al., *A Quantitative Analysis of Adverse Events and “Overwarning” in Drug Labeling*, 171 JAMA INTERNAL MED. 944 (2011); Aaron S. Kesselheim et al., *Speaking the Same Language? International Variations in the Safety Information Accompanying Top-Selling Prescription Drugs*, 22 BMJ QUALITY & SAFETY 727 (2013).

^{130.} *FDA Ruling on Effexor Suicide Warning Trumps Okla. Tort Law*, 11 ANDREWS DRUG RECALL LITIG. REP. 5 (2008) (“Overwarning consequently would lead doctors to avoid prescribing the drugs, thus discouraging the appropriate use of a beneficial drug.”).

^{131.} Lars Noah, *The Imperative to Warn: Disentangling the “Right to Know” from the “Need to Know” About Consumer Product Hazards*, 11 YALE J. ON REG. 293 (1994).

^{132.} *Id.* (“Consumers either will begin to ignore product labels altogether, thereby missing other important information, or they will become alarmed by risks that were judged insufficient to warrant any more direct attempts to curtail use.”). The cost of formulating additional warnings and re-labeling every bottle is also an additional expenditure that pharmaceutical companies would have to bear, potentially resulting in higher prices for future drugs to offset these costs.

^{133.} See Schwartz et al., *Warning*, *supra* note 117, at 1870 (“[T]he fear of such liability would likely drive many brand-name manufacturers from a drug’s market once it becomes available in generic form.”).

^{134.} Although there are some rulings that even if a drug company divests its product to another pharmaceutical company, they—and not the subsequent

before the period of exclusivity has ended, because the branded company fears class-actions or continued findings of liability by courts.¹³⁵ Drugs whose full spectrum of effects are not fully known may be abandoned entirely because generic developers may not want to shoulder the burden of unknown liability or to invest in independent research and development to create the drug.¹³⁶ These drugs may actually be more beneficial than harmful, and they may have been found defective by a court that does not have the benefit of reviewing the scientific research and clinical trial evidence submitted to the FDA.¹³⁷

Finally, the adoption of innovator liability differs within the fifty states and D.C., resulting in disparate impacts to consumers.¹³⁸ Branded drug companies are currently paying damages to consumers in some states but not others, but the cost of their drug remains consistent across states. Drug consumers within states rejecting innovator liability are thus subsidizing those within states that allow innovator liability.¹³⁹ This problem is further exacerbated

manufacturer—may remain liable for the drug, this reasoning has been largely rejected.

^{135.} See Schwartz et al., *Warning*, *supra* note 117, at 1870.

^{136.} *Id.* (asserting that branded manufacturers are in the best position to create pharmaceuticals and contrasting the branded drug approval process with the less rigorous generic drug approval process); see generally Barbara M. Davit et al., *Highly Variable Drugs: Observations from Bioequivalence Data Submitted to the FDA for New Generic Drug Applications*, 10 AAPS J. 148 (2008) (observing that the formulas of generic drugs are different from those of branded companies).

^{137.} In cases where courts rule that a drug has a design defect, the judge or jury is making a decision solely based on the specific instance of harm instead of the full scientific picture and broader potential of the drug. See *Lance v. Wyeth*, 85 A.3d 434, 458-59 (Pa. 2014).

^{138.} See, e.g., Gregory Bell et al., *Managing Product Liability in the Pharma & Healthcare Sector*, CORP. DISPUTES MAG., Jan.–Mar. 2015, at 1, 11 (2015) (describing how differences in liability may cause pharmaceutical companies to make divergent choices in different jurisdictions); Thamir M. Alshammari et al., *Comparison of the Safety Information on Drug Labels in Three Developed Countries: The USA, UK and Canada*, 25 SAUDI PHARMACEUTICAL J. 1103, 1103 (2017) (describing how the differences in regulation of medicine has caused the same brand of medicine to produce different warning labels in different regions).

^{139.} See, e.g., John Tierney, *Which States Are Givers and Which Are Takers*, THE ATLANTIC (May 5, 2014), <https://www.theatlantic.com/business/archive/2014/05/which-states-are-givers-and-which-are-takers/361668/> (discussing how consumers of different states disparately use federal tax dollars). Although this argument of disparate use pertains to taxes, it can be generalized to corporations that sell products in all states. When consumers of all states are utilizing a pharmaceutical company's product, but consumers in some states are receiving a payout from litigation whereas others in another state are not, the second set of consumers are effectively subsidizing the first set of consumers by paying for the product. See David W. Sommer, *The Impact of Firm Risk on Property-Liability Insurance Prices*, 63 J. RISK & INS. 501, 512 (1996) (observing that observance of higher risk will cause manufacturers to take out higher levels of insurance).

when pharmaceutical companies take out expensive liability insurance to continue selling their drugs to consumers in states that accept innovator liability.¹⁴⁰ Pharmaceutical companies may also implement different warning labels across states to reflect court decisions in each individualized state, resulting in different labels for states that accept versus reject innovator liability.¹⁴¹ Differing labels put consumers in different positions with respect to the information available to them and exacerbates the problem of over-warning in some states but not others.¹⁴²

B. Distortion of Tort Law

1. Overarching Principles

Tort law serves many functions, including regulating conduct, enhancing the availability of risk information, bringing corrective justice, and serving as a deterrent. A fundamental principle of traditional product liability law is that the plaintiff must prove the defendant supplied the product which caused the injury.¹⁴³ When the person who pays damages is the entity that directly produced the product, the goals of tort law are at work.¹⁴⁴ The manufacturer is incentivized to change its conduct, such as updating its warnings, improving its product, or leaving the market, thereby helping future consumers of the product.¹⁴⁵ The patient

^{140.} See Bell, *supra* note 138, at 12 (describing how increased chance of lawsuit causes pharmaceutical companies to take out expensive liability insurance). The insurance fees are reflected in increased cost of drugs, which are distributed among consumers of all the states, meaning patients within states that reject innovator liability are paying higher prices than they normally would. See, e.g., Walter Y. Oi, *The Economics of Product Safety*, 4 BELL J. ECON. & MGM'T SCI. 3, 8 (1973) (indicating that prices of insurance premiums are factored into the ultimate price of the products the company makes).

^{141.} See Bell, *supra* note 138, at 11. The difference reflected in pharmaceuticals across jurisdictions may not just be prices but also in the warning labels.

^{142.} See, e.g., Kate Sheridan, *Here's Why Everything Gives You Cancer in California*, NEWSWEEK (Feb. 3, 2018), <https://www.newsweek.com/heres-why-everything-gives-you-cancer-california-798750> (observing that when warning labels are different in one state, in this case California, consumers react differently to the product).

^{143.} See generally Richard W. Wright, *Causation in Tort Law*, 73 CAL. L. REV. 1735 (1985) (explaining the importance of the causation requirement in tort law).

^{144.} See generally JULES L. COLEMAN, *RISKS AND WRONGS* (1992); ERNEST J. WEINRIB, *THE IDEA OF PRIVATE LAW* (1995) (explaining that charging the direct manufacturer is important to retributive justice). See generally Donald G. Gifford, *The Death of Causation: Mass Products Torts' Incomplete Incorporation of Social Welfare Principles*, 41 WAKE FOREST L. REV. 943 (2006) (arguing that not sticking to individualized causation for torts risks turning tort law into a social welfare system).

^{145.} See Jonathan C. Mosher, *A Pound of Cause for a Penny of Proof: The Failed Economy of an Eroded Causation Standard in Toxic Tort Cases*, 11 N.Y.U. ENVTL. L.J.

who was injured is directly compensated by the company that produced the substance which harmed them, bringing corrective justice and deterring the company from future harmful behavior.¹⁴⁶

Allowing a plaintiff to bring suit against the manufacturer that did not create the injury-causing product circumvents traditional principles of tort law.¹⁴⁷ The generic pharmaceutical company avoids liability and therefore does not have the same incentive to improve its warning labels or proactively research the safety and efficacy of the drugs it distributes to the public.¹⁴⁸ On the other hand, innovator liability creates a problem of over-deterrence of branded pharmaceutical companies, as they are held liable for the injuries that other companies have caused.¹⁴⁹ Many of these companies may have already ceased creating the drug altogether, meaning that there is no room for them to change their behavior or for them to impact the actions of the generic manufacturer.¹⁵⁰

531 (2003) (arguing that traditional incentives for manufacturers are eroded when there is no direct tort causation liability).

^{146.} See generally WILLIAM M. LANDES & RICHARD A. POSNER, *THE ECONOMIC STRUCTURE OF TORT LAW* (1987); STEVEN SHAVELL, *ECONOMIC ANALYSIS OF ACCIDENT LAW* (1987); see Michael D. Hausfeld et al., *Toxic Torts: The Need for a New Rule of Law*, c864 ALI-ABA 223, 227 (describing that one of the functions of tort law is to identify and punish the wrongdoer).

^{147.} LAWRENCE G. CETRULO, 1 *Toxic Torts Litigation Guide* §5.2 (2018) (observing that cause-in-fact is a traditional aspect of tort law and that torts that circumvent this principle go against the norm).

^{148.} Branded pharmaceutical companies typically have superior infrastructure to their generic counterparts. See generally Tyler W. Olson, *The Supreme Court's Overreaching Preemption Interpretation and Its Consequences: Granting Generic Drug Manufacturers Legal Immunity Through "The Duty of Sameness" in Mutual Pharmaceutical Co. v. Bartlett and Pliva v. Mensing*, 12 *IND. HEALTH L. REV.* 769, 772 (2015) (observing that subverting the causation requirement and requiring branded companies to pay damages subverts liability for generic manufacturers). By punishing only the branded company, the generic companies continue to market and distribute their drugs unhindered by duties to their consumers. *Id.* at 809 (asserting that under the regime of innovator liability generic drug companies avoid liability and do not have a responsibility to update their labels).

^{149.} See Viscusi, *supra* note 118, at 1454.

^{150.} See, e.g., *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 48 (Cal. 2017) (Corrigan, J., dissenting) (arguing that companies should not be liable when they have divested themselves of the product). See also *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 710 (D. Vt. 2010); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014) (where the defendant branded company was still held liable for injuries created by the generic pharmaceutical), *superseded by statute*, ALA. CODE § 6-5-530 (2019). There may be a counterargument for corrective justice – that choices about labeling were made by the innovator company with full knowledge of FDA labeling rules and that generic companies will copy their labels. However, corrective justice principles rely on the concept of duty between the entities. It is difficult to argue that a branded manufacturer owes a duty to a consumer of a competitor's product, especially when the competitor has not been found to owe that duty. For more discussion on duty, see *infra* Section II.B.3.

Ultimately, the doctrine of innovator liability rests on theories of deep-pocket jurisprudence.¹⁵¹ When a sympathetic plaintiff, especially one who has suffered a serious injury, presents their case in front of a sympathetic jury, they are likely to recover from the defendant even if the defendant is not directly responsible for the injury.¹⁵² However, not only is deep-pocket jurisprudence an unjust mechanism of compensation that circumvents traditional tort goals of regulating conduct, corrective justice, and deterrence, it also comes without a limiting principle.¹⁵³ If innovator liability becomes established doctrine, the ideology behind competitor liability may migrate from pharmaceuticals to other industries where imitation is common, such as medical devices and biotechnology.¹⁵⁴

a. Duty

Innovator liability theories that rest on principles of negligence and strict liability would also circumvent traditional concepts of duty by establishing that companies owe duties to the customers of their competitors.¹⁵⁵ Duty is traditionally established in a relationship only when there is a pre-existing relationship between two entities.¹⁵⁶ However, when individuals buy

^{151.} See generally Victor E. Schwartz et al., *Deep Pocket Jurisprudence: Where Tort Law Should Draw the Line*, 70 OKLA. L. REV. 359, 367-69 (2018) [hereinafter Schwartz et al., *Deep Pocket*] (explaining that innovator liability is among many forms of deep-pocket jurisprudence in tort law).

^{152.} KNOX D. NUNNALLY & RONALD G. FRANKLIN, 4 *Tex. Prac. Guide Torts* § 15:52 (2019) (“Juries tend to award higher verdicts in favor of plaintiffs with whom they identify or to whom they are sympathetic.”). The chance of a payout becomes even more likely when it is known that the defendant is a large company with a wealth of funds. See Schwartz et al., *Deep Pocket*, *supra* note 151, at 367-69 (describing that expanding deep-pocket jurisprudence in innovator liability will force innovators from other industries to become liable for products they did not make).

^{153.} See Schwartz et al., *Deep Pocket*, *supra* note 151, at 367-69.

^{154.} Defendants in other industries could find themselves responsible for products that they did not manufacture or distribute Victor E. Schwartz, *Deep Pocket*, *supra* note 151, at 368 (“Where would such liability stop? If a car seat manufacturer recognized as an industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor’s seat that copied the design?”).

^{155.} See generally Weeks, *supra* note 7 (observing that innovator liability requires an innovator company to pay for its competitors).

^{156.} See, e.g., *Lawrence v. Grinde*, 534 N.W.2d 414, 416, 423 (Iowa 1995) (establishing duty between attorney and client); *Crisci v. Sec. Ins. Co. of New Haven, Conn.*, 426 P.2d 173, 175, 179 (Cal. 1967) (establishing duty between an insurer and an insured); *Hamilton v. Ford Motor Credit Co.*, 502 A.2d 1057, 1059, 1064-65 (Md. Ct. Spec. App. 1986) (establishing duty between a creditor and debtor); *Burgess v. Superior Court*, 831 P.2d 1197, 1198 (Cal. 1992); *Marlene F. v. Affiliated Psychiatric Med. Clinic, Inc.*, 770 P.2d 278, 279 (Cal. 1989); *Molien v. Kaiser Found. Hosps.*, 616 P.2d 813, 814, 821 (Cal. 1980)

pharmaceutical products from a generic manufacturer, they are not building a relationship with the branded producer. In fact, they are supporting the branded manufacturer's competitor, undercutting the company's profits and their ability to manufacture and market their own drugs.¹⁵⁷ The fact that the branded pharmaceutical company created the initial drug does not itself warrant an expansive duty of care that includes consumers of a competitor company with a similar product.¹⁵⁸

Courts that have adopted a theory of innovator liability have sometimes argued that while an innovator is not responsible for "another manufacturer's production, design, or manufacturing defect," a negligent misrepresentation claim can still be asserted because "a warning label is not a part of the manufacturing process."¹⁵⁹ However, this distorts traditional principles of product liability, which recognizes that designs and warnings are intertwined as complementary aspects of manufacturing.¹⁶⁰ When a product's design cannot eliminate its inherent risks, such as with pharmaceuticals, a warning is necessary to mitigate the dangerousness of the product and render it non-defective.¹⁶¹

The FDCA does not explicitly create a statutory duty for either branded or generic manufacturers towards their consumers. However, it creates implicit duties by requiring that manufacturers prove their drugs are safe prior to marketing them to the general public.¹⁶² Generic drugs have the same duty of safety, but they can currently satisfy their legal obligation by proving their bio-equivalency to the branded drug and applying the same labeling.¹⁶³

(establishing duty between a physician and a patient); *Boyles v. Kerr*, 855 S.W.2d 593, 594 (Tex. 1993) (establishing duty between former intimate partners).

^{157.} See Angela M. Higgins, *A Possible Perfect Storm: The Reanimated Innovator-Liability Theory*, 60 No. 4 DRI For Def. 60, April 2018 (observing that generic and branded pharmaceutical companies engage in independent conduct). See, e.g., *Moretti v. Wyeth, Inc.*, 579 F. App'x 563 (9th Cir. 2014) (indicating that the duty element is not met in innovator liability); *Metz v. Wyeth, Inc.*, 830 F. Supp. 2d 1291 (M.D. Fla. 2011) (observing that brand-name manufacturers owe no duty to consumers of generic drugs).

^{158.} *Schwartz et al., Deep Pocket*, *supra* note 151, at 361 ("The mere fact that the innovator created, designed, or manufactured the initial product does not create such an expansive duty of care.").

^{159.} *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 670 (Ala. 2014), *superseded by statute*, ALA. CODE § 6-5-530 (2019).

^{160.} See David G. Owen, *The Puzzle of Comment J*, 55 HASTINGS L.J. 1377, 1397 (2004) (observing the relationship between design and warning defects).

^{161.} See, e.g., Restatement (Second) of Torts § 402A cmt. j (AM. LAW INST. 1965) (indicating that there is a relationship between designs and warnings, and that sometimes a warning can compensate for an unavoidably unsafe product).

^{162.} See, e.g., Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 (detailing prohibited acts and penalties that would accrue to manufacturers that create unsafe products).

^{163.} U.S. FOOD & DRUG ADMIN., PRODUCT-SPECIFIC GUIDANCES FOR GENERIC DRUG DEVELOPMENT (2019).

However, since 2013, the FDA has considered imposing a new rule that would require generic manufacturers to change their product safety labels, regardless of what the branded manufacturer does.¹⁶⁴ If the generic company had authority over their own labeling, they would also have a duty of care towards their consumers. Thus, while generic manufacturers are not currently legally liable under the FDCA, the FDA's intention is to eventually create a duty of care that generics must abide by.¹⁶⁵

b. Foreseeability

Under traditional tort principles, foreseeability is the touchstone of proximate cause.¹⁶⁶ The defendant's negligence is a proximate cause of the injury if the defendant should have foreseen his or her actions would cause the injury.¹⁶⁷ Foreseeability is also typically a jury's opportunity to practice public policy and determine if a defendant is involved in the chain of liability.¹⁶⁸ Directness and remoteness underlie jury determinations of foreseeability.¹⁶⁹ In a classic example, if a defendant negligently moors a boat and the boat becomes adrift and bumps into another boat, causing it to damage a drawbridge three days later, the negligent action is considered too remote to the injury to be a proximate cause.¹⁷⁰ In the case of innovator liability, juries may consider the lapse in time between when the innovator created the medicine and the injury of the plaintiff. They may also consider when the generic manufacturer produced the drug relative to the branded company. Juries may find that injuries to generic consumers are indeed foreseeable to innovators because there is a clear chain of causation emerging from closeness in time and space.

However, some courts have ruled that foreseeability is a matter of duty and so judges instead of fact-finders should make the categorical determination of whether injury to a generic consumer is foreseeable.¹⁷¹ While some courts still rely on the concepts of

^{164.} See U.S. Food & Drug Admin., Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products (Nov. 13, 2013) [hereinafter FDA Labeling Proposal], <https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/economicanalyses/ucm375128.pdf> (describing a website where the FDA would place adverse effect information submitted by drug manufacturers that can quickly reach providers and consumers).

^{165.} *Id.* (supporting that ANDA holders would need to follow certain labeling requirements that broadly disseminate their drug information).

^{166.} See generally LANDES & POSNER, *supra* note 146.

^{167.} *Id.*

^{168.} KENNETH S. ABRAHAM, THE FORMS AND FUNCTIONS OF TORT LAW 146 (4th ed. 2012).

^{169.} *Id.*

^{170.} *Id.*

^{171.} Palsgraf v. Long Island R.R. Co., 248 N.Y. 339, 344 (1928).

closeness in space and time, many courts have migrated away from that calculus.¹⁷² Courts that analyze foreseeability from a duty perspective mostly agree that when consumers of generic drugs suffer injuries, the generic rather than the branded manufacturer owed their consumers the duty to protect them against injuries.¹⁷³ Most courts agree branded manufacturers do not owe a duty of care to consumers of generic pharmaceuticals.¹⁷⁴

Courts that have adopted innovator liability argue that it is foreseeable to branded companies that their warnings and designs will influence consumers of the generic drugs.¹⁷⁵ However, such an argument risks extending the concept of foreseeability too far; injuries sustained from generic drugs are not the foreseeable result of conduct from the branded manufacturer, but “of the laws over which the brand manufacturers have no control.”¹⁷⁶ Ultimately, Congress and state legislatures are responsible for extending laws that encourage pharmacies to fill prescriptions with the generic rather than branded drugs, and it is an overextension of foreseeability to argue branded companies should account for all factors that could influence generic consumers.

Even in the post-*Mensing* legal landscape, where branded pharmaceuticals are aware that generics will copy the better part of their design and labeling, the injuries to the consumer may still not be foreseeable. Although the generic drug is supposed to be bioequivalent to the branded drug—meaning that they effectively have the same safety, effectiveness, strength, stability, and quality—its formula, and in particular its inactive ingredients, are different.¹⁷⁷

^{172.} See Abraham, *supra* note 168, at 147 (“Both remoteness and directness, however, have tended to fade away as tests for analyzing the proximate cause issue.”).

^{173.} See, e.g., Foster v. Am. Home Prods. Corp., 29 F.3d 165, 169-70 (4th Cir. 1994); Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 184 (5th Cir. 2012).

^{174.} See *supra* Section I.C.2.

^{175.} See, e.g., Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299, 313 (Ct. App. 2008) (“[I]t is also eminently foreseeable that a physician might prescribe generic metoclopramide in reliance on Wyeth's representations about Reglan.”).

^{176.} See *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014). Branded companies cannot foresee any number of factors that influence the consequent injury, including the exact formulation of the generic drug which may contain different inactive ingredients, how the generic company packages the warning label, which drug the pharmacies fill the prescription with, etc. See generally Giuseppe Borgheini, *The Bioequivalence and Therapeutic Efficacy of Generic Versus Brand-Name Psychoactive Drugs*, 25 CLINICAL THERAPEUTICS (2003) 1578 (analyzing the differences between various generic and innovator drugs and finding that there was variability even in bioequivalent generic drugs).

^{177.} U.S. FOOD & DRUG ADMIN., GENERIC DRUG FACTS (2018) [hereinafter GENERIC DRUG FACTS], <https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/genericdrugs/ucm167991.html>; see, e.g., Borgheini, *supra* note 176

Thus, while the active ingredient needs to remain the same, generic drugs are rarely exact copies of the branded medicine.¹⁷⁸ These discrepancies may ultimately lead to different medical results.¹⁷⁹ Furthermore, even if the branded and generic drugs are bioequivalent on average, there is uncertainty as to how they impact individual patients with different arrays of conditions and medical sensitivities.¹⁸⁰ Thus, there is enough of a difference between the formula of branded and generic pharmaceuticals that injuries to specific individuals from taking the generic drug may not be directly attributable to the design of the branded drug and would not be foreseeable.

c. Alternative Liability

Innovator liability differs from traditional theories of alternative liability and market-share liability, which also implicate manufacturers that did not cause the injury.¹⁸¹ With innovator liability, the plaintiff understands which entity created the product that caused harm.¹⁸² However, the plaintiff cannot sue them because they are immune from liability.¹⁸³ The branded manufacturer then serves as a proxy in the lawsuit for its generic

(explaining that even if the FDA finds that drugs are bio-equivalent, the drugs often have variable effects on the human body).

^{178.} See Borgheini, *supra* note 176.

^{179.} See generally Giuseppe Borgherini, *The Bioequivalence and Therapeutic Efficacy of Generic Versus Brand-Name Psychoactive Drugs*, 25 CLINICAL THERAPEUTICS 1578 (2003) (explaining that despite generic drugs having the same active ingredients as their branded counterparts, they do not necessarily have the same impact on the human body). See P. Crawford et al., *Are There Potential Problems with Generic Substitution of Antiepileptic Drugs?*, 15 SEIZURE 165 (2006) (describing that seizure patients react differently not only to generic versus branded medicines but also to different types of generic medication).

^{180.} See generally Jeremi M. Carswell et al., *Generic and Brand-Name L-Thyroxine Are Not Bioequivalent for Children with Severe Congenital Hypothyroidism*, 98 J. CLINICAL ENDOCRINOLOGY & METABOLISM 610 (2013) (discussing how health conditions can alter the effectiveness of generic versus name-brand medicine).

^{181.} See generally Allen Rostron, *Beyond Market Share Liability: A Theory of Proportional Share Liability for Nonfungible Products*, 52 UCLA L. Rev. 151 (2004) (asserting that market share liability also implicates actors that are outside of the scope of but-for causation).

^{182.} See, e.g., *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Ct. App. 2008); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205 (Mass. 2018); *Lance v. Wyeth*, 85 A.3d 434, 458 (Pa. 2014); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 710 (D. Vt. 2010); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014) (where the defendant sued both the generic and branded manufacturers, knowing that the product they consumed was manufactured by the generic defendant), *superseded by statute*, ALA. CODE § 6-5-530 (2019).

^{183.} See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011) (ruling that FDA regulation of generic manufacturers preempted suits brought under state tort law).

counterpart from which the patient can recover damages.¹⁸⁴ Thus, while alternative liability and market-share liability allow for the possibility—however remote—of recovering from the responsible defendant, innovator liability yields no probability of holding the direct manufacturer responsible.¹⁸⁵

C. Unfairness

There is inherent injustice in imposing punitive judgment on a company for the transgressions of its competitor.¹⁸⁶ The innovator might not have committed an offense; it likely spent billions of dollars and many years improving the drug's safety and efficacy and ushering it through FDA approval.¹⁸⁷ To fulfill the requirements of the FDCA, the branded manufacturer must move through discovery and development, preclinical research, clinical trials, and finally submit their findings to be analyzed by a trained team of doctors, chemists, pharmacologists, and other scientists; all of these efforts ensure the manufacturer satisfies its obligation towards consumers to create as safe a drug as possible.¹⁸⁸ On the other hand, the FDCA imposes only minimum requirements on generic manufacturers. The generic company latches onto the branded manufacturer's innovation, investing much less time and fewer resources to copy the design and labeling of the original drug.¹⁸⁹ It then markets the drug for a fraction of the price and reaps hundreds of millions in profits without enduring the research and development stages such as burdensome clinical trials.¹⁹⁰ When a branded company pays damages to the generic consumer, it is paying a consumer who not only used competing products but also financially contributed to a competing company.

^{184.} Bridget M. Ahmann & Erin M. Verneris, *Name Brand Exposure for Generic Drug Use: Prescription for Liability*, 32 *HAMLIN L. REV.* 767, 769 (2009) (describing that patients that cannot sue the generic drug company will sometimes resort to suing the branded manufacturer).

^{185.} *Id.* (observing that the name-brand manufacturer is responsible even when they did not make the drug responsible for the injuries).

^{186.} *See Weeks*, *supra* note 7, at 1259 (asserting the unfairness of innovator companies picking up the tabs for their competitors).

^{187.} *See Mullin*, *supra* note 119.

^{188.} 21 U.S.C.A. §§ 321 et seq. (West 2019).

^{189.} *See* 21 U.S.C. §§ 355(j)(2)(A)(ii)-(iii) (2015) (explaining generic drugs are subject to a duty of sameness with branded medicines). *See also Olson*, *supra* note 148, at 781-82 (explaining that generic drugs can simply copy the design and labeling of branded drugs).

^{190.} U.S. GOV'T ACCOUNTABILITY OFF., *GAO-18-40, PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGERS AND ACQUISITION DEALS* (2017) [hereinafter *GAO REPORT*] (“[P]harmaceutical and biotechnology sales revenue increased from \$534 billion to \$775 billion” between 2006 and 2015.).

There is also an imbalance in the liability exposure of brand-name and generic drug manufacturers. Whereas branded manufacturers create 10% of the drugs on the market, they are responsible for 100% of the damage payouts in the market under innovator liability.¹⁹¹ Furthermore, the branded manufacturers that do bear 100% of the liability, due to principles of deep-pocket jurisprudence, are not even necessarily the most profitable manufacturers in the market.¹⁹² Imposing greater liability on the minority of the market then creates a positive feedback loop; as the branded company's percentage of the market continues to shrink and the generic manufacturers increase and multiply in the market.¹⁹³

This injustice is further exacerbated by the fact that the generic manufacturer rides on the coattails of the branded manufacturer's statements and advertising to sell its own products.¹⁹⁴ By the time the generic manufacturer enters the market with its cheaper drug, the efficacy and reputation of the drug have already been established.¹⁹⁵ In several court cases involving innovator liability, physicians prescribed drugs solely based on the reputation that the branded drugs cultivated throughout the community.¹⁹⁶ Furthermore, generic substitution laws often allow,

^{191.} See Schwartz et al., *Warning*, *supra* note 117, at 1870 (“Saddling 10 percent of a market with 100 percent of its liability is certain to create new and significant financial pressures on brand-name drugs, the effects of which would harm health care consumers.”).

^{192.} The gross profit that generic pharmaceuticals make is more than the profits of the branded manufacturer due to their high volume of distribution, lack of research and development costs, and lack of legal liability. *Id.* (describing the unfairness of saddling innovator companies with all the liability of the market). Ranit Mishori, *Why Are Generic Drugs Cheaper than Brand-Name Ones?*, WASH. POST, July 11, 2011 (“Generic makers don’t face the same costs as manufacturers of brand-name drugs. That’s because the brand-name maker often invented the drug, a process that can cost hundreds of millions of dollars.”).

^{193.} See Schwartz et al., *Warning*, *supra* note 117, at 1870-1872 (describing that when generic manufacturers enter the market, the brand-name manufacturers may exit the market, decreasing its market share and increasing the market share of the generic drug).

^{194.} *Id.* at 1867; *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) (“[T]he premarketing approval scheme Congress established for generic equivalents of previously approved drugs cannot be construed to create liability of a name brand manufacturer when another manufacturer's drug has been consumed.”).

^{195.} See, e.g., *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Ct. App. 2008) (where the physician prescribed the branded version of the drug but the patient eventually took the generic version). With generic substitution laws, the generic version of the drug is increasingly given to the patient even if it was not prescribed. While the physician may prescribe the branded version of the drug, many states have laws where pharmacists are required to dispense the cheapest generic version. This means that generic drugs are often able to sell their medicine even without brand recognition or advertisement.

^{196.} *Id.*

or even require, the pharmacist to substitute the branded drug with the generic unless the physician specifies otherwise.¹⁹⁷ Thus, the injustice of the generic company not accruing legal costs from product liability litigation is compounded: it does not need to promote its medicine to physicians and the public because it can piggyback off the branded manufacturer's efforts.¹⁹⁸

Furthermore, the branded manufacturer can continue to accrue responsibility even after it has divested the formula of its drug to another pharmaceutical company and have themselves ceased to manufacture the drug.¹⁹⁹ Meanwhile, generic manufacturers, which continue to produce and profit off the drug, have no duty to update their warning labels or conduct continued analysis that would inform the safety of the consumer, even though they are in the best position to do so.²⁰⁰ Such a result cuts against traditional notions of protecting consumers and promoting public health. Ultimately, the detriment to public health, distortion of tort law, and injustice associated with innovator liability are substantial enough to warrant a federal solution.²⁰¹

IV. A POSSIBLE ALTERNATIVE TO INNOVATOR LIABILITY

Part II showed that innovator liability has the potential to harm markets, reduce opportunities for the consumer, distort the purposes of tort law, and produce unfair outcomes for manufacturers. This Part proposes a solution and outlines how the solution would rectify each of the individual harms from Part II. This Note recommends that the FDA modify the FDCA, which, as

^{197.} See HHS REPORT, *supra* note 29.

^{198.} See Schwartz et al., *Warning*, *supra* note 117, at 1842-44 (explaining that generic drugs have a shorter ANDA process compared to branded drugs and can use the research of branded manufacturers). Often the generic manufacturer uses the clinical studies done by branded manufacturers to establish the safety of their drug.

^{199.} See *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18 (Cal. 2017). Thus, long after they are no longer able to keep abreast of scientific literature that informs the safety and efficacy of the drug, they would still be responsible for public knowledge of the side effects and latest developments regarding that drug.

^{200.} See generally Gregory J. Feeney, *Pliva, Inc. v. Mensing: How Generic-Drug Manufacturers Avoided Liability for "Failure to Warn" Tort Claims*, 58 LOY. L. REV. 251, 252 (2012) (noting that generic pharmaceuticals currently do not have a duty to warn); Beatrice Skye Resendes, *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, 112-13 (2009) (noting that pioneer drugs have a duty to update their label but that generic drugs do not have the same duty).

^{201.} Although the exclusionary rights that branded manufacturers receive to solely profit from their drug for a period of time ameliorate some of these concerns, they do not outweigh the injustice of branded manufacturers being subject to continued liability for generic drugs that they did not manufacture.

previously discussed, imposes duties on branded companies, such that it also creates duties for generic manufacturers, including duties to keep abreast of current research regarding its drugs to modify warning labels to reflect updated research. The FDCA should allow generics to vary their labels so that they are not identical to the labels of branded drugs or to each other's labels. Although modification of the FDCA would create more duties for generic companies, it would also give them the freedom to take control of their own labeling and advertising, including sending Dear Doctor letters, or correspondences intended to alert doctors and other healthcare providers about important new or updated information about a marketed drug. This Note argues that modifying the FDCA is the optimal solution for combatting the inherent problems with innovator liability.

Currently, the *Mensing* doctrine dictates that product liability suits against generic pharmaceutical companies are preempted.²⁰² The Supreme Court's reasoning in this decision was that generic drugs are bound to a "duty of sameness" imposed by the FDA—that their medical effects and label must be the same as the branded drug—and therefore the FDA labeling law preempts state tort claims against generic manufacturers.²⁰³ Since 2011, there have been proposed amendments to change the "duty of sameness" and impose a greater duty upon generic manufacturers.²⁰⁴ For example, in 2013, the FDA proposed a rule that would allow generic drug manufacturers to use the same process available to branded manufacturers to update their labeling information, speeding up the release of safety information to medical professionals.²⁰⁵ The new rule would allow generic companies to update their labels independently of branded manufacturers.²⁰⁶ The FDA is still in the decision-making process and has not released a final rule.²⁰⁷

The FDA should revamp its efforts to modify the FDCA to allow generics to update their labeling independently of branded

^{202.} *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011).

^{203.} *Id.*; see generally Olson, *supra* note 148 (discussing how the duty of sameness means FDA regulations preempt tort suits against generic companies).

^{204.} FDA Takes Action to Speed Safety Information Updates on Generic Drugs, FOOD & DRUG ADMIN. (Nov. 8, 2013), available at <https://wayback.archive-it.org/7993/20170111161039/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm374171.htm>.

^{205.} *Id.*

^{206.} See FDA Labeling Proposal, *supra* note 164.

^{207.} See Thomas M. Burton, *FDA Withdraws Proposed Rule That Would Have Exposed Generic-Drug Makers to Liability*, WALL ST. J. (Dec. 13, 2018), <https://www.wsj.com/articles/fda-withdraws-proposed-rule-that-would-have-exposed-generic-drug-makers-to-liability-11544726478>.

manufacturers.²⁰⁸ Doing so would place the burden of updating consumers on generic rather than merely branded companies.²⁰⁹ Thus, generic companies would no longer be able to rely on copying branded manufacturers' labeling information and would have to stay abreast of scientific research and developments related to their medicine, updating the label whenever they learn of adverse effects.²¹⁰

Creating a duty for generic manufacturers to keep abreast of ongoing research and update the product label would create a cause of action for consumers when these companies do not fulfill their duty.²¹¹ Such a duty would hold generic drug companies responsible for adverse health effects engendered by their drugs when they simply copy the labeling of the branded company.²¹² This would grant a source of relief to the vast majority of patients who rely on generic rather than branded medication for health conditions and may suffer from adverse consequences from side effects of the drugs.²¹³ A cause of action against generic drug companies would be especially helpful for patients who reside in states that do not accept or are not likely to accept innovator liability. These patients currently have no recourse against any drug manufacturers when they suffer from adverse health consequences—they have no choice but either to litigate against their doctor or pharmacist or accept that they will not be compensated for their injuries.²¹⁴

^{208.} The rule currently under consideration would have all generic drug labels be homogeneous such that when generics update their labels, other generics and the branded manufacturer must also reflect the change. Although this imposes a duty of care upon generics, the recommendations of this Note differ from the proposed rule. This Note suggests that each generic manufacturer be independently responsible for the impacts of their unique drugs.

^{209.} See generally Fitch Solutions Grp., *Renewed Focus on Generic Drug Labelling Issues May Finally See a Solution* (Oct. 9, 2018), <https://www.fitchsolutions.com/corporates/healthcare-pharma/renewed-focus-generic-drug-labelling-issues-may-finally-see-solution-09-10-2018> (describing how the new FDA rule would enable generic pharmaceutical companies to update their labeling independent of branded labeling).

^{210.} *Id.* (noting that the new initiative would encourage generic manufacturers to keep the labeling of their drugs up to date).

^{211.} See Burton, *supra* note 207 (describing how generic companies would be exposed to liability if the rule passes).

^{212.} *Id.* (observing that generic drug companies would be responsible for changing their own drug labels).

^{213.} Ass'n for Accessible Medicines, *Generic Drug Access & Savings in the U.S., The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report* (May 9, 2019) at 8 [hereinafter **GENERIC DRUG ACCESS**] (observing that prescriptions for generic medicines account for 89% of prescriptions dispensed), available at <https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>.

^{214.} See, e.g., *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 664 (Ala. 2014) (asserting that when no cause of action exists against a pharmaceutical company, a cause

Generic manufacturers accrue hundreds of millions of dollars in profits and can afford to pay damages to consumers who have adversely suffered from their products.²¹⁵ Doing so would relieve innovator companies of a financial burden and allow them to take more risks in research and development.²¹⁶ Ultimately this would give branded companies more incentive to develop pioneering drugs for diseases that present a higher risk of liability—such as rare diseases—that could be used to treat the most vulnerable of patient populations.²¹⁷

Imposing a duty to warn upon generic manufacturers would decrease the problem of over-warning in drug labeling. Branded drugs would have less need to update their labeling in response to court decisions as courts would increasingly find that generic labels are in need of revamped warnings.²¹⁸ As the number of lawsuits against branded manufacturers decreases, branded manufacturers would have a lessened burden of adding unnecessary side-effects into their labels.²¹⁹ Thus, branded companies could focus on crafting warning labels—approved by FDA scientists and researchers—that reflect the spectrum of side effects specific to their drugs. They will no longer need to add content based on judicial opinions that can overcrowd the label without necessarily reflecting the side effects of their drug.²²⁰ Consumers of branded pharmaceuticals will benefit

may lie against the learned intermediary), *superseded by statute*, ALA. CODE § 6-5-530 (2019).

^{215.} See GAO REPORT, *supra* note 190. The counterargument is that if generic manufacturers pay out damages then they will have to raise the cost of their products, resulting in less affordable medication. However, this effect can be offset by companies purchasing liability insurance to protect against high litigation costs. Furthermore, as there are multiple generic companies on the market producing the same medicine, there will continue to be price competition that drives prices down.

^{216.} See Epstein, *supra* note 122 (arguing that removing financial burdens from innovator companies will incentivize research and innovation).

^{217.} See Mark Crane, *When Missing a ‘Zebra’ Can Land You in Court*, MEDSCAPE (Feb. 20, 2018), <https://www.medscape.com/viewarticle/892452> (asserting that rare diseases present a case ripe for malpractice and result in legal settlements of millions of dollars). W. Kip Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976–1989*, 24 SETON HALL L. REV. 1418, 1419 (1994) (“[T]he net effect of the surge in liability costs had been to discourage innovation in the pharmaceutical industry.”).

^{218.} See Burton, *supra* note 207.

^{219.} See Labeling Requirements, *supra* note 128 (noting that lawsuits cause companies to add labels to their products that result in overwarning).

^{220.} See, e.g., *Carlin v. Superior Court*, 920 P.2d 1347, 1348 (Cal. 1996) (“We are also unpersuaded by Upjohn’s assertion that applying strict liability to claims of injury for failure to warn will inevitably result in manufacturers inundating consumers with warnings of even speculative risks from prescription drugs.”).

from decreased label clutter and increased clarity with respect to adverse effects.²²¹

Although counterintuitive, consumers of generic drugs would also benefit from generic pharmaceutical companies independently updating the warning labels of their products. Generic drug companies would be responsible for updating their labels in accordance with what is foreseeable from their products—that is, adverse events suffered by their consumers instead of consumers of other generic brands or of the branded label.²²² The warning labels of generic medications would no longer mirror that of the branded medication.²²³ Furthermore, the FDA would continue to approve the changes in warnings effected by the generic manufacturers, limiting the number of warnings that appear on the label and decreasing label clutter.²²⁴

Implicating generic pharmaceutical companies for injuries would also remove the distortion of tort law promulgated by innovator liability. When the direct manufacturer of the drug is responsible for paying damages to a consumer of its drug, proximate cause is more easily established.²²⁵ If the consumer can prove that the medication they took was created by the generic company and that their injuries were a result of mislabeling on the generic product, then it is foreseeable that the generic company should have and failed to label its product properly.²²⁶

Creating a duty of care for generic pharmaceutical companies satisfies the traditional duty element of tort.²²⁷ These

^{221.} See Noah, *supra* note 131, at 293 (arguing that consumers benefit from companies not over-cluttering label with information that may cause consumers to become alarmed or curtail use).

^{222.} Danielle L. Steele, *The "Duty of Sameness" As a Shield-Generic Drug Manufacturers' Tort Liability and the Need for Label Independence After Pliva, Inc. v. Mensing*, 43 SETON HALL L. REV. 441, 486 (2013) (“[G]eneric drugs are in at least an equivalent position to that of brand-name drug manufacturers to collect post-market safety information and report it.”).

^{223.} *Id.* at 487 (suggesting that when generic pharmaceuticals adopt their independent labeling they will be responsible for adverse event reporting specific to their drug).

^{224.} *Id.* (arguing that generic drug reporting will increase consumer knowledge). The FDA has acknowledged it has the capacity to take on the additional responsibility of monitoring different generic labels. The agency itself proposed a rule that would change generic labeling such that it would oversee all warnings submitted by generics regarding adverse effects. Even if the generic drug companies were responsible for their own labeling and independently submitting adverse effects, the number of Changes Being Effected (CBE) submitted would still be the same. See FDA Labeling Proposal, *supra* note 164.

^{225.} See Wright, *supra* note 143 (observing that holding the direct manufacturer responsible satisfies causation).

^{226.} See Steele, *supra* note 222 (observing that injuries resulting from generic could be prevented by more careful labeling from generic manufacturers).

^{227.} For considering whether there is such a duty, see *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334, 342 (Cal. 1976) (The factors to consider are “the

companies often have continuous relationships with their consumers, who suffer from life-threatening illnesses and continue to use their products over a long period of time.²²⁸ It is foreseeable that a deficient warning from the generic company would harm the consumer. Not only is there a close connection between the drug company and injury, but there is also an incentive to prevent these injuries from recurring.²²⁹ Thus, if the generic company fails to warn consumers adequately about adverse effects of its product, it has breached its duty of care.²³⁰

Furthermore, holding generic drug companies responsible for damage payments towards their customers satisfies the goals of tort law. Having the direct manufacturer pay damages to the consumer fulfills tort principles of compensation for the victim, deterrence, and retributive justice.²³¹ The company will pay damages to the victim for harm suffered from the medication, which is uncertain under innovator liability—the clear majority of states would still find neither the branded nor generic company needs to compensate the consumer.²³² Furthermore, because the damages payout is coming from profits of the generic manufacturer, the generic company will be deterred from mindless labeling that simply copies the branded manufacturer's warnings.²³³ Finally, if patients

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 injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost and prevalence of insurance for the risk involved.”).

^{228.} VICKI LAWRENCE MACDOUGALL, 8 OKLA. PRAC., PROD. LIA. L. § 7:4 (2017) (describing how pharmaceutical companies have a duty to keep the patient informed and provide full information of risks inherent to the product). Even if one can argue that the relationship between generic companies and their consumers is not strong because they do not necessarily have an ongoing relationship, generic pharmaceutical companies still owe their consumers a heightened duty of care as a provider of medical treatment, who are held to a higher standard. Given their continuous relationship, their duty of care is equivalent to that of a landlord and tenant or pharmacist and patient.

^{229.} See, e.g., *Wyeth v. Levine*, 555 U.S. 555, 577 (2009); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Ct. App. 2008). Each case mentioned in Part I involving a patient suing a pharmaceutical company underscores this point.

^{230.} *Id.* (describing how the drug company has a duty to provide the medical profession with necessary information through drug packet inserts).

^{231.} See Abraham, *supra* note 168, at 232 (discussing the importance of holding manufacturers liable for warning defects).

^{232.} See *supra* Sections I.C.3-C.4 (the majority of states have not clearly ruled on innovator liability).

^{233.} See generally 358 F.3d 659 (9th Cir. 2004), *rev'g* 127 F. Supp. 2d 1085 (C.D. Cal. 2000). The FDA's new position was first expressed in an amicus brief submitted to the Ninth Circuit. See generally Brief for United States as Amicus Curiae Supporting Defendant-Appellant, *Motus*, 358 F.3d 659 (No. 02-

have a cause of action against generic manufacturers, the relief granted to the patients would be from the manufacturer that directly created the drug responsible for their adverse health conditions, bringing about corrective justice.²³⁴

If 100% of drug manufacturers, instead of 10%, are responsible for the damage payouts in the market, there would also no longer be a disparity in the fairness of the payouts.²³⁵ As generic manufacturers accrue just as much in profits as branded manufacturers, they are also equipped to handle damages payments to their consumers without significantly raising drug pricing.²³⁶ Furthermore, as the overwhelming majority of patients are consumers of generic medicines, it is equitable for more generic companies to pay for adverse health effects for patients than branded manufacturers, especially those who take their drugs.²³⁷

An amendment to the FDCA that allows generic medicine to have labels that vary from the branded drug and warn of different side effects would mean that the generic drugs can no longer freeride on the branded drug's advertisements. Generic drugs may have to market their medicine separately from the branded pharmaceutical due to differences in effects on consumers.²³⁸ Patients can no longer rely on representations made by the branded pharmaceutical to purchase generic pharmaceuticals that they believe could be bioequivalent. They would have to read information offered by the generic drugs to assess the differences in side effects between the various generic drugs and the branded drug.²³⁹ As a result, generic companies may have the opportunity to offer literature to doctors and update the physician reference guides to reflect adverse effects and updated research regarding their drugs, competing with branded companies in information and quality.²⁴⁰

55372), 2002 WL 32303084 (describing how regulation of drug labeling can deter manufacturing of the drug).

²³⁴. See Steele, *supra* note 222, at 486.

²³⁵. See Schwartz et al., *Warning*, *supra* note 117, at 1870.

²³⁶. See Steele, *supra* note 222, at 490 (arguing that even imposition of a duty on generic drugs would not offset the “critical balance between controlling healthcare costs and preserving safety”).

²³⁷. See *GENERIC DRUG ACCESS*, *supra* note 213.

²³⁸. U.S. Food and Drug Admin., *Prescription Drug Advertising: Questions and Answers* (June 19, 2015), <https://www.fda.gov/drugs/resourcesforyou/consumers/prescriptiondrugadvertising/ucm076768.htm> (explaining that generic drug companies are required to warn consumers and intermediaries about all the risks of using the drug).

²³⁹. This would be the result of generic drugs assuming different risks resulting from different adverse effects on consumers than the branded drug.

²⁴⁰. For an example of a reference guide that includes information on generic drugs available to consumers, see Mylan, *GENERIC BRAND REFERENCE GUIDE* (2017), <http://www.mylan.com/en/mylan-resources/access-gbr>.

Finally, allowing generics to uniquely label and promote their medicine necessarily implicates freedom of speech.²⁴¹ When *Mensing* is coupled with an FDA rule that equates “advertising” of a product with “labeling,”²⁴² generic manufacturers not only cease writing labels for their products; they are also precluded from sending “Dear Doctor” letters to physicians that would describe why it would be desirable to use their particular brand of generic drugs and also caution them of any adverse effects.²⁴³ However, recent cases indicate that *Mensing*’s holding on labeling infringes on freedom of speech and that generic manufacturers should at the very least be able to send “Dear Doctor” letters.²⁴⁴ Extrapolating this further, it appears that not allowing generic manufacturers to communicate their own warnings on their labels also presents constitutional difficulties that need to be rectified.²⁴⁵ Ultimately, generics should assume both the duty and the right of communicating critical safety information about their own products to the public.

Generic manufacturers and scholars opposing this rule have made the argument that imposing liability on generic manufacturers would significantly increase the price of generic drugs, making the pharmaceuticals less accessible to consumers. However, the FDA estimates that requiring generics to manufacture their own labels would only cost between \$4,237 and \$25,852 per year.²⁴⁶ This is a trivial expense considering the high profit margins of generic pharmaceutical companies, which are in the hundreds of millions of dollars, and the costs should have negligible impact on the price of generic pharmaceuticals. Thus, there would be a minimal impact on consumers.

Despite the arguments made by generic manufacturers to the contrary, allowing them control over their own labeling would ultimately spur public health benefits. Any issues with affordability are balanced out by improvements to public safety. An amendment to the FDCA that creates a duty of care for generic manufacturers would result in the proliferation of safety information for consumers and providers, creation of safer generic drugs, and enable generic manufacturers to disseminate their information directly to providers. The ancillary benefit is that branded companies could create a broader spectrum of innovative drugs addressing more illnesses than

^{241.} See generally Connor Sullivan, *A First Amendment Approach to Generic Drug Manufacturer Tort Liability*, 123 YALE L.J. 495 (2013).

^{242.} 21 C.F.R. § 202.1(1)(2) (2010).

^{243.} See Sullivan, *supra* note 241, at 500.

^{244.} *United States v. Caronia*, 703 F.3d 149, 167 (2d Cir. 2012); *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011).

^{245.} See Sullivan, *supra* note 241, at 510.

^{246.} Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 80 Fed. Reg. 8577 (proposed Feb. 18, 2015) (to be codified at 21 C.F.R. 314, 601).

they would under an innovator liability regime. These novel drugs could later be replicated by generic manufacturing companies, creating a net benefit for all.

V. CONCLUSION

Since the Supreme Court's decisions in *Wyeth v. Levine* and *Pliva v. Mensing*, plaintiffs who use a generic drug and are unable to recover from the generic drug company have been able to recover from the branded drug company in some states, creating the doctrine of innovator liability. Since then, innovator liability has been adopted by five states and rejected by twenty. Furthermore, five other states are likely to adopt the doctrine and twenty-one other states and the District of Columbia are likely to reject it due to their existing product liability laws. However, innovator liability creates issues for public health, distortion of tort law, and unfairness to branded pharmaceutical companies. Moving forward, the FDA should adopt a rule that imposes a duty to warn on generic pharmaceutical companies, driving them to keep abreast of scientific literature regarding their drugs and granting them an avenue for disseminating their unique information.

APPENDIX A: FIFTY-STATE SURVEY

State	Innovat or Liability Position	Case Law	Statute
Alabama	Adopted	<i>Wyeth, Inc. v. Weeks</i> , 159 So. 3d 649 (Ala. 2014), <i>superseded by statute</i> , ALA. CODE § 6-5-530 (2015)	N/A
Alaska	Likely to adopt	<i>Shanks v. Upjohn Co.</i> , 835 P.2d 1189 (Alaska 1992)	N/A
Arizona	Likely to reject	<i>Watts v. Medicis Pharm. Corp.</i> , 365 P.3d 944 (Ariz. 2016)	ARIZ. REV. STAT. ANN. § 12-687 (2019)
Arkansas	Likely to reject	<i>Bell v. Pfizer, Inc.</i> , 716 F.3d 1087 (8th Cir. 2013) <i>West v. G.D. Searle & Co.</i> , 879 S.W.2d 412 (Ark. 1994)	ARK. CODE ANN. § 16-116-205 (2019)
California	Adopted	<i>T.H. v. Novartis Pharm. Corp.</i> , 407 P.3d 18 (Cal. 2017) <i>Conte v. Wyeth, Inc.</i> , 85 Cal. Rptr. 3d 299 (Ct. App. 2008)	N/A
Colorado	Rejected	<i>Sheeks v. Am. Home Prod. Corp.</i> , No. 02CV337, 2004 WL 4056060 (Colo. Dist. Ct. Oct. 15, 2004)	COLO. REV. STAT. ANN. § 13-21-402 (2019)
Connecticut	Likely to reject	N/A	CONN. GEN. STAT. ANN. § 52-572m
Delaware	Likely to reject	<i>Evans v. Flowserve U.S. Inc.</i> , 239 F.	N/A (2019)

			Supp. 3d 838 (D. Del. 2017)	
			<i>Evans v. CBS Corp.</i> , 230 F. Supp. 3d 397 (D. Del. 2017)	
D.C.	Likely to reject		<i>Kelley v. Eli Lilly & Co.</i> , 517 F. Supp. 2d 99 (D.D.C. 2007)	N/A
			<i>Weakley v. Burnham Corp.</i> , 871 A.2d 1167 (D.C. 2005)	
			<i>Bragg v. Owens-Corning Fiberglas Corp.</i> , 734 A.2d 643 (D.C. 1999)	
Florida	Rejected		<i>Guarino v. Wyeth, LLC</i> , 719 F.3d 1245 (11th Cir. 2013)	FLA. STAT. ANN. § 768.1256 (2019)
			<i>Dietrich v Wyeth, Inc.</i> , No. 50-2009-CA-021586XXX, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009)	
			<i>Sharp v. Leichus</i> , No. 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. Feb. 17, 2006), <i>aff'd</i> , 952 So. 2d 555 (Fla. Dist. Ct. App. 2007)	
Georgia	Rejected		<i>Guarino v. Wyeth, LLC</i> , 719 F.3d 1245 (11th Cir. 2013)	GA. CODE ANN. § 51-1-11 (2009)
Hawaii	Likely to reject		<i>In re Hawaii Fed. Asbestos Cases</i> , 960	N/A

		F.2d 806, 819 (9th Cir. 1992)	
		<i>Smith v. Cutter Biological, Inc., a Div. of Miles Inc.,</i> 823 P.2d 717, 719 (Haw. 1991)	
Idaho	Likely to reject	<i>J.M.F. Trucking, Inc. v. Carburetor & Elec. of Lewiston, Inc.,</i> 748 P.2d 381, 383 (Idaho 1987)	IDAHO CODE § 6-1401 (2005)
Illinois	Likely to reject	<i>Dolin v. GlaxoSmithKline LLC,</i> 901 F.3d 803 (7th Cir. 2018) <i>Guvnoz v. Target Corp.,</i> 2015 IL App (1st) 133940, 30 N.E.3d 404 <i>City of Chicago v. Am. Cyanamid Co.,</i> 823 N.E.2d 126 (Ill. App. Ct. 2005) <i>Smith v. Eli Lilly & Co.,</i> 560 N.E.2d 324 (Ill. 1990) <i>Wehmeier v. UNR Indus., Inc.,</i> 572 N.E.2d 320 (Ill. App. Ct. 1991)	735 ILL. COMP. STAT. 5/2-2103 (1995), <i>invalidated by Best v. Taylor Machine Works,</i> 689 N.E.2d 1057 (Ill. 1997)
Indiana	Likely to adopt	<i>Warren v. Boehringer Ingleheim Pharm. Inc.,</i> No. 1:16-cv-01326-SEB-DML, 2017 WL 3970666, at *15 (S.D. Ind. Sept. 8, 2017)	IND. CODE § 34-20-2-2 (1998)

		<i>Bell v. Lollar</i> , 791 N.E.2d 849 (Ind. Ct. App. 2003)	
Iowa	Rejected	<i>Huck v. Wyeth, Inc.</i> , 850 N.W.2d 353 (Iowa 2014)	IOWA CODE § 668.12 (2004)
Kansas	Rejected	<i>Anselmo v. Sanofi-Aventis Inc. USA</i> , No. 10-CV-77, 2014 WL 8849464, at *1 (Kan. Dist. Ct. Oct. 13, 2014)	KAN. STAT. ANN. § 60-3304 (1981)
Kentucky	Likely to reject	<i>Moore v. Zyodus Pharm. (USA), Inc.</i> , 277 F. Supp. 3d 873 (E.D. Ky. 2017) <i>Wilson v. PLIVA, Inc.</i> , 640 F. Supp. 2d 879 (W.D. Ky. 2009)	KY. REV. STAT. ANN. § 411.320 (West 1978), <i>invalidated by Low v. Power Tool Specialist, Inc.</i> , 803 F. Supp. 2d 655 (E.D. Ky. 2011)
Louisiana	Rejected	<i>Johnson v. Teva Pharm. USA, Inc.</i> , 758 F.3d 605 (5th Cir. 2014) <i>Demahy v. Schwarz Pharma, Inc.</i> , 702 F.3d 177 (5th Cir. 2012) <i>Stanley v. Wyeth, Inc.</i> , 991 So. 2d 31 (La. Ct. App. 2008)	LA. STAT. ANN. § 9:2800.52 (2019)
Maine	Likely to reject	<i>Grant v. Foster Wheeler, LLC</i> , 140 A.3d 1242 (Me. 2016) <i>Millett v. Atl. Richfield Co.</i> , No. Civ.A. CV-98-555,	ME. REV. STAT. tit. 14, § 161 (2019)

		2000 WL 359979 (Me. Super. Mar. 2, 2000)	
Maryland	Rejected	<i>Gross v. Pfizer, Inc.</i> , No. 10-CV-00110-AW, 2010 WL 4485774 (D. Md. Nov. 9, 2010) <i>Foster v. Am. Home Prods. Corp.</i> , 29 F.3d 165 (4th Cir. 1994)	MD. CODE ANN., CTS. & JUD. PROC. § 5-629 (LexisNexis 2019)
Massachusetts	Adopted	<i>Rafferty v. Merck & Co.</i> , 92 N.E.3d 1205 (Mass. 2018)	MASS. GEN. LAWS ANN. ch. 106, § 2-318 (West 2019)
Michigan	Likely to reject	<i>Attorney Gen. v. Merck Sharp & Dohme Corp.</i> , 807 N.W.2d 343 (Mich. 2011) <i>Auto Club Ins. Ass'n v. Gen. Motors Corp.</i> , 552 N.W.2d 523 (Mich. 1996)	MICH. COMP. LAWS ANN. § 600.2946 (2019)
Minnesota	Rejected	<i>Flynn v. Am. Home Prods. Corp.</i> , 627 N.W.2d 342 (Minn. Ct. App. 2001)	N/A
Mississippi	Rejected	<i>Gardley-Starks v. Pfizer, Inc.</i> , 917 F. Supp. 2d 597 (N.D. Miss. 2013) <i>Chatman v. Pfizer, Inc.</i> , 960 F. Supp. 2d 641 (S.D. Miss. 2013), <i>modified</i> , No. 5:11-cv-69(DCB)(MTP), 2014 WL 4546042	MISS. CODE ANN. § 11-1-63 (2019)

		(S.D. Miss. Sept. 11, 2014)	
		<i>3M Co. v. Johnson</i> , 895 So. 2d 151 (Miss. 2005)	
Missouri	Rejected	<i>Nicely v. Wyeth, Inc.</i> , 451 S.W.3d 694 (Mo. Ct. App. 2014)	MO. REV. STAT. § 196.050 (2019)
		<i>Franzman v. Wyeth LLC</i> , 451 S.W.3d 676 (Mo. Ct. App. 2014)	
		<i>Neeley v. Wolters Kluwer Health, Inc.</i> , No. 4:11-CV-325 JAR, 2013 WL 3929059, at *23 (E.D. Mo. July 29, 2013), <i>as amended</i> (July 30, 2013), <i>on reconsideration in part sub nom. Neeley v. Wyeth LLC</i> , No. 4:11-CV-00325-JAR, 2015 WL 1456984 (E.D. Mo. Mar. 30, 2015)	
Montana	Likely to reject	<i>Meyer v. Creative Nail Design, Inc.</i> , 975 P.2d 1264 (Mont. 1999)	N/A
		<i>Schelske v. Creative Nail Design, Inc.</i> , 933 P.2d 799 (Mont. 1997)	
Nebraska	Likely to reject	<i>Freeman v. Hoffman-La Roche, Inc.</i> , 618 N.W.2d 827 (Neb. 2000)	NEB. REV. STAT. § 25-21,181 (1978)

		<i>Menne v. Celotex Corp.</i> , 861 F.2d 1453 (10th Cir. 1988)	
Nevada	Rejected	<i>Moretti v. Wyeth, Inc.</i> , 579 F. App'x 563 (9th Cir. 2014)	N/A
		<i>Baymiller v. Ranbaxy Pharm., Inc.</i> , 894 F. Supp. 2d 1302 (D. Nev. 2012)	
New Hampshire	Likely to reject	<i>Univ. Sys. of New Hampshire v. U.S. Gypsum Co.</i> , 756 F. Supp. 640 (D.N.H. 1991)	N.H. Rev. Stat. Ann. tit. LII, Ch. 507-D, Refs & Annos
New Jersey	Rejected	<i>Condouris v. Wyeth</i> , No. ATL-L-1940-10, 2012 WL 2401776 (N.J. Super. Ct. Law Div. June 26, 2012)	N.J. STAT. ANN. § 2A:58C-4 (West 1987)
New Mexico	Likely to adopt	<i>Michael v. Warner/Chilcott</i> , 579 P.2d 183 (N.M. Ct. App. 1978)	N/A
New York	Rejected	<i>Coleson v. Janssen Pharm., Inc.</i> , 251 F. Supp. 3d 716 (S.D.N.Y. 2017)	N/A
		<i>Goldych v. Eli Lilly & Co.</i> , No. 5:04CV1477(GLS/GJD), 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006)	
		<i>Glucksman v. Halsey Drug Co.</i> , 553 N.Y.S.2d 724 (App. Div. 1990)	

North Carolina	Rejected	<p><i>Perdue v. Wyeth Pharm., Inc.</i>, 209 F. Supp. 3d 847 (E.D.N.C. 2016), <i>appeal dismissed per stipulation sub nom. Perdue v. Teva Pharm. USA, Inc.</i>, No. 16-1947, 2018 WL 994177 (4th Cir. Feb. 8, 2018)</p> <p><i>Couick v. Wyeth, Inc.</i>, 691 F. Supp. 2d 643 (W.D.N.C.), <i>judgment entered</i>, No. 3:09-cv-210-RJC-DSC, 2010 WL 1837912 (W.D.N.C. May 6, 2010)</p> <p><i>Stoddard v. Wyeth, Inc.</i>, 630 F. Supp. 2d 631 (E.D.N.C. 2009)</p>	N.C. GEN. STAT. § 99B-1 (2018)
North Dakota	Likely to reject	N/A	N.D. CENT. CODE § 28-01.3-09 (2019)
Ohio	Rejected	<p><i>Hendricks v. Pharmacia Corp.</i>, No. 2:12-cv-613, 2014 WL 4961550, at *1 (S.D. Ohio Oct. 2, 2014)</p> <p><i>Hogue v. Pfizer, Inc.</i>, 893 F. Supp. 2d 914 (S.D. Ohio 2012)</p>	OHIO REV. CODE ANN. § 2307.73 (West 2019)
Oklahoma	Rejected	<i>Schrock v. Wyeth, Inc.</i> , 727 F.3d 1273 (10th Cir. 2013)	OKLA. STAT. tit. 76, § 57.2 (2019)

Oregon	Rejected	<i>Phelps v. Wyeth, Inc.</i> , 857 F. Supp. 2d 1114 (D. Or. 2012)	OR. REV. STAT. § 30.900 (2019); OR. REV. STAT. § 30.927 (2019)
Pennsylvania	Adopted	<i>Lance v. Wyeth</i> , 85 A.3d 434 (Pa. 2014)	N/A
Rhode Island	Likely to adopt	<i>Koch v. I-Flow Corp.</i> , 715 F. Supp. 2d 297 (D.R.I. 2010)	N/A
South Carolina	Likely to reject	<i>Fisher v. Pelstring</i> , No. 4:09-cv-00252-TLW, 2010 WL 2998474 (D.S.C. July 28, 2010) <i>Ryan v. Eli Lilly & Co.</i> , 514 F. Supp. 1004 (D.S.C. 1981)	S.C. CODE ANN. § 15-73-10 (2019)
South Dakota	Likely to reject	<i>Bradley v. Firestone Tire & Rubber Co.</i> , 590 F. Supp. 1177 (D.S.D. 1984)	S.D. CODIFIED LAWS § 20-9-6 (2019)
Tennessee	Likely to reject	<i>Strayhorn v. Wyeth Pharms., Inc.</i> , 737 F.3d 378 (6th Cir. 2013) <i>McDaniel v. Upsher-Smith Labs., Inc.</i> , 893 F.3d 941 (6th Cir. 2018); <i>Barnes v. Kerr Corp.</i> , 418 F.3d 583 (6th Cir. 2005)	TENN. CODE ANN. § 29-28-104 (2019)
Texas	Rejected	<i>Wells v. Wyeth Pharms., Inc.</i> , 233 F. Supp. 3d 534 (W.D. Tex. 2017)	TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (West 2019)

		<p><i>Willis v. Schwarz-Pharma, Inc.</i>, 62 F. Supp. 3d 560 (E.D. Tex. 2014)</p> <p><i>Eckhardt v. Qualitest Pharm. Inc.</i>, 889 F. Supp. 2d 901 (S.D. Tex. 2012), <i>aff'd</i>, 751 F.3d 674 (5th Cir. 2014)</p> <p><i>Pustejovsky v. Wyeth, Inc.</i>, No. 4:07-CV-103-Y, 2008 WL 1314902, at *2 (N.D. Tex. Apr. 3, 2008)</p> <p><i>Del Valle v. Pliva, Inc.</i>, No. CIV. B-11-113, 2012 WL 4747259, at *1 (S.D. Tex. Sept. 12, 2012), <i>aff'd sub nom. Lashley v. Pfizer, Inc.</i>, 750 F.3d 470 (5th Cir. 2014)</p> <p><i>Burke v. Wyeth, Inc.</i>, No. CIV. A. G-09-82, 2009 WL 3698480 (S.D. Tex. Oct. 29, 2009)</p>	
Utah	Rejected	<p><i>Beutella v. A.H. Robins Co.</i>, No. 980502372, 2001 WL 35669202, at *3 (Utah Dist. Ct. Dec. 10, 2001)</p>	<p>UTAH CODE ANN. § 78B-6-703 (LexisNexis 2019)</p>
Vermont	Adopted	<p><i>Kellogg v. Wyeth</i>, 762 F. Supp. 2d 694 (D. Vt. 2010)</p>	<p>VT. STAT. ANN. tit. 9, § 2466a (2019)</p>

Virginia	Likely to reject	<p><i>Ford Motor Co. v. Boomer</i>, 736 S.E.2d 724 (Va. 2013)</p> <p><i>Torkie-Tork v. Wyeth</i>, 739 F. Supp. 2d 895 (E.D. Va. 2010)</p> <p><i>McCauley v. Purdue Pharma L.P.</i>, 331 F. Supp. 2d 449 (W.D. Va. 2004)</p>	<p>VA. CODE ANN. tit. 54.1, Subt. III, Ch. 34, Refs & Annos (West)</p>
Washington	Likely to reject	<p><i>Ayers By & Through Ayers v. Johnson & Johnson Baby Prod. Co.</i>, 818 P.2d 1337 (Wash. 1991)</p> <p><i>Martin v. Abbott Labs.</i>, 689 P.2d 368 (Wash. 1984)</p>	<p>WASH. REV. CODE § 7.72.050 (2019)</p>
West Virginia	Rejected	<p><i>McNair v. Johnson & Johnson</i>, No. 17-0519, 2018 WL 2186550 (W. Va. May 11, 2018)</p> <p><i>Meade v. Parsley</i>, No. 2:09-CV-00388, 2010 WL 4909435, at *5 (S.D.W. Va. Nov. 24, 2010)</p>	N/A
Wisconsin	Likely to reject	<p><i>Wagner v. Teva Pharm. USA, Inc.</i>, 840 F.3d 355 (7th Cir. 2016)</p> <p><i>Singer v. Pneumo Abex, LLC</i>, 809 N.W.2d 900 (Wis. Ct. App. 2012)</p>	<p>WIS. STAT. ANN. § 895.047 (2019)</p> <p>WIS. STAT. ANN. § 893.54 (2019)</p>

<i>Rogers v. AAA Wire Prod., Inc.</i> , 513 N.W.2d 643 (Wis. Ct. App. 1994)			
Wyoming	Likely to adopt	N/A	WYO. STAT. ANN. § 1-1-109 (2019)

To classify the states, the author searched for and read through numerous cases and statutes related to innovator liability, product liability, and preemption in each state. Data were collected from WestLaw, Lexis Nexis, Hein Online, Google Scholar, and various other scholarly sources. Cases were included regardless of whether they predated or postdated the *Mensing* decision. State Supreme Court and appellate court decisions were prioritized as governing authority over a state.