

IT IS EMPHATICALLY THE PROVINCE AND DUTY OF STATE COURTS TO SAY WHAT TORT LAW IS

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*Following the U.S. Supreme Court's 2011 decision in *PLIVA, Inc. v. Mensing*, consumers of generic prescription drugs suffering from unwarned-of side effects largely remain without an avenue of legal recourse due to their inability to sue their own manufacturers. But in the pursuit for legal redress, some generic plaintiffs have pursued a narrow window of liability by bringing failure-to-warn claims, sounding in negligence, against the manufacturer responsible for producing the brand-name equivalent of the generic drug. Such claims rest on the rationale that the sui generis federal regulatory scheme governing the prescription drug industry furnishes an inextricable nexus between the brand-name manufacturer and generic-drug user such that it generates a negligence duty of care between them.*

The case law on this duty question remains fractured. Until late 2017, the majority of courts confronting the duty issue ruled for the brand-name defendant and held no duty as a matter of law. However, beginning in December of 2017, two landmark decisions by the California and Massachusetts supreme courts, in support of duty, have called for a reexamination of settled case law and, accordingly, given new hope to the generic-drug user's pursuit of legal remedy.

In light of these recent developments, this Note seeks to equip future courts confronting the duty question with a functional understanding of the considerations that lie on both sides of the duty inquiry. In addition, this Note proposes a remedial position that incorporates both the policy concerns cutting against duty and the doctrinal considerations undergirding it. At its core, this Note argues that doctrine demands a duty be recognized and, further, that courts have the core institutional competence to craft tort law in

* J.D. Candidate, 2020, Fordham University School of Law; B.A., 2017, Boston College. The following remarks are not exhaustive, as there are too many people I owe my sincere gratitude to. First and foremost, I would like to thank Professor Benjamin C. Zipursky for not only providing tremendous guidance on this Note, but also for sparking my love for jurisprudence. In addition, I would like to thank my parents, Sion, and Marco for their perpetual love and unwavering support. Finally, I am indebted to the legal titans—Professors Abner S. Greene, Daniel J. Capra, Martin S. Flaherty, and Russell G. Pearce—for being the champions of my law school career, the *Fordham Law Review* for providing me this platform to express my ideas, and Tracey Tomlinson for her gentle reminders to enjoy the ride.

ways that will avert ruinous public policy consequences. In making this argument, this Note conveys a fighting message to courts: where tort doctrine says a duty of care exists, courts should endeavor to give effect to that duty.

INTRODUCTION.....	2215
I. RETRACING THE CASE LAW’S FOOTSTEPS.....	2217
A. <i>Wyeth: A False Alarm</i>	2218
B. <i>PLIVA: The Collision</i>	2219
II. THE CASE LAW TODAY	2219
A. <i>The National Landscape</i>	2220
B. <i>The Minority Position: California and Massachusetts</i>	2221
C. <i>The Majority Position: Iowa and West Virginia</i>	2223
III. KEY ARGUMENTS UNDERGIRDING BOTH SIDES OF THE DUTY QUESTION	2225
A. <i>Key Arguments Supporting the Existence of Duty</i>	2226
1. Reasonable Foreseeability Supports Duty	2226
2. Recognizing Duty Is Sound Public Policy	2228
a. <i>The Incentive to Keep Warning</i>	2229
b. <i>“A Right Without a Remedy”</i>	2230
B. <i>Key Arguments Undergirding the No Duty Position</i>	2231
1. Negligence Is an End Run Around Strict Products Liability	2231
2. Doctrinal Arguments Weighing Against Duty.....	2233
3. Public Policy Concerns Weighing Against Duty	2237
a. <i>Recognizing Duty Will Open the Floodgates</i>	2237
b. <i>Imposing Duty Could Chill Innovation</i>	2239
IV. RESOLUTION.....	2240
A. <i>Rebutting the No Duty Arguments</i>	2241
1. The Negligence Cause of Action Has No End Run Effect.....	2241
2. No Duty Findings Misconstrue Basic Tort Doctrine	2243
B. <i>The Case for Duty</i>	2244
1. Back to the Basics: Cardozo’s <i>MacPherson</i>	2245
2. The “Integration” Principle.....	2247
3. A Fighting Message to Courts	2250
a. <i>Core Judicial Competence in Crafting Tort Law to Prevent Public Policy Concerns</i>	2250

<i>b. The Political Branches Provide a Safe Harbor</i>	2251
CONCLUSION	2252
ADDENDUM	2253

INTRODUCTION

It is a settled expectation under modern norms that where a product's defect causes physical injury to its user, that user has a remedy at law. Indeed, perhaps the telltale sign of this settled expectation is the crown jewel of consumer protection law: the imposition of strict liability on manufacturers for their products' defects.¹ Yet, despite this ubiquitous modern understanding, consumer relief remains unrealized for users² of generic-version prescription drugs³ who suffer from unwarned-of and injurious side effects. Though generic users' injuries plainly arise out of a product defect—the generic drug's deficient warning label—tort law nevertheless shuts them out from pursuing any legal recourse.

This current lack of legal redress for generic users traces its roots to the 2011 U.S. Supreme Court case, *PLIVA, Inc. v. Mensing*.⁴ In *PLIVA*, the Court held that federal warning-label law “preempts” state tort failure-to-warn claims brought against generic manufacturers.⁵ The Court reached this conclusion after interpreting federal law to *prohibit* generic manufacturers from unilaterally strengthening their own warning labels and, instead, only obligating them to *replicate* the warnings of their brand-name counterparts.⁶ Thus, the Court held that preemption was triggered under the Supremacy Clause because it was impossible for generic manufacturers to comply with state tort warning-label obligations while also heeding federal law's prohibition on unilateral strengthening.⁷

1. *See Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 461–62 (Cal. 1944) (Traynor, J., concurring) (pioneering strict products liability).

2. Users of generic drugs will hereinafter be referred to as “generic users” or “generic plaintiffs.”

3. Prescription drugs come in two forms: brand name and generic. The brand-name manufacturer is the first mover in the market who invests in research and development and subsequently brings a newly developed drug to market. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470 (2013). This newly innovated drug is the “brand-name drug.” *See id.* In contrast, generic manufacturers create a product—the “generic drug”—that replicates an existing brand-name drug. *See id.* The generic drug is virtually a carbon copy of the brand-name equivalent drug and is introduced into the market once the brand-name drug's exclusivity period expires. *See id.*

4. 564 U.S. 604 (2011).

5. *Id.* at 617–18. A generic prescription drug manufacturer will hereinafter be referred to as a “generic manufacturer” or simply a “generic.”

6. *Id.* at 613; *see also* 21 U.S.C. § 355(j)(2)(A)(v) (2012) (codifying the requirement that warning labels of generic drugs be the same as their brand-name counterparts). Brand-name prescription drug manufacturers will hereinafter be referred to as “brand-name manufacturers.” Brand-name drug consumers will hereinafter be referred to as “brand-name users.”

7. *PLIVA*, 564 U.S. at 617–18.

Today, as a consequence of *PLIVA*, generic users suffering from unwarned-of side effects are shut out from suing their own manufacturers for failure to warn of injurious side effects.⁸ This shut-out effect has, however, inspired a new form of tort litigation in which generic plaintiffs have sued the manufacturer responsible for creating the brand-name equivalent of their injury-causing drug.⁹ These suits allege *negligent* failure to warn, not strict products liability, as the cause of action against the brand-name defendant¹⁰ and rest on the core contention that brand names owe generic users a duty to warn of adverse side effects because of *PLIVA*'s obligation of warning-label sameness.¹¹ Accordingly, the crucial issue predominating the case law today is whether generic users are owed a duty of care by brand-name manufacturers in promulgating adequate warning labels.¹²

Courts appear sharply divided on this duty question. Until recently, the vast majority of courts confronted with generic users' failure-to-warn claims ruled for the brand-name manufacturer and held no duty as a matter of law.¹³ However, beginning in December of 2017, two landmark decisions by the California and Massachusetts supreme courts, in favor of duty,¹⁴ have reinvigorated the generic plaintiff's cause and, more notably, marked a key development in prescription drug jurisprudence. Now, with the arrival of these two decisions, it is likely that courts across the country will be asked to reconsider generic users' failure-to-warn claims brought against brand-name manufacturers.

The sharp divide in the case law regarding duty is entirely plausible.¹⁵ Inherent in this difficult duty question are complex and interrelated considerations that provide a smattering of doctrine, public policy, history, fairness, and, more profoundly, the metaphysical role of duty in tort law.¹⁶ Crucially, how courts view generic users' negligence claims is often dispositive of how they will come out on the duty question: if causation or

8. *See id.* at 643 (Sotomayor, J., dissenting).

9. *See, e.g.*, *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010); *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18 (Cal. 2017); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Ct. App. 2008); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205 (Mass. 2018).

10. *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342 (Minn. Ct. App. 2001); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676 (Mo. Ct. App. 2014); *Silva v. Smithkline Beecham Corp.*, No. 31,276, 2013 WL 4516160 (N.M. Ct. App. Feb. 7, 2013); *Weese v. Pfizer, Inc.*, No. 153742/12, 2013 WL 5691993 (N.Y. Sup. Ct. Oct. 8, 2013); *McNair v. Johnson & Johnson*, 818 S.E.2d 852 (W. Va. 2018).

11. *See infra* Part III.A.

12. *See* John C. P. Goldberg & Benjamin C. Zipursky, *The Restatement (Third) and the Place of Duty in Negligence Law*, 54 VAND. L. REV. 657, 658–59 (2001) (surveying the laws of fifty jurisdictions and concluding that every state, except two, retains duty as a prima facie element of negligence). In negligence suits, the duty element is a question of law for the court to decide in the first instance. *See* 57A AM. JUR. 2D *Negligence* § 78 (2018) (surveying tort law across the country). Failure to prove the duty element will thus prevent the negligence case from proceeding to trial. *See id.*

13. *See infra* note 53 and accompanying text.

14. *Novartis*, 407 P.3d at 18; *Rafferty*, 92 N.E.3d at 1205.

15. *See infra* Part III.

16. *See infra* Part III.

public policy is used as a proxy for duty, then indeed, there is no cause of action because the generic user did not ingest the brand name's product and imposing duty presents serious policy risks;¹⁷ but if duty is analyzed using traditional doctrinal considerations—such as reasonable foreseeability—the case for duty grows much stronger.¹⁸

Against this backdrop, this Note argues that there is a way for courts to recognize a duty of care while maintaining fidelity to both the public policy and doctrinal justifications that lie at the crux of the duty question.¹⁹ This remedial approach, which is discussed extensively in Part IV, rests on two fundamental planks: first, history and the distinctive features of the brand-name, generic-user relationship generate a duty of care, and second, courts have the core institutional competence to craft tort law in ways that will avert the relevant public policy concerns. Put simply, this Note sets forth a judicial solution that will allow courts to achieve a win-win situation by recognizing duty.

This Note is organized into four Parts. Part I examines the development of failure-to-warn jurisprudence in the prescription drug context by examining two landmark Supreme Court decisions, *Wyeth v. Levine*²⁰ and *PLIVA*. Part II analyzes the key implications of *PLIVA* on prescription drug jurisprudence and subsequently looks at the current state of affairs through an in-depth discussion of four emblematic cases on the duty question. Part III then isolates the key arguments found in the case law underlying each side of the duty inquiry. Finally, Part IV argues for the recognition of a duty of care using a remedial duty framework that encapsulates both the doctrinal and public policy rationales at stake. A brief Addendum at the end of this Note addresses the Court's recent opinion in *Air & Liquid Systems Corp. v. DeVries*.²¹ This decision, despite being a maritime law case, is included because it provides reasoning that further substantiates the position this Note advances.

At bottom, this Note seeks to equip future courts confronting the duty question with a functional understanding of the considerations coloring the duty discussion while also delivering its own core message: where tort doctrine tells us there is a duty, yet public policy considerations stand in the way, courts should endeavor to give effect to that duty.

I. RETRACING THE CASE LAW'S FOOTSTEPS

Since the advent of products liability law for prescription drugs, it was widely assumed that a prescription drug manufacturer's duty to warn of harmful side effects progressed along two parallel tracks: state tort law and

17. *See infra* Part III.A.

18. *See infra* Part III.A.

19. *See infra* Part IV.

20. 555 U.S. 555 (2009).

21. No. 17-1104 (U.S. Mar. 19, 2019).

the federal regulatory scheme.²² Ostensibly, these two bodies of law were understood to coexist and operate in distinct spheres of influence.²³ Beginning in 2009, however, this long-held understanding came under attack as efforts intensified in forcing a collision between state and federal law.²⁴ In 2011, those efforts bore fruit and culminated in a direct collision.²⁵

A. Wyeth: A False Alarm

In *Wyeth v. Levine*, plaintiff Diane Levine developed gangrene after ingesting the brand-name drug Phenergan.²⁶ Shortly thereafter, Levine sued Phenergan's manufacturer, Wyeth, claiming that under Vermont tort law, Wyeth was liable for her injuries because it had failed to include the risk of gangrene on Phenergan's warning label.²⁷ At first blush, Levine's suit seemed to be a standard failure-to-warn products liability claim brought by an injured consumer against her product's manufacturer.²⁸ Wyeth, however, defended with a novel argument: because Phenergan's warning label had been approved by the Food and Drug Administration (FDA) pursuant to federal regulations, federal law preempted Levine's state tort claims alleging failure to warn.²⁹ In essence, Wyeth's position claimed that federal warning-label law had collided with state tort law, and thus, the latter had to give way.³⁰ Suddenly, what had historically been viewed as two conceptually distinct bodies of law were now being pitted directly against one another in the shadow of the Supremacy Clause.³¹

Wyeth's suspected collision, however, turned out to be a false alarm.³² The Court, in a 6-3 decision, distinguished state tort law from the FDA's prescription drug warning-label obligations and declined to find preemption.³³ To reach this decision, the Court reasoned that federal law sets the *floor* on the level of warning-label obligations drug manufacturers owe to their consumers, not the *ceiling*.³⁴ Accordingly, state tort law could impose supplementary warning-label obligations that were otherwise lacking under federal law.³⁵ *Wyeth* thus reaffirmed the customary understanding that state tort law and federal law compelled separate warning-label obligations that run on parallel tracks.

22. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 634 (2011) (Sotomayor, J., dissenting) (examining the history of state and federal regulation of the prescription drug industry).

23. See *id.*

24. See generally *Wyeth*, 555 U.S. 555.

25. See *PLIVA*, 564 U.S. at 634 (Sotomayor, J., dissenting).

26. *Wyeth*, 555 U.S. at 558–60.

27. *Id.*

28. See *id.*

29. *Id.* at 580–81.

30. See *id.* at 581.

31. See *id.*

32. See *id.* at 572.

33. *Id.* at 573.

34. *Id.* at 575.

35. *Id.* at 572.

B. PLIVA: The Collision

Just one year after deciding *Wyeth*, the Court granted certiorari on another potential collision case: *PLIVA*. Like Diane Levine in *Wyeth*, the plaintiffs in *PLIVA* also suffered a serious side effect—tardive dyskinesia—after ingesting the prescription drug metoclopramide.³⁶ Seeking damages for their injuries, the plaintiffs brought state tort claims against metoclopramide’s manufacturer for its failure to warn of the paralyzing disease.³⁷ In response to the plaintiffs’ claims, the defendant-manufacturer argued federal preemption, which proceeded on a similar theory to that of the preemption defense in *Wyeth*.³⁸ As before, the defense was steering the failure-to-warn litigation toward a collision between federal and state law.

This time, however, the Court saw things differently and distinguished *Wyeth* on the preemption question.³⁹ To the Court, *PLIVA* did, in fact, trigger preemption because the defendant happened to be a generic manufacturer and not a brand-name manufacturer, which had been the case in *Wyeth*.⁴⁰ The Court held that this pivotal distinction—brand name versus generic—created fundamentally discrepant warning-label obligations under federal law that dictated the disposition of the preemption issue: while brand-name manufacturers were under a duty to continuously monitor and warn of newly discovered side effects, generic manufacturers were simply obligated to maintain a warning label that replicated the brand name’s label.⁴¹ Furthermore, the Court granted deference to the FDA’s views, as espoused in an amicus brief, and found that generic manufacturers were prohibited under federal law from *unilaterally* strengthening their own warning labels.⁴² Thus, because generic manufacturers could not unilaterally strengthen their own warnings labels, the Court held preemption was triggered because the plaintiffs’ failure-to-warn claims sought to impose warning-label obligations on the generic defendant that federal law expressly prohibited it from discharging.⁴³

II. THE CASE LAW TODAY

As stated before, the Court’s decision in *PLIVA* has set the stage for modern prescription drug jurisprudence. Most notably, in an effort to circumvent preemption, generic users have pursued a narrow window of liability by bringing negligence suits alleging failure to warn against brand-

36. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 609 (2011).

37. *Id.* at 610.

38. *Id.*

39. *See id.* at 624.

40. *Id.*

41. *Id.*

42. *Id.* It is important to remember that failure-to-warn claims brought against brand-name manufacturers are not preempted because brand names can unilaterally strengthen their prescription drug warning labels. *See Wyeth v. Levine*, 555 U.S. 555, 572–73 (2009).

43. *See PLIVA*, 564 U.S. at 617–18.

name manufacturers.⁴⁴ As a threshold matter, generic plaintiffs must first establish the duty element under negligence law if their claims are to survive summary judgment. Accordingly, how courts come out on the duty element is crucial to determining the viability of generic users' claims and, more fundamentally, their ability to collect damages.⁴⁵

This Part picks up where *PLIVA* left off by analyzing *PLIVA*'s key legal effects on failure-to-warn jurisprudence. This Part then builds toward the threshold duty issue underlying generic users' failure-to-warn claims and surveys the national landscape of past decisions that have addressed this duty question. Finally, this Part details four emblematic cases on the duty question decided by the highest courts of California, Iowa, Massachusetts, and West Virginia.⁴⁶

A. The National Landscape

PLIVA has produced an anomalous pocket of tort law where generic users who suffer from unwarned-of and injurious side effects are left without an avenue of legal recourse against the manufacturers of their generic drugs.⁴⁷ Yet, litigation over the prescription drug industry's warning-label obligations continues albeit in a different context⁴⁸: generic plaintiffs have homed in on a new target by bringing failure-to-warn claims, sounding in negligence, against the brand-name manufacturer responsible for creating their drug's brand-name equivalent.⁴⁹ Pursuant to *Wyeth*, such claims are not preempted because, unlike generic manufacturers, brand-name manufacturers *can* unilaterally strengthen their own warning labels.⁵⁰ Putting aside preemption, then, the crucial legal issue that is now the locus of failure-to-warn litigation is whether brand-name manufacturers owe a duty to generic users to adequately warn of a drug's adverse side effects. Indeed, this duty question remains hotly contested due, in substantial part, to the salient fact that generic users have neither bought nor directly ingested the brand-name product.⁵¹ Thus, the duty question can be condensed and rephrased: Can a brand-name

44. See, e.g., *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18 (Cal. 2017); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205 (Mass. 2018).

45. See *supra* note 12 and accompanying text.

46. There are many well-reasoned cases addressing the duty question. This Note, however, has selected the California, Iowa, Massachusetts, and West Virginia decisions for further discussion because of their recency and their status as binding authoritative precedent in their respective states.

47. See *PLIVA*, 564 U.S. at 643 (Sotomayor, J., dissenting).

48. See Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 FORDHAM L. REV. 1835, 1837 (2013).

49. See, e.g., *Novartis*, 407 P.3d at 18; *Rafferty*, 92 N.E.3d at 1205.

50. See *Wyeth v. Levine*, 555 U.S. 555, 572–73 (2009).

51. See, e.g., *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169–70 (4th Cir. 1994) (holding that there was no duty of care owed due to a lack of privity); *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643, 645 (W.D.N.C. 2010) (concluding that no duty of care existed because the generic plaintiff did not ingest the brand-name drug); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 634 (E.D.N.C. 2009) (holding that no duty of care existed due to lack of causation).

manufacturer be held to owe a duty of care to consumers of its competitor's product?⁵²

Courts are deeply divided on this duty question. Until December 2017, the case law on the duty question remained lopsided: a majority of courts addressing the issue had sided with the brand-name manufacturer and held that no duty existed as a matter of law.⁵³ Reflecting this majority position, two state supreme courts—Iowa⁵⁴ and West Virginia⁵⁵—made the no duty position the law of the land in their respective states.⁵⁶ Conversely, courts recognizing a duty of care seemed firmly entrenched in the minority camp.⁵⁷ However, two recent state supreme court decisions—from California and Massachusetts—may indicate a resurgence of the minority position.

B. The Minority Position: California and Massachusetts

In late 2017, the Supreme Court of California in *T.H. v. Novartis Pharmaceuticals Corp.*⁵⁸ held that the brand-name manufacturer, Novartis,

52. Some have referred to this form of liability as “competitor liability” or “innovator liability.” See generally Schwartz et al., *supra* note 48 (using the phrase “competitor liability”); Wesley E. Weeks, *Picking Up the Tab for Your Competitors: Innovator Liability After PLIVA, Inc. v. Mensing*, 19 GEO. MASON L. REV. 1257 (2012) (using the phrase “innovator liability”).

53. See, e.g., *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 939 (6th Cir. 2014); *Moretti v. Wyeth, Inc.*, 579 F. App'x 563, 565 (9th Cir. 2014); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 478 (5th Cir. 2014); *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 406 (6th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1290 (10th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1093–94 (8th Cir. 2013); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 184 (5th Cir. 2012); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011); *Foster*, 29 F.3d at 167; *Coleson v. Janssen Pharm., Inc.*, 251 F. Supp. 3d 716, 721–22 (S.D.N.Y. 2017); *Chatman v. Pfizer, Inc.*, 960 F. Supp. 2d 641, 658 (S.D. Miss. 2013); *Couick*, 691 F. Supp. 2d at 645; *Stoddard*, 630 F. Supp. 2d at 631; *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532, at *7 (Fla. Cir. Ct. Feb. 17, 2006); *PLIVA, Inc. v. Dement*, 780 S.E.2d 735, 743 (Ga. Ct. App. 2015); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 380 (Iowa 2014); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 35 (La. Ct. App. 2008); *Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 350 (Minn. Ct. App. 2001); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676, 691 (Mo. Ct. App. 2014); *Silva v. Smithkline Beecham Corp.*, No. 31,276, 2013 WL 4516160, at *4 (N.M. Ct. App. Feb. 7, 2013); *Weese v. Pfizer, Inc.*, No. 153742/12, 2013 WL 5691993, at *2 (N.Y. Sup. Ct. Oct. 8, 2013); *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 867 (W. Va. 2018).

54. See *Huck*, 850 N.W.2d at 380.

55. See *McNair*, 818 S.E.2d at 867.

56. Issues of tort law are generally a matter of state substantive law. Thus, federal court decisions on the duty question are predictions of what the state's highest court would hold as a matter of law. Accordingly, while federal decisions are relevant to the duty question, they are not dispositive on substantive state law questions. See *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 663 (Ala. 2014) (recognizing a duty of care in response to a question certified from the Middle District of Alabama). As the Eleventh Circuit observed, “considerations of comity and federalism counsel that we proceed gingerly when venturing into uncharted waters of state substantive law.” See *Guarino*, 719 F.3d at 1251.

57. See, e.g., *Garner v. Johnson & Johnson*, No. 1:16-cv-01494-SLD-JEH, 2017 WL 6945335, at *7–8 (C.D. Ill. Sept. 6, 2017); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 709 (D. Vt. 2010); *Weeks*, 159 So. 3d at 649; *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 47–48 (Cal. 2017); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 318 (Ct. App. 2008); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1219–20 (Mass. 2018).

58. 407 P.3d 18 (Cal. 2017).

owed injured generic users a duty to warn of adverse side effects.⁵⁹ In *Novartis*, the plaintiffs were newborns who had developed brain defects while in utero because their mothers had ingested the generic drug terbutaline.⁶⁰ The newborns subsequently brought suit against Novartis for negligently failing to warn of terbutaline's developmental side effects.⁶¹ In its defense, Novartis contended that it owed no duty to warn of the developmental side effects at issue for the plain fact that their mothers had not ingested Novartis's drug.⁶²

The Supreme Court of California, however, emphatically disagreed with Novartis, and after applying a multifactor duty test, held that a duty of care flowed between Novartis and the injured generic plaintiffs.⁶³ Embedded in the court's rationale was a "constellation of [duty] factors," led by foreseeability and public policy.⁶⁴ On the foreseeability consideration, the court reasoned that it was "entirely foreseeable" to Novartis that any defects in its warning label would generate risks of harm to generic users because of federal law's requirement that generic manufacturers maintain the *same* warning labels as their brand-name counterparts.⁶⁵ Thus, because Novartis could foresee harm to generic users, the court stated that the company owed a duty to adequately warn generic users of adverse side effects.⁶⁶

In addition to foreseeability, the *Novartis* court also found public policy to cut in favor of imposing a duty of care.⁶⁷ For one, the court observed that recognizing duty would expose Novartis to increased failure-to-warn liability and, accordingly, would further incentivize Novartis to diligently update its warning labels once new side effects came to light.⁶⁸ Indeed, the court found this public policy justification particularly compelling since brand-name manufacturers, under *PLIVA*, are the only market participants capable of unilaterally strengthening prescription drug warning labels.⁶⁹ Thus, after balancing both principle and policy, the court concluded that a duty of care existed and paved the way for the newborn plaintiffs' failure-to-warn claims to proceed to trial.⁷⁰

Just three months after the *Novartis* decision, the Massachusetts Supreme Judicial Court in *Rafferty v. Merck & Co.*⁷¹ also held that a duty of care

59. *Id.* at 47.

60. *Id.* at 22.

61. *Id.*

62. *Id.* A wrinkle in the facts was that, by the time of litigation, Novartis had divested ownership of the brand-name drug. *See id.* at 40. Novartis claimed that this divestment extinguished liability, but the court ultimately rejected this argument. *See id.* at 47.

63. *Id.* at 28.

64. *Id.*

65. *Id.* at 29.

66. *Id.* The court also found additional considerations—the degree of certainty that the plaintiff suffered injury, closeness of the relationship, moral blame, and availability of insurance—to weigh in favor of recognizing a duty of care. *Id.* at 28–30.

67. *Id.* at 31–32.

68. *See id.*

69. *Id.*

70. *Id.* at 47.

71. 92 N.E.3d 1205 (Mass. 2018).

existed between brand-name manufacturers and generic users.⁷² Like its predecessor court in *Novartis*,⁷³ the *Rafferty* court agreed that foreseeability cut in favor of recognizing a duty of care;⁷⁴ however, on the public policy issue, the court found itself at a crossroads.⁷⁵ On the one hand, the court reasoned that recognizing a duty of care would provide much-needed relief to injured generic users and enhance the financial incentive for brand names to vigilantly warn of adverse side effects.⁷⁶ But on the other hand, the court observed that imposing a duty could expose brand-name manufacturers to excessive liability and potentially chill prescription drug innovation.⁷⁷ After weighing the competing policy considerations at stake, the court split the baby and held that brand-name manufacturers owe generic users a duty “not to act in reckless disregard of an unreasonable risk of death or grave bodily injury.”⁷⁸ Thus, by recalibrating the standard of care under the breach element from negligence to recklessness, the court endeavored to limit brand-name manufacturer liability while still holding the manufacturer accountable for its more egregious conduct.⁷⁹ Under *Rafferty*, then, generic users could bring reckless—but not negligent—failure-to-warn claims against brand-name manufacturers.⁸⁰

In sum, this pair of well-reasoned state supreme court decisions, *Novartis* and *Rafferty*, represents a pivotal development in prescription drug failure-to-warn jurisprudence. To be sure, although courts recognizing a duty of care are still the exception—not the norm⁸¹—this minority view now has bite due to the endorsement of the high courts of California and Massachusetts. At the same time, however, it is necessary to temper this optimism with pragmatism, given the status quo majority “no duty” view.⁸² Thus, this Part now turns to two emblematic cases of this majority view.

C. The Majority Position: Iowa and West Virginia

In July 2014, the Supreme Court of Iowa decided *Huck v. Wyeth, Inc.*,⁸³ a now-leading authority in the no duty case law. In *Huck*, the plaintiff consumed the generic drug—metoclopramide—and consequently developed severe tardive dyskinesia, a disease which the manufacturer had failed to

72. *Id.* at 1219.

73. Interestingly, despite the two cases’ close proximity to one another, the Massachusetts Supreme Judicial Court did not reference the California decision in its opinion.

74. *Rafferty*, 92 N.E.3d at 1213–14.

75. *See id.* at 1215–20.

76. *Id.* at 1217–18.

77. *Id.* at 1215–17. *But see* T.H. v. Novartis Pharm. Corp., 407 P.3d 18, 32 (Cal. 2017) (observing that imposing a duty of care would not place an onerous burden on brand-name manufacturers because they are already obligated under federal law to warn of ongoing risks).

78. *Rafferty*, 92 N.E.3d at 1219.

79. *Id.*

80. *Id.* at 1219–20.

81. *See supra* note 53 and accompanying text.

82. *See supra* note 53 and accompanying text.

83. 850 N.W.2d 353 (Iowa 2014).

adequately warn her about.⁸⁴ Shortly thereafter, the plaintiff sued the manufacturers of metoclopramide and metoclopramide's brand-name equivalent on a failure-to-warn theory.⁸⁵ But from the outset, the plaintiff's claims against the generic manufacturer were preempted under *PLIVA*.⁸⁶ Thus, the only tenable claims left standing before the Supreme Court of Iowa were the plaintiff's failure-to-warn claims alleged against the manufacturer of metoclopramide's brand-name equivalent.⁸⁷ The viability of these claims, in turn, rested on the threshold question of whether the brand-name defendant owed a duty to warn of tardive dyskinesia to the generic plaintiff.⁸⁸

In addressing this gateway duty question, the court concluded that the brand-name defendant owed no duty to warn of injurious side effects to generic users, such as the plaintiff.⁸⁹ Though the court's opinion contained a treasure trove of arguments supporting no duty,⁹⁰ the driving engine of its decision rested on two primary rationales. First, the plaintiff's case was essentially a product liability action—cloaked in negligence—which lacked the necessary causation predicate,⁹¹ and, second, compelling public policy considerations counseled against finding a duty of care.⁹²

To begin, the court held that causation was a necessary predicate for imposing a duty of care under Iowa tort law. This proved fatal to the plaintiff's claim since her injury was caused by the generic drug—metoclopramide—and not the brand-name drug.⁹³ Accordingly, duty could not exist because the causation requirement necessary under Iowa law could not be met.⁹⁴ In addition, the court took into consideration the public policy implications of imposing a duty of care and found duty undesirable because it would levy a substantial burden on brand-name manufacturers to compensate a vast population of the prescription drug industry; thus, this policy concern provided an additional justification to reject duty.⁹⁵ Indeed, by emphasizing the public policy considerations in conducting its duty analysis, the *Huck* court manifested its conception of the duty element under negligence as merely a euphemism for a cost-benefit analysis of liability, which in this case, warranted a no duty decision.⁹⁶

84. *Id.* at 358–60.

85. *Id.* at 360–62.

86. *Id.* at 361; *see also* *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 614–15 (2011).

87. *Huck*, 850 N.W.2d at 361.

88. *See id.*

89. *Id.* at 380.

90. *See id.* at 369–82.

91. *See id.* at 371–75; *see also infra* Part III.B.1.

92. *See Huck*, 850 N.W.2d at 376–81.

93. *See id.* at 376.

94. *See id.*

95. *Id.* at 377.

96. *See id.* at 376 (“In short, a lack of duty may be found if either the relationship between the parties or [public] policy considerations warrants such a conclusion.” (quoting *McCormick v. Nikkel & Assocs.*, 819 N.W.2d 368, 371 (Iowa 2012))).

Four years later, the Supreme Court of Appeals of West Virginia followed suit in *McNair v. Johnson & Johnson*⁹⁷ and declined to recognize duty.⁹⁸ In *McNair*, the plaintiff began suffering from acute respiratory distress syndrome (ARDS) after consuming the generic drug levofloxacin.⁹⁹ Levofloxacin's warning label, however, did not include the risk of ARDS because its brand-name counterpart, Levaquin, also lacked warning of ARDS in its label.¹⁰⁰ Hence, the injured plaintiff filed suit against Levaquin's manufacturer on the theory that it had negligently failed to warn about the risk of ARDS.¹⁰¹ Here, like *Huck*, the duty question took center stage as the focus of appellate review before West Virginia's highest court.

After examining a series of duty considerations, the Supreme Court of Appeals of West Virginia concluded that Levaquin's manufacturer owed no duty to warn of ARDS to the plaintiff.¹⁰² Similar to the reasoning in *Huck*, the court found the lack of causation by the brand-name product¹⁰³ and underlying public policy concerns to foreclose the possibility of duty.¹⁰⁴ Additionally, while the court acknowledged that foreseeability cut against its position,¹⁰⁵ it nevertheless hunkered down and buttressed its reasoning with a litany of federal and state no duty precedents.¹⁰⁶ In sum, West Virginia's highest court, too, viewed the duty element of negligence as predominantly a question of public policy and, after weighing the competing policy interests at stake, declined to recognize duty in order to cater to compelling policy interests.¹⁰⁷

III. KEY ARGUMENTS UNDERGIRDING BOTH SIDES OF THE DUTY QUESTION

Generic users have predominantly litigated failure-to-warn claims against brand-name defendants under the traditional tort of negligence or the tort of negligent misrepresentation.¹⁰⁸ Regardless, the inquiry that is universally significant, and the central focus of this Note, is the threshold question of whether the brand-name manufacturer owes a duty of care to generic users in providing adequate warning labels.¹⁰⁹ This inquiry is crucial because a finding of no duty by courts in the first instance sounds the death knell for

97. 818 S.E.2d 852 (W. Va. 2018).

98. *Id.* at 861.

99. *Id.* at 858–59.

100. *Id.*

101. *Id.*

102. *Id.* at 861.

103. *Id.* at 863.

104. *Id.* at 865–67.

105. *See id.* at 862.

106. *See id.* at 863.

107. *See id.* at 865.

108. *See, e.g., T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 26 (Cal. 2017) (addressing both negligence and negligent misrepresentation claims).

109. *See Goldberg & Zipursky, supra* note 12, at 658–59 (observing that forty-eight states retain duty as an element of negligence).

generic users' negligence claims.¹¹⁰ Thus, this Note now turns to the key arguments courts have considered in reaching their conclusions about the existence of a duty of care. This Part begins by discussing the principal arguments supporting duty and then transitions to the key rationales undergirding the no duty position.

A. Key Arguments Supporting the Existence of Duty

Courts, in finding a duty of care, have advanced a string of recurring arguments in support of their positions. Chief among them are prominent doctrinal factors, such as reasonable foreseeability, and public policy considerations. This section discusses these in turn.

1. Reasonable Foreseeability Supports Duty

Since the dawn of negligence in common law,¹¹¹ the foreseeability of physical harm has endured as a significant consideration with respect to the duty element.¹¹² This is not a coincidence given that the principle underlying foreseeability is a powerfully intuitive one: when conducting an activity that raises a foreseeable risk of harm to a class of persons, take due care to prevent such harms from being realized. This timeless principle, as applied to the brand-name, generic-user context, produces a compelling justification for courts recognizing a duty of care from the former to the latter.¹¹³

Well established under federal law is the obligation of generic manufacturers to maintain the same warning labels as those of the brand name.¹¹⁴ Accordingly, due to this *sui generis* federal scheme, the brand-name manufacturer “knows to a legal certainty” that any deficiencies in its own warning label will also contaminate the generic drug’s label.¹¹⁵ Precisely because the brand name knows this crucial fact—that a defective brand-name label will cause an identically defective generic label—courts have found that the risk of harm to generic users is foreseeable and that this foreseeability, in turn, generates a duty of care between brand names and

110. See *supra* note 12 and accompanying text.

111. *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (N.Y. 1916) (considering foreseeability under duty); *Thomas v. Winchester*, 6 N.Y. 397, 409–10 (1852) (same); see also *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 311–12 (Ct. App. 2008) (stating that foreseeability has been a primary consideration under duty for over eighty years).

112. See Benjamin C. Zipursky, *Foreseeability in Breach, Duty, and Proximate Cause*, 44 WAKE FOREST L. REV. 1247, 1258–62 (2009) (finding that every state, except three, treats foreseeability as a “significant factor” in analyzing duty of care in negligence cases).

113. See, e.g., *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 706 (D. Vt. 2010) (finding that the risk of harm to generic users was “entirely foreseeable”); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 670 (Ala. 2014) (holding that foreseeability favors finding a duty of care); *Novartis*, 407 P.3d at 29–30; *Conte*, 85 Cal. Rptr. 3d at 311–12 (finding a duty of care based on foreseeability); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1215 (Mass. 2018).

114. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011).

115. *Novartis*, 407 P.3d at 29; see also *Kellogg*, 762 F. Supp. 2d at 706; *Rafferty*, 92 N.E.3d at 1215.

generic users.¹¹⁶ Furthermore, some courts have gone even further and observed that injury to generic users is not simply foreseeable but *eminently* foreseeable and that federal law's obligation of warning-label equivalence elevates the degree of foreseeability to near certitude.¹¹⁷ Therefore, the conclusion follows that the amplified degree of harm foreseen by the brand-name manufacturer obligates it to take reasonable care to avoid causing such harm to generic users.¹¹⁸

As the case law demonstrates, foreseeability has turned out to be a powerful justification: nearly every court ruling in favor of duty has relied substantially on foreseeability to supply its rationale.¹¹⁹ Among them, three state supreme courts—Alabama,¹²⁰ California,¹²¹ and Massachusetts¹²²—have found foreseeability to be highly probative of duty. Conversely, courts coming out the other way and holding no duty have also acknowledged that foreseeability cuts against their position.¹²³ Nevertheless, these courts justify their no duty holdings with other considerations, such as public policy.¹²⁴

Though federal law does most of the heavy lifting in furnishing foreseeability, state regulatory regimes also play a prominent role. Currently, all fifty states have “state substitution laws” which permit—and sometimes even require—pharmacists to substitute brand-name prescriptions with generic drugs where it is more affordable for the patient.¹²⁵ Under such a regulatory regime, a generic user may have been originally prescribed a

116. See *Kellogg*, 762 F. Supp. 2d at 706; *Novartis*, 407 P.3d at 29–30; *Rafferty*, 92 N.E.3d at 1215.

117. *Conte*, 85 Cal. Rptr. at 311–13; see *Kellogg*, 762 F. Supp. 2d at 706; *Novartis*, 407 P.3d at 29; *Rafferty*, 92 N.E.3d at 1215.

118. See *Kellogg*, 762 F. Supp. 2d at 706; *Novartis*, 407 P.3d at 29; *Conte*, 85 Cal. Rptr. at 311–12; *Rafferty*, 92 N.E.3d at 1215.

119. See, e.g., *Garner v. Johnson & Johnson*, No. 1:16-cv-01494-SLD-JEH, 2017 WL 6945335, at *7 (C.D. Ill. Sept. 6, 2017) (recognizing a duty of care because injuries to generic users were reasonably foreseeable); *Kellogg*, 762 F. Supp. 2d at 705; *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 670 (Ala. 2014) (ruling for duty based on the foreseeability of harm); *Novartis*, 407 P.3d at 29–30; *Conte*, 85 Cal. Rptr. at 311–12; *Rafferty*, 92 N.E.3d at 1214.

120. See *Weeks*, 159 So. 3d at 670.

121. See *Novartis*, 407 P.3d at 29–30.

122. See *Rafferty*, 92 N.E.3d at 1214.

123. See, e.g., *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1284–86 (10th Cir. 2013) (discussing foreseeability but finding no duty on other grounds); *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 862 (W. Va. 2018) (noting that foreseeability is “important” but finding no duty on policy grounds). *But see Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 375–76 (Iowa 2014) (holding that there existed no duty of care but observing that foreseeability does not enter the analysis).

124. See *infra* Part III.B.

125. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 628 (2011) (Sotomayor, J., dissenting) (“Currently, all States have some form of generic substitution law.”); *Rafferty*, 92 N.E.3d at 1216; see also Schwartz et al., *supra* note 48, at 1846–48 (observing that all fifty states have adopted some version of state substitution laws allowing pharmacists to fill a brand-name prescription with a more affordable generic equivalent). Note that generic drugs are generally cheaper than their brand-name counterparts, which makes statutory substitution highly likely in many states. See DEP’T OF HEALTH & HUMAN SERVS., UNDERSTANDING RECENT TRENDS IN GENERIC DRUG PRICES I (2016), <https://aspe.hhs.gov/system/files/pdf/175071/GenericsDrugpaperr.pdf> [<https://perma.cc/434C-B5GE>].

brand-name drug but, due to statutory substitution, is forced to consume the generic version¹²⁶ and thus preempted from suing under *PLIVA*.¹²⁷

As applied to duty, courts have found that statutory substitution laws enhance the foreseeability argument because they alert the brand-name manufacturer to the reality that many generic users will rely directly on its warning label despite ultimately consuming a generic counterpart.¹²⁸ Accordingly, whether the consumer bought and ingested the brand-name drug is no longer an accurate litmus test for who, in fact, initially relied on the brand-name drug's warning label.¹²⁹ As a result, state substitution laws have been construed to add an extra layer of depth to the foreseeability argument.¹³⁰

Additionally, state substitution laws—as applied to the brand-name, generic-user context—arguably pose a fundamental fairness concern. In her scathing dissent in *PLIVA*, Justice Sotomayor claimed that preempting generic users from suing is inequitable because state substitution laws permit pharmacists to unilaterally swap brand-name prescriptions with generic ones.¹³¹ Therefore, in a jurisdiction with a statutory substitution regime, preempting generic users from bringing suit would unfairly penalize them for the state-mandated dispensing decisions of their pharmacists.¹³² Were it not for state substitution laws, Justice Sotomayor contended, generic users who had initially been prescribed brand-name drugs would have retained their right to sue if they suffered injurious side effects.¹³³ Thus, to conclude, state substitution laws present a basic fairness concern that sheds doubt on the brand-name, generic-user dichotomy.

2. Recognizing Duty Is Sound Public Policy

Although opponents of duty have relied heavily on public policy considerations to justify their positions,¹³⁴ courts taking the minority view have managed to advance several public policy rationales of their own.

126. See *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 670 (Ala. 2014); *Novartis*, 407 P.3d at 30; *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 299, 313 (Ct. App. 2008).

127. See *PLIVA*, 564 U.S. at 609.

128. See *Weeks*, 159 So. 3d at 670; *Novartis*, 407 P.3d at 30; *Conte*, 85 Cal. Rptr. at 313.

129. See *Weeks*, 159 So. 3d at 670.

130. See *id.*; *Novartis*, 407 P.3d at 30; *Conte*, 85 Cal. Rptr. at 313.

131. See *PLIVA*, 564 U.S. at 643 (Sotomayor, J., dissenting) (“[W]hether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug.”). Also note that this problem is further perpetuated by the reality that most prescription drug consumers do not know *ex ante* that consuming the brand-name drug preserves their right to legal redress, while consuming the generic drug shuts them out under *PLIVA*. Thus, maintaining the distinction between generic-drug and brand-name-drug users effects an inequitable result not attributable to a conscious purchase decision by the consumer.

132. *Id.*

133. See *id.*; see also *Weeks*, 159 So. 3d at 670; *Novartis*, 407 P.3d at 30.

134. See *infra* Part III.B.

a. The Incentive to Keep Warning

One public policy served by imposing a duty of care is the incentive it would provide for brand-name manufacturers to continuously update their warning labels beyond their exclusivity periods.¹³⁵ It is a widely known fact that brand-name manufacturers experience a “precipitous decline” in sales once their exclusivity periods end and generic drugs enter the market.¹³⁶ Unsurprisingly, due to competition from their cheaper generic-drug counterparts, brand-name pharmaceuticals occupy less than 10 percent of the market after the exclusivity period.¹³⁷ In turn, commensurate with the brand-name drug’s decline in drug sales is its manufacturer’s waning incentive to vigilantly warn of ongoing and future side effects.¹³⁸ Indeed, this incentive deficit is a natural offshoot of the brand name’s substantially reduced market share, which translates to an equally reduced threat of consumer litigation.¹³⁹ Thus, once the brand-name drug’s exclusivity protection ends, its manufacturer is under little financial incentive to carefully research and warn of new risks that flow from its drug.¹⁴⁰

Some courts have found that one way to cure this incentive problem is to recognize a duty of care between brand-name manufacturers and generic users.¹⁴¹ The *Rafferty* court reasoned that if it were to recognize duty, thereby paving the way for generic users to bring failure-to-warn claims against brand-name manufacturers, then the brand name would have a considerable financial incentive to continuously update its warning label even when its monopoly had ceased.¹⁴² The court opined that this would make for sound public policy because stronger warnings on brand-name drugs would have a trickle-down effect on generic-drug labels, and this trickle-down effect would enhance the overall safety of prescription drug use throughout the industry.¹⁴³

The *Novartis* and *Rafferty* courts also contended that replenishing the financial incentive to warn was of heightened importance because the brand-name manufacturer is the only authority, under *PLIVA*, that can unilaterally strengthen prescription drug warning labels.¹⁴⁴ Thus, without a sufficient incentive to warn, the whole industry could suffer from underwarning because generic manufacturers are also immune from failure-to-warn

135. See *Novartis*, 407 P.3d at 31; *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1217 (Mass. 2018).

136. *Rafferty*, 92 N.E.3d at 1216; see also DEP’T OF HEALTH & HUMAN SERVS., *supra* note 125, at 2 (“88 percent of dispensed prescriptions are for generic drugs . . .”).

137. See *Rafferty*, 92 N.E.3d at 1217; DEP’T OF HEALTH & HUMAN SERVS., *supra* note 125, at 14.

138. See *Rafferty*, 92 N.E.3d at 1217.

139. See *id.*

140. See *id.* Note, however, that under federal law, brand-name manufacturers are already under an obligation to continuously research and warn of potential side effects. See *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 32 (Cal. 2017); *Schwartz et al.*, *supra* note 48, at 1844.

141. See *Novartis*, 407 P.3d at 31; *Rafferty*, 92 N.E.3d at 1217.

142. See *Rafferty*, 92 N.E.3d at 1217.

143. See *id.*

144. See *id.*; see also *Novartis*, 407 P.3d at 32.

liability.¹⁴⁵ Indeed, the *Rafferty* court made this concern abundantly clear when it stated that “no one—neither the generic manufacturer nor the brand-name manufacturer—would have a complete incentive to maintain safe labels.”¹⁴⁶ Therefore, it found that recognizing a duty of care would help effectuate the prudent public policy of incentivizing adequate prescription drug warning throughout the industry.¹⁴⁷

b. “A Right Without a Remedy”

The other major public policy served by recognizing a duty of care is the avenue of legal recourse it would provide for injured generic users in vindicating the harms they suffered.¹⁴⁸ As stated before, generic manufacturers are currently immunized from failure-to-warn liability, meaning injured generic users cannot bring suit against the manufacturers of their drugs.¹⁴⁹ Therefore, the only viable option left is for generic users to bring suit against the brand-name manufacturer.¹⁵⁰ Against this backdrop, the Massachusetts Supreme Judicial Court expressed concern that its finding of no duty would, in effect, foreclose the last opportunity for generic plaintiffs to obtain legal relief for their injuries.¹⁵¹ This concern is certainly plausible given that nearly 90 percent of all prescription drug consumers are generic-drug users.¹⁵² Accordingly, to find no duty of care would in essence shut out 90 percent of all prescription drug consumers from any means of legal redress should they suffer adverse side effects.¹⁵³ Therefore, while the *Rafferty* court believed this “a right without a remedy” argument did not, by itself, establish a duty of care, it nevertheless found it to be a compelling public policy consideration.¹⁵⁴

145. See *Rafferty*, 92 N.E.3d at 1217–18.

146. *Id.* at 1217. Some brand-name defendants have argued in response that imposing a duty of care will lead to overwarning of side effects, which will “dilute the effectiveness of any individual warning.” *But see Novartis*, 407 P.3d at 33 (rejecting this overwarning argument).

147. See *Rafferty*, 92 N.E.3d at 1217–18.

148. See *id.* at 1218.

149. See *supra* Part II.A.

150. See *Rafferty*, 92 N.E.3d at 1218.

151. See *id.*

152. See PHRMA, BIOPHARMACEUTICALS IN PERSPECTIVE 1, 49 (2017), <http://phrma-docs.phrma.org/files/dmfile/Biopharmaceuticals-in-Perspective-2017.pdf> [<https://perma.cc/3SBW-JCNJ>].

153. See *id.*

154. It is important to observe that imposing a duty of care does not necessarily provide legal compensation to injured generic plaintiffs. Also note that this public policy argument has not been embraced by many courts in finding a duty of care; indeed, as this Note’s discussion indicates, only the Massachusetts Supreme Judicial Court seemingly accounted for this policy interest in reaching its conclusion. One hypothesis for why this argument has not gained traction in the case law is that it falls prey to the opposition’s argument that “[d]eep-pocket jurisprudence is law without principle.” See Schwartz et al., *supra* note 48, at 1844. Likewise, this Note does not rely on this argument to advance its position.

B. Key Arguments Undergirding the No Duty Position

The majority position, as reflected in the case law, is the position that manufacturers of brand-name drugs do not owe a duty of care to generic users.¹⁵⁵ Embedded within this position are various arguments—advanced by courts, brand-name defendants, and commentators alike—that provide a smattering of tort doctrine, public policy, and general legal principles. Among them, this Note identifies and discusses the emblematic arguments undergirding the no duty position.

This section begins by examining the argument that negligence suits by generic plaintiffs are an end run around strict products liability claims that cannot proceed due to lack of causation. This section then discusses the doctrinal arguments for finding no duty and concludes with an analysis of the key public policy considerations put forth by duty opponents.

1. Negligence Is an End Run Around Strict Products Liability

Duty opponents have argued that failure-to-warn negligence suits brought by generic users against brand-name defendants are merely an end run around strict products liability law that should be prohibited.¹⁵⁶ Strict products liability jurisprudence traces its origins to section 402A of the Restatement (Second) of Torts, which advocated a new theory of liability—strict liability—borne by manufacturers for injuries caused by their products' defects.¹⁵⁷ The Restatement's rationale for this liability was grounded in fairness: a seller should assume responsibility for harms caused by its own product.¹⁵⁸ Another rationale was public policy, as sellers were thought to be in the best position to compensate their injured users by absorbing such costs as the price of doing business.¹⁵⁹ Thus, for a plaintiff to assert a strict products liability claim, Restatement section 402A required proof of *causation*: the plaintiff must prove that her alleged injury was caused by the defendant's product.¹⁶⁰

These core principles of fairness and public policy have, in turn, provided a substantial justification for shielding brand-name manufacturers from

155. See *supra* note 53 and accompanying text.

156. See, e.g., *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169–70 (4th Cir. 1994); *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643, 645 (W.D.N.C. 2010) (“While the plaintiff’s claims are masked in various legal theories, they are premised on a single claim of product liability.”); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631, 633 (E.D.N.C. 2009) (“Although cloaked in different theories for recovery, plaintiffs’ claims are nevertheless product liability claims.”); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 373 (Iowa 2014); see also *Schwartz et al.*, *supra* note 48, at 1860–61.

157. RESTATEMENT (SECOND) OF TORTS § 402A (AM. LAW INST. 1965).

158. See *id.* (justifying strict liability on the rationale that a product’s seller “has undertaken and assumed a special responsibility toward” its user); see also *Huck*, 850 N.W.2d at 378 (holding that products liability law “place[s] responsibility for the harm caused by a product” because the manufacturer profited from it).

159. RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (AM. LAW INST. 1965); see also *Huck*, 850 N.W.2d at 376; *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 866 (W. Va. 2018).

160. See RESTATEMENT (SECOND) OF TORTS § 402A (AM. LAW INST. 1965).

liability for failure to warn generic plaintiffs.¹⁶¹ The argument's starting point is that generic users are precluded from bringing strict products liability actions against brand-name manufacturers because their injuries flow from a generic drug, not the brand-name drug.¹⁶² But, in addition, opponents of duty further argue that the same rationales precluding generic users from asserting strict products liability claims apply equally and with the same effect to negligence claims brought against the brand-name defendant.¹⁶³ This can be appropriately referred to as the "end run" argument because it essentially views generic users' failure-to-warn claims as an end run around traditional strict products liability.

The crux of the end run argument is that permitting the generic user to get a second bite at the apple through a negligence suit frustrates the narrowly confined and carefully crafted parameters of strict products liability.¹⁶⁴ Implicit here is the premise that strict products liability is the exclusive form of liability for product defects under tort law; thus, generic users' negligence suits perpetuate an impermissible circumvention around section 402A.¹⁶⁵ Indeed, when viewed in a vacuum, permitting the end run presents an inherently uncomfortable proposition by requiring one manufacturer—the brand name—to potentially absorb the liability costs of its competitors.¹⁶⁶

In addition, courts have also found that allowing generic users' failure-to-warn claims to proceed based on the technical distinction that they sound in negligence, rather than strict products liability, would also frustrate strict products liability's core public policy aim of limiting a manufacturer's liability to harm caused by only its own products.¹⁶⁷ As the *McNair* court observed, brand-name manufacturers "cannot spread the cost of compensating generic consumers" because they do not market or profit from the generic drug's sale.¹⁶⁸ Thus, the argument holds that the brand name is not best situated to absorb the burdens of liability for injuries caused by generic drugs.¹⁶⁹

Numerous state legislatures have taken steps to prevent the end run around strict products liability by enacting products liability statutes.¹⁷⁰ Products liability statutes collapse all claims alleging harm from a defective product, regardless of the theory of liability, under the unitary heading of "product

161. See *Huck*, 850 N.W.2d at 376; *McNair*, 818 S.E.2d at 866.

162. See *McNair*, 818 S.E.2d at 866 (rejecting generic plaintiff's strict products liability claim for lack of causation).

163. See, e.g., *Huck*, 850 N.W.2d at 376; *McNair*, 818 S.E.2d at 866.

164. See *Huck*, 850 N.W.2d at 376; *McNair*, 818 S.E.2d at 866.

165. See *Huck*, 850 N.W.2d at 376; *McNair*, 818 S.E.2d at 866.

166. Commentators have, in fact, viewed this proposition to be in tension with the basic spirit of products liability law, which is to place liability flowing from a product's defects on the manufacturer of that particular product. Schwartz et al., *supra* note 48, at 1844.

167. See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994) ("We also reject the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug.").

168. *McNair*, 818 S.E.2d at 866.

169. See *id.*

170. Twenty-five states have products liability statutes. See Schwartz et al., *supra* note 48, at 1861.

liability action.”¹⁷¹ In turn, courts have interpreted these statutes to require proof of causation for *any* claim arising out of a defective product.¹⁷² This practice has indeed proven fatal to generic plaintiffs’ negligence suits because generic users, by definition, cannot prove that the brand-name manufacturer caused their injuries.¹⁷³ As a result, many courts applying products liability statutes to generic users’ failure-to-warn claims do not even go so far as to entertain the duty question because they can dispose the case on statutory grounds.¹⁷⁴ Thus, these statutes provide courts with a powerful tool—causation—to sidestep the duty question and thereby render the generic user’s claim a nonstarter.

To summarize, proponents of the end run argument view generic users’ failure-to-warn claims to be in conflict with core principles underlying strict products liability, and they further contend that such claims amount to nothing more than a circumvention of strict products liability law that ought not be sanctioned. At the same time, state products liability statutes give courts the means to stop this end run effect and rid their dockets of generic users’ failure-to-warn claims. While this may certainly incur collateral costs—for example, shutting injured generic users out from legal redress—such costs nevertheless take a backseat to the more egregious end run effect which takes precedence.¹⁷⁵

2. Doctrinal Arguments Weighing Against Duty

Courts and brand-name defendants have argued in the alternative that, even if generic users’ failure-to-warn claims are truly distinct and are not merely an end run around strict products liability, these claims *still* cannot

171. *See, e.g.*, KY. REV. STAT. ANN. § 411.300(1) (West 2018) (“[A] ‘product liability action’ shall include any action brought for or on account of personal injury . . . caused by or resulting from the manufacture . . . of any product.”); N.J. STAT. ANN. § 2A:58C-8 (West 2019) (“‘Product liability action’ means any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim . . .”).

172. *See, e.g.*, *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476–77 (5th Cir. 2014) (holding that, under Mississippi and Texas statutes, the plaintiff must establish that his injuries were caused by the defendant’s product to proceed with failure-to-warn claims); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676, 690 (Mo. Ct. App. 2014) (“To succeed on a product liability claim under [the Kentucky product liability statute] . . . a plaintiff must show that the defendant’s product is the legal cause of her injuries.”). Some states have folded negligence into strict products liability by requiring proof of causation even without a state statute. *See, e.g.*, *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1251 (11th Cir. 2013) (requiring the plaintiffs to prove causation under Florida common law); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 371 (Iowa 2014) (finding that, under Iowa common law, a plaintiff must establish causation to proceed with failure-to-warn claims against a defendant).

173. *See, e.g.*, *Demahy v. Schwarz Pharm. Inc.*, 702 F.3d 177, 182 (5th Cir. 2012) (applying the Louisiana product liability statute and dismissing generic users’ failure-to-warn claims); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423–24 (6th Cir. 2011) (applying the Kentucky statute to dismiss claims).

174. *See, e.g.*, *Lashley*, 750 F.3d at 476–77 (applying a products liability statute and not addressing the negligence duty question).

175. *See Guarino*, 719 F.3d at 1253 (prioritizing the causation argument over providing a remedy to generic users); *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 866 (W. Va. 2018) (same).

proceed to trial because brand-name manufacturers do not owe a duty of care to generic users.¹⁷⁶ At its base, the claim is that brand-name manufacturers owe a duty to warn of adverse side effects *only* to the users of its products and no one else.¹⁷⁷ Although courts have fashioned their no duty findings predominantly on a public policy rationale—which is examined in the next section—they have also advanced a number of doctrinal arguments.

First, courts have reasoned that recognizing a duty of care between brand-name manufacturers and generic users would “stretch the concept of foreseeability too far.”¹⁷⁸ In *Foster v. American Home Products Corp.*,¹⁷⁹ the Fourth Circuit authored this famous line and declined to recognize a duty of care; however, the court failed to adequately explain what it is about recognizing a duty of care that stretches the doctrinal principle of foreseeability *too* far.¹⁸⁰ And although subsequent courts have latched onto this argument when concluding no duty, they have not adequately analyzed its meaning or effect.¹⁸¹

A proper reading of the Fourth Circuit’s argument is in order. In articulating its “foreseeability stretched too far” proposition, the Fourth Circuit was *not* arguing it was unforeseeable that generic users would rely on brand-name drug warning labels.¹⁸² Quite the contrary, the court acknowledged that foreseeability cut for the generic user, but it nevertheless downplayed the significance of foreseeability in its analysis.¹⁸³ As evidence of this, the Fourth Circuit’s opinion pivoted from discussing foreseeability to examining privity and reasoned that the absence of privity between generic users and brand-name manufacturers justified its conclusion.¹⁸⁴ Thus, while foreseeability is relevant to the duty analysis, to find it dispositive would “stretch” the concept of foreseeability too far,¹⁸⁵ and therefore, courts should

176. See, e.g., *Strayhorn v. Wyeth Pharm., Inc.*, 737 F.3d 378, 405 (6th Cir. 2013); *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994); *Simpson v. Wyeth, Inc.*, No. 7:10-cv-01771-HGD, 2010 WL 5485812, at *5 (N.D. Ala. Dec. 9, 2010); *PLIVA, Inc. v. Dement*, 780 S.E.2d 735, 743 (Ga. Ct. App. 2015) (holding under Georgia tort law that a manufacturer’s duty of care only extends to users of its products); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 371 (Iowa 2014); *McNair*, 818 S.E.2d at 866.

177. See, e.g., *Strayhorn*, 737 F.3d at 405 (holding that, under Tennessee law, a product manufacturer owes a duty of care to only its own users, not another product’s users); *Foster*, 29 F.3d at 171; *Dement*, 780 S.E.2d at 743 (holding that, under Georgia tort law, a manufacturer’s duty only extends to users of its product); *Huck*, 850 N.W.2d at 371; *McNair*, 818 S.E.2d at 866.

178. *Foster*, 29 F.3d at 171; see also *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013); *Chatman v. Pfizer, Inc.*, 960 F. Supp. 2d 641, 656 (S.D. Miss. 2013); *Huck*, 850 N.W.2d at 370; *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34 (La. Ct. App. 2008); *McNair*, 818 S.E.2d at 862.

179. 29 F.3d 165 (4th Cir. 1994).

180. See *id.* at 171.

181. See, e.g., *In re Darvocet*, 756 F.3d at 944; *Schrock*, 727 F.3d at 1285; *Chatman*, 960 F. Supp. 2d at 656; *Huck*, 850 N.W.2d at 370; *Stanley*, 991 So. 2d at 34; *McNair*, 818 S.E.2d at 862.

182. See *Foster*, 29 F.3d at 171.

183. See *id.*

184. See *id.* (declining to recognize a duty of care because of the lack of privity).

185. See *id.*

judiciously factor in countervailing considerations when deciding the duty element.¹⁸⁶ The Fourth Circuit's rebuttal of foreseeability is often construed by citing courts as an open invitation to afford generous weight to policy rationales that favor a finding of no duty.¹⁸⁷

Second, courts have held that manufacturers of brand-name drugs do not owe a duty of care to generic users because they only "intend to communicate" with their own consumers.¹⁸⁸ In practice, this contention has primarily been used to rebuff generic plaintiffs who pursue claims on the tort of negligent misrepresentation.¹⁸⁹

One rationale underlying the recognition of the tort of negligent misrepresentation is based on equity or fairness: a party "who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance on such information."¹⁹⁰ Thus, the tort generally requires a showing of reasonable reliance by the injured party in order to give rise to a cause of action.¹⁹¹ Consequently, courts have found reasonable reliance to be the Achilles' heel of generic users' negligent misrepresentation claims because brand-name manufacturers only endeavor to warn their *own* users of adverse side effects, not the entire market.¹⁹² Privity thus establishes the parameters of reasonable reliance on brand-name warning labels, and since generic users lie outside the scope of privity, their efforts to prove reasonable reliance are unavailing.¹⁹³

186. See *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 28 (Cal. 2017) ("To determine . . . duty . . . we balance [a] constellation of factors . . ."); *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532, at *7 (Fla. Cir. Ct. Feb. 17, 2006) ("[A]lthough foreseeability is clearly relevant to the existence of a duty . . . 'duty is not established by . . . foreseeability alone.'" (quoting *Hernandez v. Tallahassee Med. Ctr., Inc.*, 896 So. 2d 839, 841 (Fla. Dist. Ct. App. 2005))). A proper understanding of the Fourth Circuit's argument is necessary to avoid misconstruing which way foreseeability cuts in the duty analysis. Indeed, one can erroneously construe the Fourth Circuit's argument to mean that the risk of harm to generic users is unforeseeable. This Note, however, views such an interpretation to be mistaken and, more plainly, an indefensible position. See *infra* Part IV.A.

187. See, e.g., *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 370 (Iowa 2014); *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 862 (W. Va. 2018) (recognizing foreseeability as one consideration but declining to find that the brand-name defendant owed a duty of care in light of "broader policy considerations").

188. See *Schrock*, 727 F.3d at 1285; *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613 n.9 (8th Cir. 2009); *Huck*, 850 N.W.2d at 371; *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34–35 (La. Ct. App. 2008).

189. See, e.g., *Schrock*, 727 F.3d at 1283; *Mensing*, 588 F.3d at 613 (holding that negligent misrepresentation requires "direct communication"); *Huck*, 850 N.W.2d at 371; *Stanley*, 991 So. 2d at 33.

190. RESTATEMENT (SECOND) OF TORTS § 311 (AM. LAW INST. 1965); see also *id.* § 311 cmt. b; cf. *Huck*, 850 N.W.2d at 371 (limiting the tort of negligent misrepresentation to sellers in the business of disseminating information).

191. See *Huck*, 850 N.W.2d at 391; RESTATEMENT (SECOND) OF TORTS § 311 (AM. LAW INST. 1965).

192. See, e.g., *Schrock*, 727 F.3d at 1282–83; *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994) (finding that generic users had no basis to justify reliance); *Huck*, 850 N.W.2d at 391; *Stanley*, 991 So. 2d at 33–34.

193. See *Schrock*, 727 F.3d at 1285; *Mensing*, 588 F.3d at 613 n.9; *Foster*, 29 F.3d at 170; *Huck*, 850 N.W.2d at 377; *Stanley*, 991 So. 2d at 34.

The other rationale—fairness—also does not translate well given that brand-name manufacturers do not further any self-interest by having generic users rely on their warning labels.¹⁹⁴ Therefore, the argument runs, it is inappropriate to impose a duty of care where the brand-name manufacturer neither intends to communicate with the generic user nor benefits from the generic user's reliance on its drug's warning label.¹⁹⁵

Third, courts have argued that recognizing a duty is unfair to brand-name manufacturers because they retain “no control” over the generic manufacturer's product.¹⁹⁶ The central premise underlying this argument is that a party's liability is limited to that which it has control over.¹⁹⁷ Likewise, brand-name manufacturers do not market, manufacture, or provide warning labels for generic drugs, meaning they have no control over the generic drug's quality or pharmaceutical safety.¹⁹⁸ Therefore, courts have declined to find a duty of care where the brand-name manufacturer clearly lacked control over the generic drug.¹⁹⁹

Finally, some commentators and courts have confronted the foreseeability argument head-on by arguing that the generic user's injury is *not* a foreseeable consequence of the brand's conduct but merely a foreseeable outcome of federal law.²⁰⁰ That is, the risk of harm to generic users generated by inadequate warning labels is purely a product of federal law and not the brand's own doing.²⁰¹ Thus, a rule that obliges brand-name defendants to pick up the liability tabs of competitors because of a federal regulatory scheme completely out of their control contravenes basic notions of justice and puts the generic user's injury outside the scope of foreseeability.

194. See *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340, 1346 (S.D. Ala. 2010) (finding negligent misrepresentation claims to be limited to sellers of information such as real estate appraisers and accountants); *Huck*, 850 N.W.2d at 372 (noting that negligent misrepresentation claims are limited to sellers of information in the business of supplying information).

195. See *Schrock*, 727 F.3d at 1285; *Foster*, 29 F.3d at 170; *Mosley*, 719 F. Supp. 2d at 1346; *Huck* 850 N.W.2d at 372.

196. *Foster*, 29 F.3d at 170; see *Schrock*, 727 F.3d at 1285; *Huck*, 850 N.W.2d at 378.

197. See *Schrock*, 727 F.3d at 1285; *Foster*, 29 F.3d at 170; *Huck*, 850 N.W.2d at 378.

198. See *Schrock*, 727 F.3d at 1285; *Foster*, 29 F.3d at 170; *Huck*, 850 N.W.2d at 378 (stating that the brand-name manufacturer played no part in placing the generic drug in the stream of commerce or controlling its pharmaceutical safety).

199. See *Schrock*, 727 F.3d at 1285; *Foster*, 29 F.3d at 170; *Huck*, 850 N.W.2d at 378. One interesting argument generic plaintiffs have made, albeit unsuccessfully, is that the brand-name manufacturer voluntarily undertook a duty of care to generic users by promulgating its warning label. See, e.g., *Swicegood v. PLIVA, Inc.*, 543 F. Supp. 2d 1351, 1356 (N.D. Ga. 2008) (rejecting the plaintiff's “Good Samaritan” duty argument).

200. See *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 944 (6th Cir. 2014) (“[T]he generic consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control.”); *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 862 (W. Va. 2018); see also Schwartz et al., *supra* note 48, at 1865 (arguing that federal law creates the foreseeable harm, not the brand-name manufacturer's conduct).

201. See *In re Darvocet*, 756 F.3d at 944; *McNair*, 818 S.E.2d at 862; see also Schwartz et al., *supra* note 48, at 1865.

3. Public Policy Concerns Weighing Against Duty

In finding no duty of care, various state and federal courts have relied substantially on public policy considerations.²⁰² Furthermore, the high courts of Iowa and West Virginia have given these policy considerations great weight.²⁰³ Indeed, this cost-benefit approach to duty rests on the belief that the duty element's metaphysical purpose is to draw definite lines on tort liability,²⁰⁴ and thus, because the benefits of recognizing a duty of care between brand-name manufacturers and generic users are outweighed by the costs, no duty ought to be recognized. Having already examined the policy virtues of a duty of care,²⁰⁵ this Part now turns to the major public policy considerations undergirding the opposite position.

a. Recognizing Duty Will Open the Floodgates

Courts have held that imposing liability on brand-name manufacturers for generic users' injuries would turn them into de facto general insurers of the generic-drug market.²⁰⁶ This fear of opening the floodgates of liability has, in turn, nudged courts to reject a duty of care.²⁰⁷ To their credit, the floodgates concern is not merely hypothetical but, indeed, plausible: according to one study, nearly 70 percent of Americans will at some point in their lives consume prescription drugs, and, of this massive figure, roughly 2460 people will die each week of harmful side effects.²⁰⁸ Given the sheer size of the prescription drug market and the number of potential plaintiffs—

202. See, e.g., *Schrock*, 727 F.3d at 1285; *Sharp v. Leichus*, No. 2004-CA-0643, 2006 WL 515532, at *7 (Fla. Cir. Ct. Feb. 17, 2006); *Huck*, 850 N.W.2d at 378; *McNair*, 818 S.E.2d at 862. Courts ruling in favor of duty have also assessed the public policy considerations cutting against this finding. See, e.g., *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 706 (D. Vt. 2010) (recognizing a duty of care, under Vermont law, on foreseeability grounds despite public policy arguments to the contrary); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1220 (Mass. 2018).

203. See, e.g., *Huck*, 850 N.W.2d at 380; *McNair*, 818 S.E.2d at 865 (holding that tort law is “a question of public policy” that the court should clearly delineate limits on liability). *But see Rafferty*, 92 N.E.3d at 1220 (holding that generic plaintiffs do not have a negligence cause of action but can claim recklessness after balancing policy considerations).

204. See WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS § 31, at 180 (1941) (“[D]uty’ is not sacrosanct in itself, but only an expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection.”). For a critique of this view, see generally John C. P. Goldberg & Benjamin C. Zipursky, *The Moral of MacPherson*, 146 U. PA. L. REV. 1733 (1998).

205. See *supra* Part III.A.2.

206. See, e.g., *Huck*, 850 N.W.2d at 380; *McNair*, 818 S.E.2d at 863. *But see T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 32 (Cal. 2017) (arguing that recognizing a duty of care does not impose any additional burden on brand-name manufacturers).

207. See *Huck*, 850 N.W.2d at 380; *McNair*, 818 S.E.2d at 863. In addition to the floodgates issue, some argue that to recognize a duty and expose the brand-name manufacturer to generic liability perpetuates unfairness because the generic manufacturer takes advantage of the brand name's marketing, research, and development while also shifting liability to the brand name. See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169–70 (4th Cir. 1994).

208. See Michael O. Schroeder, *Death by Prescription*, U.S. NEWS & WORLD REP. (Sept. 27, 2016, 9:00 AM), <https://health.usnews.com/health-news/patient-advice/articles/2016-09-27/the-danger-in-taking-prescribed-medications> [<https://perma.cc/C6C8-4WM2>].

roughly 2460 new candidates each week²⁰⁹—duty opponents argue that the brand-name manufacturer would be exposed to far too much liability and far too high litigation costs were courts to impose on them a duty of care to generic users.²¹⁰ Thus, to prevent this form of liability without limits, many courts have held no duty of care as a matter of law and effectively put the brakes on generic users' claims before they even get to trial.²¹¹

Nestled in the public policy discussion is also an institutional competency argument that lends support to the no duty position.²¹² In declining to recognize a duty of care, some courts have espoused the view that the judiciary is ill-equipped to adequately assess the broader public policy ramifications of recognizing a duty of care.²¹³ In a nutshell, this argument asserts that because the potential liability attached to recognizing duty is great, the judiciary ought to refrain from finding duty and pass the buck to the political branches, which possess institutional advantages in tailoring liability in order to avert a potential floodgates problem.²¹⁴ This belief was succinctly expressed by the Supreme Court of Iowa when it observed that “courts are not institutionally qualified to balance the complex, interrelated, and divergent policy considerations in determining . . . liability obligations of brand and generic pharmaceuticals.”²¹⁵

Another floodgates concern is the “spillover effect” it could have on other factual situations. In *Huck*, the Supreme Court of Iowa contended that, if it were to impose a duty of care between brand-name manufacturers and generic users, then it would similarly have to find duty in every other case where one company “mimics” the designs of another company.²¹⁶ In articulating this spillover concern, the court referred to a vital premise underlying the no duty position: a manufacturer is only liable for the injuries caused by its own product, not the products of its competitors.²¹⁷

209. *See id.*

210. *See Huck*, 850 N.W.2d at 380; *McNair*, 818 S.E.2d at 863.

211. *See Huck*, 850 N.W.2d at 380; *McNair*, 818 S.E.2d at 863. In addition to the pragmatic justification of preventing boundless litigation, some have gone further and argued that this kind of excessive liability conflicts with a basic value underlying tort law: to protect free enterprise and to create a climate of economic prosperity. *See Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 684 (Ala. 2014) (Murdock, J., dissenting) (“An enterprising spirit alone, however, is not enough. The law must protect the fruits of enterprise and create a climate in which trade and business innovation can flourish.”).

212. *See Huck*, 850 N.W.2d at 377; *McNair*, 818 S.E.2d at 866–67 (stating that courts should not interfere with congressional policy choices).

213. *See Huck*, 850 N.W.2d at 377; *McNair*, 818 S.E.2d at 866–67.

214. *See Huck*, 850 N.W.2d at 377; *McNair*, 818 S.E.2d at 866–67.

215. *Huck*, 850 N.W.2d at 377. The institutional competency argument has also served an additional function in addressing the injustice of leaving injured generic users without legal redress. *See Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013); *McNair*, 818 S.E.2d at 866. Although ruling that there is no duty of care leaves the injured generic user without any remedy, courts contend that the ultimate solution should be determined by Congress or the FDA, not the judiciary. *See Guarino*, 719 F.3d at 1253; *McNair*, 818 S.E.2d at 866.

216. *Huck*, 850 N.W.2d at 380.

217. *See id.* at 380–81.

b. Imposing Duty Could Chill Innovation

The other significant public policy consideration undergirding the no duty position is the prospect of chilling prescription drug innovation.²¹⁸ In the last quarter century, breakthroughs in prescription pharmaceuticals have advanced effective treatments for diseases such as “HIV/AIDS, cancer, and heart disease,” among many others.²¹⁹ Indeed, this impressive track record affirms the social desirability of drug innovation and corroborates the need for further breakthroughs in the prescription drug industry.

Given the valuable purposes prescription drugs serve, there are those who have argued that future medicinal innovations will be stymied if brand-name manufacturers are asked to shoulder the tort liability of their generic competitors.²²⁰ This argument is particularly persuasive in light of the complex and expensive federal regulatory process that already stymies successful prescription drug innovation.²²¹ Indeed, after accounting for research and development and navigation of the FDA approval process²²² the cost of innovation rises to the billions.²²³ In addition, the substantial risk of denial by the FDA makes prescription drug innovation an inherently precarious venture.²²⁴

Understandably then, courts have been reluctant to impose additional costs on brand-name manufacturers out of concern that this imposition may chill prescription drug innovation.²²⁵ This judicial posture has, in turn, laid the groundwork for rejecting a duty of care between brand-name manufacturers and generic users, as courts have reasoned that the additional burden of compensating generic users—when added to the already high transaction costs of drug innovation—may be enough for brand name C-suites across the country to halt drug innovation altogether.²²⁶ Thus, imposing duty promotes

218. *See* *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1215 (Mass. 2018) (holding that public policy favors marketing new and effective drugs).

219. *See* PHRMA, *supra* note 152, at 3.

220. *See* Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1153–54 (1987) (“If in the aggregate the net gains are wiped out by the liability costs, then the product will no longer be made.”); Schwartz et al., *supra* note 48, at 1879. *But see* STEVEN GARBER, RAND INST. FOR CIV. JUSTICE, ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION INVOLVING THE SAFETY AND EFFECTIVENESS OF PHARMACEUTICALS 62 (2013), <https://www.rand.org/pubs/monographs/MG1259.html> [<https://perma.cc/BNE5-63RF>] (stating that there is “no reliable empirical basis” for determining the effect of products liability on drug innovation).

221. *See* *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013).

222. The FDA approval process takes, on average, ten to fifteen years. *See* *Rafferty*, 92 N.E.3d at 1217.

223. *See* Schwartz et al., *supra* note 48, at 1842; *see also* PHRMA, *supra* note 152, at 29.

224. *See* U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-17-564, INVESTIGATIONAL NEW DRUGS 14 (2017), <https://www.gao.gov/assets/690/685729.pdf> [<https://perma.cc/B2FS-4HP5>] (finding that fewer than one in ten prescription applications are ultimately approved by the FDA).

225. *See, e.g.*, *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 377 (Iowa 2014); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1217 (Mass. 2018); *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 866 (W. Va. 2018).

226. *See* *Huck*, 850 N.W.2d at 377; *McNair*, 818 S.E.2d at 866; *see also* Schwartz et al., *supra* note 48, at 1842.

unsound public policy because of the potential chilling effect it could have on future pharmaceutical innovations.²²⁷

In conclusion, as this Part illustrates, there are meritorious arguments supporting each side of the duty issue. Understandable, then, is the current reality that courts remain deeply divided on this question.²²⁸ With this in mind, this Note now turns to its own remedial approach for courts to apply in addressing whether there exists a duty of care from brand-name manufacturers to generic users.

IV. RESOLUTION

This Note contends that a duty of care exists between brand-name manufacturers and injured generic users and that this duty, in essence, generates an obligation on the brand name to take reasonable care in adequately warning generic users of adverse side effects. In taking this stance, this Note conceptualizes the duty element of negligence law as a normative obligation that flows from one class of persons to another by virtue of the context in which those persons find themselves situated.²²⁹ Appropriately then, the job of the court is to probe the factual circumstances in which a given relationship exists in the category of cases at issue and—based on that initial inquiry—to articulate a decision on whether tort law ought to recognize a duty of care.²³⁰

Yet, in the same breath, this Note also acknowledges the countervailing Prosserian view of duty adopted by many courts: that, at its core, duty is a question of public policy.²³¹ Using this framework, some commentators²³² and courts have concluded that prudent policy in the context of brand-name manufacturers and generic users warrants a no duty conclusion.

Large philosophical issues of how to think about the duty element in negligence law, however, need not be addressed here²³³ because whichever framework is selected, there is a way for courts to recognize a duty of care between brand-name manufacturers and generic users. That is, courts can

227. See *Huck*, 850 N.W.2d at 377; *McNair*, 818 S.E.2d at 866. The Massachusetts Supreme Judicial Court found the chill on innovation to be particularly worrisome because the liability from generic users would only arise when the brand-name manufacturer's exclusivity period had ended, whereupon it would barely profit from its drug. See *Rafferty*, 92 N.E.3d at 1216. The court also expressed concern over the fact that the liability could continue "indefinitely" and could thus shroud the brand-name manufacturer's financial future in uncertainty. See *id.*

228. See *supra* Part II.A.

229. See *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (N.Y. 1916) (holding that there was no duty of care by examining features of the litigants' relationship); see also *Goldberg & Zipursky*, *supra* note 204, at 1819 (analyzing *MacPherson*).

230. See *MacPherson*, 111 N.E. at 1053; see also *Goldberg & Zipursky*, *supra* note 204, at 1819.

231. See PROSSER, *supra* note 204, § 31, at 180 ("'[D]uty' is not sacrosanct in itself, but only an expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection.").

232. See generally *Schwartz et al.*, *supra* note 48.

233. This Note leaves this important issue to the Calabresis and Zipurskys of the academic world to debate and resolve.

impose a duty of care on brand-name manufacturers and still retain fidelity to both public policy concerns and doctrinal considerations. This remedial position—which Part IV.B discusses at length—rests on two fundamental planks.

First and foremost, the history of tort law and circumstances unique to the brand-name, generic-user relationship provide compelling arguments for recognizing a duty of care. This is the doctrinal plank. Second, in recognizing duty, courts are institutionally equipped to address the public policy concerns embedded in the duty question because of their core competence in crafting tort law. This is the public policy plank.

Prior to that discussion, however, this Note does not turn a blind eye to the existing no duty arguments found in the case law. As a token of respect for those arguments' validity, this Part begins by rebutting the key arguments advanced by courts in support of no duty.

A. Rebutting the No Duty Arguments

This section rebuts the end run argument and doctrinal considerations undergirding the no duty position in the case law. The public policy discussion is reserved for Part IV.B.

1. The Negligence Cause of Action Has No End Run Effect

Duty opponents' argument that generic users' negligence suits are a mere end run around strict products liability is unpersuasive for several reasons.²³⁴ First, this contention rests on the implicit assumption that strict products liability limits manufacturer liability because it forecloses the negligence cause of action. That assumption, however, profoundly misconstrues the role of strict products liability in tort law. Strict products liability, as it originated and developed in the common law, did not set out to supplant traditional theories of tort liability against manufacturers but rather to create an additional pocket of liability based on the closeness of the buyer-seller relationship.²³⁵ This original intent is thus interpreted to mean that section 402A of the Restatement (Second) of Torts is a sword to inflict more liability on corporate America, not a shield to protect it from conventional theories of tort liability.²³⁶ Indeed, by wielding strict products liability as a shield against negligence, it is the brand-name defendant, and not the generic user, who promotes an inequitable end run effect: the brand wrongly uses strict products liability as an end run around traditional negligence law to limit its own liability.

234. See *supra* notes 156–75 and accompanying text.

235. See *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 461–62 (Cal. 1944) (Traynor, J., concurring) (finding that public policy establishes the need for greater protection than negligence in the seller-buyer relationship); RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (AM. LAW INST. 1965) (justifying strict liability on the rationale that a product's seller “has undertaken and assumed a special responsibility toward” its user).

236. See *Escola*, 150 P.2d at 461–62; RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (AM. LAW INST. 1965).

Second, the end run argument fails in another respect because there is, in fact, a plausible distinction between strict liability and negligence in the failure-to-warn context.²³⁷ As a threshold matter, it is undisputed that consumers of brand-name drugs are owed a greater duty of care than what is owed to generic users. This is the case because brand-name users directly transact, rely upon, and ultimately ingest the brand-name manufacturer's product. Accordingly, these circumstances create an inextricable nexus—the seller-buyer relationship—that generates the highest duty of vigilance to provide adequate warning labels. And indeed, in acknowledging this special relationship, tort law permits brand-name users to succeed on failure-to-warn claims on a strict liability theory, thereby allowing plaintiffs to prevail at trial without having to prove fault or negligence.²³⁸ But there is a catch: to unlock this special privilege, tort law requires that the brand-name user establish that her injuries were *caused* by the brand-name drug.²³⁹

Generic users, in contrast, do not have the power to claim liability without fault because they cannot prove causation, meaning they are confined to bringing failure-to-warn claims, sounding in negligence, against the brand-name defendant.²⁴⁰ Such claims are distinct from their strict products liability siblings because they require a showing of actual fault under the breach element to prevail at trial. To meet this fault element, the plaintiff must demonstrate that the brand-name manufacturer negligently promulgated its warning label and that this act of negligence constituted a breach of the duty of care owed to the generic user.²⁴¹ Against this backdrop, it makes little sense to require the generic user to prove causation by the brand-name product because her suit claims negligence—not strict products liability—as the basis for liability.

Paradoxically, a telling symptom of the end run argument's flaws is the leading no duty case, *McNair*. As discussed in Part II.C, the Supreme Court of Appeals of West Virginia held in *McNair* that the generic plaintiffs were barred from bringing strict products liability claims against the brand-name defendant due to a lack of causation.²⁴² The court, however, then proceeded to part two of its analysis, where it separately addressed the plaintiffs' negligence claims and concluded that there was no duty based on public

237. See *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 670 (Ala. 2014) (finding that precedents confused strict liability with other areas of tort law); *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 37 (Cal. 2017) (holding that California tort law does not conflate strict liability and negligence law); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 299, 310 (Ct. App. 2008) (“Negligence and strict products liability are separate and distinct bases for liability that do not automatically collapse into each other . . .”).

238. See, e.g., *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 860–61 (W. Va. 2018) (holding that strict products liability requires the defendant to be the manufacturer of the defective product).

239. See *id.*

240. See *id.*

241. See *Palsgraf v. Long Island R. Co.*, 162 N.E. 99, 101 (N.Y. 1928) (holding that the defendant's conduct must be a breach of duty owed to the plaintiff).

242. See *McNair*, 818 S.E.2d at 861.

policy considerations.²⁴³ Although the court's duty determination was erroneous,²⁴⁴ its analytical approach of distinguishing strict products liability from negligence was correct: strict products liability and negligence are two fundamentally distinct theories of liability that do not turn on either's viability.²⁴⁵ Thus, because the two theories run parallel to one another, allowing one theory to proceed in lieu of the other does not produce an end run effect.²⁴⁶

2. No Duty Findings Misconstrue Basic Tort Doctrine

The doctrinal considerations advanced by courts in finding no duty of care also rest on shaky legs, starting with the contention that brand-name manufacturers do not “intend to communicate” with generic users and thus cannot be held to owe them a duty of care.²⁴⁷ This argument's fatal flaw flows from its unsubstantiated position that the brand-name manufacturer is only in privity with its own consumers, and thus, its duty to warn tracks the limits of contract.²⁴⁸ Indeed, this reasoning is flawed because it conflates the very nature of obligations that arise under tort law with those that originate in contract. Over a century ago, in *MacPherson v. Buick Motor Co.*,²⁴⁹ then-Judge Benjamin Cardozo abolished privity as a limit on duty in tort law:

We have put aside the notion that the duty to safeguard life and limb, when the consequences of negligence may be foreseen, grows out of contract and nothing else. We have put the source of the obligation where it ought to be. We have put its source in the law.²⁵⁰

Thus, those owed a duty of care by brand-name manufacturers are not limited to persons with whom the manufacturers have contracted, but to whom tort law says they owe such obligations to. While contract may, without doubt, be one source of legal obligation, it does not subsume the duties imposed on brand-name manufacturers by the institution that is tort law. Therefore, privity as a basis for the intended-communication argument presents an unworkable model.

Next, the doctrinal argument claiming that brand-name manufacturers possess “no control” over generic drugs and that liability should therefore not follow²⁵¹ also falls short of establishing no duty. While it is true that brand-name manufacturers do not retain control over the generic drug's manufacture or marketing, it is equally true that they *do* control the contents

243. *See id.* at 866.

244. *See infra* Part IV.B.

245. *See McNair*, 818 S.E.2d at 866.

246. *See id.*

247. *See supra* notes 195–98 and accompanying text.

248. *See Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1285 (10th Cir. 2013); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613 n.9 (8th Cir. 2009); *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 371 (Iowa 2014); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31, 34 (La. Ct. App. 2008).

249. 111 N.E. 1050 (N.Y. 1916).

250. *Id.* at 1053.

251. *See supra* notes 199–200 and accompanying text.

of the generic drug's warning label.²⁵² This sort of control is relevant and sufficient for duty to attach because generic plaintiffs do not claim negligent manufacture²⁵³ as the basis for their cause of action but rather that the brand-name defendant was careless in promulgating its warning label and that this carelessness furnished a but-for cause of their injury. Because the claim arises out of the brand-name manufacturer's handling of its own warning label and not the generic drug's manufacture or marketing, liability does, in fact, follow control.

Finally, the argument that injury to generic users is merely a foreseeable outcome of federal law—not the brand-name manufacturer's conduct²⁵⁴—is of no moment. It is one thing to minimize the *effect* of foreseeability in the duty analysis,²⁵⁵ but another to suggest that there are *no* foreseeable risks of harm to generic users stemming from negligent labeling of brand-name drugs. While the former is a defensible position, the latter is not.

As the case law indicates, federal law's mandate that generic drugs have the same warning labels as their brand-name counterparts supplies foreseeability.²⁵⁶ This federal mandate makes it plainly foreseeable to the brand-name manufacturer that deficiencies in its warning label “will be perpetuated in the label for its generic bioequivalent.”²⁵⁷ Thus, while one can certainly criticize such a federal regulatory regime as promoting unsound public policy or engendering unfairness, one cannot credibly contend that harm to generic users is unforeseeable.

B. *The Case for Duty*

This Note argues, in essence, that traditional tort doctrine and public policy considerations can coalesce in finding a duty of care. Indeed, in reflecting upon the history of the common law and the distinctive features of the brand-name, generic-user relationship, courts can cobble together a compelling doctrinal narrative for finding a duty of care. But in doing so, courts do not work injustice to the other substantial consideration—public policy—that underlies the duty inquiry. This much is true, for courts have the institutional expertise—indeed, it's perhaps their core competence—to craft negligence

252. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011); see also 21 U.S.C. § 355(j)(2)(A)(v) (2012).

253. If generic plaintiffs claimed negligent manufacture, not negligent failure to warn, then the “no control” argument would indeed apply with full effect since the brand-name manufacturer does not exercise any control over the generic drug's physical production.

254. See *supra* notes 199–200 and accompanying text.

255. See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994) (downplaying the significance of foreseeability); see also *supra* notes 178–86 and accompanying text.

256. See, e.g., *Garner v. Johnson & Johnson*, No. 1:16-cv-01494-SLD-JEH, 2017 WL 6945335, at *7 (C.D. Ill. Sept. 6, 2017); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 705 (D. Vt. 2010); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 670 (Ala. 2014); *T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 29–30 (Cal. 2017); *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 299, 311–12 (Ct. App. 2008); *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1214 (Mass. 2018).

257. See *Novartis*, 407 P.3d at 29.

law in small-bore ways that allow for a duty of care while limiting liability.²⁵⁸ Furthermore, even if courts fail to rise to the occasion and the floodgates do, in fact, burst from recognizing a duty of care, state legislatures and Congress have shown the political will and aptitude to regulate the prescription drug industry; thus, the political branches stand as a backstop to suspected judicial shortcomings. Against this backdrop, this Note endeavors to convey a fighting message to future courts deciding this difficult question: where tort doctrine tells us there is a duty, yet public policy considerations stand in the way, we must at least *try* to remain faithful to principle by giving effect to that duty.

1. Back to the Basics: Cardozo's *MacPherson*

History lends formidable support to finding a duty to warn between brand-name manufacturers and generic users. In 1916, Judge Cardozo, in the seminal tort case *MacPherson v. Buick Motor Co.*, confronted the daunting question of whether an automobile manufacturer owed a duty of care to an injured user of its vehicle with whom it lacked privity.²⁵⁹ In concluding that a duty of care was owed, Judge Cardozo articulated several factors that lie at the core of duty in negligence: whether the manufacturer *knew* “of a danger, not merely possible, but probable” that would result from negligent conduct and whether it was “reasonably certain” that the defendant’s negligent conduct would put “life and limb in peril.”²⁶⁰ By examining such considerations—awareness and probability of harm and the nature of the injury—the *MacPherson* court grappled with the context in which the litigants’ relationship arose to answer the duty question.²⁶¹ Likewise, and over a century later, *MacPherson*’s emphasis on context provides a powerful justification for recognizing a duty of care between brand-name manufacturers and generic users.

As applied here, the first batch of *MacPherson* considerations—awareness and probability of harm²⁶²—cuts for duty in light of the prescription drug industry’s distinctive federal regulatory scheme. Because federal law obligates generic manufacturers to adopt the brand-name warning label,²⁶³ the brand-name manufacturer is aware that generic users will suffer harm should the label fail to adequately warn of any adverse side effects. Accordingly, it is awareness—not mere foreseeability²⁶⁴—that enhances the case for duty because brand-name manufacturers know *ex ante* that negligently crafting its own warning labels will inevitably cause physical

258. This is what the Massachusetts Supreme Judicial Court did in recalibrating the breach element from negligence to recklessness. *See Rafferty*, 92 N.E.3d at 1219.

259. *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1051 (N.Y. 1916).

260. *Id.* at 1053.

261. *See id.*

262. *See id.*

263. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011).

264. *See T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18, 29–30 (Cal. 2017) (discussing foreseeability of harm).

harm to generic users.²⁶⁵ In addition, the probability of this harm is great²⁶⁶ because, under *PLIVA*, brand-name manufacturers are the only ones that can unilaterally strengthen drug warning labels.²⁶⁷ Therefore, since the power to draft a drug's warnings label lies exclusively within the domain of the brand-name manufacturer, the likelihood of harm to generic users is at its maximum where the brand-name manufacturer declines to use reasonable care in making this label.

From a more fundamental perspective, holding that there exists no duty of care despite the brand's awareness of impending harm to generic consumers cannot be squared with the rest of our legal system, which places a premium on *knowledge*—that is, the *mens rea* element in criminal law or intentional torts like assault and battery. A colorable argument can even be made that this premium on knowledge is a *fortiori* in tort law.²⁶⁸ Indeed, our legal system operates this way because of the bedrock legal principle that knowledge of harm generates a legal obligation to avoid causing that harm. And history, as embodied in *MacPherson*, crystallizes this bedrock principle by providing the key insight that brand-name manufacturers owe a duty of care to generic users because of their awareness of potential harm and the near certitude of injury that will befall generic users should manufacturers fail to exercise due care.²⁶⁹

Continuing on, the second *MacPherson* consideration—the nature of the injury²⁷⁰—also cuts overwhelmingly in favor of finding a duty of care. Deficient prescription drug warning labels generate risks of injury that are of a serious and permanent character. As evident from the California, Iowa, Massachusetts, and West Virginia line of cases,²⁷¹ defective warnings have contributed to palpable harms such as gangrene, tardive dyskinesia, respiratory disease, and, of course, death.²⁷² Accordingly, in *MacPherson*'s terms, inadequate brand-name warning labels cast the generic user's "life and limb in peril," and, thus, this feature of the brand-name, generic-user relationship obligates the brand-name manufacturer to use reasonable care when crafting its warning label.

It is also crucial to note that in asking courts to recognize a duty of care, the generic user does not seek relief for subservient discomforts under tort law, such as emotional distress or economic loss.²⁷³ Instead, she seeks legal recourse for lifelong harms that—in addition to causing profound physical discomfort—can deprive her of her ability to live out her life with dignity. On such injuries, our centuries-old common law has clearly spoken: tort law does not turn a blind eye to such harms. Thus, the real, irreversible, and

265. See *MacPherson*, 111 N.E. at 1053.

266. See *id.*

267. See *PLIVA*, 564 U.S. at 614–15.

268. See *supra* Part III.A.1.

269. See *MacPherson*, 111 N.E. at 1053.

270. See *id.*

271. See *supra* Parts II.B–C.

272. See *supra* Parts II.B–C.

273. See *supra* Parts II.B–C.

concrete injuries suffered by the generic user must be actionable under the tort of negligence because it is precisely this category of harms that *MacPherson* and enduring tort tradition say that tortfeasors have a duty to prevent.²⁷⁴

The third and final insight that *MacPherson* provides is the fighting message to courts to retain fidelity to doctrine when deciding whether a duty of care exists. This Note concedes, frankly and sympathetically, that the duty question in the brand-name, generic-user context is difficult and rife with conflicting justifications that courts must grapple with. But in tackling these issues, courts can take comfort in the fact that Judge Cardozo, too, grappled with the same difficult questions over a century ago in *MacPherson*.²⁷⁵ As two leading tort scholars remark:

From a modern perspective, the question [of whether a manufacturer owes a duty of care to a product user not in privity] may seem too trivial to merit asking, but in Cardozo's day, it was not quite so easy. It is now part of our ordinary social and moral understanding that businesses which manufacture and market products to consumers have certain responsibilities to those consumers, and that those consumers have certain legitimate expectations of manufacturers. These sorts of expectations are built by the law itself in some measure.²⁷⁶

Thus, *MacPherson* tells the tale that courts, in following where tort doctrine leads them, can break from current social norms and understandings when articulating new duties of care.²⁷⁷ At bottom, though recognizing a duty of care between a manufacturer and the consumers of generic equivalents of its products may very well seem novel and unintuitive under modern societal norms, *MacPherson*'s core takeaway is that courts are not shackled by social intuitions when crafting tort law.²⁷⁸ Indeed, just as *MacPherson* eradicated privity as the defining flavor of negligence law over a century ago,²⁷⁹ so too can modern courts shape new understandings and expectations of the prescription drug industry by recognizing a duty of care.

2. The "Integration" Principle

In addition to history, the intimate nature of the brand-name, generic-user relationship, as furnished by federal law, provides further support for the position that a duty of care flows from the former to the latter. To start off, duty opponents are correct in contending that there is no formal relationship between brand-name manufacturers and generic users; after all, generic users are neither the immediate buyers nor the direct users of the brand-name

274. See *MacPherson*, 111 N.E. at 1053.

275. See *id.*

276. See Goldberg & Zipursky, *supra* note 204, at 1816.

277. See *MacPherson*, 111 N.E. at 1053; Goldberg & Zipursky, *supra* note 204, at 1816.

278. See *MacPherson*, 111 N.E. at 1053; Goldberg & Zipursky, *supra* note 204, at 1816.

279. See *MacPherson*, 111 N.E. at 1053.

product.²⁸⁰ Nonetheless, despite the lack of formal privity, a duty of care endures because of the close association the brand name and generic user find themselves in by virtue of federal law.

Under the federal regulatory scheme, the brand name's innovation supplies the foundation for producing its generic-drug counterparts: the generic manufacturer is obligated to ensure that its drug has the same physical composition and warning label as that of the brand name.²⁸¹ Consequently, this *sui generis* framework for the prescription drug industry turns the brand-name manufacturer into a component manufacturer of the generic drug by making it the *de facto* supplier of a constituent part—the *intellectual property*—that is integrated into the final generic product.²⁸² Among other things, “intellectual property” here encompasses the brand name's research and development, representations of pharmaceutical safety to the FDA and the public at large, and, most importantly, the biochemical composition of the generic drug. The integration of this intellectual property into the generic product thus establishes a tight nexus between brand-name manufacturers and generic users that is exceeded only by the buyer-seller relationship shared by the brand-name manufacturer and its direct consumer.

To reiterate then, the integration argument states that the closely intimate relationship between brand-name manufacturers and generic users is a creature of federal law that provides the requisite foundation for finding duty by turning the brand name into a component manufacturer of the generic drug. Viewed from this vantage point, a duty of care undoubtedly exists because the brand name's original intellectual property and representations of pharmaceutical safety—as integrated into the generic drug—lie at the crux of generic users' failure-to-warn claims.²⁸³ Indeed, it is the brand name's pharmaceutical recipe that the generic user comes into contact with and the lack of adequate warning accompanying this intellectual property causes injury from such contact. To the contrary, the argument that no duty of care is owed because generic users ingest the generic drug, not the brand-name drug,²⁸⁴ is unavailing because it focuses on trivial features—the plastic exterior enveloping the substance and the commercial identity of the manufacturer—that are of no consequence to generic users' claims. Their

280. *See, e.g.*, *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994) (discussing the lack of privity).

281. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013) (stating that federal law requires a generic drug to be chemically and biologically equivalent to its “brand-name counterpart”).

282. This Note does not go as far as saying that the brand-name manufacturer is strictly liable to generic users. Although the manufacturer supplies the intellectual property for the generic drug, it does not partake in the selling of the generic product, thus precluding the application of strict products liability.

283. One might also add that the integration argument hits back at the core of the duty opponents' end run argument because, in viewing the intellectual property as a component part of the generic drug, the brand-name manufacturer has directly caused the generic user's injury with its product, the intellectual property. *See supra* notes 156–75 and accompanying text.

284. *See supra* notes 156–75 and accompanying text.

legal claim is, at its core, not about the generic pill's physical casing or the drug's commercial name—which are indeed discrepant between brand-name and generic drugs—but about the drug's intellectual property and its lack of accompanying warning, both of which are exclusively supplied and controlled by the brand-name manufacturer.²⁸⁵ In light of this inextricable link, brand-name manufacturers do owe generic users a duty of care.

Before turning to the public policy discussion, it is worth addressing the inherent fairness—or alleged lack thereof—of imposing a duty of care on the makers of brand-name drugs. Opponents can certainly attack this Note's integration argument by contending that federal law's esoteric framework for the prescription drug industry is beyond the brand-name manufacturer's control,²⁸⁶ and thus, it is unfair to impose a duty of care based on this rationale. However, there are two succinct responses that turn this argument on its head. First, duty in negligence law does not turn on fairness but on doctrinal considerations as applied to a particular plaintiff-defendant relationship.²⁸⁷ And in fact, many duties of care that tort law recognizes or rejects can be characterized, to some degree, as inherently unfair: the duty of care owed to trespassers on one's property,²⁸⁸ the duty of care a Good Samaritan assumes upon initiating a benevolent rescue,²⁸⁹ and, conversely, no duty on local police to save members of the public.²⁹⁰ Thus, tort doctrine, not fairness, draws the contours of duty.

Second, even if one were to concede that fairness is relevant to duty, fairness is inherently unreliable and subject to variation based on which lens one uses to view a set of facts. A brand-name manufacturer faced with a duty of care to generic users may very well argue that it is unfair to expose it to liability for another competitor's product.²⁹¹ At the same time, for the injured generic user who has just had her arm amputated because of gangrene caused by a generic drug,²⁹² no duty is just as, if not more, unfair because it shuts her out from legal recourse.²⁹³ Thus, these contradictory views beg the fatal question: Even if fairness enters the duty calculus, what exactly is fairness and how do we go about consistently construing it under the duty question?

285. See *Bartlett*, 133 S. Ct. at 2471 (observing that federal law requires generic drugs to be chemically and biologically equivalent to the brand-name drugs); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (holding that generic manufacturers must replicate the brand-name drug's warning label).

286. See *supra* notes 195–200 and accompanying text.

287. See *supra* Part IV.B.

288. See, e.g., *Rowland v. Christian*, 443 P.2d 561, 568 (Cal. 1968) (holding that “a man's life or limb does not become less worthy” because he is a trespasser).

289. See, e.g., *Swicegood v. PLIVA, Inc.*, 543 F. Supp. 2d 1351, 1356 (N.D. Ga. 2008).

290. See, e.g., *Riss v. City of New York*, 240 N.E.2d 860, 861 (N.Y. 1968).

291. See *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 169–70 (4th Cir. 1994).

292. See *Wyeth v. Levine*, 555 U.S. 555, 558 (2009).

293. See *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676, 691 (Mo. Ct. App. 2014) (stating that generic users are “cut adrift in a sea of hopelessness” because they are shut out from relief).

3. A Fighting Message to Courts

As noted above, this Note does not wish to engage in the substantive public policy debate coloring the duty question.²⁹⁴ Instead, this Note contends that, notwithstanding the veracity of the policy concerns undergirding the no duty position,²⁹⁵ courts are institutionally equipped to address these concerns because of their core competence in crafting tort law. Furthermore, this Note contends that even if courts do fall short and fallout ensues from their recognition of a duty of care, state legislatures and Congress have shown the political will and wherewithal to regulate the prescription drug industry. Thus, this two-tiered system of defense against the public policy considerations at stake provides a safe harbor for courts to experiment with and find a duty of care.

a. Core Judicial Competence in Crafting Tort Law to Prevent Public Policy Concerns

Courts have the institutional capacity to meet the public policy challenges associated with recognizing a duty of care because of their core competence in crafting tort law.²⁹⁶ As noted above, the Massachusetts Supreme Judicial Court's decision in *Rafferty* is a prime example of such core competence.²⁹⁷

As discussed in Part II, the *Rafferty* court came upon a fork in the road when it found principle to cut for duty and policy to cut against it.²⁹⁸ But instead of treating duty as a zero-sum issue, the court split the baby and found duty by applying its core competence in tort law and recalibrating the breach element from negligence to recklessness.²⁹⁹ The court's tweaking of the breach element thus kept the policy concerns at bay while providing injured generic users an avenue of legal recourse against the more flagrant behavior of brand-name manufacturers.³⁰⁰ And in making this judicial adjustment, the court was able to remain faithful to tort doctrine while alleviating its pressing public policy concerns.³⁰¹

Likewise, future courts in deciding this question can follow Massachusetts's remedial approach because all courts share the same core judicial competence in crafting tort law. Furthermore, courts have a wealth of options to address public policy issues via negligence claims given

294. For a discussion of the public policy considerations embedded in the duty analysis, see *supra* Parts III.B–C.

295. *But see* GARBBER, *supra* note 220, at 62 (disagreeing with these policy concerns).

296. *See, e.g.*, *Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1222 (Mass. 2018) (“[W]e do not believe that by recognizing liability for recklessness we overstep our bounds and intrude into matters for which ‘courts are not institutionally qualified.’” (quoting *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 377 (Iowa 2014))). *But see* *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 377 (Iowa 2014); *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 866 (W. Va. 2018).

297. *Rafferty*, 92 N.E.3d at 1222.

298. *Id.* at 1215–22.

299. *Id.* at 1219–20.

300. *Id.*

301. *Id.*

negligence's four-element structure of duty, breach, causation, and injury.³⁰² Thus, in addition to tinkering with breach, as Massachusetts did, courts can recognize a duty of care and address public policy concerns by finessing a variety of elements under the tort of negligence.

For example, courts may limit liability through proximate causation, especially if the sequence by which the generic user's injuries transpire is unforeseeable or too attenuated from the brand-name manufacturer's negligent conduct.³⁰³ Courts could also finesse the injury element by capping the damages ultimately afforded to generic plaintiffs or by making actionable only a certain class of injuries. Finally, courts could ratchet up the evidentiary standard from preponderance of the evidence to clear and convincing, which would enhance protection for brand-name defendants against meritless claims. Accordingly, these examples make clear that courts could retain fidelity to doctrine and recognize duty while simultaneously stifling the outbreak of ominous policy consequences.³⁰⁴

Of course, duty opponents may question what good recognizing duty even does if courts can employ alternative ways to limit generic plaintiffs' ultimate recovery. This argument, however, fails because it misconceives duty and, more broadly, tort law, as solely a vehicle for compensation.³⁰⁵ While compensation is undoubtedly an important feature of negligence law, it is emphatically not its defining characteristic; there is intrinsic value to recognizing a duty of care that exists independent of compensating private parties.³⁰⁶ For this intrinsic value flows from the empowerment conferred upon the injured generic user against her tortfeasor, and the humanistic gesture of the legal system in telling the generic user, "I understand and recognize the wrong that has been afflicted upon you." Duty in negligence, thus, is not a means to an end but an end in and of itself, and, accordingly, to conceive of duty as merely a question of liability discounts the considerable deontic value inherent in it.

b. The Political Branches Provide a Safe Harbor

Courts can also rest assured when finding a duty of care because, should palpable policy harms ensue, state legislatures and Congress will step in to address those concerns. Evidence of the political branches' will and ability

302. Indeed, this wealth of options idea extends to courts viewing tort law primarily through a law and economics lens. *See, e.g.*, Guido Calabresi, *Civil Recourse Theory's Reductionism*, 88 *IND. L.J.* 449, 452 (2013) ("I am traditional enough to begin with the four classic elements and what they mean: duty, breach, causation, and damages.").

303. *See In re Kinsman Transit Co.*, 338 F.2d 708, 726 (2d Cir. 1964) (limiting liability to where there exists proximate cause).

304. There is an inherent argument to be made as well. If a second-year law student—like this Note's author—can think of such judicial adjustments, there is no reason to believe courts cannot also do so with greater creativity and proficiency.

305. *See generally* Benjamin C. Zipursky, *Civil Recourse, Not Corrective Justice*, 91 *GEO. L.J.* 695 (2003) (arguing that tort law is about providing recourse, not merely monetary compensation).

306. *See generally id.*

to intervene is perhaps most clear from the complex federal regulatory scheme,³⁰⁷ supplemented by state regulations,³⁰⁸ that currently governs the prescription drug industry. The complex and comprehensive nature of these regulations suggest that the political branches take a keen interest in the prescription drug industry and, further, that they do not perceive the common law to be the sole arbiter of the industry's warning-label obligations. Successful past tort reform movements also reinforce the notion that state legislatures can help out if public policy fallouts result.³⁰⁹ In sum, then, the political branches operate effectively as a second line of defense. Courts should therefore take stock of the safe harbor that this provides and recognize a duty of care according to the compelling doctrinal justifications presented by the brand-name, generic-user context.³¹⁰

CONCLUSION

The duty question embedded in the brand-name, generic-user context is one that raises serious concerns and has uncomfortable real-world effects. But despite this, courts should not shy away from the task of faithfully applying tort doctrine as embodied in history and precedent. As Justice Felix Frankfurter once argued, "the judiciary is jeopardized when courts become embroiled in the passions of the day and assume primary responsibility in choosing between competing political, economic and social pressures."³¹¹ No doubt, while endorsing duty requires an abundance of courage in the face of colossal socioeconomic pressures, courts should nevertheless do so because the doctrine demands that a duty of care be recognized.³¹² As history demonstrates, some of the greatest snippets of tort law—Cardozo's abolishment of privity over a century ago³¹³ and Justice Roger Traynor's introduction of strict products liability³¹⁴—also required judicial courage at their inception. These instances, in closing, thus reaffirm and underscore the core message of this Note: where tort law says there is a duty of care, courts should endeavor to effectuate that duty.

307. See generally *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (discussing the complex federal regulatory scheme for the prescription drug industry); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (discussing the modern federal regulatory framework for the prescription drug industry).

308. See *PLIVA*, 564 U.S. at 628 (Sotomayor, J., dissenting) (discussing how every state has enacted some form of prescription substitution laws); Schwartz et al., *supra* note 48, at 1861 (finding that many states have enacted products liability statutes).

309. See generally F. Patrick Hubbard, *The Nature and Impact of the "Tort Reform" Movement*, 35 HOFSTRA L. REV. 437 (2006) (surveying recent tort reform).

310. See *supra* Part IV.B.

311. *Dennis v. United States*, 341 U.S. 494, 525 (1951) (Frankfurter, J., concurring).

312. Cf. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803) ("It is emphatically the province and duty of the judicial department to say what the law is.").

313. See generally *MacPherson v. Buick Motor Co.*, 111 N.E. 1050 (N.Y. 1916).

314. See *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 461–62 (Cal. 1944) (Traynor, J., concurring).

ADDENDUM

As this Note was going to press, a 6-3 majority of the U.S. Supreme Court handed down a decision on a federal maritime tort claim that was strikingly analogous to the generic users' claims against brand-name pharmaceutical manufacturers analyzed above. *Air & Liquid Systems Corp. v. DeVries*³¹⁵ is a self-described federal common law decision that focuses on the duty issue in a negligence claim against a product manufacturer. As described briefly below, Justice Kavanaugh's decision for six members of the Court provides strong—albeit indirect—support for the recognition of a duty of care between brand-name manufacturers and generic users.

In *DeVries*, the defendants had manufactured ship equipment for the U.S. Navy, which the Navy later integrated with asbestos products made by third parties.³¹⁶ Many years later, plaintiffs—Navy veterans who had been exposed to this integrated asbestos—brought negligence claims against the equipment manufacturer, alleging that the manufacturer owed them a duty to warn of asbestos's harmful effects because of the noxious material's foreseeable incorporation into the defendants' ship equipment.³¹⁷ In response, the defendants argued that they had not manufactured the asbestos and, accordingly, could not be held liable for harms flowing from another manufacturer's product.³¹⁸

The Court ruled for the injured plaintiffs and held that, in the maritime context, a “manufacturer does have a duty to warn [users of the final integrated product] when its product *requires* incorporation of a part and the manufacturer knows or has reason to know that the integrated product is likely to be dangerous for its intended uses.”³¹⁹ In so reasoning, the Court rejected the defendants' argument that, because they had not manufactured the asbestos itself, the plaintiff must fail on the duty element.³²⁰ Moreover, the Court rejected the defendants' public policy arguments against such liability.³²¹ In lieu of such considerations, the Court rested its rationale for the recognition of a duty on: (1) the combination of the foreseeability of the integrated product *and* the knowledge that future uses of its product would *require* the inclusion of the asbestos, and (2) economic efficiency, which the Court concluded supported duty because of the defendants' superior position to warn of asbestos harms.³²²

DeVries strongly supports the proposal defended in the body of this Note: clear doctrinal and policy analysis yields a duty of care from brand-name manufacturers to generic users in the prescription drug context. Here, as in

315. No. 17-1104 (U.S. Mar. 19, 2019).

316. *Id.* at 1.

317. *Id.* at 1–2.

318. *Id.* at 2.

319. *Id.* at 6.

320. *Id.*

321. *Id.* at 8–9.

322. *Id.* at 8–10. It is important to note, however, that the Court did not hold foreseeability to be sufficient alone in justifying a duty of care. *Id.* at 7 (“To begin, we agree with the manufacturers that a rule of mere foreseeability would sweep too broadly.”).

the maritime context of *DeVries*, the brand name “knows or has reason to know” that its product—the prescription warning label—will be integrated into the generic drug due to the FDA’s mandate requiring integration;³²³ furthermore, this integration of the brand name’s warning label and the generic drug is *required* under federal law,³²⁴ just as the integration of asbestos and the *DeVries* defendants’ equipment was *required* for its intended use by the Navy.³²⁵ Accordingly, the integration rationale undergirding the Court’s duty conclusion in *DeVries* likewise triggers a duty of care between brand-name manufacturers and generic users. Finally, the *DeVries* Court’s economic efficiency justification³²⁶—which asks the question of *who is in the best position to warn*—also supports the recognition of a brand-name manufacturer duty to generic users: not only is the brand name in the best position to warn of harmful side effects, but it is also the *only* actor in a position to warn given *PLIVA*’s requirement of warning-label sameness.³²⁷

To be sure, the Supreme Court notes that “[m]aritime law has always recognized a ‘special solicitude for the welfare’ of those who undertake to ‘venture upon hazardous and unpredictable sea voyages,’” and the subject of this Note is state products liability law, not federal maritime law.³²⁸ Nonetheless, if there were ever an element of state common law designed to be solicitous of plaintiffs, it is that involving persons injured by consumer products. As this Note’s introduction aptly observed, the emergence of strict products liability in the common law serves as a telltale sign of tort law’s solicitude for injured product consumers. Consequently, it is this Note’s view that the Court’s theoretical framework underpinning duty in *DeVries* may carry over and, indeed, furnish a duty of care in the brand-name manufacturer, generic-user relationship.

323. See generally *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011) (outlining the federal regulatory framework governing the prescription drug industry).

324. *Id.* at 613 (observing that federal law requires generic drugs to integrate the warning labels of their brand-name counterparts).

325. *Id.*

326. *DeVries*, No. 17-1104, slip op. at 8 (“Importantly, the product manufacturer will often be in a better position than the parts manufacturer to warn of the danger from the integrated product.”).

327. *PLIVA*, 564 U.S. at 613.

328. *DeVries*, No. 17-1104, slip op. at 9 (quoting *Am. Exp. Lines, Inc. v. Alvez*, 446 U.S. 274, 285 (1980) (plurality opinion)).