

WHY COURTS SHOULD CONTINUE TO REJECT INNOVATOR LIABILITY THEORIES THAT SEEK TO HOLD BRANDED DRUG MANUFACTURERS LIABLE FOR GENERIC DRUG INJURIES

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I. INTRODUCTION

Nearly a decade has passed since the Alabama Supreme Court in *Wyeth, Inc. v. Weeks*¹ became the first state high court to hold that a brand-name prescription drug manufacturer may be liable for injuries to a consumer who ingests a copycat generic drug made by a different company. The theory of liability in *Weeks*, known as innovator liability,² posits that a branded drug manufacturer is subject to liability for a warnings-based generic drug injury because the branded drug manufacturer is primarily responsible for creating the warnings that accompany not only its branded drug *but also* the generic medication.³ The *Weeks* decision was quickly

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1. 159 So. 3d 649 (Ala. 2014), *superseded by statute*, Ala. Code § 6-5-530, *as recognized in* Forest Labs., LLC v. Feheley, 296 So. 3d 302 (Ala. 2019).

2. Innovator liability was first recognized by a California Court of Appeal in *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).

3. RESTATEMENT (THIRD) OF TORTS: MISCELLANEOUS PROVISIONS, § 18A cmt. q (AM. L. INST., Tentative Draft No. 3, 2024) [hereinafter TD 3]; *see also* Eric Lasker et al., *Taking the "Product" Out of Product Liability: Litigation Risks and Business Implications of Innovator and Co-promoter Liability*, 82 DEF. COUNS. J. 295, 295-96 (2015) (noting the responsibility of branded drug manufacturers for prescribing information).

overturned by the state legislature.⁴ Nevertheless, the decision led to significant litigation by plaintiffs in other states seeking to hold branded drug manufacturers liable for generic drug injuries.⁵

Plaintiffs in innovator liability cases typically allege that they were injured because a branded drug manufacturer misrepresented its product (by misstatement or omission), and plaintiffs' doctors reasonably and foreseeably relied on those representations to prescribe the generic form of the drug to plaintiffs.⁶ Under plaintiffs' theory, it does not matter that the branded drug and generic drug manufacturers have no relationship, that the branded drug company has no control over the generic drug manufacturer's operations, that the two entities may be competitors, or that the branded drug manufacturer may no longer sell the product.⁷

Plaintiffs are targeting branded drug companies—rather than the companies that made the generic drugs they ingested—because federal law generally preempts state law warnings-based claims against generic drug manufacturers,⁸ while claims against brand-name drug manufacturers are generally not preempted.⁹ This incongruity reflects the different regulatory regimes that govern brand-name and generic drugs.¹⁰

Federal law bars manufacturers from marketing new brand-name drugs unless they satisfy the federal Food and Drug Administration (FDA) that the drug “is safe and effective and that the proposed label is accurate and adequate.”¹¹ This involves “a long, comprehensive, and costly testing

4. See Ala. Code § 6-5-530 (“In any civil action for personal injury, death, or property damage caused by a product, . . . the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product.”). The legislation passed with strong bipartisan support. See S.B. 80, Reg. Sess. (Ala. 2015), <https://legiscan.com/AL/bill/SB80/2015>.

5. Victor E. Schwartz et al., *Deep Pocket Jurisprudence: Where Tort Law Should Draw the Line*, 70 OKLA. L. REV. 359, 361 (2018) (stating that “more than a hundred courts have rejected innovator liability, generally finding that under bedrock principles of both product liability and negligence, a manufacturer is not subject to liability for harms caused by a product that it did not make or sell,” while noting the Alabama decision and a few others that “broke from this orthodoxy”).

6. See *Weeks*, 159 So. 3d at 676.

7. See generally *T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18 (Cal. 2017).

8. See generally *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013).

9. *Wyeth v. Levine*, 555 U.S. 555, 558–59 (2009).

10. 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, 1857–64 (2013).

11. *Mensing*, 564 U.S. at 612.

process.”¹² In exchange, federal law provides branded drug manufacturers with enhanced patent and regulatory exclusivities. A generic drug manufacturer, on the other hand, only needs to show that its product is biologically equivalent to a previously approved branded drug.¹³ As the U.S. Supreme Court explains:

[B]rand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name’s.¹⁴

After FDA approval, branded and generic drug manufacturers generally may not change their drugs’ labeling without the FDA’s prior permission. There is a narrow exception for branded drug manufacturers. These manufacturers may unilaterally add or strengthen a warning under the FDA’s “changes being effected” (CBE) regulation to reflect “newly acquired information” that was “not previously submitted to [the FDA].”¹⁵ The FDA has the authority to reject the change.¹⁶ There is no CBE process for generic drugs; their labeling must always match the corresponding brand-name drug’s label.¹⁷ Because generic drug manufacturers cannot unilaterally change their labels, the companies lack the ability to comply with federal law and state tort law duties that may be different. Thus, the U.S. Supreme Court has held that warnings-based tort claims against generic drug manufacturers are generally preempted.¹⁸

Innovator liability provides a way for plaintiffs’ lawyers to try to obtain compensation for plaintiffs injured by generic drugs by shifting the liability for those injuries to branded drug manufacturers. The theory forces branded drug manufacturers to act as insurers of their generic competitors’ products.

Courts in “over 150 decisions”¹⁹ have rejected innovator liability claims,²⁰ with few exceptions such as in California²¹ and in Massachusetts

12. Federal Trade Comm’n v. Actavis, Inc., 570 U.S. 136, 142 (2013); *see also* *Mensing*, 564 U.S. at 612 (noting that meeting FDA’s requirements for new drugs “involves costly and lengthy clinical testing”).

13. *Mensing*, 564 U.S. at 612 (reasoning that “generic drugs can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA”).

14. *Id.* at 613 (citations omitted).

15. 21 C.F.R. § 314.70(c)(6)(iii) (2016); 21 C.F.R. § 314.3(b) (2016).

16. 21 C.F.R. § 314.70(c)(7).

17. *See* *Mensing*, 564 U.S. at 613 (citing 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7)).

18. *Id.* at 623–24.

19. TD 3, *supra* note 3, § 18A cmt. q.

for brand-name manufacturer recklessness.²² Advocates for innovator liability may find new inspiration, however, in a pending “Miscellaneous Provisions” Restatement from the American Law Institute (ALI).²³ This Restatement discusses innovator liability in the context of a novel provision addressing “negligent misrepresentation causing physical harm.”²⁴ The proposed rule states that “[a]n actor who negligently furnishes false information is subject to liability for any physical harm factually caused by another’s reliance on the information that is within the actor’s scope of liability . . . regardless of whether the person who received or relied upon the actor’s misrepresentation is the person who suffered physical harm.”²⁵

The proposed Restatement acknowledges that “almost half of U.S. states have no definitive case law” recognizing or expressly rejecting the tort of negligent misrepresentation causing physical harm.²⁶ With respect to innovator liability in particular, the Restatement acknowledges that the substantial majority of courts deciding such cases “have concluded that brand-name manufacturers cannot be held liable if they did not manufacture the drug consumed by the plaintiff.”²⁷

Nevertheless, the Restatement is not joining the “overwhelming body of case law developed over a quarter century” that has repudiated innovator liability.²⁸ Instead, the Restatement takes “no position” on whether courts should allow innovator liability claims, leaving the issue to future common law development.²⁹ As this article explains, though, a deeper analysis of the proposed Restatement rule and its supporting commentary reveals a less agnostic approach that at least indirectly endorses innovator liability.³⁰

20. See, e.g., *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 938 (6th Cir. 2014) (stating “an overwhelming majority of courts . . . have rejected ‘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’”) (citation omitted).

21. See *T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18 (Cal. 2017).

22. See *Rafferty v. Merck & Co*, 92 N.E.3d 1205, 1219 (Mass. 2018).

23. The Miscellaneous Provisions Restatement is the final installment in the ALI’s multi-part Restatement (Third) of Torts.

24. TD 3, *supra* note 3, § 18A.

25. *Id.*

26. *Id.* § 18A cmt. b.

27. *Id.* § 18A cmt. q.

28. *Id.*

29. *Id.*

30. *Id.* § 18A cmt. q, Reporters’ Notes q. Reporters’ Notes “are regarded as the work of” the Reporters, so the views expressed are “not necessarily those of the Institute.” AM. L. INST., CAPTURING THE VOICE OF THE AMERICAN LAW INSTITUTE: A HANDBOOK FOR ALI REPORTERS AND THOSE WHO REVIEW THEIR WORK 45 (rev. ed. 2015) [hereinafter ALI STYLE MANUAL].

Part II of the article provides an overview of the origins and evolution of innovator liability. Part III analyzes the Restatement's treatment of negligent misrepresentation causing physical harm and the potential for the proposed rule to foster innovator liability claims if courts adopt it. Part IV explains why courts should continue to reject innovator liability claims notwithstanding the proposed Restatement.

II. THE ORIGINS AND EVOLUTION OF INNOVATOR LIABILITY

Congress established separate FDA approval processes for branded and generic drugs to meet public demand for lower cost generic drugs.³¹ Beginning in 2009, the U.S. Supreme Court issued several decisions interpreting the preemptive effect of federal law over state warnings-based tort claims against pharmaceutical manufacturers.³² Two of these decisions established the predicate for innovator liability claims.

In *Wyeth v. Levine*,³³ the Court held that federal law does not preempt state tort law warnings-based claims against brand-name pharmaceutical manufacturers. The Court rejected a branded drug manufacturer's claim that it was "impossible" to comply with both its state law duty to warn, as determined by a jury, and its federal labeling duties.³⁴ The Court reasoned that the FDA's CBE regulation permitted the branded drug manufacturer to "unilaterally strengthen its warning."³⁵ Further, the "mere fact that the FDA approved [a drug's label] does not establish that it would have prohibited" a stronger warning.³⁶ The Court also held that plaintiff's common law tort claims did not "obstruct" the federal regulation of drug labeling.³⁷

The Court next examined preemption in the context of FDA-approved generic drugs. In *PLIVA, Inc. v. Mensing*,³⁸ the Court reached the opposite conclusion that it did in *Levine* with respect to branded drugs. In *Mensing*,

31. See Schwartz et al., *supra* note 10, at 1839–48 (detailing the separate regulatory approvals processes for branded and generic drugs).

32. See *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019); *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Bruesewitz v. Wyeth, LLC*, 562 U.S. 223 (2011); *Wyeth v. Levine*, 555 U.S. 555 (2009); see also Victor E. Schwartz & Christopher E. Appel, *Where's the Beef?: A Guide to Judges on Preemption of State Tort Litigation Involving Branded Drugs*, 89 U. CIN. L. REV. 597, 598–602 (2021) (discussing the U.S. Supreme Court's pharmaceutical preemption jurisprudence).

33. 555 U.S. 555 (2009).

34. *Id.* at 573.

35. *Id.*

36. *Id.*

37. *Id.* at 581.

38. 564 U.S. 604 (2011).

the Court invoked the doctrine of impossibility to hold that federal law preempts state law warnings-based claims against generic drug manufacturers.³⁹ The Court explained that, under the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly called the Hatch-Waxman Act), FDA approval of a generic drug is contingent upon “showing equivalence” with an FDA-approved branded drug, including a “warning label [that] is the same as the brand name’s.”⁴⁰ This “sameness” requirement applies to any warning label changes after the FDA’s initial approval.⁴¹ Thus, in contrast to brand-name drug manufacturers’ ability to use the CBE process to add or strengthen their labels, generic drug manufacturers may not unilaterally change their labeling without violating federal law.⁴²

The Court in *Mensing* acknowledged that from plaintiffs’ perspective, finding preemption of warnings-based claims for generic drugs in *Mensing* but not for branded drugs in *Levine* “makes little sense,”⁴³ but “it is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers.”⁴⁴ The Court added that “the special, and different, regulation of generic drugs [has] allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public.”⁴⁵

Imaginative plaintiffs’ lawyers developed the innovator liability theory to try to hold branded drug manufacturers liable for generic drug injuries because branded drug manufacturers can be sued for representations on drug labels whereas generic drug companies cannot. Under the innovator liability theory, manufacturers of branded drugs—which account for about ten percent of the prescription drug market⁴⁶—would bear 100% of the liability for warnings-based claims involving brand-name and generic drugs.

Courts have long expressed skepticism about imposing liability on branded drug manufacturers for generic drug injuries. For example, in 1994, the U.S. Court of Appeals for the Fourth Circuit in *Foster v.*

39. *Id.* at 624.

40. *Id.* at 613.

41. *Id.* at 615.

42. *Id.* at 614.

43. *Id.* at 625.

44. *Id.* at 626.

45. *Id.*

46. Today, generic drugs comprise around 90% of all drug prescriptions in the U.S. See Matej Mikulic, *Proportion of Branded Versus Generic Drug Prescriptions Dispensed in the United States from 2005 to 2021*, STATISTA (June 15, 2022), <https://www.statista.com/statistics/205042/proportion-of-brand-to-generic-prescriptions-dispensed/> [<https://perma.cc/LYS6-QPW7>].

*American Home Products Corp.*⁴⁷ issued one of the earliest decisions squarely addressing innovator liability. The court rejected a negligent misrepresentation claim against the manufacturer of a brand-name sedative for a death allegedly caused by another company's generic drug.⁴⁸ The court explained, "[t]here is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control."⁴⁹ The court added that allowing liability against the branded drug manufacturer would be "especially unfair."⁵⁰

Over the next fifteen years, courts steadfastly rejected innovator liability claims⁵¹ until a 2008 decision by a California Court of Appeal in *Conte v. Wyeth, Inc.*⁵² In *Conte*, the court held that a branded drug manufacturer's duty "extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug."⁵³

47. 29 F.3d 165 (4th Cir. 1994) (applying Maryland law).

48. *See id.* at 167.

49. *Id.* at 170.

50. *Id.*

51. *See Flynn v. American Home Prods. Corp.*, 627 N.W.2d 342 (Minn. Ct. App. 2001); *Beutella v. A.H. Robins Co., Inc.*, No. 980502372, 2001 WL 35669202 (Utah Dist. Ct. Dec. 10, 2001); *DaCosta v. Novartis AG*, 242 F. Supp. 2d 765 (D. Or., 2002) (Oregon law); *Block v. Wyeth, Inc.*, No. 3:02-CV-1077, 2003 WL 203067 (N.D. Tex. Jan. 28, 2003) (Texas law); *Murphy v. Aventis Pasteur, Inc.*, 270 F. Supp. 2d 1368 (N.D. Ga. 2003) (Georgia law); *Sloan v. Wyeth*, No. MRS-L-1183-04, 2004 WL 5767103 (N.J. Super. Ct. Oct. 13, 2004); *Sheeks v. American Home Prods. Corp.*, No. 02CV337, 2004 WL 4056060 (Colo. Dist. Ct. Oct. 15, 2004); *Reynolds v. Anton*, No. 01A-76719-3, 2004 WL 5000272 (Ga. Super. Ct. Oct. 28, 2004); *Tarver v. Wyeth*, No. Civ. A. 3-04-2036, 2005 WL 4052382 (W.D. La. June 7, 2005) (Louisiana law); *Tarver v. Wyeth*, No. Civ. A. 3-04-2036, 2006 WL 1517546 (W.D. La. Jan. 26, 2006) (Louisiana law); *Sharp v. Leichus*, No. 04-CA-643, 2006 WL 515532 (Fla. Cir. Ct. Feb. 17, 2006), *aff'd per curiam*, 952 So. 2d 555 (Fla. Dist. Ct. App. 2007); *Possa v. Eli Lilly & Co.*, No. 05-1307-JJB-SCR, 2006 WL 6393160 (M.D. La. May 10, 2006) (Louisiana law); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (Pennsylvania law), *aff'd*, 521 F.3d 253 (3d Cir. 2008), *cert. granted and judgment vacated on other grounds*, 556 U.S. 1101 (2009); *Goldych v. Eli Lilly & Co.*, No. 5:04-CV-1477, 2006 WL 2038436 (N.D.N.Y. July 19, 2006) (New York law); *Leblanc v. Wyeth, Inc.*, No. Civ. A. 04-0611, 2006 WL 2883030 (W.D. La. Oct. 5, 2006) (Louisiana law); *Rossi v. Hoffman-LaRoche*, No. ATL-L-690-05, 2007 WL 7632318 (N.J. Super. Ct. Law Div. Jan. 3, 2007).

52. 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008).

53. *Id.* at 304–05; *see generally In re Darvocet, Darvon, and Propoxyphene Prod. Liab. Litig.* (Buch v. Xanodyne Pharm., Inc.), No. 2: 11–324–DCR, 2012 WL 3984871, at *2 (E.D. Ky. Sept. 5, 2012) (allowing innovator liability claim under California law but observing that "with the notable exception of California[,] the majority of courts" that have addressed innovator liability claims have rejected them).

In 2010, a Vermont federal court in *Kellogg v. Wyeth*⁵⁴ imposed innovator liability under a negligent misrepresentation theory—despite acknowledging that its ruling was inconsistent with the uniform rejection of innovator liability by federal courts in at least fifteen states.⁵⁵ Against the national backdrop, the *Conte* and *Kellogg* decisions were aberrations as courts continued to overwhelmingly reject innovator liability claims.⁵⁶

54. 762 F. Supp. 2d 694 (D. Vt. 2010).

55. *Id.* at 708–09.

56. *See* *Wilson v. Wyeth, Inc.*, No. 3:07-CV-378, 2008 WL 2677049 (W.D. Ky. June 30, 2008) (Kentucky law), *aff'd sub nom.* *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011); *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351 (N.D. Ga. 2008) (Georgia law); *Pustejovsky v. Wyeth, Inc.*, No. 4:07-CV-103-Y, 2008 WL 1314902 (N.D. Tex. Apr. 3, 2008) (Texas law); *Stanley v. Wyeth, Inc.*, 991 So. 2d 31 (La. Ct. App. 2008); *Westerlund v. Wyeth, Inc.*, No. MID-2174-05, 2008 WL 5592753 (N.J. Super. Ct. Law Div. Oct. 20, 2008); *Huck v. Trimark Physicians Grp.*, No. LACV018947, 2009 WL 3760458 (Iowa Dist. Ct. Feb. 27, 2009); *Cousins v. Wyeth Pharm., Inc.*, No. 3:08-CV-0310-N, 2009 WL 648703 (N.D. Tex. Mar. 10, 2009) (Texas law); *Short v. Eli Lilly & Co.*, No. 49D12-0601-CT-2187, 2009 WL 9867531 (Ind. Sup. Ct. Mar. 25, 2009); *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056 (W.D. Ark. 2009) (Arkansas law); *Stoddard v. Wyeth, Inc.*, 630 F. Supp. 2d 631 (E.D.N.C. 2009) (North Carolina law); *Burke v. Wyeth, Inc.*, Civ. No. G-09-82, 2009 WL 3698480 (S.D. Tex. Oct. 29, 2009) (Texas law); *Meade v. Parsley*, No. 2:09-cv-0038, 2009 WL 3806716 (S.D. W. Va. Nov. 13, 2009) (West Virginia law); *Morris v. Wyeth, Inc.*, No. 09-cv-00854, 2009 WL 4064103 (W.D. La. Nov. 23, 2009) (Louisiana law); *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009) (Minnesota law), *rev'd on other grounds sub nom.* *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011); *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586, 2009 WL 4924722 (Fla. Cir. Ct. Dec. 21, 2009); *Washington v. Wyeth, Inc.*, No. 3:09-CV-01343, 2010 WL 450351 (W.D. La. Feb. 8, 2010) (Louisiana law); *Levine v. Wyeth Inc.*, 684 F. Supp. 2d 1338 (M.D. Fla. 2010) (Florida law); *Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643 (W.D.N.C. 2010) (North Carolina law); *Hardy v. Wyeth, Inc.*, No. 9:09-CV-152, 2010 WL 1049588 (E.D. Tex. Mar. 8, 2010) (Texas law), *report and recommendation adopted*, No. 9:09-CV-152, 2010 WL 1222183 (E.D. Tex. Mar. 29, 2010); *Howe v. Wyeth, Inc.*, No. 8:09-CV-610, 2010 WL 1708857 (M.D. Fla. Apr. 26, 2010) (Florida law); *Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616 (E.D. Tex. 2010) (Texas law); *Negron v. Teva Pharms. USA, Inc.*, No. 09-16519, 2010 WL 8357563 (Tex. Dist. Ct. May 7, 2010); *Craig v. Pfizer, Inc.*, No. 3:10-cv-00227, 2010 WL 2649545 (W.D. La. May 26, 2010) (Texas law), *report and recommendation adopted*, No. 3:10-cv-00227, 2010 WL 2649544 (W.D. La. June 29, 2010); *Phelps v. Wyeth, Inc.*, No. 09-cv-6168, 2010 WL 2553619 (D. Or. May 28, 2010) (Oregon law), *report and recommendation adopted*, No. 09-cv-6168, 2010 WL 2553614 (D. Or. June 21, 2010); *Neal v. Teva Pharms. USA, Inc.*, No. 09-CV-1027, 2010 WL 2640170 (W.D. Ark. July 1, 2010) (Arkansas law); *Fisher v. Pelstring*, No. 4:09-cv-00252, 2010 WL 2998474 (D.S.C. July 28, 2010) (South Carolina law); *Johnson v. TEVA Pharms. USA, Inc.*, No. 2:10-cv-404, 2010 WL 3271934 (W.D. La. Aug. 16, 2010) (Louisiana law); *Cooper v. Wyeth, Inc.*, No. 09-CV-929, 2010 WL 4318816 (M.D. La. Oct. 26, 2010) (Louisiana law); *Gross v. Pfizer, Inc.*, No. 10-cv-00110, 2010 WL 4485774 (D. Md. Nov. 9, 2010) (Maryland law); *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) (Kentucky law); *see also In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 856 F. Supp. 2d 904 (E.D. Ky. 2012) (dismissing claims under Arkansas, Georgia, Indiana, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, and Texas law), *aff'd*, 756 F.3d 917 (6th Cir. 2014); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-MD-02226-DCR, 2012 WL 767595 (E.D. Ky. Mar. 7, 2012) (dismissing claims under Arkansas, Connecticut, Georgia, Indiana, Kentucky, Louisiana, Mississippi, New Jersey, New York, Oklahoma, Pennsylvania,

In 2014, the Alabama Supreme Court in *Wyeth, Inc. v. Weeks*⁵⁷ became the first state high court to permit innovator liability. The court, relying on the *Conte* and *Kellogg* decisions, determined that a branded drug company may be held liable for fraud or misrepresentation based on statements it made in connection with its drug that were relied upon by a physician prescribing a generic drug that caused the plaintiff's injury.⁵⁸ The court reasoned that liability was appropriate "as a result of statements made by the brand-name manufacturer that Congress, through the FDA, has mandated be the same on the generic version of the brand-name drug."⁵⁹ The Alabama Legislature overruled *Weeks* within a year.⁶⁰ Alabama law now provides that a plaintiff asserting a claim for injury caused by a

Tennessee, and Texas law), *aff'd in relevant part and rev'd in part on other grounds*, 756 F.3d 917 (6th Cir. 2014); *Phelps v. Wyeth, Inc.*, 857 F. Supp. 2d 1114 (D. Or. 2012) (Oregon law); *Coundouris v. Wyeth*, No. ATL-L-1940-10, 2012 WL 2401776 (N.J. Super. Ct. Law Div. June 26, 2012); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-MD-02226-DCR, 2012 WL 3610237 (E.D. Ky. Aug. 21, 2012) (dismissing claims under Arkansas, Connecticut, Georgia, Kentucky, Louisiana, Oklahoma, and West Virginia law), *aff'd*, 756 F.3d 917 (6th Cir. 2014); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-02226-DCR, 2012 WL 3842045 (E.D. Ky. Sept. 5, 2012) (dismissing claims under Arizona, Florida, Nebraska, New Hampshire, New Jersey, North Carolina, South Carolina, and West Virginia law), *aff'd*, 756 F.3d 917 (6th Cir. 2014); *Baymiller v. Ranbaxy Pharms. Inc.*, 894 F. Supp. 2d 1302 (D. Nev. 2012) (Nevada law); *In re Darvocet, Darvon, and Propoxyphene Prod. Liab. Litig.* (Buch v. Xanodyne Pharm., Inc.), No. 2: 11-324-DCR, 2012 WL 3984871 (E.D. Ky. Sept. 5, 2012) (dismissing claims under Florida, Georgia, Michigan, Mississippi, New Hampshire, Oklahoma, South Carolina, Tennessee, and Texas law); *Hogue v. Pfizer, Inc.*, 893 F. Supp. 2d 914 (S.D. Ohio 2012) (Ohio law); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-02226-DCR, 2012 WL 4831632 (E.D. Ky. Oct. 10, 2012) (dismissing claims under Arizona, Florida, Kentucky, Louisiana, Michigan, Mississippi, New Jersey, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, and West Virginia law), *aff'd*, 756 F.3d 917 (6th Cir. 2014); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177 (5th Cir. 2012) (Louisiana law); *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597 (N.D. Miss. 2013) (Mississippi law); *Washington v. Medicis Pharms. Corp.*, No. 3:12-cv-00126, 2013 WL 496063 (S.D. Miss. Feb. 7, 2013) (Mississippi law); *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.* (Capitano v. McKesson Corp.), No. 2:11-md-02226-DCR, 2013 WL 1332437 (E.D. Ky. Mar. 29, 2013) (Illinois law); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014); *Bell v. Pfizer, Inc.*, 716 F.3d 1087 (8th Cir. 2013) (Arkansas law); *Guarino v. Wyeth, LLC*, 719 F.3d 1245 (11th Cir. 2013) (Florida law); *Fullington v. Pfizer, Inc.*, 720 F.3d 739 (8th Cir. 2013) (Arkansas law); *Neeley v. Wolters Kluwer Health, Inc.*, No. 4:11-cv-00325, 2013 WL 3929059 (E.D. Mo. July 30, 2013) (Kentucky law), *on reconsideration in part on other grounds sub nom.* *Neeley v. Wyeth LLC*, No. 4:11-CV00325-JAR, 2015 WL 1456984 (E.D. Mo. Mar. 30, 2015); *Metz v. Wyeth LLC*, 525 F. App'x 893 (11th Cir. 2013) (Florida law); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273 (10th Cir. 2013) (Oklahoma law); *Weese v. Pfizer, Inc.*, No. 153742/12, 2013 WL 5691993 (N.Y. Sup. Ct. Oct. 8, 2013); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378 (6th Cir. 2013) (Tennessee law).

57. 159 So. 3d 649 (Ala. 2014), *superseded by statute*, Ala. Code § 6-5-530, *as recognized in* *Forest Labs., LLC v. Fehelley*, 296 So. 3d 302 (Ala. 2019).

58. *See id.* at 668–71.

59. *Id.* at 677.

60. *See* Ala. Code § 6-5-530.

product “must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product.”⁶¹

Weeks was an outlier, as numerous courts around the same time continued to reject innovator liability claims.⁶² Significantly, the Iowa Supreme Court rejected innovator liability in 2014 in *Huck v. Wyeth, Inc.*⁶³ The plaintiff in *Huck* alleged injury from a generic version of a drug used to treat heartburn caused by gastroesophageal reflux. The Iowa Supreme Court said it would not “alter long-standing Iowa products liability law to allow recovery against a manufacturer for injuries caused by use of its competitor’s product.”⁶⁴ Instead, the court joined the “overwhelming majority of courts, including every federal circuit court of appeals,” in holding that the branded drug manufacturer was not subject to liability.⁶⁵ The court explained that it was “unwilling to make brand manufacturers the de facto insurers for competing generic manufacturers.”⁶⁶ The court added that allowing innovator liability would provide no clear stopping point for the imposition of liability with respect to other types of products that may be copied by a competitor.⁶⁷

61. *Id.*

62. See *Lashley v. Pfizer, Inc.*, 750 F.3d 470 (5th Cir. 2014) (Mississippi and Texas law); *Whitener v. PLIVA, Inc.*, No. 2:10-cv-01552, 2014 WL 1276489 (E.D. La. Mar. 27, 2014) (Louisiana law); *Stewart v. Sanofi Aventis U.S., LLC*, 15 F. Supp. 3d 1151 (N.D. Ala. 2014) (Indiana law); *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674 (5th Cir. 2014) (Texas law); *Kruszka v. Novartis Pharms. Corp.*, 19 F. Supp. 3d 875 (D. Minn. 2014) (Minnesota law); *Tanner v. Alaven Pharm., LLC*, No. 10EV009036-4, 2014 WL 2404287 (Ga. Super. Ct. May 27, 2014); *Dement v. Alaven Pharm., LLC*, No. 10EV009036-3, 2014 WL 2404289 (Ga. Super. Ct. May 27, 2014); *Moretti v. Wyeth, Inc.*, 579 F. App’x 563 (9th Cir. 2014) (Nevada law); *Willis v. Schwarz-Pharma, Inc.*, 62 F. Supp. 3d 560 (E.D. Tex. 2014) (Texas law); *In re Darvocet, Darvon, and Propoxyphene Prod. Liab. Litig. (Germain v. Teva Pharms., USA, Inc.)*, 756 F.3d 917 (6th Cir. 2014) (68 appeals involving laws of 22 states); *but see Dolin v. Smithkline Beecham Corp.*, 62 F. Supp. 3d 705 (N.D. Ill. 2014) (Illinois law), *rev’d*, 901 F.3d 803 (7th Cir. 2018).

63. 850 N.W.2d 353 (Iowa 2014).

64. *Id.* at 356.

65. *Id.*; see also *Guarino*, 719 F.3d at 1252 (“[T]he overwhelming national consensus—including . . . the vast majority of district courts around the country to consider the question—is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product.”).

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

67. *Id.* (“Where would such liability stop? If a car seat manufacturer recognized as the industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor’s seat that copied the design? Why not, under [plaintiff’s] theory, if it is foreseeable others will copy the design?”).

Over the next several years, courts continued to reject innovator liability claims nationwide.⁶⁸ In 2017, the California Supreme Court broke with this increasingly uniform treatment of innovator liability in *T.H. v. Novartis Pharmaceuticals Corp.*,⁶⁹ affirming the common law duty initially recognized by a California Court of Appeal in *Conte*.⁷⁰ The California Supreme Court recognized that only a “handful of courts have followed *Conte*,” but found decisions rejecting innovator liability to be unpersuasive given California’s emphasis on foreseeability as the “most important” factor for determining when legal duties are owed.⁷¹ The court said that, because the defendant branded drug manufacturer could have foreseen that its warning label could affect physicians’ prescribing behavior, users of either the brand name or generic version of its drug could bring a claim for negligence or negligent misrepresentation based on alleged insufficient labeling.⁷²

In *T.H.*, the defendant branded drug manufacturer had stopped making the brand name version of the subject medicine and sold its interests to another company years before plaintiffs’ alleged injuries.⁷³ The California Supreme Court nevertheless concluded that the defendant could have foreseen that the company that bought the rights to its drug would continue to use the prior labeling.⁷⁴ A dissenting judge criticized the decision as “a substantial and unprecedented expansion of tort duties” that “extend[s] indefinitely a drug manufacturer’s duty to warn the customers of its

68. See *Johnson v. Teva Pharms. USA, Inc.*, 758 F.3d 605 (5th Cir. 2014) (Louisiana law); *Nicely v. Wyeth, Inc.*, 451 S.W.3d 694 (Mo. Ct. App. 2014) (Kentucky law); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676 (Mo. Ct. App. 2014) (Kentucky law); *Chatman v. Pfizer, Inc.*, No. 5:11-cv-69, 2014 WL 4546042 (S.D. Miss. Sept. 11, 2014) (Mississippi law); *Anselmo v. Sanofi-Aventis Inc. USA*, No. 10-cv-77, 2014 WL 8849464 (Kan. Dist. Ct. Oct. 13, 2014); *Truddle v. Wyeth, LLC*, No. 2:11-cv-00207, 2015 WL 160696 (N.D. Miss. Jan. 12, 2015) (Mississippi law); *Phares v. Actavis-Elizabeth LLC*, No. B-11-63, 2015 WL 12780637 (S.D. Tex. Mar. 19, 2015) (Texas law); *Tsavaris v. Pfizer, Inc.*, 154 F. Supp. 3d 1327 (S.D. Fla. 2016) (Florida law); *PLIVA, Inc. v. Dement*, 780 S.E.2d 735 (Ga. Ct. App. 2015); *In re Mirapex Prods. Liab. Litig.*, No. 07-1836 (MJD/FLN), 2016 WL 4217758 (D. Minn. June 16, 2016), *report and recommendation adopted*, 2016 WL 4203422 (D. Minn. Aug. 9, 2016) (Indiana law); *Perdue v. Wyeth Pharms., Inc.*, 209 F. Supp. 3d 847 (E.D.N.C. 2016) (North Carolina law); *Wells v. Wyeth Pharms., Inc.*, 233 F. Supp. 3d 534 (W.D. Tex. 2017) (Texas law); *Coleson v. Janssen Pharm., Inc.*, 251 F. Supp. 3d 716 (S.D.N.Y. 2017) (New York law); *Akerman v. GlaxoSmithKline, LLC (In re Zofran (Ondansetron) Prods. Liab. Litig.)*, 261 F. Supp. 3d 62 (D. Mass. 2017) (dismissing claims under Georgia, Indiana, Kentucky, New York, and Oklahoma law).

69. 407 P.3d 18 (Cal. 2017).

70. See *id.* at 25–26.

71. *Id.* at 29; see also *id.* at 35–40 (discussing “[o]ut-of-state authorities”).

72. See *id.* at 23.

73. See *id.* at 23, 40.

74. See *id.* at 40–43.

successor” in a manner “never before . . . recognized by *any* court, in any jurisdiction.”⁷⁵

In 2018, the Massachusetts Supreme Judicial Court in *Rafferty v. Merck & Co.*⁷⁶ held that a branded drug manufacturer may be subject to liability for a generic drug injury if the branded drug manufacturer’s warnings demonstrate a “reckless disregard of an unreasonable risk of death or grave bodily injury.”⁷⁷ The court chose to “draw[] the line at recklessness,”⁷⁸ because it concluded that “allowing a generic drug consumer to bring a general negligence claim for failure to warn against a brand-name manufacturer poses too great a risk of chilling drug innovation, contrary to the public policy goals embodied in the Hatch–Waxman amendments.”⁷⁹

Since *Rafferty*, no other state appellate court has adopted innovator liability.⁸⁰ West Virginia’s high court expressly rejected innovator liability later in 2018. In *McNair v. Johnson & Johnson*,⁸¹ the West Virginia Supreme Court of Appeals held that a plaintiff alleging injury after ingesting a generic antibiotic could not recover against the manufacturer of the branded drug under either a product liability or negligent misrepresentation theory.⁸² The court said that “[r]equiring the defendant in a products liability case to be either the manufacturer or the seller of the product is the majority rule in this country,” and that West Virginia follows this approach by subjecting manufacturers “to the duty to warn about the risks of *their* products.”⁸³ The court also rejected plaintiff’s negligent misrepresentation claim, finding the Iowa Supreme Court’s reasoning in *Huck* and a 2014 decision by the U.S. Court of Appeals for the Sixth Circuit, *In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation*,⁸⁴ to be persuasive.

The Sixth Circuit case involved a multi-district litigation (MDL) action for personal injuries related to a prescription pain reliever that included

75. *Id.* at 48 (Corrigan, J., concurring and dissenting in part).

76. 92 N.E.3d 1205 (Mass. 2018).

77. *Id.* at 1219.

78. *Id.*

79. *Id.*

80. *See generally* James M. Beck & Mark Herrmann, *Scorecard: Innovator Liability In Generic Drug Cases*, DRUG & DEVICE L. BLOG (originally published Nov. 12, 2009), <https://www.druganddevicelawblog.com/2009/11/scorecard-non-manufacturer-name-brand.html> [<https://perma.cc/YV2U-LRC7>] (surveying innovator liability decisions).

81. 818 S.E.2d 852 (W. Va. 2018).

82. *See id.* at 861–62.

83. *Id.* at 860–61.

84. 756 F.3d 917 (6th Cir. 2014).

plaintiffs from twenty-two states, including West Virginia. The Sixth Circuit conducted a state-by-state analysis and concluded that plaintiffs' misrepresentation claims against branded drug manufacturers for generic drug injuries were not supported by state law.⁸⁵ The court said that "an overwhelming majority of courts . . . have rejected 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."⁸⁶ Some courts have held that "regardless of the label a generic consumer plaintiff might use (*e.g.*, misrepresentation), [plaintiff] has effectively brought a product liability action and cannot circumvent the product identification requirement of applicable state product liability law."⁸⁷ Other courts have held that, even if a misrepresentation cause of action is distinct from a product liability claim, "a brand name defendant owes no duty of care to consumers of the generic bioequivalent of its product."⁸⁸ Only a "minority of courts have held the opposite," the court said.⁸⁹

The West Virginia high court found especially instructive the Sixth Circuit's treatment of foreseeability with respect to duty. The federal court stated:

[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. Congress made the public policy decisions to lower barriers of entry for generic drugs, as has the . . . state legislature in enacting laws to require certain prescriptions be filled with available generics. Using these laws as the basis of supplying the duty element for tort liability stretches foreseeability too far.⁹⁰

West Virginia's high court further explained that its rejection of innovator liability aligned with the "vast majority of courts" and that "[a]ny recognition of an outlier theory of [innovator] liability . . . would be plainly at odds with [West Virginia] public policy."⁹¹

85. *Id.* at 939.

86. *Id.* at 938 (citations omitted).

87. *Id.*

88. *Id.*

89. *Id.*

90. *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 862 (W. Va. 2018) (quoting *Darvocet*, 756 F.3d at 944); *see also* *Dietrich v. Wyeth, Inc.*, No. 50-2009-CA-021586, 2009 WL 4924722, at *7 (Fla. Cir. Ct. Dec. 21, 2009) (stating that "[n]o federal statute or FDA regulation imposes a duty or suggests that a name brand manufacturer is responsible for the labeling of competing generic products").

91. *McNair*, 818 S.E.2d at 863, 866.

Numerous other courts have rejected innovator liability claims in recent years.⁹² For example, at the end 2020, a federal district court in Florida overseeing an MDL involving injury claims from a widely used heartburn drug and its generic forms surveyed the law of thirty-five jurisdictions and concluded that none would support innovator liability claims.⁹³

In sum, the current state of the law is that innovator liability predicated on negligence theories such as negligent misrepresentation is only clearly viable in California.⁹⁴ Massachusetts recognizes a limited form of innovator liability based on recklessness.⁹⁵ These jurisdictions stand in stark contrast to more than “150 court decisions” over a quarter century rejecting innovator liability.⁹⁶

III. THE AMERICAN LAW INSTITUTE’S TREATMENT OF INNOVATOR LIABILITY

The ALI’s pending Miscellaneous Provisions Restatement includes a novel provision on “negligent misrepresentation causing physical harm,” which is a tort theory that is often alleged in innovator liability cases.⁹⁷ The Miscellaneous Provisions Restatement is a “grab bag” of different tort law

92. For post-*McNair* cases rejecting innovator liability, see *In re Zofran (Ondansetron) Prod. Liab. Litig.*, No. 1:15-md-2657, 2018 WL 2317525 (D. Mass. May 21, 2018) (dismissing claims under Connecticut, New Jersey, and Oklahoma law); *Rosser v. Sanofi-Aventis*, No. 17-cv-2396 (VSB), 2018 WL 4080351 (S.D.N.Y. Aug. 26, 2018) (New York law); *Preston v. Janssen Pharms., Inc.*, No. 158570/17, 2018 WL 5017045 (N.Y. Sup. Ct. Oct. 12, 2018); *Trower v. Janssen Pharms., Inc.*, No. 1:16-cv-00135-RGA, 2019 WL 1571834 (D. Del. Apr. 11, 2019) (Delaware law); *Stirling v. Novartis Pharms. Corp.*, No. CV-01-18-4880, 2019 WL 6456186 (D. Idaho Sept. 25, 2019) (Idaho law); *Forest Labs., LLC v. Feheley*, 296 So. 3d 302 (Ala. 2019); *Montero v. Teva Pharms. USA Inc.*, 19 Civ. 9304 (AKH), 2019 WL 6907467 (S.D.N.Y. Dec. 4, 2019) (New York law); *Evans v. Johnson & Johnson Co.*, No. 14-1316-RGA, 2020 WL 616575 (D. Del. Feb. 10, 2020) (Delaware law); *Johnson v. Novartis Pharms. Corp.*, No. 5:19-cv-01087-OLG, 2020 WL 2300139 (W.D. Tex. May 7, 2020), *aff’d*, 845 F. App’x 305 (5th Cir. 2021) (Texas law); *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 510 F. Supp. 3d 1175 (S.D. Fla. 2020) (surveying law in 35 jurisdictions); *R.S.B. v. Merck & Co., Inc.*, No. 1:2020cv01402, 2021 WL 6113765 (E.D. Wis. Dec. 27, 2021) (Wisconsin law); *but see Butkiewicz v. Bayer Corp. (In re Fluoroquinolone Prods. Liab. Litig.)*, 517 F. Supp. 3d 806 (D. Minn. 2021) (Illinois law); *Doran v. Glaxosmithkline PLC*, 607 F. Supp. 3d 192 (D. Conn. 2022) (Connecticut law).

93. *See Zantac*, 510 F. Supp. 3d at 1193.

94. *See T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18, 18 (Cal. 2017).

95. *See Rafferty v. Merck & Co.*, 92 N.E.3d 1205, 1219 (Mass. 2018).

96. TD 3, *supra* note 3, § 18A cmt. q.

97. *Id.*

issues not covered in other parts of the Third Restatement of Torts, a multi-volume ALI work product that has been developed over several decades.⁹⁸

ALI restatements seek to articulate “clear formulations of common law . . . as it presently stands or might appropriately be stated by a court.”⁹⁹ To fulfill this objective, the ALI’s Style Manual instructs law professors who are appointed to author restatements (called “Reporters”) to adhere to four “principal elements” in developing a restatement: (1) “ascertain the nature of the majority rule” on a topic; (2) “ascertain trends in the law”; (3) choose the “specific rule [that] fits best with the broader body of law and therefore leads to more coherence in the law”; and (4) “ascertain the relative desirability of competing rules.”¹⁰⁰

Restatement Reporters are not required to adopt the “majority rule” on an issue of state common law doctrine, but must explain their rationale when endorsing a minority rule.¹⁰¹ The Style Manual also explains that the ALI “has limited competence and no special authority to make major innovations in matters of public policy” and that proposed “[w]ild swings [in law] are inconsistent with the work of . . . a Restatement.”¹⁰²

In recent years, the ALI has come under fire for proposing novel, plaintiff-friendly rules for courts to adopt.¹⁰³ As the late U.S. Supreme Court Justice Antonin Scalia explained,

[M]odern Restatements . . . are of questionable value, and must be used with caution. The object of the original Restatements was ‘to present an orderly statement of the general common law.’ Over time, the Restatements’ authors have abandoned the mission of describing the law,

98. The Third Restatement of Torts includes restatements on Products Liability (1998), Apportionment of Liability (2000), Liability for Physical and Emotional Harm (2010), Liability for Economic Harm (2020), Intentional Torts to Persons (completed in 2021), Remedies, Medical Malpractice, Defamation and Privacy, and Miscellaneous Provisions. The Remedies, Medical Malpractice, Defamation and Privacy, and Miscellaneous Provisions parts have not been completed.

99. ALI STYLE MANUAL, *supra* note 30, at 3.

100. *Id.* at 5.

101. *Id.* at 7.

102. *Id.* at 6.

103. See, e.g., Kim V. Markkand, *How a Broken Process, Broken Promises, and Reimagined Rules Justify the Bench and Bar’s Skepticism Regarding the Reliability of the Restatement of the Law, Liability Insurance*, 50 THE BRIEF 20 (2020); Lisa A. Rickard, *Is The American Law Institute About To ‘Jump The Shark’?*, INVESTOR’S BUS. DAILY (Jan. 15, 2019) <https://www.investors.com/politics/commentary/ali-american-law-institute-summaries/> [<https://perma.cc/T2F6-25N5>] (stating that proposed Restatement of the Law, Consumer Contracts proposes to “create an entirely new body of law for contracts between businesses and consumers”).

and have chosen instead to set forth their aspirations for what the law ought to be.¹⁰⁴

Justice Scalia added that where restatements revise rather than restate the law, they “should be given . . . no more weight regarding what the law ought to be than the recommendations of any respected lawyer or scholar.”¹⁰⁵

Despite these criticisms, the ALI continues to endorse legal rules in some restatements that lack common law support¹⁰⁶—always seeming to move in the direction of increasing civil liability.¹⁰⁷ This shift has led to additional criticism that some modern restatements no longer strive to reflect a balanced perspective of the legal community.¹⁰⁸

The ALI’s treatment of negligent misrepresentation causing physical harm in the Miscellaneous Provisions Restatement exemplifies these concerns, especially with respect to innovator liability claims. The proposed Restatement rule, which is likely to be considered at the ALI’s 2024 Annual Meeting, states:

(a) An actor who negligently furnishes false information is subject to liability for any physical harm factually caused by another’s reliance on the information that is within the actor’s scope of liability.

104. *Kansas v. Nebraska*, 574 U.S. 445, 475 (2015) (Scalia, J., concurring and dissenting in part) (citations omitted).

105. *Id.* at 476.

106. *See generally* Victor E. Schwartz & Christopher E. Appel, *Restating or Reshaping the Law?: A Critical Analysis of the Restatement of the Law, Liability Insurance*, 22 U. PA. J. BUS. L. 718 (2020) (examining multiple aspirational provisions in the Restatement of the Law, Liability Insurance, which, if adopted by courts, would dramatically change liability insurance law); *see also* Christopher E. Appel, *The American Law Institute’s Unsound Bid to Reinvent Contract Law in the Proposed Restatement of the Law, Consumer Contracts*, 32 LOY. CONSUMER L. REV. 339, 362 (2020) (discussing the “remarkable extent to which [the proposed Restatement of the Law, Consumer Contracts] fails to satisfy the ALI’s most basic standards for a developing a Restatement” and the project’s “one-sided purpose of increasing a consumer’s ability to challenge and invalidate . . . agreements” between businesses and consumers).

107. *See* James M. Beck, “ALI” Should Not Mean “Always Liability Increases” – *Apportionment Misadventures*, DRUG & DEVICE L. BLOG (Oct. 14, 2019), <https://www.druganddevicelawblog.com/2019/10/ali-should-not-mean-always-liability-increases-apportionment-misadventures.html> [<https://perma.cc/RZZ2-G8CW>] (article by ALI-appointed Adviser to Miscellaneous Provisions Restatement).

108. *See, e.g.*, Mark Behrens, *ALI, Bar Groups Need More Defense Engagement For Balance*, LAW360 (June 12, 2023), <https://www.law360.com/articles/1686909/ali-bar-groups-need-more-defense-engagement-for-balance> [<https://perma.cc/EJ4Z-22PB>] (stating the “personal injury plaintiffs bar has an impressive level of participation in organizations that are involved in the development of the law” such as the ALI, resulting in “a lack of balance that is palpable”); Laura A. Foggan & Rachel Padgett, *Rules of Policy Interpretation Reflect Lingering Policyholder Bias in the ALI’s Restatement of the Law, Liability Insurance*, 50 THE BRIEF 26 (2020) (article co-authored by ALI-appointed insurer liaison to Restatement of the Law, Liability Insurance).

(b) An actor's negligence may occur in ascertaining the accuracy of the information, in the manner in which it is communicated, or in other ways that result in the communication of false information.

(c) An actor is subject to liability pursuant to this Section regardless of whether the person who received or relied upon the actor's misrepresentation is the person who suffered physical harm.¹⁰⁹

A comment supporting the proposed rule acknowledges that "almost half of U.S. states have no definitive case law" recognizing or expressly rejecting the tort of negligent misrepresentation causing physical harm.¹¹⁰ The Restatement explains, "the paucity of precedent addressing negligent misrepresentation causing physical harm" may be traceable to courts that "still think that liability for misrepresentation is limited to financial and business relationships and the pure economic loss that occurs in those realms."¹¹¹ This "paucity of precedent" is even more extreme with respect to several novel aspects of the proposed rule.¹¹²

Most significantly, the Restatement takes the approach that "if an actor makes a false statement that, when relied upon, poses a risk of physical harm, the basic condition for a duty of reasonable care has been satisfied."¹¹³ According to the Restatement, "because there is an affirmative act (i.e., the communication), resort to a basis for an affirmative duty . . . is unnecessary."¹¹⁴

No jurisdiction adopts such an approach to negligent misrepresentation.¹¹⁵ In fact, the jurisdictions cited in the Restatement's Reporters' Note as evidencing "strong case law" support for a claim of negligent misrepresentation causing physical harm consistently apply a traditional duty analysis that does not presuppose the existence of a duty based on the mere act of communicating a false statement.¹¹⁶ For instance,

109. TD 3, *supra* note 3, § 18A.

110. *Id.* § 18A cmt. b.

111. *Id.*

112. *Id.*

113. *Id.* § 18A cmt. d.

114. *Id.*

115. See Letter from ALI Members Victor E. Schwartz and Christopher E. Appel to Reporters Michael Green, Mark Hall, and Nora Freeman Engstrom regarding "Negligent Misrepresentation Creating Risk of Physical Harm in Restatement (Third) of Torts: Concluding Provisions" (Sept. 7, 2021) (on file with author) (explaining "a major flaw of § 18A is that it rejects any meaningful duty requirement" because the approach has "nonexistent case law support").

116. The Reporters' Notes identifies approximately a dozen states as having "strong case law evidencing clear acceptance of claims for negligent misrepresentation." TD 3, *supra* note 3, § 18A, Reporters' Notes b; see *Randi W. v. Muroc Joint Unified Sch. Dist.*, 929 P.2d 582, 588 (Cal. 1997) (applying "general analytical principles used to determine the existence of duty in particular cases"); *Garcia v. Superior Court*, 789 P.2d 960, 964 (Cal. 1990) (referencing "the duty

the California Supreme Court said in *T.H.* that “[w]hether a party has a duty of care in a particular case is a question of law for the court.”¹¹⁷ The court engaged in a lengthy duty analysis that considered various criteria before permitting innovator liability under a negligent misrepresentation theory.¹¹⁸

The Restatement rule further relaxes the requirements for a negligent misrepresentation claim by dispensing with a showing that reliance on an alleged misrepresentation must be reasonable. Instead, the Restatement endorses liability where a claimant *unreasonably* relies on a false statement and physical harm results.¹¹⁹ This is a dramatic departure from the Restatement (Second) of Torts.¹²⁰ The Restatement argues that the “advent

question in th[at] case”); *Bloskas v. Murray*, 646 P.2d 907, 914 (Colo. 1982) (extending doctrine of negligent misrepresentation “to representations *made in the course of the professional relationship existing here*”) (emphasis added); *Doe v. Cochran*, 210 A.3d 469, 482–83 (Conn. 2019) (applying “the various factors and considerations . . . relevant to the duty analysis” under Connecticut law); *Daye v. General Motors Corp.*, 720 So. 2d 654, 659 (La. 1998) (finding actions for negligent misrepresentation governed by statutory law and evaluated under “duty-risk analysis . . . employed on a case by case basis”); *Foster v. American Home Prods. Corp.*, 29 F.3d 165 (4th Cir. 1994) (noting that one of “[t]he elements of the tort of negligent misrepresentation under Maryland law” is whether “the defendant, *owing a duty of care to the plaintiff*, negligently asserts a false statement”) (emphasis added) (quoting *Martens Chevrolet v. Seney*, 439 A.2d 534, 539 (Md. 1982)); *Clark v. St. Dominic-Jackson Mem’l Hosp.*, 660 So. 2d 970, 974 (Miss. 1995) (finding that hospital that provided patient consent form owed duty to patient to “ensure that the information contained therein was accurate and not misleading”); *Elizabeth E. v. ADT Sec. Sys. W., Inc.*, 839 P.2d 1308, 1311 (Nev. 1992) (recognizing negligent misrepresentation claim where “the duty owed to [plaintiff] by [defendant] is attributable to the contract between [defendant] and [plaintiff’s employer]”); *Reynolds v. Lancaster Cnty. Prison*, 739 A.2d 413, (N.J. Super. Ct. 1999) (noting that “[i]n deciding whether [Restatement (Second) of Torts] section 311 should be applied to the gift of a vicious dog, [courts] are guided by the general [tort duty] principles” that recognize the “imposition of a duty is the conclusion of a rather complex analysis”) (quoting *Dunphy v. Gregor*, 642 A.2d 372 (N.J. 1994)), *abrogated on other grounds by Goldhagen v. Pasmowitz*, 255 A.3d 1191 (N.J. 2021); *Davis v. Board of Cnty. Comm’rs of Dona Ana Cnty.*, 987 P.2d 1172, 1179 (N.M. Ct. App. 1999) (“In the context of this case, we accept the principles set forth in [Restatement (Second) of Torts] Section 311, *as they apply to an employer’s duty of care in making employment references* and the circumstances under which that duty extends to foreseeable third parties.”) (emphasis added); *Heard v. City of New York*, 623 N.E.2d 541, 545 (N.Y. 1993) (stating “[f]or there to be an actionable [negligent misrepresentation] claim, the defendant must be under a duty to the plaintiff to exercise reasonable care in giving the information” and finding lifeguard had no such duty to prevent physical injury by swimmer diving off jetty into shallow water).

117. *T.H. v. Novartis Pharms. Corp.*, 407 P.3d 18, 28 (Cal. 2017).

118. *Id.* at 29–35.

119. *See* TD 3, *supra* note 3, § 18 A cmt. h. An illustration in the Restatement posits that a political commentator with one million online followers would be subject to liability for the injury or death of hundreds of people who rely on a single “tweet” urging followers to decline a vaccine to “prevent the government from monitoring your brain.” *Id.* at § 18A ill. 5.

120. *See* RESTATEMENT (SECOND) OF TORTS § 311 (AM. L. INST. 1965) (Negligent Misrepresentation Involving Risk of Physical Harm) (noting that “[o]ne who negligently gives false information to another is subject to liability for physical harm caused by action taken by the

of comparative responsibility” supports imposition of liability in this situation, but concedes no court has expressly adopted this approach in the more than half-century since most states transitioned to comparative fault.¹²¹

Here, the proposed Restatement again adopts an approach that is even more extreme than California. The California Supreme Court has maintained—including well after California adopted comparative negligence in 1975—that “in all cases for negligent misrepresentation, plaintiffs must allege facts sufficient to show that [recipient] actually and *reasonably relied* on the alleged misrepresentations.”¹²²

The Restatement recognizes that the application of its novel, expansive version of negligent misrepresentation “gets more complicated . . . when the product user is injured by a generic (rather than brand-name) prescription drug and sues the brand name manufacturer for misrepresentation.”¹²³ A Comment discussing these drug claims recognizes that “[s]ince 1994, over 150 court decisions have addressed the liability of brand-name manufacturers” and the “overwhelming number of these decisions have concluded that brand-name manufacturers cannot be held liable,” including “a significant number of state trial and intermediate appellate courts.”¹²⁴

The Restatement focuses on the fact that only five state supreme courts have expressly decided whether to allow innovator liability.¹²⁵ As discussed, only California adopts a negligence-based innovator liability claim. The state high courts of West Virginia and Iowa rejected innovator liability, the Massachusetts Supreme Judicial Court expressly limits innovator liability to claims of branded manufacturer recklessness, and the Alabama Supreme Court’s approval of innovator liability was legislatively overturned. Thus, even though only one of these five states allows innovator liability under a negligent misrepresentation theory, the pending Restatement does not side with the “overwhelming” number of decisions

other in reasonable reliance upon such information,” where the harm results “(a) to the other, or (b) to such third persons as the actor should expect to be put in peril by the action taken.”).

121. See TD 3, *supra* note 3, § 18A cmt. h.

122. *Garcia*, 789 P.2d at 965 (emphasis added); see also *T.H.*, 407 P.3d at 27 (recognizing plaintiff’s reliance on RESTATEMENT (SECOND) OF TORTS § 311 and its reasonable reliance requirement to support innovator liability claim); *Fox v. Pollack*, 181 Cal. App. 3d 954, 962 (Cal. Ct. App. 1986) (holding that California negligent misrepresentation claims require “justifiable reliance,” among other elements); *AToN Ctr., Inc. v. United Healthcare Ins. Co.*, 93 Cal. App. 5th 1214, 1246 (Cal. Ct. App. 2023) (elements of negligent misrepresentation include “justifiable reliance on the misrepresentation”) (citing *Apollo Capital Fund, LLC v. Roth Capital Partners, LLC*, 158 Cal. App. 4th 226, 243 (2007)).

123. TD 3, *supra* note 3, § 18A cmt. q.

124. *Id.*

125. *Id.*

during the past quarter century that reject innovator liability. Instead, the Restatement takes “no position” on the issue.¹²⁶ The Restatement cites a “paucity of state-supreme-court decisions” as a reason to defer “to further developments in state high courts.”¹²⁷

The Restatement’s commentary discussing innovator liability is less agnostic, expressing skepticism with respect to the reasoning applied by many of the courts rejecting innovator liability.¹²⁸ The Comment states that while a few courts have rejected innovator liability theories pursuant to a jurisdiction’s product liability statute, other courts have “denied recovery on less persuasive grounds.”¹²⁹ The Comment directs readers to the Reporters’ Note—commentary by the project’s authors that is separate from ALI-approved restatement content.¹³⁰ The cross-reference to the Reporters’ Note further undercuts the Restatement’s purported neutral treatment of innovator liability. The Reporters’ Note argues that while courts appropriately reject “a *products liability* theory against a different seller of the drug than the one the victim consumed, the courts fail to appreciate that a different *non-products liability* claim may exist if this Section’s requirements are satisfied.”¹³¹

The Reporters’ Note challenges the reasoning of cases that reject innovator liability. The Fourth Circuit’s decision in *Foster v. American Home Products Corp.*,¹³² discussed in Part I, is described as the “seminal case” rejecting innovator liability and presented as an example where “the court failed to appreciate that there is a stand-alone negligent misrepresentation that *can* be asserted against non-sellers of the product.”¹³³ The Reporters’ Note asserts that other courts rejecting innovator liability have also relied on “questionable” reasoning.¹³⁴

For instance, the Reporters’ Note recognizes that some courts have rejected negligent misrepresentation claims on the basis that a branded drug manufacturer owes no duty to users of others’ generic drugs.¹³⁵ It argues “[t]hese courts fail to appreciate the ordinary duty of reasonable care that exists when an actor creates a risk of harm to others—and the fact that

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.*

131. *Id.* at Reporters’ Notes q.

132. 29 F.3d 165 (4th Cir. 1994) (applying Maryland law).

133. TD 3, *supra* note 3, § 18A & Reporters’ Notes q.

134. *Id.*

135. *Id.*

misrepresentations about the safety of a drug create such a risk.”¹³⁶ The Reporters’ Note also reflects frustration that “some courts, especially federal courts, have expressed an unwillingness to venture into adopting a new theory of liability that had not been recognized by the state.”¹³⁷

Moreover, a straightforward application of the proposed Restatement’s novel negligent misrepresentation rule would appear to permit innovator liability claims as well as other types of claims that are contrary to overwhelming case law authority. The provision is a radical proposed expansion of tort law.

IV. WHY COURTS SHOULD CONTINUE TO REJECT INNOVATOR LIABILITY

The “overwhelming” number of courts that have rejected innovator liability claims have expressed a variety of rationales for doing so. Several core reasons—any one of which warrants courts’ continued rejection of innovator liability—can be distilled from innovator liability case law and scholarship.

A. Branded Drug Manufacturers Are Only Responsible for Harms Caused by Their Own Products

Most courts have rejected innovator liability claims on the basis that a defendant must have made or sold the specific product alleged to have caused the plaintiff’s injury.¹³⁸ Numerous courts have held that product liability law does not support innovator liability.¹³⁹ Likewise, courts have held that product liability statutes applicable to all product-related damage claims preclude innovator liability claims brought on a negligent

136. *Id.*

137. *Id.*

138. See Schwartz et al., *supra* note 10, at 1879 (“It is a bedrock principle of product liability and tort law that a product manufacturer is subject to liability only for harms caused by its products.”); see also Schrock v. Wyeth, Inc., 727 F.3d 1273, 1276 (10th Cir. 2013) (Oklahoma law); Bell v. Pfizer, Inc., 716 F.3d 1087, 1093 (8th Cir. 2013) (Arkansas law).

139. See, e.g., Mensing v. Wyeth, Inc. 588 F.3d 603, 612 (8th Cir. 2009) (“Traditional products liability requires a plaintiff to show that she actually consumed the defendant’s product.”), *rev’d on other grounds sub nom.* PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011).

misrepresentation theory.¹⁴⁰ Other courts have held that “negligence-based claims are, in reality, products liability claims” and treat them as such.¹⁴¹

Many other courts, including “[e]very [federal] circuit court,” have “held (under the laws of several different states) that a brand-name manufacturer does not owe a duty to consumers who use a generic version of the drug.”¹⁴² For instance, in *Foster*, the Fourth Circuit concluded that imposing a duty of care on branded drug manufacturers for generic drug injuries “would be to stretch the concept of foreseeability too far.”¹⁴³ West Virginia’s high court in *McNair* said that “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,” concluding that innovator liability “stretches foreseeability too far.”¹⁴⁴

B. *Innovator Liability Would Impair Drug Innovation*

Another reason frequently given by courts for rejecting innovator liability is that such claims would chill the development and marketing of new drugs.¹⁴⁵ Bringing a new drug to market requires substantial time and resource investments, with only about twelve percent of drugs that enter

140. See, e.g., *Smith v. Wyeth, Inc.*, 657 F.3d 420 (6th Cir. 2011) (Kentucky law); *Franzman v. Wyeth, Inc.*, 451 S.W.3d 676 (Mo. Ct. App. 2014) (Kentucky law); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378 (6th Cir. 2013) (Tennessee law); *Stewart v. Sanofi Aventis U.S., LLC*, 15 F. Supp. 3d 1151 (N.D. Ala. 2014) (Indiana law); *Tarver v. Wyeth*, No. Civ. A. 3-04-2036, 2005 WL 4052382 (W.D. La. June 7, 2005) (Louisiana law).

141. *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 510 F. Supp. 3d 1175, 1197 (S.D. Fla. 2020) (examining innovator liability claims under Arizona, Arkansas, Colorado, Connecticut, Mississippi, North Carolina, and Oregon law); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 375 (Iowa 2014) (stating that “a plaintiff seeking recovery for the side effects of a prescription who sues a pharmaceutical company under any theory, including misrepresentation, must prove she was injured by using the prescription drug manufactured or supplied by that defendant”).

142. *Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 681 (5th Cir. 2014) (citing cases finding no duty under Oklahoma, Florida, Arkansas, Kentucky, Maryland, Mississippi, and Texas law); *Smith*, 657 F.3d at 424 (“As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company.”).

143. *Foster v. American Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994).

144. *McNair v. Johnson & Johnson*, 818 S.E.2d 852, 863, 818 S.E.2d 866, 862 (W. Va. 2018) (quoting *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, (*Germain v. Teva Pharms., USA, Inc.*), 756 F.3d 917, 944).

145. See, e.g., *Foster*, 29 F.3d at 170 (citing the expense in development, research, and promotion undertaken by name-brand manufacturers not undertaken by generic manufacturers); *Darvocet*, 756 F.3d at 944 (noting the “grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher priced brand name drugs and fewer innovative drugs”).

clinical trials ultimately obtaining FDA approval.¹⁴⁶ According to the Congressional Budget Office, the development of a new drug often takes a decade or more and can cost over \$2 billion.¹⁴⁷ To warrant this investment and to incentivize future investments in drug innovations, a branded drug manufacturer must necessarily recoup its costs through sales—the lion’s share of which typically occur during the limited period the product is entitled to patent exclusivity.¹⁴⁸ Shifting a drug’s future warnings-related liability onto the branded manufacturer after its patent exclusivity expires and competitors enter the marketplace completely changes the investment calculation.

As a practical matter, it would be virtually impossible for a branded drug company to “price in” the added liability costs associated with an unknown number of future harms associated with an unknown number of generic drug market competitors over the unknown lifespan of a drug after it goes off patent. Some drugs may be used decades after first approved for sale, while others may be quickly overtaken in the marketplace by newer, more effective drugs, including during the branded drug manufacturer’s exclusivity period.

Innovator liability would require a branded drug manufacturer to account for all these unknowns, and do so into perpetuity, before a drug even enters the marketplace and regardless of whether the company later makes a course correction. In this environment, a branded drug manufacturer may rethink investing potentially billions of dollars to develop certain drug innovations.¹⁴⁹ For instance, as a strategy by branded drug manufacturers to reduce potential losses, innovations in drugs that treat rare medical conditions or that may have higher risk profiles might be deprioritized in favor of lower risk products that can treat large segments of the population.

C. *Innovator Liability Would Impair Drug Safety*

Innovator liability creates an incentive for branded drug manufacturers to try to over-warn of risks. Branded drug manufacturers looking ahead to the generic phase of a drug’s lifespan would be incentivized to “pile on warnings for every conceivable adverse reaction, no matter how remote the

146. See *Research and Development in the Pharmaceutical Industry*, CONGR. BUDGET OFF. (Apr. 2021), <https://www.cbo.gov/publication/57126> [<https://perma.cc/354D-X6BM>].

147. See *id.*

148. See *id.*

149. See generally W. Kip Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 SETON HALL L. REV. 1418, 1419 (1994) (“[T]he net effect of the surge in liability costs ha[s] been to discourage innovation in the pharmaceutical industry.”).

odds” as a means to mitigate potential liability exposure.¹⁵⁰ As courts have long appreciated, inundating physicians with “any and every hint of danger . . . inevitably dilut[es] the force of any specific warning given,”¹⁵¹ and may prompt physicians “to ignore or discount the warnings.”¹⁵² This potential is particularly acute given that warnings on pharmaceutical labeling are already extensive. One analysis found that the average drug package insert lists around forty-nine potential adverse events, and one out of every ten labels contains over 500 warnings.¹⁵³ Over-warning of remote risks can overwhelm patients too.¹⁵⁴

D. Innovator Liability Would Increase Drug Prices

Increased liability costs for branded drug manufacturers will lead to higher prices for new drug treatments that attempt to account for the branded drug manufacturer’s perpetual warnings-related liability exposure.¹⁵⁵ Liability exposure costs would exacerbate Americans’ existing concerns regarding high drug prices.¹⁵⁶ These added drug costs would also frustrate other federal and state efforts to reduce drug prices for consumers. For example, in 2022, Congress enacted the Inflation Reduction Act,¹⁵⁷ which includes provisions designed to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government

150. Frank Scaglione, *Resolving Drug Manufacturer Liability for Generic Drug Warning Label Defects*, 47 ST. MARY’S L.J. 219, 238 (2015); *see also* 73 FED. REG. 49603, 49605–06 (Aug. 22, 2008) (unfounded statements in FDA labeling may cause “more important warnings” to be “overshadow[ed]”).

151. *Finn v. G. D. Searle Co.*, 677 P.2d 1147, 1153 (Cal. 1984).

152. *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 816 n.40 (5th Cir. 1992) (Mississippi law); *see also* *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 13 (Cal. 2004) (noting that “[a]gainst the benefits that may be gained by a warning must be balanced the dangers of overwarning and of less meaningful warnings crowding out necessary warnings”) (quoting *Carlin v. Superior Court*, 920 P.2d 1347 (Cal. 1996) (Kennard, J, concurring and dissenting)).

153. Jon Duke et al., *A Quantitative Analysis of Adverse Events and “Overwarning” in Drug Labeling*, 171 ARCHIVES OF INTERNAL MED. 944, 945 (2011).

154. *See, e.g.*, *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 869 (7th Cir. 2010) (Virginia law) (“The resulting information overload [from describing every remote risk] would make label warnings worthless to consumers.”).

155. *See* Richard A. Epstein, *What Tort Theory Tells Us About Federal Preemption: The Tragic Saga of Wyeth v. Levine*, 65 N.Y.U. ANN. SURV. AM. L. 485, 514 (2010) (“Properly understood, the entire duty-to-warn apparatus has become a tax on drugs, which, in some instances, may drive both old and new products off the market and, in most instances, will increase drug cost and reduce the levels of beneficial patient use.”).

156. *See States Curb Racial Inequities in Rx Drug Affordability with Targeted Legislation*, NAT’L ACAD. FOR STATE HEALTH POL’Y, <https://nashp.org/states-curb-racial-inequities-in-rx-drug-affordability-with-targeted-legislation/> [<https://perma.cc/S7TX-5LBZ>] (“high drug prices disproportionately affect low-income, uninsured, and people of color”).

157. Inflation Reduction Act of 2022, Pub. Law No. 117–169, 136 Stat. 1818.

by an estimated \$237 billion over ten years.¹⁵⁸ Broad acceptance of innovator liability would undercut this federal policy by introducing substantial system-wide costs for branded prescription drugs that would be reflected in higher consumer drug prices.

E. Innovator Liability Would Be Indeterminate and Unbounded

The potential for indeterminate, unbounded, or crushing liability often serves as a policy reason for limiting the scope of tort liability.¹⁵⁹ Innovator liability, in contrast, invites unpredictable and potentially endless liability by exposing a branded drug manufacturer to claims for generic drug injuries for as long as generic drug manufacturers sell a copycat product. The role of a product manufacturer is “clearly not that of an insurer,”¹⁶⁰ even with respect to strict liability, yet innovator liability proposes to transform a branded drug manufacturer into *the* insurer of its drug and others’ generic version too.¹⁶¹

A branded drug manufacturer’s options for limiting its potential liability exposure are also problematic. As seen with California’s approach to innovator liability, a branded drug manufacturer cannot simply divest its interests in a drug to avoid liability.¹⁶² It could, as discussed, attempt to “pile on” additional warnings, but doing so would impair drug safety and carry no guarantee of foreclosing litigation.¹⁶³ The branded drug manufacturer could also stop selling its product and attempt to convince the FDA to ban the product in light of new risks. This dramatic approach, however, would necessitate that significant new risks indeed exist and that they outweigh the drug’s overall benefits.¹⁶⁴ Convincing the FDA to

158. See Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KAISER FAM. FOUND. (Jan. 24, 2023), <https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/> [<https://perma.cc/KH36-9Q4U>] (citing Congressional Budget Office analysis).

159. See, e.g., *Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 443 (1997) (citing concerns about “unlimited and unpredictable liability” in rejecting medical monitoring cause of action for claims brought under the Federal Employers’ Liability Act); *Eckhardt v. Kirts*, 534 N.E.2d 1339, 1345 (Ill. Ct. App. 1989) (recognizing that decisions limiting duty of psychiatrists to warn third parties “evinces a sound public policy against expanding the liability of health professionals to an indeterminate class of potential plaintiffs”).

160. John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 MISS. L.J. 825, 828 (1973).

161. *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 380 (Iowa 2014) (“[Court] unwilling to make brand manufacturers the de facto insurers for competing generic manufacturers.”).

162. *T.H. v. Novartis Pharms.*, 407 P.3d 18, 23, 40 (Cal. 2017).

163. Scaglione, *supra* note 150, at 238.

164. See Schwartz & Appel, *supra* note 32, at 616–21 (discussing the limited circumstances in which a change in a branded drug’s warning may be appropriate).

withdraw approval for a drug would also likely trigger significant warnings-related litigation by users of the branded or generic versions of the drug. The branded drug manufacturer could additionally try to buy out its generic drug competitors, but there would be no guarantee that others would not take their place.

The potential for uncontrollable liability also threatens to create insurability problems. A branded drug manufacturer may be unable to procure liability insurance in the face of unbounded liability or do so only with substantially greater costs. This additional layer of drug costs would ultimately be passed onto consumers via higher prices.

F. Innovator Liability is Fundamentally Unfair

As a court rejecting innovator liability claims over a decade ago recognized, requiring a product manufacturer to have made or sold the product that allegedly caused harm “is rooted in common sense.”¹⁶⁵ In the innovator liability context, the branded drug manufacturer has no relationship with generic drug injury plaintiffs or generic drug manufacturers; no communication with the generic drug company; may no longer sell its drug; and obtains no profit or other material benefit from sales of copycat generic versions of its products.

Further, consider a branded drug manufacturer that decides within the first year of exclusivity to stop marketing a drug because a greater incidence of adverse event reports than initially foreseen has changed the manufacturer’s risk assessment and expected return on investment. Several generic drug manufacturers come along after the branded drug’s exclusivity period ends and sell a generic version to millions of consumers. Innovator liability would effectively punish the branded drug manufacturer that acted cautiously by saddling the manufacturer with all resulting warnings-related liability for as long as the generic drug manufacturers keep selling those products and the FDA does not ban the drug’s sale.

Finally, the predicate for innovator liability—*i.e.*, preemption of state law tort claims against generic drug manufacturers—is outside the branded drug manufacturer’s control. Liability is imposed simply because generic drug consumers generally lack a remedy for warnings-based tort claims. This is not the fault of branded drug companies but was a policy choice by Congress to lower drug prices for consumers through greater availability of

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

generic drugs.¹⁶⁶ As the Iowa Supreme Court in *Huck* appreciated, shifting all warnings-based liability to the branded drug company is “[d]eep-pocket jurisprudence [that] is law without principle.”¹⁶⁷

V. CONCLUSION

Despite numerous attempts during the past several decades to have courts buy into the theory of innovator liability, the law remains very one-sided against such claims. The response of almost all courts has been that branded drug manufacturers are liable only for harms caused by their own products. At present, only California clearly recognizes innovator liability based on negligence theories such as negligent misrepresentation. Nevertheless, the pending *Restatement (Third) of Torts: Miscellaneous Provisions* proposes to breathe new life into innovator liability claims through its novel “negligent misrepresentation causing physical harm” provision. Although the proposed Restatement recognizes that courts overwhelmingly reject innovator liability, the Restatement declines to follow that consensus. Instead, the Restatement purports to take no formal position on the issue. A close examination of the novel proposed rule and its supporting commentary, however, reveals at least an indirect endorsement of innovator liability. The overwhelming case law rejecting innovator liability takes the right approach. Judges should continue to reject innovator liability notwithstanding the proposed Restatement.

166. See *Huck*, 850 N.W.2d at 377 (“Through carefully crafted legislation, Congress has made policy choices that impact the economics of prescription drug sales to increase access to medication.”).

167. *Id.* at 380 (quoting Schwartz et al., *supra* note 10, at 1871); see also Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor’s Copycat Product*, 45 TORT TRIAL & INS. PRAC. 673, 694 (2010) (“Brand-name drug manufacturers should not face liability for injuries caused by their generic competitors’ products.”).