ON THE ROAD TO RECOVERY: PROVIDING GENERIC DRUG CONSUMERS WITH A REMEDY IN FAILURE-TO-WARN CASES

Abstract: On March 16, 2018, in *Rafferty v. Merck & Co*., the Supreme Judicial Court of Massachusetts held that brand-name drug manufacturers owe generic drug users a duty to not act recklessly in creating and updating warning labels. Courts deciding this issue have disagreed about whether and to what extent a duty should be imposed on brand-name manufacturers concerning injuries caused by generic products they do not produce. The Supreme Judicial Court is among the minority of courts that has correctly imposed a duty on brand-name manufacturers in this context. Its imposition of a recklessness standard, however, is incorrect because it inappropriately weighs public policy concerns.

INTRODUCTION

The United States is one of only two countries in the world that permits direct-to-consumer pharmaceutical advertising.[1] Advocates of this system extol its benefits: helping patients engage with the health care system, make educated treatment decisions, and adhere more consistently to their medications.[2] Critics, however, note that ads often over-emphasize the benefits of the drug, under-emphasize its risks, and lead to overuse.[3] To mitigate the hazards of direct-to-consumer marketing and ensure consumers are fully informed before ingesting a product, federal regulations require drug manufacturers to fully disclose their products' health and safety risks on warning labels.[4]

The Hatch-Waxman Act, passed in 1984, modernized these regulations by placing different labeling responsibilities on brand-name and generic drug

[1] Neeraj Sood, *Should the Government Restrict Direct-to-Consumer Prescription Drug Advertising? Six Takeaways on their Effects*., USC SCHAEFFER CTR. FOR HEALTH POL'Y & ECON. (Mar. 23, 2023), https://healthpolicy.usc.edu/article/should-the-government-restrict-direct-to-consumer-prescription-drug-advertising-six-takeaways-from-research-on-the-effects-of-prescription-drug-advertising/ [https://perma.cc/3D2X-L9BK].

[2] Natasha Parekh & William H. Shrank, *Dangers and Opportunities of Direct-to-Consumer Advertising*, 33 J. GEN. INTERNAL MED. 586, 586 (2018).

[3] *Id.* In a 2005 study, patients who requested a particular drug were significantly more likely to receive a prescription for it. Richard L. Kravitz et al., *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 JAMA 1995, 1995 (2005).

[4] *See* Parekh & Shrank, *supra* note 2, at 586 (explaining the regulatory authority of the Food and Drug Administration).

manufacturers.[5] A brand-name drug is a uniquely named or trademarked drug with patent-protected market exclusivity for a period of time.[6] A generic drug is one with an active-ingredient formula identical to a brand-name drug already on the market, but sold for a much lower price once the patent of its brand-name counterpart expires.[7] Under the amended system, brand-name manufacturers must create adequate warning labels and generic manufacturers must use the same label as the brand-name drug.[8] For generic manufacturers, this duty of sameness imposed by the Hatch-Waxman Act conflicts with their pre-existing state-level duty to inform consumers of risks, leaving generic drug consumers with potentially no path to recover for harm caused by inadequate labeling.[9]

Courts have grappled with this dilemma, but are split on its resolution.[10] A few courts impose a duty of care on brand-name manufacturers, who create the labels generic manufacturers must use, to ensure generic users are adequately informed of the risks of certain drugs.[11] Most others refrain from doing

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[5] *See* 21 U.S.C. § 355(b)(1)(A), (d), (j)(2)(A)(v), (j)(4)(G) (explaining brand-name manufacturers' duty to create adequate warning labels and generic manufacturers' duty to replicate the brand-name label exactly under the Hatch-Waxman Act).

[6] *Brand Name (Drugs)*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/brand-name-drugs/ [https://perma.cc/2NVK-JAMY]. The responsibility to maintain adequate labels means that brand-name manufacturers have a duty to ensure the information included on their warning labels is complete and accurate. *See* 21 U.S.C. § 355(b)(1)(A), (d) (explaining the application process for new brand-name drugs and stating that such applications will be denied if they do not comply with the requirements and show that the drug is safe to use).

[7] *Generic Drugs*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/generic-drugs/ [https://perma.cc/3DHB-XL73]. In their new drug applications, generic manufacturers must ensure that their proposed warning labels are exactly the same as those of their brand-name equivalents. 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G).

[8] *See* 21 U.S.C. § 355(b)(1)(A), (d), (j)(2)(A)(v), (j)(4)(G) (laying out the respective duties of generic and brand-name manufacturers imposed by the Act).

[9] *See* Rafferty v. Merck & Co., 92 N.E.3d 1205, 1211 (Mass. 2018) (stating that generic manufacturers cannot uphold their state-imposed duty to warn consumers of the dangers of using their product when they knew or should have known of the risk because they lack the ability to change or update their warning labels unilaterally under federal law).

[10] *See, e.g.*, T.H. v. Novartis Pharms. Corp., 407 P.3d 18, 29 (Cal. 2017) (deciding that a brand-name manufacturer has a duty of care in providing complete and accurate product information to consumers of the generic counterpart); Wyeth, Inc. v. Weeks, 159 So.3d 649, 676 (Ala. 2014), *superseded by statute*, ALA. CODE § 6-5-530(a) (2015) (holding that brand-name manufacturers owe a duty to not make false representations, by omission or misstatement, to those people they have reason to believe will be influenced by such representations); Huck v. Wyeth, Inc., 850 N.W.2d 353, 380 (Iowa 2014) (holding that a brand-name manufacturer cannot be found liable for injuries to a generic drug consumer because it did not produce the offending product); Guarino v. Wyeth, LLC, 719 F.3d 1245, 1253 (11th Cir. 2013) (same); Smith v. Wyeth, Inc., 657 F.3d 420, 421 (6th Cir. 2011) (same).

[11] *See, e.g.*, *T.H.*, 407 P.3d at 29 (holding that a brand-name manufacturer has a duty of care to generic drug users); *Weeks*, 159 So.3d at 676 (same); *Rafferty*, 92 N.E.3d at 1211 (holding that brand-name manufacturers have a duty to not act recklessly).

so.[12] In 2018, in *Rafferty v. Merck & Co*., the Supreme Judicial Court of Massachusetts took the minority approach a step further by holding brand-name manufacturers to a recklessness standard when sued by generic drug users for inadequate warning labels.[13] This Comment evaluates the majority and minority approaches courts have taken.[14] Part I provides the legal, factual, and procedural background of *Rafferty*.[15] Part II describes the reasoning courts have employed in deciding whether to impose a duty.[16] Finally, Part III argues that the negligence variation of the minority approach is correct because all actors owe a duty to those whom their actions may foreseeably injure.[17]

I. The Legal, Factual, and Procedural Background of *Rafferty v. Merck & Co.*

In 2018, in *Rafferty v. Merck & Co*., the Supreme Judicial Court of Massachusetts (SJC) held that brand-name manufacturers owe a duty to generic drug users to not act recklessly in creating warning labels.[18] Section A of this Part discusses the regulations imposed on drug manufacturers by the Hatch-Waxman amendment to the Federal Food, Drug, and Cosmetic Act, causing the federal and state laws to conflict, as well as its implications for injured consumers.[19] Section B discusses the history of *Rafferty*.[20]

A. The Hatch-Waxman Act and Its Implications

Prior to 1984, generic drug manufacturers were required to follow the same lengthy and expensive application process as brand-name manufacturers when bringing a new product to market.[21] To both lessen the cost of drugs and

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[12] *See, e.g.*, *Huck*, 850 N.W.2d at 380 (holding that a brand-name manufacturer has no duty to a generic drug consumer when it did not produce the offending product); *Guarino*, 719 F.3d at 1253 (same); *Smith*, 657 F.3d at 421 (same); *see also* Allison Stoddart, Note, *Missing After Mensing: A Remedy for Generic Drug Consumers*, 53 B.C. L. Rev. 1967, 1987 (2012) (explaining that, with only a few exceptions, every court deciding the issue has refused to allow generic consumers to recover against brand-name manufacturers).

[13] 92 N.E.3d at 1205.

[14] *See infra* notes 18–97 and accompanying text.

[15] *See infra* notes 18–48 and accompanying text.

[16] *See infra* notes 49–74 and accompanying text.

[17] *See infra* notes 82–97 and accompanying text.

[18] 92 N.E.3d 1205, 1205 (Mass. 2018).

[19] *See infra* notes 14–31 and accompanying text.

[20] *See infra* notes 38–48 and accompanying text.

[21] *Rafferty*, 92 N.E.3d at 1209 (citing PLIVA, Inc. v. Mensing, 564 U.S. 604, 612 (2011)); *see also* Mutual Pharm. Co. v. Bartlett, 570 U.S. 472, 476 (2013) (explaining that the process of gaining approval for a new drug is long and burdensome). A manufacturer attempting to bring a new brand-name drug to market must submit a new drug application (NDA) including, among other things, proof the product works and is safe, a list of components and their composition, the methods and facilities used in production, and the adequacy and accuracy of the proposed warning label, which costs a sig-

encourage greater investment in the research and development of innovative new medications, Congress amended the regulatory requirements for generic drug manufacturers by passing the Hatch-Waxman Act (Act) in 1984.[22] The Act created a more efficient approval process for generic drugs, requiring manufacturers to submit only an abbreviated application showing the generic drug is identical to its brand-name equivalent in specific ways.[23] Notably, the Act mandates that a generic drug's proposed warning label be exactly the same as the one already approved for the brand-name version.[24]

This new regulatory scheme created different labeling responsibilities for generic and brand-name drug manufacturers.[25] Brand-name manufacturers must ensure their warning labels are accurate and adequate,[26] but generic manufacturers must simply ensure sameness.[27] Consequently, only brand-name manufacturers can substantively change their labels, and they may do so without waiting for FDA approval.[28] Generic manufacturers can only update their

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nificant amount of time and resources. *See Bartlett*, 570 U.S. at 476 (explaining the required components of an NDA); *see also* 21 U.S.C. § 355(b)(1)(A), (d) (describing the necessary components of an NDA and the grounds for disapproval); Applications for FDA Approval to Market New Drugs, 21 C.F.R. § 314.50(c)(2)(i), (d)(5)(iv)-(vi), (viii) (2021) (requiring that an NDA include the proposed text of the warning label and all information available about the product's safety and associated risks).

[22] *See* Abbott Lab'ys v. Young, 920 F.2d 984, 985 (D.C. Cir. 1990) (citing H.R. REP. NO. 98-857, pt. 1, at 14–15 (1984)) (stating that Congress, facing a trade-off between incentivizing innovation and increasing the affordability of new products, tried to balance accelerating the generic drug application process and preserving the rights of brand-name drug manufacturers). The Hatch-Waxman Act is credited with creating the modern-day generic drug industry. Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011) (quoting Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 175 (2008)).

[23] 21 U.S.C. § 355(j)(2)(A), (8)(B); *see also Rafferty*, 92 N.E.3d at 1210 (explaining that generic drug manufacturers now only have to submit a much shorter application that shows the generic drug is the same as its brand-name equivalent in particular ways). Specifically, the application must show the generic and brand-name drugs contain the same active ingredients, are administered the same way, have the same dosage, and are bioequivalent. 21 U.S.C. § 355(j)(2)(A)(ii)-(iii), (8)(B). Generic and brand-name drugs are bioequivalent if they have the same rate and extent of absorption. *Id.* § 355(j)(8)(B).

[24] 21 U.S.C. § 355(j)(2)(A)(v).

[25] *See* PLIVA, Inc. v. Mensing, 564 U.S. 604, 613 (2011) (explaining that the Act imposed a federal duty to ensure accurate and adequate labels on brand-name manufacturers and a duty to create labels identical to the brand-name's labels on generic manufacturers).

[26] 21 U.S.C. § 355(b)(1)(A), (d).

[27] *Id.* § 355(j)(2)(A)(v), (j)(4)(G).

[28] *See* Rafferty v. Merck & Co., 92 N.E.3d 1205, 1210 (Mass. 2018) (explaining that brand-name manufacturers may change their labels through the "changes being effected" (CBE) process); *see also* Applications for FDA Approval to Market New Drugs, 21 C.F.R. § 314.70(c) (2021) (explaining and laying out the steps of the CBE process). This allows brand-name manufacturers to add to or enhance a warning label based on new information without prior approval from the FDA as long as a supplemental NDA is filed simultaneously. 21 C.F.R. § 314.70(c)(3), (c)(6)(iii)(A) (2021). The FDA does, however, reserve the right to subsequently disapprove of any supplemental NDA and force the manufacturer to halt distribution of the altered product. 21 C.F.R. § 314.70(c)(7) (2021); *see also* Wyeth v.

warning labels to accommodate changes made by their brand-name counterparts or to comply with FDA regulations.[29]

Separately, tort law in many states places a duty on drug manufacturers to warn consumers of any possible risks or dangers associated with the use of a product when the manufacturer knew or should have known of them.[30] Generally, when a failure to warn results in injury, the breaching party may be implicated under products liability law, common law negligence, or common law recklessness.[31] For generic manufacturers, however, this state-level duty to warn directly conflicts with their federal duties under the Act.[32]

In 2011, in *PLIVA, Inc. v. Mensing*, the Supreme Court sought to clarify these conflicting duties.[33] The Court held that generic manufacturers' federal duty of sameness preempts their state tort law duty to warn.[34] Federal law preempts state law when the two conflict and it would be impossible to adhere to both at the same time.[35] Here, a generic manufacturer's federally-imposed

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Levine, 555 U.S. 555, 571 (2009) (explaining the responsibility of manufacturers to ensure the adequacy of labels and the authority of the FDA to disapprove of any changes made in line with CBE regulations).

[29] *See Mensing*, 564 U.S. at 613 (explaining that generic manufacturers do not have the same authority as brand-name manufacturers because of the duty of sameness imposed on them by federal regulation); 21 U.S.C. § 355(j)(4)(G) (noting that a generic drug application will not be approved if its proposed label is not the identical to its brand-name equivalent); 21 C.F.R. § 314.150(b)(10) (2021) (stating that approval for a generic drug may be withdrawn by the FDA if the label is not the same as its brand-name equivalent); *see also* Brief for the United States as Amicus Curiae Supporting Respondents at 15–16, PLIVA, Inc. v. Mensing, 564 U.S. 604, 613 (2011) (Nos. 09-993, 09-1039, 09-1501) (discussing, in part, the different duties of brand-name and generic manufacturers to ensure their labels are permissible).

[30] *See Mensing*, 564 U.S. at 611 (stating that tort law in both Minnesota and Louisiana requires drug manufacturers to include the dangers of usage on their product labels when they are aware or should be aware of such dangers); *see also* Mitchell v. Sky Climber, Inc., 487 N.E.2d 1374, 1376 (Mass. 1986) (noting that a product manufacturer has a duty to warn "foreseeable users" of the potential harms resulting from usage that the manufacturer is aware of or should be aware of).

[31] *See* H.P. Hood & Sons v. Ford Motor Co., 345 N.E.2d 683, 688 (Mass. 1976) (stating that a manufacturer that knows or has reason to know its product is dangerous owes a duty to consumers to exercise care in preventing injury, including by providing warnings); *Mitchell*, 487 N.E.2d at 1376 (stating that manufacturers are only liable for a failure to warn under products liability law when the injury-causing product was made by the manufacturer itself); Dinsky v. Framingham, 438 N.E.2d 51, 53 (Mass. 1982) (explaining the circumstances under which a claim of common law negligence may be applicable); Boyd v. Nat'l R.R. Passenger Corp., 845 N.E.2d 356, 362–63 (Mass. 2006) (quoting RESTATEMENT (SECOND) OF TORTS § 500 (AM. L. INST. 1965)) (explaining the circumstances under which a claim of common law recklessness may be applicable).

[32] *See Rafferty*, 92 N.E.3d at 1211 (explaining that, because generic manufacturers lack the authority to change their warning labels independently, they are unable to fulfill their state duty).

[33] 564 U.S. at 608–09.

[34] *Id.*; *see also* Mutual Pharm. Co. v. Bartlett, 570 U.S. 472, 476 (2013) (upholding *Mensing*).

[35] *Mensing*, 564 U.S. at 618 (quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)). Per the Supremacy Clause, the Constitution is "the supreme Law of the Land." U.S. CONST., Art. VI, cl. 2. Therefore, when a state law is in direct conflict with a federal law, the federal law preempts the state law. Wyeth v. Levine, 555 U.S. 555, 583 (2009) (Thomas, J., concurring in judgment).

inability to alter its labels makes it impossible to warn consumers of any additional risks it is aware or should be aware of.[36] Because of this holding, consumers who suffer injury because of an inadequately labeled generic drug cannot sue the generic manufacturer.[37]

B. History of Rafferty v. Merck & Co.

Merck & Co. (Merck) manufactures Proscar, the brand-name version of the drug finasteride.[38] It is an FDA-approved medication indicated to treat benign prostatic hyperplasia (BPH) in men with enlarged prostates.[39] Brian Rafferty began taking generic finasteride in August 2010 to treat his enlarged prostate.[40] Shortly thereafter, he began to experience erectile dysfunction and decreased libido.[41] Believing these side effects would subside after discontinuing usage, based on the warning information he received with the drug, Rafferty weaned himself off the finasteride.[42] Despite this, his side effects not only continued but worsened, and eventually Rafferty was diagnosed with hypogonadism and an androgen deficiency purportedly caused by the drug.[43]

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[36] *Mensing*, 564 U.S. at 618. The parties agreed that, if the manufacturers knew or should have known of the risks of the generic product, state law required them to adopt a better warning label. *Id.* at 613. They disagreed as to whether generic manufacturers can change their warning labels after their initial FDA approval. *Id.* Ultimately, the Court found that, despite the generic manufacturers having a duty to approach the FDA for help, the impossibility existed because asking for such help is not a state concern and federal law made it impossible for manufacturers to do on their own what the state law required. *Mensing*, 564 U.S. at 623–24; *but see Levine*, 555 U.S. at 573 (holding that the manufacturer did not demonstrate impossibility because the CBE process permitted it to unilaterally update its label).

[37] *See Mensing*, 564 U.S. at 625 (explaining that federal law preempts state law here because the consumer was given the generic drug).

[38] Rafferty v. Merck & Co., 92 N.E.3d 1205, 1211 (Mass. 2018); *see also Patient Information about Proscar*, ORGANON & CO., (2021), https://www.organon.com/product/usa/pi_circulars/p/proscar/proscar_ppi.pdf [https://perma.cc/B4GG-GV5V] (defining Proscar, known generically as finasteride).

[39] *Rafferty*, 92 N.E.3d at 1211. BPH is an enlargement of the prostate, located below the bladder, caused by higher levels of the hormone dihydrotestosterone (DHT). *Patient Information about Proscar*, *supra* note 38. As the prostate grows larger, it can restrict the flow of urine. *Id.* Proscar, or finasteride, lowers the levels of DHT in the body to help shrink the prostate and improve urine flow and symptoms. *Id.*

[40] *Rafferty*, 92 N.E.3d at 1211; Amended Complaint at 7, Rafferty v. Merck & Co., 2018 WL 3188967 (Mass. Super. May 21, 2018) (No. MICV201304459).

[41] *Rafferty*, 92 N.E.3d at 1211; Amended Complaint, *supra* note 40. A common side effect of Proscar is impotence. *Patient Information about Proscar*, *supra* note 38.

[42] *Rafferty*, 92 N.E.3d at 1211; Amended Complaint, *supra* note 40, at 9–12. Rafferty alleges that the warning label discussed potential side effects leading to sexual dysfunction but maintained that they would subside after discontinuing usage. Amended Complaint, *supra* note 40, at 9. Following federal regulations, the generic label matched the label designed by Merck for Proscar exactly. *Rafferty*, 92 N.E.3d at 1211.

[43] Amended Complaint, *supra* note 40, at 11–14. Hypogonadism occurs when the body does not produce enough testosterone, sperm, or both. *Male hypogonadism*, MAYO CLINIC (Sept. 29, 2021), https://www.mayoclinic.org/diseases-conditions/male-hypogonadism/symptoms-causes/syc-20354881 [https://perma.cc/8655-F3DL]. Symptoms include lower sex drive, less energy, and depression. *Id.* It

Rafferty sued Merck in 2013, claiming the manufacturer was negligent in failing to warn him of the drug's risks and had violated Mass. Gen. Laws chapter 93A, section 9.[44] Though neither party disputed that Rafferty consumed the generic finasteride rather than the brand-name Proscar, Rafferty nevertheless claimed that Merck's exclusive federal authority to change the drug's warning label created a duty to warn resulting in liability.[45] Merck moved to dismiss both claims in the Superior Court and the court entered final judgment in its favor, holding that Merck could not be held liable for injuries caused by a product it did not produce and that Rafferty was owed no duty of care.[46]

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can lead to long term effects including erectile dysfunction, infertility, decreased hair growth, decreased muscle mass, the development of breast tissue, and the loss of bone mass. *Id.* Androgens are sex hormones like testosterone. *Androgens*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/articles/22002-androgens [https://perma.cc/3GDX-DEZT]. They help with bone density, the development of muscle, puberty, the production of red blood cells, and sexual function. *Id.* Rafferty began treatment to mitigate the effects of these diagnoses that doctors said he may have to continue for as long as he lives. *Rafferty*, 92 N.E.3d at 1211; Amended Complaint, *supra* note 40, at 15.

[44] *See Rafferty*, 92 N.E.3d at 1212 (laying out Rafferty's claims against Merck). Chapter 93A of the General Laws of Massachusetts is the state consumer protection statute promulgating the civil actions and remedies available for those injured because of a violation. MASS. GEN. LAWS ch. 93A, § 9 (2004).

[45] *Rafferty*, 92 N.E.3d at 1211–12; *see also* 21 U.S.C. § 355(b)(1)(A), (d) (establishing that brand-name manufacturers are responsible for ensuring the correctness and sufficiency of their warning labels). Through the Act, the CBE process can only be utilized by brand-name manufacturers to add to or enhance warning labels based on new information. Applications for FDA Approval to Market New Drugs, 21 C.F.R. § 314.70(c)(6)(iii)(A) (2021). Meanwhile, generic manufacturers must continuously ensure sameness according to their federal duties. *See* PLIVA, Inc. v. Mensing, 564 U.S. 604, 613 (2011) (explaining that generic manufacturers are federally obligated to ensure their labels match their brand-name equivalents exactly). Moreover, the Supreme Court has held that generic manufacturers cannot be liable under state tort law for failure to warn because their state duties are preempted by their federal duties. *Id.* at 618. For these reasons, Rafferty claimed it is appropriate to impose a duty of care on Merck because anyone who takes the drug must rely on Merck's warning label. *See* Amended Complaint, *supra* note 40, at 64 (stating that brand-name manufacturers owe a duty of care in creating and updating warning labels to all who take or prescribe the drug in either form). Rafferty alleged that Merck breached that duty because it had knowledge from a multitude of trusted sources that side effects like the ones he suffered could indeed persist after discontinuing use, and had already updated its warning labels to reflect that information in foreign markets. *Id.* at 22–29; *Rafferty*, 92 N.E.3d at 1212. As of 2010, when Rafferty began taking the generic drug, the label in the United States had not been similarly updated; it still stated that these side effects resolved after discontinuing use. *Rafferty*, 92 N.E.3d at 1212; Amended Complaint, *supra* note 40, at 21.

[46] *Rafferty*, 92 N.E.3d at 1212. The court held that Merck could not be liable according to two tenets of Massachusetts products liability law. *Id.* First, a plaintiff suing a manufacturer for products liability must prove that the injurious product was produced by the defendant-manufacturer. Mathers v. Midland-Ross Corp., 532 N.E.2d 46, 49 (Mass. 1989). Second, a manufacturer is not liable for risks created by a product manufactured by a different entity. Mitchell v. Sky Climber, Inc., 487 N.E.2d 1374, 1376 (Mass. 1986); *see also* Carrier v. Riddell, Inc., 721 F.2d 867, 869 (1st Cir. 1983) (stating that no Massachusetts case law exists imposing liability on a manufacturer for failing to warn of the risks of a product produced by someone else). Based on these principles, the court reasoned that Merck could not be liable without consumption of a product it manufactured. *Rafferty*, 92 N.E.3d at 1212. It felt that imposing such liability on Merck despite not having produced the injurious product would harm the balance established by the Act and negate the fundamental legal concept that liability

Rafferty appealed both the final judgment and the court's grant of the motion to dismiss.[47] On appeal, the SJC held that brand-name manufacturers owe a duty of care to generic drug users under a recklessness standard, though they have no common law negligence duty.[48]

II. State Law Split on Brand-Name Manufacturers' Duty to Generic Drug Users

In 2018, in *Rafferty v. Merck & Co.*, the SJC diverged from most other courts on whether brand-name manufacturers are liable for injuries to generic drug users by imposing a duty on brand-name manufacturers to not act recklessly in creating warning labels.[49] The states are split on this theory of "innovator liability."[50] Five states have explicitly adopted the theory, whereas twenty have explicitly rejected it.[51] The remaining twenty-five states have not directly confronted the issue.[52] Section A of this Part discusses examples of the majority approach imposing no liability.[53] Section B discusses examples of the

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flows from control. *See id.* (quoting Huck v. Wyeth, Inc., 850 N.W.2d 353, 376–77, 378 (Iowa 2014)). The court also concluded, regarding the chapter 93A claim, that the consumer protection statute had not been violated because Merck owed no duty to the consumer. *Id.*

[47] *Rafferty*, 92 N.E.3d at 1212. On appeal, Rafferty argued that the findings of the Superior Court were erroneous because Merck alone had the ability to modify warning labels based on new information. Brief of Plaintiff-Appellant at 4–5, Rafferty v. Merck & Co., 92 N.E.3d 1205 (Mass. 2018) (No. SJC-12347). As a result, he believed Merck had a duty to all who would foreseeably rely on its label, including generic finasteride consumers. *Id.* at 5. Moreover, Rafferty asserted that public policy supported this position, as otherwise injured generic consumers would be left with no recourse. *Id.* at 5–6; *see also Mensing*, 564 U.S. at 625 (recognizing the unfortunate position this places generic drug consumers injured by improper warning labels in).

[48] 92 N.E.3d 1205, 1205 (Mass. 2018); *see also infra* notes 71–81 and accompanying text (explaining the SJC's reasoning). The SJC transferred the case on its own initiative from the Appeals court. *Rafferty*, 92 N.E.3d at 1205.

[49] *Compare Rafferty*, 92 N.E.3d at 1220, *with Huck*, 850 N.W.2d at 380 (holding that a brand-name manufacturer could not be held liable because it did not produce the offending product), *and* Guarino v. Wyeth, LLC, 719 F.3d 1245, 1253 (11th Cir. 2013) (same). *But see, e.g.*, T.H. v. Novartis Pharms. Corp., 407 P.3d 18, 29 (Cal. 2017) (holding that the duty of care to disseminate warning information imposed on brand-name manufacturers includes consumers injured by the generic counterpart); Wyeth, Inc. v. Weeks, 159 So.3d 649, 676 (Ala. 2014), *superseded by statute*, ALA. CODE § 6-5-530(a) (2015) (holding that brand-name manufacturers have a duty to not make false representations to those they have reason to believe will be influenced by such representations).

[50] Jenny Ange, Note, *Am I My Competitor's Keeper? Innovator Liability in the Fifty States*, 21 COLUM. SCI. & TECH. L. REV. 186, 189 (2019). Innovator liability refers to holding brand-name manufacturers liable under tort law for harm caused by a generic product. *Id.*

[51] *Id.* at 192. The states that have explicitly adopted the theory include Alabama, California, Massachusetts, Pennsylvania, and Vermont. *Id.* at 193. The states that have explicitly rejected it include Colorado, Florida, Georgia, Iowa, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Texas, Utah, and West Virginia. *Id.* at 196.

[52] *Id.* at 192.

[53] *See infra* notes 55–64 and accompanying text.

minority approach, including the *Rafferty* court, imposing a duty on brand-name manufacturers.[54]

A. The Majority Approach

In 2011, in *Guarino v. Wyeth, LLC*, the Eleventh Circuit upheld the district court's finding that Florida state law imposes no duty of care to generic drug users on brand-name manufacturers.[55] The plaintiff claimed that two Florida Supreme Court decisions supported a finding that the brand-name manufacturer could be liable for negligent failure to warn.[56] The Eleventh Circuit, however, found not only that these cases were wholly unsupportive of her claims but also that every Florida court confronted with the question of innovator liability for brand-name drug manufacturers had declined to impose such a duty of care.[57] Because Florida law allows recovery only against the manu-

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[54] *See infra* notes 65–74 and accompanying text.

[55] 719 F.3d 1245, 1247 (11th Cir. 2013). The district court previously dismissed the plaintiff's claims against the brand-name manufacturer, finding that injured consumers who have ingested the generic drug have no cause of action against the manufacturer of the brand-name version. *Id.* at 1247–48. The plaintiff brought claims against the brand-name manufacturer of Reglan, the brand-name equivalent of metoclopramide, a drug used for treating gastroesophageal reflux and diabetic gastric stasis. *Id.* at 1245. After ingesting the generic metoclopramide for over twelve weeks, the plaintiff allegedly developed tardive dyskinesia. Complaint and Demand for Jury Trial at 20–25, Guarino v. Wyeth, LLC, 2010 WL 5199537 (M.D. Fla. Dec. 23, 2010) (No. 10CV02885). Tardive dyskinesia is a disorder causing repetitive movement of the face and other parts of the body, and can be incredibly debilitating. *Tardive Dyskinesia*, NAT'L INST. OF NEUROLOGICAL DISORDERS AND STROKE, (Jan. 20, 2023) https://www.ninds.nih.gov/health-information/disorders/tardive-dyskinesia [https://perma.cc/R589-R2LL]. The plaintiff alleged that the drug was indicated for no more than twelve weeks of use, though it was safe to exceed that limit when treating nausea or esophageal reflux. Complaint and Demand for Jury Trial, *supra* at 20–25. This was actually not true, but the proper information did not appear in any of the warning material she relied on. *Id.* at 14–15, 22. The district court found that because the plaintiff had never ingested the brand-name drug, the brand-name manufacturer could not be liable. *Guarino*, 719 F.3d at 1247.

[56] *Guarino*, 719 F.3d at 1251; *see also* Conley v. Boyle Drug Co., 570 So.2d 275 (Fla. 1990) (allowing liability for a brand-name manufacturer based on its market share when it was not possible to determine which manufacturer actually produced the injurious product); Engle v. Liggett Group, Inc., 945 So.2d 1246 (Fla. 2006) (reversing judgment against a cigarette manufacturer that did not manufacturer or sell the injurious product when there was no claim of fraud against it).

[57] *Guarino*, 719 F.3d at 1251, 1253 (citing Metz v. Wyeth LLC, 830 F. Supp. 2d 1291, 1293 (M.D. Fla. 2011); Howe v. Wyeth, Inc., No. 8:09-CV-610-T-17AEP, 2010 WL 1708857, at *3 (M.D. Fla. Apr. 26, 2010); Levine v. Wyeth, Inc., 684 F. Supp. 2d 1338, 1343 (M.D. Fla. 2010); Dietrich v. Wyeth, Inc., No 50-2009-CA-021586, 2009 WL 4924722, at *2 (Fla. Cir. Ct. Dec. 21, 2009); Sharp v. Leichus, No. 2004-CA-0643, 2006 WL 515532, at *2 (Fla. Cir. Ct. Feb. 17, 2006)). The court found that consideration of this authority supports the notion that injured consumers who ingested only the generic drug do not have a claim against the manufacturer of the brand-name version. *Id.* at 1252–53. It felt that *Conley* was unsupportive because it only allowed for liability when it was unclear who produced the product ingested by the plaintiff, but not when it is known for sure that the manufacturer did not produce the harmful product. *Id.* at 1251. It found that *Engle* was unsupportive because it does not affirmatively support the theory that a fraud claim against a manufacturer that definitely did not

facturer who produced the injury-causing product, the court refused to create a claim for the plaintiff.[58] The Eleventh Circuit recognized that this holding leaves consumers of generic drugs without a path to recovery when harmed by inadequate warnings, but reasoned that courts are not legislatures and their only role is to interpret the law.[59]

In 2014, in *Huck v. Wyeth, Inc.*, a split Iowa Supreme Court reached the same conclusion as the Eleventh Circuit.[60] The district court dismissed the case because the brand-name manufacturer did not produce the generic version of the drug ingested by the plaintiff, and the Iowa Supreme Court's majority agreed.[61] Concerned about the slippery slope of liability it would create, the court did not want to make brand-name manufacturers the insurers of their generic competitors.[62] Such a holding, it reasoned, would have the undesirable effect of making any company that implements a novel product design liable for injuries caused by a competitor's copycat product.[63] Instead, the court adhered to the Iowa tort law principle that only the manufacturer of a product can be held liable for the harm it causes, leaving the creation of a remedy for generic consumers to the legislature.[64]

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produce the injurious product is permissible. *Id.* at 1252. The Eleventh Circuit similarly upheld the grant of summary judgment in favor of the generic manufacturer. *Id.* at 1253.

[58] *Id.* at 1252; *see also* Bravo v. United States, 577 F.3d 1324, 1326 (11th Cir. 2009) (stating that the court is bound to the holding of a state appeals court in the absence of a compelling reason that the state's highest court would come to a different conclusion). The Eleventh Circuit acknowledged that it is not bound by the rulings of other jurisdictions, but still found the similar precedents of other courts around the country persuasive. *Guarino*, 719 F.3d at 1252–53.

[59] *Guarino*, 719 F.3d at 1253; *see also* PLIVA, Inc. v. Mensing, 564 U.S. 604, 626 (2011) (explaining that it is not the job of the court to change a statutory scheme).

[60] 850 N.W.2d 353, 380 (Iowa 2014). *Huck* is very similar factually to *Guarino*. *Id.* at 359–60; *see also Guarino*, 719 F.3d at 1247 (explaining that Guarino developed tardive dyskinesia after extended exposure to metoclopramide and holding that a brand-name manufacturer cannot be held liable for injuries caused by a product it did not produce). In *Huck*, after being prescribed the generic metoclopramide by two different doctors beginning in February 2004, the plaintiff began exhibiting symptoms of tardive dyskinesia and was formally diagnosed in June 2006. Petition at 36–44, Huck v. Trimark Physicians Grp., 2008 WL 8809749 (Iowa Dist. Ct. May 27, 2008) (No. LACV018947). In prescribing this drug treatment, the plaintiff claimed her doctors relied upon inaccurate and misleading information disseminated by the brand-name manufacturer and were unaware of the risks of ingesting metoclopramide for an extended period of time. *Id.* at 38. She further alleged that the brand-name manufacturer knew the information it shared would be relied upon by prescribing physicians and that the manufacturer both negligently and intentionally misled medical practitioners about the risks of long-term use of the drug. *Id.* at 55–56.

[61] *Huck*, 850 N.W.2d at 356, 380.

[62] *Id.* at 380.

[63] *Id.* A copycat product is one designed or marketed to look just like the product of an established competitor. *Copycat Product*, MONASH UNIV., https://www.monash.edu/business/marketing/marketing-dictionary/c/copycat-product [https://perma.cc/78FW-24LE].

[64] *Huck*, 850 N.W.2d at 380 (citing *Mensing*, 564 U.S. at 626). The dissent argued that who produced the injury-causing product was unimportant, given that the warning label created by the brand-name manufacturer was responsible for the injury. *Id.* at 387 (Hecht, J., dissenting). Instead, the brand-name manufacturer developed an inadequate warning label which it knew would be copied by

B. The Minority Approach and Its Variations

Rejecting the products liability focus of the majority, some courts have charged brand-name manufacturers with a duty of care to generic drug consumers.[65] Most courts following this minority approach have done so by imposing a common law negligence standard.[66] The *Rafferty* court, however, held brand-name manufacturers to a recklessness standard, which is stricter than general negligence.[67]

1. Negligence Standard

In 2017, in *T.H. v. Novartis Pharms. Corp*., the Supreme Court of California held that brand-name manufacturers owe a duty of care to generic drug consumers in disseminating warning information when they know or reasonably should know of the dangers of a product.[68] The court noted that the federal labeling statutes give clear notice to brand-name manufacturers of the reliance on their labels by generic manufacturers and consumers.[69] As matters of public policy, the court found that this holding imposes no additional burden on

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the generic manufacturer and relied upon by generic drug consumers. *Id.* at 393–94. The risks resulting from its warning label necessitated a duty of care that public policy concerns could not outweigh. *Id.* at 394, 396–97. The dissent reasoned that an entity is not precluded from liability simply because it did not manufacture or sell the injurious product. *Id.* at 403.

[65] *See, e.g.*, T.H. v. Novartis Pharms. Corp., 407 P.3d 18, 29 (Cal. 2017) (holding that a brand-name manufacturer can be held liable for injuries to a generic drug consumer because it has a duty of care in disseminating complete and accurate warning information); Wyeth, Inc. v. Weeks, 159 So.3d 649, 676 (Ala. 2014), *superseded by statute*, ALA. CODE § 6-5-530(a) (2015) (holding that brand-name manufacturers have a duty to not make false representations to those people they have reason to believe will be influenced by them, including generic drug consumers); Rafferty v. Merck & Co., 92 N.E.3d 1205, 1205 (Mass. 2018) (holding that brand-name manufacturers have an obligation to generic drug consumers to not act recklessly in disseminating warning information).

[66] *See,* e.g., *T.H.*, 407 P.3d at 29 (holding that a brand-name manufacturer can be held negligently liable for injuries to a generic drug user); *Weeks*, 159 So.3d at 676 (finding that brand-name manufacturers have a duty of care to all those who may foreseeably rely on their information, including generic drug consumers).

[67] *See* 92 N.E.3d at 1205 (holding that brand-name manufacturers must have acted recklessly in disseminating warning information for generic drug users to succeed on failure-to-warn claims).

[68] 407 P.3d at 21–23, 29. In 2012, the twin plaintiffs were diagnosed with autism allegedly caused by their mother's use of terbutaline, a generic drug indicated for the treatment of asthma, to stop preterm labor. Petition for Review at 10–11, T.H. v. Novartis Pharms. Corp., 2016 WL 3208752 (Cal. Mar. 9, 2016) (No. S233898). The plaintiffs allege that the pharmaceutical manufacturer defendants promoted terbutaline for use in this manner despite the fact that they knew or should have known, based on many existing studies, that such usage caused autism in children exposed to it in the womb. *Id.* at 11. The brand-name manufacturer argued that it owed no duty in this situation because it had left the market for terbutaline six years before the plaintiffs' mother ingested the generic drug. *Id.* at 12–13. The trial court agreed, but the appellate court reversed. *Id.*

[69] *T.H.*, 407 P.3d at 29–30. To this point, the court added that, because pharmacists are permitted to substitute the generic version when a prescription is written for a brand-name drug (and insurance companies often mandate that they do so), it is foreseeable that the warning labels on the brand-name drug will influence the consumption of the generic drug. *Id.* at 30.

brand-name manufacturers because they already have a continuing duty to ensure the adequacy of their labels for their brand-name consumers and that concerns of chilling innovation are unfounded.[70]

2. Recklessness Standard

In 2018, in *Rafferty*, the SJC similarly extended a brand-name manufacturer's duty to warn to generic drug users, albeit in a different way than the *T.H.* court.[71] Here, the plaintiff also appealed the denial of its general negligence claim against the brand-name manufacturer, arguing that every actor has a duty of care to those whom its actions could foreseeably injure.[72] The SJC acknowledged the existence of a duty but, in contrast to *T.H.*, found that public policy weighed against imposing a normal duty of care on brand-name manufacturers.[73]

Concerned that allowing general negligence failure-to-warn claims could dampen drug innovation, the SJC concluded that public policy would best be served by granting generic drug users the right to recover from brand-name manufacturers only when their failure to warn rises beyond negligence to reck-

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[70] *Id.* at 32.

[71] *See* Rafferty v. Merck & Co., 92 N.E.3d1205, 1205 (Mass. 2018) (holding that brand-name manufacturers owe a duty of care to generic drug users on recklessness claims); *see also T.H.*, 407 P.3d at 29 (holding that brand-name manufacturers owe a duty of care to generic drug users on negligence claims).

[72] *See Rafferty*, 92 N.E.3d at 1213–14 (stating that the plaintiff relied on a general negligence theory that says that actors owe a duty of care to all persons who may be foreseeably put in harm's way by their conduct, instead of a products liability theory). The plaintiff concedes that under products liability law, Merck owed him no duty of care because it did not produce the product that caused injury. *Id.* at 1213. Still, Rafferty believed the manufacturer generally owed a duty of reasonable care not to engage in conduct that could foreseeably result in injury to others. *Id.* at 1213–14.

[73] *Id.* at 1214 (quoting Jupin v. Kask, 849 N.E.2d 829, 838 (Mass. 2006)). Even when the elements of a negligence claim can be satisfied, public policy reasons may weigh in favor of not imposing a duty of care. *Jupin*, 849 N.E.2d at 838 (quoting Remy v. MacDonald, 801 N.E.2d 260, 260 (Mass. 2004)). The existence of a duty must be reconciled with social values and policy. *Rafferty*, 92 N.E.3d at 1214 (quoting Cremins v. Clancy, 612 N.E.2d 1183, 1185 (Mass. 1993)); *see also* RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM § 7(b) (AM. L. INST. 2010) (stating that in certain cases, a court can choose not to impose a duty or the typical duty when public policy weighs in favor of it). The court reasoned that, because of the Hatch-Waxman Act, it is certain that the generic manufacturer's warning label will be the same as the brand-name manufacturer's label, and the brand-name label will accordingly be relied upon by generic drug users. *Rafferty,* 92 N.E.3d at 1215. It follows that when a brand-name manufacturer creates an incomplete or inaccurate warning label for its product, it knows or otherwise should know that both consumers of its own product and consumers of the generic product are put at risk. *Id.* This satisfies the elements of a general negligence claim. *Id.* The court, however, felt that there was a pressing public policy concern to take into consideration, namely the development and sale of innovative new drugs. *Id.* (quoting Payton v. Abbott Lab'ys, 437 N.E.2d 171, 190 (Mass. 1982).

lessness.[74] Liability under common law negligence arises when an actor violates a duty owed to the plaintiff.[75] In contrast, liability under common law recklessness arises when the breaching party violates its duty to another while knowing or having reason to know that its actions, or inactions, increase the risk of harm to another.[76]

For three main reasons, the SJC believed implementing a negligence standard could lead to a chilling of pharmaceutical innovation.[77] First, the brand-name manufacturer would incur the costs of litigating these claims after its patent expires, when sales and profit decline.[78] Second, sales of the generic drug may exceed sales of the brand-name drug during its period of market exclusivity and continue long after, yet the brand-name manufacturer would have to incur the cost of liability.[79] Third, any failure-to-warn claims would name only the brand-name manufacturer, who would be unable to share the costs of litigation with the generic manufacturer.[80] As a result, the court instead imposed a stricter recklessness standard.[81]

III. Brand-Name Manufacturers Owe a Duty of Care to Generic Drug Users Under a Negligence Standard

Most courts have imposed no liability on brand-name manufacturers when generic drug users are injured by inadequate warning labels.[82] Courts should, however, adopt the negligence variation of the minority approach because it recognizes that a brand-name manufacturer has a duty of care to all

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[74] *See Rafferty*, 92 N.E.3d at 1215 (explaining that, although the requirements of a general negligence claim are met, public policy reasons require that brand-name manufacturers not be held liable on such claims, though they could possibly be held liable under a recklessness theory).

[75] Dinsky v. Framingham, 438 N.E.2d 51, 53 (Mass. 1982). Whether the injured party was owed a duty is a matter of law to be decided by the court. Cottam v. CVS Pharmacy, 764 N.E.2d 814, 819 (Mass. 2002) (citing Davis v. Westwood Group, 652 N.E.2d 567, 569 (Mass. 1995)).

[76] Boyd v. Nat'l R.R. Passenger Corp., 845 N.E.2d 356, 362–63 (Mass. 2006) (quoting Restatement (Second) of Torts § 500 (Am. L. Inst. 1965)). In addition to knowing that the conduct creates an unreasonable risk of harm, the party must also realize that the risk is greater than the risk that would be present in a negligence context. Restatement (Second) of Torts § 500.

[77] *Rafferty*, 92 N.E.3d at 1216.

[78] *Id.*

[79] *Id.*

[80] *Id.* at 1217.

[81] *Id.* at 1218. The SJC recognized that barring claims against brand-name manufacturers for public policy reasons would leave generic drug consumers without recourse when injured in a failure-to-warn context. *Id.* To balance the interests of both manufacturers and consumers, the SJC affirmed that even when negligence liability is circumvented by public policy concerns, there is still a core duty not to bring harm intentionally or recklessly upon others. *Id.* Therefore, brand-name manufacturers owe a duty to not act recklessly. *Id.*

[82] *See, e.g.*, Huck v. Wyeth, Inc., 850 N.W.2d 353, 380 (Iowa 2014) (holding that brand-name manufacturers cannot be held liable in a failure-to-warn context if they did not produce the injurious product); Guarino v. Wyeth, LLC, 719 F.3d 1245, 1253 (11th Cir. 2013) (same); Smith v. Wyeth, Inc., 657 F.3d 420, 421 (6th Cir. 2011) (same).

those who could foreseeably rely on the information it disseminates, and it is certainly foreseeable that a user of the generic version would rely on that information.[83] Regardless of who manufactured the injurious product, the warning label created by the brand-name manufacturer caused the harm.[84] Moreover, brand-name manufacturers are in the best position to provide a remedy to injured generic consumers.[85]

With the Hatch-Waxman Act, Congress mandated that the warning labels on generic drugs be identical to their brand-name counterparts and that generic drug manufacturers are forbidden from altering their warning labels unless done to match the brand-name label or to comply with FDA regulations.[86] In addition, most states have laws that allow pharmacists to substitute the generic drug on prescriptions for the brand-name drug absent an explicit prohibition.[87] Because of these requirements, the reasonable generic drug user would rely on the warning label of a brand-name drug whether that is the version ingested or not.[88] The existence of foreseeability is typically a question of fact for the jury, except in instances where it is so obvious that reasonable people cannot come to different conclusions.[89] Given this context, brand-name manufacturers are

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[83] *See, e.g.*, T.H. v. Novartis Pharms. Corp., 407 P.3d 18, 29 (Cal. 2017) (holding that a brand-name manufacturer's duty of care in disseminating product information extends to consumers injured by ingesting its generic counterpart); Rafferty v. Merck & Co., 92 N.E.3d 1205, 1215–18 (Mass. 2018) (same, but declining to hold the brand-name manufacturer liable under a general negligence claim for public policy reasons, instead extending a duty to not act recklessly).

[84] *Huck*, 850 N.W.2d at 387 (Hecht, J., dissenting) (citing Dolin v. SmithKline Beecham Corp., No. C6403, 2014 WL 804458, at *5 (N.D. Ill. Feb. 28, 2014), *rev'd sub nom.* Dolin v. Glaxo SmithKline LLC, 901 F.3d 803 (7th Cir. 2018)).

[85] *See T.H.*, 407 P.3d at 31, 34 (holding that brand-name manufacturers are in the best position to provide recovery to generic consumers).

[86] *See* PLIVA, Inc. v. Mensing, 564 U.S. 604, 613, 614 (2011) (explaining that brand-name manufacturers are responsible for ensuring the accuracy and adequacy of warning labels and generic manufacturers must make sure their labels are identical and cannot unilaterally alter them); 21 U.S.C. § 355(j)(4)(G) (explaining that a generic drug warning label must be identical to its brand-name equivalent or else its application will not be approved).

[87] *See* Inwood Lab'ys v. Ives Lab'ys, 456 U.S. 844, 847–48 n. 4 (1982) (explaining that most states have enacted laws allowing pharmacists to give a patient the generic drug instead of the brand-name drug in some instances). Because federal law mandates that generic drugs be bioequivalent to their brand-name counterparts, a physician could realistically prescribe a generic drug in reliance upon information regarding the brand-name equivalent. *Id.*

[88] *See Rafferty*, 92 N.E.3d at 1215 (stating that it is certain that generic and brand-name labels will be identical and generic consumers will, therefore, rely on brand-name manufacturer warning information); *see also* Sijin Choi, Note, *It is Emphatically the Province and Duty of State Courts to Say What Tort Law Is*, 87 FORDHAM L. REV. 2213, 2228 (2019) (explaining that courts have held that substitution statutes strengthen the foreseeability argument because brand-name manufacturers are put on notice that generic drug consumers will rely on their warning labels although they consume a drug the manufacturer does not produce).

[89] DAN B. DOBBS, PAUL T. HAYDEN & ELLEN M. BUBLICK, DOBBS' LAW OF TORTS § 159 (2d ed. 2023); Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 104–05 (2008) (quoting Hedlund v. Superior Court, 669 P.2d 41, 46 (Cal. 1983)).

on notice and should clearly foresee that their inaccurate, incomplete, or misleading warning labels put generic consumers at risk, too.[90]

The *Rafferty* variation of the minority approach recognizes this, but incorrectly concludes that public policy concerns weigh against applying a negligence standard.[91] The SJC believed that imposing this standard would add an additional cost to the production of drugs by extending liability long after brand-name patent exclusivity expires and the manufacturer pivots away from production of the drug, therefore disincentivizing innovation.[92] In reality, it is difficult to estimate any such chilling effect, and the SJC itself recognized this.[93] Certain studies have explained the difficulty in measuring the true impact of liability on pharmaceutical innovation, and stated that any estimation of the costs or benefits of liability is purely speculative.[94] In fact, a negligence standard would incentivize brand-name manufacturers to be more thorough in their labeling from the beginning.[95] At the very least, it imposes no additional

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[90] *See Rafferty*, 92 N.E.3d at 1215 (stating that when a brand-name manufacturer provides an inadequate warning label, it knows or should know that generic drug users are also at risk); *see also* Huck v. Wyeth, Inc., 850 N.W.2d 353, 393–94 (Iowa 2014) (Hecht, J., dissenting) (explaining that a duty exists because of the dangers created by the brand-name manufacturer's warning label, which the generic manufacturer had to replicate and consumers foreseeably relied upon). This shows that even though the requirements of a failure-to-warn claim brought under products liability law are not met, a general negligence claim establishing a brand-name manufacturer's duty of care to generic drug users is still valid and provable. *Rafferty*, 92 N.E.3d at 1215.

[91] *See Rafferty*, 92 N.E.3d at 1215–16 (noting that the public policy of encouraging research and innovation is an important consideration).

[92] *Id.* at 1216–17.

[93] *See id.* at 1217 (noting the difficulty in estimating the chilling effect of general negligence liability.); STEVEN GARBER, RAND INST. FOR CIV. JUST., ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION INVOLVING THE SAFETY AND EFFECTIVENESS OF PHARMACEUTICALS 58, 62 (2013) (explaining that it is difficult to actually assess to what extent liability impacts innovation).

[94] *See* GARBER, *supra* note 93, at 58, 62 (stating that it is impossible to gather direct evidence of the effect of liability on pharmaceutical innovation and no reliable empirical evidence exists for determining the costs and benefits to society). This speculative public policy concern should not prevent courts from imposing negligence liability where the facts of the case and tort law of the state allow for it. *See* Choi, *supra* note 88, at 2252 (stating that the political branches of government can remedy any ill effects). Though it is uncertain, should any social harm result from the imposition of such liability, both the federal and state legislatures can and will step in to remedy it. *Id.* at 2251.

[95] *See Rafferty*, 92 N.E.3d at 1217 (noting that it is clear that brand-name manufacturers would have greater incentive to maintain adequate warnings if the scope of their liability was extended); T.H. v. Novartis Pharms. Corp., 407 P.3d 18, 34 (Cal. 2017) (same); *see also* Ezra Friedman & Abraham L. Wickelgren, *Who (if Anyone) Should be Liable for Injuries from Generic Drugs?*, 33 J.L. ECON. & ORG. 541, 544 (2017) (explaining that brand-name manufacturers have a greater incentive to create effective warning labels in a system giving them sole liability for injuries to generic drug consumers as a result of inadequate warning labels). In an economic analysis of different liability schemes, the authors state that imposing liability on brand-name manufacturers in failure-to-warn situations functions as an additional fixed cost for the manufacturer. Friedman & Wickelgren, *supra*. By making effective warning labels, brand-name manufacturers can eliminate this cost and, therefore, increase their profits. *Id.*

burden on brand-name manufacturers as they are already liable for any harm to brand-name consumers.[96] Because of the uncertainty of chilling innovation, increasing the standard and heightening the burden for generic consumers is a step too far.[97]

Public policy cuts in favor of imposing a negligence standard on brand-name manufacturers.[98] Under federal law, brand-name manufacturers are the only entity able to issue warnings to consumers and, therefore, the only entity responsible for insufficient labeling.[99] Brand-name manufacturers are also best situated to bear the costs of liability.[100] Research has shown that brand-name drugs provide manufacturers with greater gross profits than those provided by generic drugs.[101] Without negligence liability for brand-name manufacturers, it would be a difficult road to recovery for generic drug consumers who become innocent victims.[102]

CONCLUSION

In 2018, in *Rafferty v. Merck & Co.*, the Supreme Judicial Court of Massachusetts held that brand-name manufacturers owe consumers of their generic equivalents a duty to not act recklessly in providing warning information. Most other courts have declined to impose any duty on brand-name manufacturers because of products liability principles stating that a manufacturer cannot be held liable for injuries caused by a product it did not produce. Both the no-liability and recklessness approaches are incorrect. All actors still owe a duty of care to those whom their actions could foreseeably injure. Under the current regulatory scheme, it is foreseeable to brand-name manufacturers that generic drug users will rely on their warning labels, and they should be held accountable under a negligence standard for harm caused by inadequate labeling. Any purported public policy concerns used by courts to justify not doing so are too

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[96] *T.H.*, 407 P.3d at 32; Huck v. Wyeth, Inc., 850 N.W.2d 353, 397 (Iowa 2014) (Hecht, J., dissenting).

[97] *See Rafferty*, 92 N.E.3d at 1217 (noting the unclear effect this kind of liability would have on research and development); GARBER, *supra* note 93, at 58, 62 (explaining the lack of definite empirical evidence on the costs and benefits of liability on innovation).

[98] *See T.H.*, 407 P.3d at 31, 34 (explaining that brand-name manufacturers are in the best position to provide warnings and bear the costs of inadequate warnings).

[99] *Id.*

[100] *See id.* at 34 (explaining that brand-name manufacturers are in the best position not only to provide warning information but also to deal with the costs associated with liability).

[101] Sarah Owermohle, *High Profit Margins Along Drug Supply Chain Raise Cost Questions in Report*, S&P GLOBAL MARKET INTELLIGENCE (June 15, 2017), https://www.spglobal.com/marketintelligence/en/news-insights/trending/5bfnNWPkfglCPHKEyORQJQ2 [https://perma.cc/2ZZ8-KVHJ] (discussing research showing that brand-name drugs provide manufacturers with gross profits approximately three times greater than those provided by generic drugs).

[102] *See* PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011) (acknowledging that without a duty of care imposed on brand-name manufacturers, generic consumers cannot recover for their injuries).

uncertain to warrant eschewing general negligence liability as a path to recovery for generic drug users.

KATELYN BRADLEY