SJC-12347

BRIAN RAFFERTY vs. MERCK & CO., INC., & another.[1]

Middlesex. November 6, 2017. - March 16, 2018.

Present: Gants, C.J., Gaziano, Budd, & Cypher, JJ.

Negligence, Pharmaceutical manufacturer, Adequacy of warning, Duty to warn, Standard of care. Actionable tort. Public Policy. Consumer Protection Act, Unfair or deceptive act, Trade or commerce. Practice, Civil, Motion to dismiss.

Civil action commenced in the Superior Court Department on October 10, 2013.

A motion to dismiss was heard by Kenneth J. Fishman, J., and entry of separate and final judgment was ordered by him.

The Supreme Judicial Court on its own initiative transferred the case from the Appeals Court.

Emily E. Smith-Lee for the plaintiff.

Richard L. Neumeier (Aaron Rice, of Mississippi, & David L. Johnson, of Tennessee, also present) for Merck & Co., Inc.

The following submitted briefs for amici curiae:

Michael X. Imbroscio & Gregory L. Halperin, of the District of Columbia, & Paul W. Schmidt for Pharmaceutical Research and Manufacturers of America & others.

[1] Sidney Rubenstein.

Mark C. Fleming & Tyler L. Sparrow for International Association of Defense Counsel.

Hugh F. Young, Jr., of Virginia, & David R. Greiger & Richard G. Baldwin for Product Liability Advisory Council, Inc.

Kannon K. Shanmugam, Allison Jones Rushing, & Connor S. Sullivan, of the District of Columbia, & Jennifer G. Wicht for Chamber of Commerce of the United States of America.

Lawrence G. Cetrulo, Kyle E. Bjornlund, Elizabeth S. Dillon, & Brian D. Fishman for Massachusetts Defense Lawyers Association.

GANTS, C.J. Under Federal law, a manufacturer of a generic drug must provide its users with a warning label that is identical to the label of the brand-name counterpart. See PLIVA, Inc. v. Mensing, 564 U.S. 604, 613 (2011) (PLIVA). The issue on appeal is whether a plaintiff who alleges that he was injured from his use of a generic drug, because of a failure to warn of the drug's side effects, may bring a common-law general negligence claim and a statutory claim under G. L. c. 93A against the brand-name drug manufacturer that created the warning label. Applying our general principles of tort law and as a matter of public policy, we conclude that the plaintiff may not bring a negligence claim against the brand-name manufacturer for a failure to warn. We further conclude that the plaintiff, if he were to amend his complaint, and if the amended allegations would so warrant, may bring a common-law recklessness claim against the brand-name manufacturer if it intentionally failed to update the label on its drug, knowing or having reason to know of an unreasonable risk of death or grave

bodily injury associated with its use. We also conclude that a plaintiff who is injured by a generic drug due to a failure to warn cannot bring a claim under G. L. c. 93A, § 9, against a brand-name manufacturer that did not advertise, offer to sell, or sell that drug because such failure did not occur in the conduct of "trade or commerce" as defined in § 1 (b).[2]

Background. 1. Regulatory background. Under the Federal Food, Drug, and Cosmetic Act (act), 21 U.S.C. §§ 301 et seq. (2012), drug manufacturers may not market drugs in interstate commerce without the approval of the United States Food and Drug Administration (FDA). 21 U.S.C. § 355(a). As such, a manufacturer that seeks to market a new brand-name drug must submit a new drug application, showing that the drug is safe and effective. See 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50(d)(5)(iv)-(vi) (2017). As part of the new drug application, the manufacturer must also show that the proposed warning label for the drug is accurate and adequate. See 21 U.S.C. § 355(b)(1), (d); 21 C.F.R. § 314.50(c)(2)(i), (d)(5)(v), (d)(5)(viii) (2017). The process of obtaining FDA approval is

[2] We acknowledge the amicus briefs submitted in support of Merck & Co., Inc., by the Pharmaceutical Research and Manufacturers of America, the American Tort Reform Association, and the National Association of Manufacturers; the International Association of Defense Counsel; the Product Liability Advisory Council, Inc.; the Chamber of Commerce of the United States of America; and the Massachusetts Defense Lawyers Association.

"both onerous and lengthy," requiring manufacturers to expend significant time and resources. Mutual Pharm. Co., v. Bartlett, 570 U.S. 472, 476 (2013).

Originally, the same process was required for generic drugs. See PLIVA, 564 U.S. at 612. This changed in 1984, when Congress enacted the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman amendments to the act. See id. The purpose of the amendments was twofold: to improve the affordability of prescription drugs while also encouraging innovation and investment in new drugs. See Abbott Labs. v. Young, 920 F.2d 984, 985 (D.C. Cir. 1990), cert. denied, 502 U.S. 819 (1991), citing H.R. Rep. No. 98-857, 98th Cong., 2nd Sess., pt. 1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2648 (House Report). In striking a balance between these competing goals, Congress made two significant changes to the existing regulatory scheme.

First, the amendments established a simpler and speedier approval process for generic drugs. See 21 U.S.C. § 355(j). A manufacturer now seeking to market a generic version of an approved brand-name drug need only submit an abbreviated new-drug application, indicating that the generic drug is equivalent to its brand-name counterpart in certain key respects. 21 U.S.C. § 355(j)(2)(A). Specifically, the manufacturer must show that the proposed generic drug has the same active ingredients,

route of administration, dosage form, and strength as the approved brand-name drug. 21 U.S.C. § 355(j)(2)(A)(ii)-(iii). It also must show that the generic drug is "bioequivalent" to the brand-name drug, 21 U.S.C. § 355(j)(2)(A)(iv), meaning that it has the same rate and extent of absorption. 21 U.S.C. § 355(j)(8)(B). Finally, it must show that the proposed warning label for the generic drug is the same as the labeling approved for the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(v). As a result, generic manufacturers can bring their drugs to market much less expensively and can therefore make these lower-cost alternatives more widely available to consumers. See PLIVA, 564 U.S. at 612.

Second, in order to safeguard the interests of brand-name manufacturers and incentivize continued innovation, the amendments also authorized the FDA to extend the length of its patent terms to offset delays caused by the FDA's regulatory review. See 35 U.S.C. § 156 (2012). See also House Report, supra at 15. For patents issued after the amendments were enacted, patent terms can now be extended for up to five years, depending on the length of the review period, thereby allowing brand-name manufacturers to enjoy a monopoly over their newly developed drugs for a longer period of time. 35 U.S.C. § 156(a), (c), (g)(6)(A).

A key feature of the current regulatory scheme is that it imposes different labeling responsibilities on brand-name manufacturers and generic manufacturers. See PLIVA, 564 U.S. at 613. A manufacturer of a brand-name drug must ensure that its label is accurate and adequate. See 21 U.S.C. § 355(b)(1), (d). In contrast, a manufacturer of a generic drug must ensure only that its label is identical to the label of the brand-name counterpart. See 21 U.S.C. § 355(j)(2)(A)(v), (j)(4)(G). See also PLIVA, supra. Furthermore, although all drug manufacturers are required to continue to monitor the safety of their products after approval, 21 C.F.R. §§ 314.80, 314.81, 314.98 (2017), only brand-name manufacturers have the power to change the contents of their labels without FDA approval. Under FDA regulations, a manufacturer may, through a process known as "changes being effected," "add or strengthen" a warning on its label by filing a simultaneous application with the FDA, without waiting for the agency's approval. 21 C.F.R. § 314.70(c)(3), (c)(6)(iii)(A) (2017).[3] This process is not available to generic manufacturers that, pursuant to their "ongoing [F]ederal duty of 'sameness,'"

[3] The United States Food and Drug Administration (FDA) retains the authority to disapprove any labeling changes made through the "changes being effected" process, in which case it may order the manufacturer to cease distribution of the drug with the disapproved label change. See 21 C.F.R. § 314.70(c)(3), (7) (2017). See also Wyeth v. Levine, 555 U.S. 555, 571 (2009).

may change a label only when necessary to match an updated brand-name label or to follow FDA instructions. PLIVA, supra at 613, 614-615. See 21 C.F.R. § 314.150(b)(10) (2017) (FDA approval for generic drug may be withdrawn if label is "no longer consistent" with brand-name label).

This allocation of labeling responsibilities under Federal law has proved difficult to reconcile with the duties required of generic drug manufacturers under State tort law. Many States, including this one, impose on manufacturers a duty to warn consumers of dangers arising from the use of their products where the manufacturers know or should have known of the dangers. See PLIVA, 564 U.S. at 611; Mitchell v. Sky Climber, Inc., 396 Mass. 629, 631 (1986). Under Federal regulations, however, manufacturers of generic drugs -- because they lack the power to change the warning labels on their products unilaterally -- cannot independently fulfil these State law duties. For this reason, in PLIVA, 564 U.S. at 608-609, the United States Supreme Court held that State tort law claims against generic manufacturers arising out of a failure to warn are preempted by Federal drug regulations. See Mutual Pharm. Co., 570 U.S. at 476 ("[S]tate-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by [F]ederal law under PLIVA"). The practical consequence is that a consumer who suffers injury arising from an inaccurate or

inadequate drug warning label can sue the manufacturer for damages caused by his or her injury only if the consumer ingested a brand-name version of the drug -- but not if the consumer ingested the generic version. See PLIVA, supra at 625.

2. Plaintiff's claims. We summarize the facts as stated in the plaintiff's complaint. Merck & Co., Inc. (Merck), is the manufacturer of Proscar, an FDA-approved, brand-name version of the drug finasteride. Finasteride is used to treat benign prostatic hyperplasia in persons with an enlarged prostate.

In August, 2010, Brian Rafferty was prescribed finasteride by his physician to treat an enlarged prostate. Shortly after he started taking finasteride, Rafferty began to experience side effects causing sexual dysfunction, including erectile dysfunction and decrease in libido. In October, 2010, Rafferty weaned himself off of the drug but the side effects continued and even worsened. He was eventually diagnosed with hypogodanism and androgen deficiency allegedly induced by the finasteride, and is now undergoing treatment that, according to his physicians, may continue indefinitely.

It is undisputed that Rafferty ingested the generic version of finasteride, not Merck's brand-name version Proscar. At the time that Rafferty was prescribed the finasteride, the product label warned of the potential for side effects related to sexual dysfunction, but represented that these side effects would

resolve after discontinued use of the drug. As required under Federal law, this generic label conformed to Merck's label for Proscar.

Rafferty alleged that by the time he was prescribed finasteride, several reports and studies had already emerged suggesting that those side effects could in fact persist even after discontinued use. He also alleged that, starting in 2008, Merck changed the label for Proscar in certain foreign markets, including Sweden, the United Kingdom, and Italy, to include a warning about persistent erectile dysfunction. Nevertheless, as of 2010, when Rafferty ingested finasteride, Merck had not changed its label for Proscar in the United States to include this warning.

In 2013, Rafferty commenced an action against Merck in the Massachusetts Superior Court, asserting claims of negligence for failure to warn, and a violation of G. L. c. 93A, § 9.[4] Crucial to Rafferty's negligence claim was his contention that, although he had never ingested Merck's brand-name version of finasteride, Merck nevertheless owed him a duty to warn of its dangers because, under Federal law, Merck controlled the label on the generic version that Rafferty did ingest. The case was removed

[4] Rafferty also sued his prescribing physician for negligent failure to obtain informed consent. He later voluntarily dismissed the claim against the physician.

to Federal court but subsequently remanded to the Superior Court.

Merck filed a motion to dismiss the complaint, and the judge allowed the motion. With respect to Rafferty's negligence claim, the judge ruled that Merck owed no duty of care to Rafferty. The judge relied on "two well-established . . . principles" of Massachusetts products liability law: first, that "[a] plaintiff who sues a particular manufacturer for product liability generally must be able to prove that the [product] which it is claimed caused the injury can be traced to that specific manufacturer," Mathers v. Midland-Ross Corp., 403 Mass. 688, 691 (1989); and second, that a manufacturer cannot be held liable "for failure to warn of risks created solely in the use or misuse of the product of another manufacturer" (emphasis added). Mitchell, 396 Mass. at 631. Because Merck did not manufacture the finasteride that allegedly caused Rafferty's injury, the judge concluded that Merck could not be held liable for his injuries. The judge, quoting the Iowa Supreme Court opinion in Huck v. Wyeth, Inc., 850 N.W.2d 353, 376-377 (Iowa 2014), cert. denied, 135 S. Ct. 1699 (2015), declared that imposing liability on Merck for an injury caused by a competitor's product would not only disturb the balance struck between brand-name and generic manufacturers in the Hatch-Waxman amendments -- which courts are not "institutionally qualified"

to second-guess -- but also run contrary to the fundamental principle of tort law that "[l]iability generally follows control." Id. at 378. Similarly, with respect to Rafferty's c. 93A claim, the judge concluded that there could be no violation of the consumer protection statute where there was no duty of care owed to the consumer.

After the judge dismissed both claims, a final judgment entered in favor of Merck. Rafferty now appeals from that final judgment and from the judge's decision allowing Merck's motion to dismiss. We transferred this case from the Appeals Court on our own motion.

Discussion. We review a judge's decision to dismiss a claim de novo, accepting as true the allegations in the complaint and drawing every reasonable inference in favor of the plaintiff. See Curtis v. Herb Chambers I-95, Inc., 458 Mass. 674, 676 (2011). Our task is to "consider whether the factual allegations in the complaint are sufficient, as a matter of law, to state a recognized cause of action or claim, and whether such allegations plausibly suggest an entitlement to relief." Dartmouth v. Greater New Bedford Regional Vocational Tech. High Sch. Dist., 461 Mass. 366, 374 (2012). Here, Rafferty has asserted two claims, the first for negligence based on failure to warn, and the second for a violation of c. 93A. We address each of these claims in turn.

1. Negligence claim. "To recover for negligence, a plaintiff must show 'the existence of an act or omission in violation of a . . . duty owed to the plaintiff[] by the defendant.'" Cottam v. CVS Pharmacy, 436 Mass. 316, 320 (2002), quoting Dinsky v. Framingham, 386 Mass. 801, 804 (1982). The existence of a duty is a question of law for the courts. Cottam, supra at 321. Here, the question is whether Merck, as the brand-name manufacturer of finasteride, owed a duty to warn to those, like Rafferty, who ingested the generic version of the drug.

Typically, where a consumer is injured by a product, our law holds the manufacturer or seller responsible under a theory of products liability. See, e.g., H.P. Hood & Sons, Inc. v. Ford Motor Co., 370 Mass. 69, 75 (1976). But Rafferty concedes, as he must under our prevailing law, that Merck owes him no duty to warn under the law of products liability. As noted by the judge, a manufacturer may be found liable for a failure to warn only where the product that caused the injury was made by that manufacturer; its duty of care extends only to users of its own product. See Mathers, 403 Mass. at 691; Mitchell, 396 Mass. at 631. This principle was applied in Carrier v. Riddell, Inc., 721 F.2d 867, 868 (1st Cir. 1983), where the plaintiff, a high school football player, suffered a severe spinal injury playing football and sued the defendant, a helmet manufacturer, claiming

that it negligently failed to warn his team that helmets offer little protection to a player's neck and spine. When the plaintiff learned in discovery that the helmet he wore was made by another manufacturer, not the defendant, the plaintiff continued to press his claim, arguing that his teammates wore helmets made by the defendant manufacturer and that, if it had provided a general warning about a helmet's limitations, he would have heard that warning and taken additional precautions that would have prevented his injury. Id. In an opinion written by now United States Supreme Court Justice Stephen Breyer, the United States Court of Appeals for the First Circuit, applying Massachusetts law, held that the defendant manufacturer could not be liable for failing to warn the plaintiff. Id. at 870. The court reasoned, "In the absence of some special circumstance one would expect a purchaser or a user of a product to rely for warnings upon the maker of the product they buy or use, not upon the maker of another, similar product." Id. at 869. As a general principle of products liability law, the court concluded that a manufacturer's "duty of care runs to those who buy or use the product itself, not a different [manufacturer's] product." Id.

Here, however, Rafferty did not bring a products liability claim and does not contend that Merck owed him a duty to warn as a manufacturer. Instead, he has brought a general negligence

claim, relying on "a general principle of tort law" that we articulated in Jupin v. Kask, 447 Mass. 141, 147 (2006), quoting Remy v. MacDonald, 440 Mass. 675, 677 (2004). In Jupin, supra, we declared:

> "'[E]very actor has a duty to exercise reasonable care to avoid physical harm to others.' . . . A precondition to this duty is, of course, that the risk of harm to another be recognizable or foreseeable to the actor. . . . Consequently, with some important exceptions, 'a defendant owes a duty of care to all persons who are foreseeably endangered by his conduct, with respect to all risks which make the conduct unreasonably dangerous.'" (Citations omitted.)

Applying this "general principle," id., we held in Jupin that a homeowner who stores firearms on his or her property has a duty of reasonable care to ensure that those firearms are properly secured, and that that duty was owed to, among others, a law enforcement officer shot by a person granted unsupervised access, because he was a "foreseeable victim" of the improper storage. Id. at 143. Under that same principle, we also have held, for example, that a limousine driver who discharges an intoxicated passenger, knowing that that passenger is likely to drive while intoxicated, owes a duty of reasonable care to those who are foreseeably endangered by the passenger's drunk driving. Commerce Ins. Co. v. Ultimate Livery Serv., Inc., 452 Mass. 639, 649-651 (2008). Similarly, we have held that an attorney owes a duty of reasonable care to nonclients, absent a conflict with a

client's interest, if he or she knows or should know that the nonclient will rely on the attorney's advice, see Lamare v. Basbanes, 418 Mass. 274, 276 (1994), and that an accountant owes a duty of reasonable care to third parties if the accountant knows that they will rely on the audit he or she prepares. Nycal Corp. v. KPMG Peat Marwick, LLP, 426 Mass. 491, 495-498 (1998).

At the same time, we recognized in Jupin that, even where the requirements of negligence are satisfied, there may nevertheless be a public policy justification for declining to impose a duty of care where "the imposition of a precautionary duty is deemed to be either inadvisable or unworkable." Jupin, 447 Mass. at 150-151, quoting Remy, 440 Mass. at 677. "The concept of 'duty' . . . 'is not sacrosanct in itself, but is only an expression of the sum total of . . . considerations of policy which lead the law to say that the plaintiff is entitled to protection.'" Luoni v. Berube, 431 Mass. 729, 735 (2000), quoting W.L. Prosser & W.P. Keeton, Torts § 53, at 358 (5th ed. 1984). Thus, the existence of duty is ultimately determined with "reference to existing social values and customs and appropriate social policy." Cremins v. Clancy, 415 Mass. 289, 292 (1993). This approach comports with the one taken by the Restatement (Third) of Torts, which provides:

> "(a) An actor ordinarily has a duty to exercise reasonable care when the actor's conduct creates a risk of physical harm.
>
> "(b) In exceptional cases, when an articulated countervailing principle or policy warrants denying or limiting liability in a particular class of cases, a court may decide that the defendant has no duty or that the ordinary duty of reasonable care requires modification."

Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 7 (2010).

Merck contends that, where a plaintiff alleges injury caused by a product arising from a failure to warn, we should limit the duty to warn to the manufacturer of that particular product, regardless of whether the claim is framed as a products liability claim or, as here, as a general negligence claim. It is true that, in the vast majority of such cases, the duty to warn would be limited to the manufacturer of the product -- even if the plaintiff were to bring a general negligence claim -- because the risk of harm arising from an inadequate warning would be foreseeable to a manufacturer only with respect to users of its own product, not the users of another product. Where the product causing the injury carries its own warning, one would expect the plaintiff to rely on that warning, not on the warning given for another product. Moreover, apart from any duty arising from the risk of foreseeable injury, only in rare

cases could a plaintiff contend that his or her injury was caused by the inadequate warning given for another product.

But this case presents an exception to the usual pattern. Because the Hatch-Waxman amendments to the act require that the warning label of a generic drug be identical to the warning label of its brand-name counterpart, and because the United States Supreme Court in PLIVA, 564 U.S. at 614-615, interpreted the resulting regulatory scheme to forbid a generic drug manufacturer from independently revising its warning labels, duty to warn claims involving generic drugs are potentially viable as general negligence claims, although not as products liability claims. With generic drugs, it is not merely foreseeable but certain that the warning label provided by the brand-name manufacturer will be identical to the warning label provided by the generic manufacturer, and moreover that it will be relied on, not only by users of its own product, but also by users of the generic product. Unlike in Carrier, 721 F.2d at 869, where the defendant manufacturer exercised no control whatsoever over the warnings attached to another manufacturer's product, Federal labeling requirements for generic drugs present precisely the kind of "special circumstance" where a consumer would rely on the warnings created by someone other than the manufacturer of the product causing the injury, because those will be identical to (and inseparable from) the warnings

provided by the generic manufacturer. Where a brand-name drug manufacturer provides an inadequate warning for its own product, it knows or should know that it puts at risk not only the users of its own product, but also the users of the generic product. Consequently, this is the rare (perhaps the only) type of case involving a manufactured product where the requirements of general negligence may be satisfied even where the requirements of products liability are not.

However, as noted earlier, even where the requirements of general negligence are satisfied, we must still consider as a matter of public policy whether the imposition of a duty is "inadvisable or unworkable," see Jupin, 447 Mass. at 151, quoting Remy, 440 Mass. at 677, or, in the words of the Restatement (Third) of Torts, supra at § 7, whether this is an "exceptional case[]" where a "countervailing principle or policy warrants denying or limiting liability" in this class of cases.

"Public policy favors the development and marketing of new and more efficacious drugs." Payton v. Abbott Labs, 386 Mass. 540, 573 (1982). Therefore, we must carefully consider whether the imposition of general negligence liability on brand-name manufacturers for injuries suffered by generic drug consumers arising from a failure to warn would materially diminish the development and marketing of new drugs.

Inevitably, imposing on brand-name manufacturers a duty to warn generic drug consumers would add to the manufacturer's costs. Where there is a duty to warn, negligence may be found where there is a failure "to exercise reasonable care in warning potential users of hazards associated with use of the product." Laaperi v. Sears, Roebuck & Co., 787 F.2d 726, 729 (1st Cir. 1986) (applying Massachusetts law). "The common law duty to warn . . . necessitates a warning 'comprehensible to the average user and . . . convey[ing] a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person.'" MacDonald v. Ortho Pharm. Corp., 394 Mass. 131, 140, cert. denied., 474 U.S. 920 (1985), quoting Ortho Pharm. Corp. v. Chapman, 180 Ind. App. 33, 49 (1979). "Whether a particular warning measures up to this standard is almost always an issue to be resolved by a jury; few questions are 'more appropriately left to a common sense lay judgment than that of whether a written warning gets its message across to an average person.'" MacDonald, supra, quoting Ferebee v. Chevron Chem. Co., 552 F. Supp. 1293, 1304 (D.D.C. 1982). The breadth and uncertain scope of this standard for a negligent failure to warn means that, where a consumer suffers injury from a generic drug, there would be broad latitude to bring a failure to warn claim and great difficulty in defeating it before trial. As a result, brand-name manufacturers faced with failure to warn claims would bear

the significant cost not only of compensating injured consumers, but also of litigating their claims, meritorious or not.

Where failure to warn claims are brought by consumers of a manufacturer's own product, "the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business." Escola v. Coca Cola Bottling Co. of Fresno, 24 Cal. 2d 453, 462 (1944) (Traynor, J., concurring). The cost of litigation and of damage awards or settlements is in this sense treated as "a cost of production." Restatement (Second) of Torts § 402A comment c (1965). But if consumers of generic drugs were allowed to recover damages for a brand-name manufacturer's negligent failure to warn, it would be far more difficult for the manufacturer to shoulder these costs, for three reasons.

First, these costs would not be incurred until after the brand-name manufacturer's patent monopoly expires and generic competitors enter the market, at which point the brand-name manufacturer will have suffered a precipitous decline in sales of its product. When there is such competition, generic manufacturers command approximately ninety per cent of the market, see Association for Accessible Medicines, Generic Drug Access & Savings in the U.S. 16 (2017), in part because many States, including Massachusetts, have enacted laws that authorize or even require pharmacists to substitute generic

drugs when filling prescriptions for brand-name drugs. See, e.g., G. L. c. 112, § 12D (requiring generic substitution unless prescribing physician indicates "no substitution"). See also PLIVA, 564 U.S. at 628 (Sotomayor, J., dissenting); Grabowski, Long, Mortimer, & Boyo, Updated Trends in US Brand-Name and Generic Drug Competition, 19 J. Med. Econ. 836, 840 (2016) (brand-name drugs facing generic competition between 2013 and 2014 saw market share by volume fall to average of twelve per cent within first year).

Second, because prices drop with generic drug competition, the sales of generic drugs may exceed the sales generated during the patent monopoly period, and may even continue indefinitely, long after the brand-name manufacturer has moved on to focus on other patented products. See United States Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, Issue Brief: Understanding Recent Trends in Generic Drug Prices 1-2 (Jan. 27, 2016).

Third, because the United States Supreme Court in PLIVA, 564 U.S. at 624, ruled that Federal preemption bars any generic drug consumer from bringing a failure to warn claim against any generic manufacturer, all such claims would be brought only against the brand-name manufacturer that drafted the warning label, leaving the brand-name manufacturer without any ability

to share the costs of litigation, or of a damage award or settlement, with the generic manufacturer.

Therefore, although brand-name manufacturers are in the best position, because of their Federal labeling responsibilities, to prevent an injury arising from the inaccurate or inadequate warning on a generic drug, they are not in the best position to bear its costs. To recognize negligence liability here would impose on brand-name manufacturers an additional "cost of production" for products that, in reality, they no longer produce. Restatement (Second) of Torts, supra at § 402A comment c.

These additional costs, and the uncertainty regarding their scope and duration, would inevitably affect to some degree the financial incentives to invest in the research and development of new drugs. Having said that, it is difficult to accurately assess whether, and to what extent, this would have a chilling effect on drug innovation. See S. Garber, RAND Institute for Civil Justice, Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals 55-56, 58, 62 (2013) (some evidence that expanded products liability has discouraged drug innovation, but "there is no reliable empirical basis for estimating in dollar terms the social costs or benefits of liability-induced . . . price increases, or effects on product safety, effectiveness, or

innovation"). We realize that bringing a new drug to market is already a long, expensive, and risky process; studies have shown that, on average, the process of developing and obtaining FDA approval for a new drug takes ten to fifteen years and costs $2.6 billion, and only a small fraction of compounds under development are ever approved. See Pharmaceutical Research and Manufacturers of America, Biopharmaceuticals in Perspective 29 (2017). See also United States Department of Health and Human Services, Report to Congress, Prescription Drugs: Innovation, Spending, and Patient Access 25-36 (Dec. 7, 2016). Given that the costs of research and development are already so high and the odds of FDA approval so low, it is far from clear whether the development of any new drug would be prevented merely because of the incremental costs that would arise from the imposition of a duty to warn generic drug consumers.

Meanwhile, imposing such a duty on brand-name manufacturers would have undeniable benefits. We can be confident that, if brand-name manufacturers owed generic drug consumers a duty to warn, they would have a greater financial incentive to revise their warnings through the change being effected process where new information demonstrates the need to do so, in order to prevent failure to warn suits. Without such a duty, the only threat of a failure to warn suit would be from consumers of the brand-name drug who, once the patent has expired and generic

drugs enter the market, might comprise as little as ten per cent or less of the market for such drugs. As a result, no one -- neither the generic manufacturer nor the brand-name manufacturer -- would have a complete incentive to maintain safe labels for the overwhelming share of prescription drugs dispensed. State tort law always has been an important source of consumer protection with respect to prescription drugs, "provid[ing] incentives for drug manufacturers to disclose safety risks promptly." Wyeth v. Levine, 555 U.S. 555, 579 (2009). See Kessler & Vladeck, A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims, 96 Geo. L.J. 461, 483, 491-495 (2008). If generic drug consumers could not sue drug manufacturers for a failure to warn, they would be denied an important safeguard against future injuries.

We also recognize that, if we were to shield brand-name manufacturers entirely from liability for the failure to warn generic drug consumers, we would leave those consumers with no chance of obtaining compensation for their injuries because generic manufacturers are already immune from State law claims. In PLIVA, 564 U.S. at 625, the United States Supreme Court recognized "the unfortunate hand that [F]ederal drug regulation has dealt" generic drug consumers, whose claims against manufacturers are barred only because they ingested generic rather than brand-name drugs. See id. at 643 (Sotomayor, J.,

dissenting) ("[Under PLIVA,] a drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic"). Were we also to bar their claims against brand-name manufacturers, we would only exacerbate the unfairness of this regulatory scheme. Such a result would be especially troubling given that, as discussed, generic drugs represent close to ninety per cent of the prescription drug market, and many drug consumers do not even have a choice under State generic substitution laws whether they receive a brand-name or generic drug when they fill a prescription. See PLIVA, supra at 628 (Sotomayor, J., dissenting). The widespread use of generic drugs means that, if we decline to impose any liability on brand-name manufacturers, countless consumers would be left without a remedy.

The need to deter failures to warn, and to compensate for the resulting harm, is especially urgent where the failure is not merely inadvertent and the risk of harm is most serious. In other types of cases where we have circumscribed liability for public policy reasons, we have nevertheless consistently recognized that there is a certain core duty -- a certain irreducible minimum duty of care, owed to all persons -- that as a matter of public policy cannot be abrogated: that is, the duty not to intentionally or recklessly cause harm to others.

For instance, we have long held in premises liability cases that a landowner owes no duty of reasonable care to a trespasser, Schofield v. Merrill, 386 Mass. 244, 245-246 (1982), based on the rationale that landowners should not be "bound to protect or provide safeguards for wrongdoers." Sweeny v. Old Colony & Newport R.R. Co., 10 Allen 368, 372 (1865). Yet, we have held that a landowner still owes a trespasser a duty to "refrain from wilful, wanton[,] or reckless disregard for the trespasser's safety." Schofield, supra at 245-246. And in cases involving contractual waivers, we have hewed to "the well-established principle of contract law" that "while a party may contract against liability for harm caused by its negligence, it may not do so with respect to its gross negligence" or, for that matter, its reckless or intentional conduct. Maryland Cas. Co. v. NSTAR Elec. Co., 471 Mass. 416, 422 (2015), quoting Zavras v. Capeway Rovers Motorcycle Club, Inc., 44 Mass. App. Ct. 17, 19 (1997). See Sharon v. Newton, 437 Mass. 99, 110 n.12 (2002) (distinguishing waivers for ordinary negligence from waivers for "gross negligence, or reckless or intentional conduct"); Restatement (Second) of Contracts § 195(1), at 65 (1981) ("A term exempting a party from tort liability for harm caused intentionally or recklessly is unenforceable on grounds of public policy").

We have applied this same reasoning in many other types of cases where we have tolerated ordinary negligence but drawn the line at recklessness. In defamation cases, a plaintiff who is a public officer or a public figure cannot recover damages on proof of the defendant's negligence, but can recover if the defendant acted with "actual malice," meaning wilful or reckless disregard of the truth. See Stone v. Essex County Newspapers, Inc., 367 Mass. 849, 851 (1975). See also New York Times Co. v. Sullivan, 376 U.S. 254, 279-280 (1964). In cases involving bailments, the traditional rule has been that where bailments are for the sole benefit of the bailor, the bailee is not liable for ordinary negligence but can be liable for gross negligence. See Altman v. Aronson, 231 Mass. 588, 590 (1919), quoting Foster v. Essex Bank, 17 Mass. 479, 498-499, 507 (1821). Similarly, in cases involving sporting events, we have held that athletes and coaches cannot be liable for injuries caused by their negligence, but will be held liable if they act in "reckless disregard of safety." Gauvin v. Clark, 404 Mass. 450, 454 (1989). See Kavanagh v. Trustees of Boston Univ., 440 Mass. 195, 204-205 (2003).

In enacting statutes, the Legislature, too, has distinguished between ordinary negligence and reckless conduct, granting immunity or indemnification in some situations in claims of negligence but not in claims of recklessness. See,

e.g., G. L. c. 21, § 17C (landowner who makes land open to public for recreational use free of charge not liable for personal injuries "in the absence of wilful, wanton, or reckless conduct"); G. L. c. 229, § 2 (railroads not liable for negligence in causing death of trespasser but liable for reckless conduct). See also G. L. c. 258, § 9 (public employees may not be indemnified for civil rights violations if employee "acted in a grossly negligent, willful[,] or malicious manner); G. L. c. 258, § 9A (police officers may not be indemnified for violations of Federal or State law if officer "acted in a wilful, wanton, or malicious manner").

Implicit in both our common and statutory law, then, is a longstanding public policy that, although we may be willing in certain circumstances to excuse ordinary negligence, we will not tolerate the reckless disregard of the safety of others.

Having weighed these considerations, we conclude as a matter of public policy 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. But we also conclude that public policy is not served if generic drug consumers have no remedy for the failure of a brand-name manufacturer to warn in cases where such failure exceeds ordinary negligence, and rises to the

level of recklessness. In cases where, for instance, a brand-name manufacturer learns that its drug is repeatedly causing death or serious injury, or causes birth defects when used by pregnant mothers, and still fails to warn consumers of this danger, public policy does not dictate that these consumers be left with no remedy when those risks are realized, or that the manufacturer have little financial incentive to reveal these risks. We therefore hold that a brand-name manufacturer that controls the contents of the label on a generic drug owes a duty to consumers of that generic drug not to act in reckless disregard of an unreasonable risk of death or grave bodily injury. This recklessness standard strikes the most appropriate balance between competing public policy interests, limiting liability for brand-name manufacturers while also providing remedies for the most serious injuries and deterring the most dangerous forms of conduct.

Under our common law, a defendant's conduct is in reckless disregard of the safety of another where

> "he does an act or intentionally fails to do an act which it is his duty to the other to do, knowing or having reason to know of facts which would lead a reasonable man to realize, not only that his conduct creates an unreasonable risk of physical harm to another, but also that such risk is substantially greater than that which is necessary to make his conduct negligent."

Boyd v. National R.R. Passenger Corp., 446 Mass. 540, 546 (2006), quoting Restatement (Second) of Torts, supra at § 500, at 587.

Recklessness is distinguishable from negligence in two key respects. See Manning v. Nobile, 411 Mass. 382, 387-388 (1991). First, the reckless conduct must be intended. "While negligence may result from 'inadvertence, incompetence, . . . or a failure to take [adequate] precautions,' recklessness 'requires a conscious choice of a course of action, either with knowledge of the serious danger to others involved in it or with knowledge of facts which would disclose this danger to any reasonable man.'" Boyd, 446 Mass. at 547, quoting Restatement (Second) of Torts, supra at § 500 comment g, at 590. Importantly, only the conduct need be intended; the resulting harm need not be. Boyd, supra at 548.

Second, reckless conduct must involve a substantially greater risk than is required for ordinary negligence. "Reckless failure to act involves an intentional or unreasonable disregard of a risk that presents a high degree of probability that substantial harm will result to another." Sandler v. Commonwealth, 419 Mass. 334, 336 (1995). "The risk of death or grave bodily injury must be known or reasonably apparent, and the harm must be a probable consequence of the defendant's election to run that risk or of his failure reasonably to

recognize it." Id. The difference between recklessness and mere negligence is therefore not only "a difference in degree but also a difference in kind." Id. at 337.

Under this standard, a brand-name manufacturer that intentionally fails to update the label on its drug to warn of an unreasonable risk of death or grave bodily injury, where the manufacturer knows of this risk or knows of facts that would disclose this risk to any reasonable person, will be held responsible for the resulting harm.

We acknowledge that, by imposing on brand-name manufacturers any duty to warn generic consumers, we find ourselves in the minority of courts that have decided this issue. We also are the only court to limit the scope of liability arising under this duty to reckless disregard of the risk of death or grave bodily injury. As Merck has repeatedly reminded us, most courts have held that brand-name manufacturers owe no duty to generic drug consumers who have been injured by inaccurate or inadequate labels. See, e.g., Johnson v. Teva Pharms. USA, Inc., 758 F.3d 605, 616 (5th Cir. 2014); Guarino v. Wyeth, LLC, 719 F.3d 1245, 1250-1253 (11th Cir. 2013); Smith v. Wyeth, Inc., 657 F.3d 420, 424 (6th Cir. 2011), cert. denied, 566 U.S. 974 (2012); Mensing v. Wyeth, Inc., 588 F.3d 603, 613-614 (8th Cir. 2009), vacated on other grounds, 564 U.S. 604, and revised, 658 F.3d 867 (2011); Foster v. American Home Prods.

Corp., 29 F.3d 165, 171 (4th Cir. 1994); Huck, 850 N.W.2d at 378.[5] We note that many of these decisions are distinguishable, some because they were resolved under the products liability statutes of other States, see Johnson, supra at 615-616 (applying Louisiana Products Liability Act); Smith, supra at 423-424 (applying Kentucky Products Liability Act), and others because they were issued by Federal courts that are constrained in their interpretation of State law in the absence of clear guidance from State appellate courts. See Guarino, supra at 1251 ("[C]onsiderations of comity and federalism counsel that we proceed gingerly when venturing into uncharted waters of [S]tate substantive law"). Further, to the extent that several of these decisions predate the United States Supreme Court's decision in PLIVA, 564 U.S. at 613, 624, we find them less persuasive because they failed to consider the Federal preemption of State tort law claims against generic manufacturers and the unique remedial gap that this has created.[6]

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[5] Only a few courts have held otherwise. See Wyeth, Inc. v. Weeks, 159 So. 3d 649, 676 (Ala. 2014), superseded by statute, Ala. Code § 6-5-530(a); Conte v. Wyeth, Inc., 168 Cal. App. 4th 89, 114 (2008). See also Kellogg v. Wyeth, 762 F. Supp. 2d 694, 706 (D. Vt. 2010).

[6] For example, in Foster v. American Home Prods. Corp., 29 F.3d 165, 169-171 (4th Cir. 1994), the United States Court of Appeals for the Fourth Circuit held that a brand-name manufacturer owed no duty to a generic drug consumer based in part on the premise that generic manufacturers have some control over the contents of their labels and can therefore be held

We also conclude that, by limiting liability to circumstances where there has been reckless disregard of an unreasonable risk of death or grave bodily injury, we adequately address the many policy concerns that have led other courts to deny liability altogether. See, e.g., Huck, 850 N.W.2d at 376-380. First, our ruling does not undo the careful balance struck in the Hatch-Waxman amendments by imposing unwarranted new burdens on brand-name manufacturers. We emphasize that, although we limit the brand-name manufacturer's duty to warn generic drug consumers, we do not limit its duty to warn its own customers; as to them, brand-name manufacturers still owe a duty to "exercise reasonable care in warning [them] of hazards associated with use of [their] product." Laaperi, 787 F.2d at 729. In addition to this common-law duty they already owe to their own customers, brand-name manufacturers also have a duty under the act to ensure that the labels on their products are accurate and adequate. 21 U.S.C. § 355(b)(1), (d). FDA regulations impose on all drug manufacturers, both brand-name and generic, an ongoing obligation to monitor a drug's risks and report any adverse drug experiences that may not be indicated by the drug's label. 21 C.F.R. §§ 314.80, 314.81, 314.98. Drug

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liable for negligent failure to warn. This premise is obviously no longer true in light of the United States Supreme Court's decision in PLIVA, Inc. v. Mensing, 564 U.S. 604, 613, 624 (2011).

manufacturers also have a regulatory obligation to revise their labeling "to include a warning about a clinically significant hazard as soon as there is reasonable evidence." 21 C.F.R. § 201.57(c)(6)(i) (2017). See 21 C.F.R. § 201.80(e) (2017). To avoid liability for recklessness toward generic drug consumers, a brand-name manufacturer need only fulfil those obligations it already has towards its own customers. Cf. Coombes v. Florio, 450 Mass. 182, 191 (2007) (Ireland, J., concurring) (extension of doctor's duty to warn to nonpatients "d[id] not impose a heavy burden" where it "require[d] nothing . . . not already required by his duty to his patient").

Second, to the extent that our decision makes investments in new drugs any "riskier" -- by exposing manufacturers to additional liability -- we expect that this marginal risk will not materially chill innovation or increase drug prices. After all, what drug manufacturer, when deciding whether to invest in a new drug or in setting prices during its patent monopoly, would factor in substantial liability costs that might be incurred after its patent expires, premised on the probability that it will act in reckless disregard of an unreasonable risk of death or grave bodily injury?

Third, we do not believe that by recognizing liability for recklessness we overstep our bounds and intrude into matters for which "courts are not institutionally qualified." Huck, 850

N.W.2d at 377. In enacting the Hatch-Waxman amendments, Congress has determined that public health and safety is best served by a particular allocation of labeling responsibilities between brand-name and generic manufacturers. We cannot (nor do we seek to) disturb that allocation. Congress recognized and expected that its Federal regulatory scheme would be supplemented with traditional State law remedies. When Congress enacted the act, it rejected an earlier draft that would have provided a Federal cause of action for injured consumers, "[e]vidently, [because] it determined that [State law] provided appropriate relief." Wyeth, 555 U.S. at 574 & n.7.

Fourth, our decision does not subvert the fundamental principles of tort law. On the contrary, it is fully consistent with them. As earlier noted, the relief we provide, limited to reckless disregard of an unreasonable risk of death or grave bodily injury, is coextensive with the irreducible minimum duty of care that as a matter of public policy cannot be abrogated, even where a trespasser invades a person's property or when the parties contractually agree to a waiver of liability.

In this case, the question whether Rafferty has stated a failure to warn claim that meets the standard of a reckless disregard of an unreasonable risk of death or grave bodily injury must be determined by a trial judge. Because Merck owed Rafferty a limited duty to warn, and because Rafferty, to state

a claim that falls within this limited duty, must allege facts supporting a finding that Merck acted recklessly, not just negligently, we vacate the dismissal of this claim and remand the case to the Superior Court. We direct the court to grant leave to Rafferty to amend his complaint if he believes that he can state facts sufficient to support such a claim. Cf. Cheney v. Automatic Sprinkler Corp. of Am., 377 Mass. 141, 150 (1979) (plaintiff given opportunity to amend complaint where court "for the first time . . . [indicated] the relevant considerations" for his claim).

2. Chapter 93A claim. To state a claim under the consumer protection statute, G. L. c. 93A, § 9, a plaintiff must allege facts sufficient to establish four elements: first, that the defendant has committed an unfair or deceptive act or practice; second, that the unfair or deceptive act or practice occurred "in the conduct of any trade or commerce;" third, that the plaintiff suffered an injury; and fourth, that the defendant's unfair or deceptive conduct was a cause of the injury. See G. L. c. 93A, § 2 (a); Herman v. Admit One Ticket Agency LLC, 454 Mass. 611, 615-616 (2009).

Under § 2, "unfair or deceptive acts or practices" are "declared unlawful" only where they occur "in the conduct of any trade or commerce." "Trade" and "commerce" are defined in § 1 (b) to include "the advertising, the offering for sale,

. . . the sale, . . . or distribution of any services and any property, tangible or intangible, . . . and any other article, commodity, or thing of value wherever situate, and shall include any trade or commerce directly or indirectly affecting the people of this [C]ommonwealth."

To satisfy the "trade or commerce" requirement in a failure to warn claim under G. L. c. 93A, § 9, a plaintiff need not have purchased the product directly from the defendant. See Kattar v. Demoulas, 433 Mass. 1, 14-15 (2000) ("Parties need not be in privity for their actions to come within the reach of c. 93A"). It suffices that the plaintiff used the product, even if it was sold to another, and was injured as a result of the defendant's failure to warn. See Maillet v. ATF-Davidson, Co., 407 Mass. 185, 190 (1990) (injured printing press operator could sue manufacturer of printing press purchased by his employer, even though he was "neither a consumer nor in privity with the defendant"). See also Ciardi v. F. Hoffmann-La Roche, Ltd., 436 Mass. 53, 65 (2002) (indirect purchaser of product could assert c. 93A claim for unfair competition against manufacturer of that product, notwithstanding lack of privity, because she "alleged a connection between herself and the defendants, albeit an indirect one, as parties to consumer transactions").[7]

[7] It is important to distinguish between claims brought under G. L. c. 93A, § 9, typically by consumers against

Here, however, Rafferty does not allege that he used Merck's brand-name drug. Rather, he alleges that he suffered injury from the use of a drug that Merck did not advertise, offer to sell, or sell. Although c. 93A does not require privity, it is limited "only to actions taken in the course of 'trade or commerce'" (emphasis added). Morrison v. Toys "R" Us, Inc., Mass., 441 Mass. 451, 457 (2004). In this context, Merck's alleged unfair and deceptive action -- that is, its failure to warn Rafferty of the side effects of the drug -- was not taken in the course of "any trade or commerce" because it was not taken in the course of the advertising, offer to sell, or sale of any Merck product. Of course, if one of Merck's own consumers was injured from Merck's brand-name version of the drug as a result of its failure to warn, that failure would have been in the course of Merck's sale of its own product, and therefore "in the conduct of any trade or commerce." G. L. c. 93A, § 2 (a). But where the failure to warn is with respect to a drug that Merck has never advertised, offered to sell, or sold, it would stretch the limits of c. 93A to hold that such

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businesses, and claims brought under § 11, typically by businesses against other businesses. Unlike claims under § 9, claims under § 11 require not only that the defendant's conduct occur in "trade or commerce" but also that there be a commercial transaction between the parties. See Linkage Corp. v. Trustees of Boston Univ., 425 Mass. 1, 22-23, cert. denied, 522 U.S. 1015 (1997).

failure occurred "in the conduct of any trade or commerce." Id. We therefore conclude that Rafferty has failed to allege sufficient facts to state a claim under c. 93A, § 9.

Conclusion. For the reasons stated above, the order dismissing Rafferty's common-law claim is vacated and the case is remanded to the Superior Court, with instructions that Rafferty be granted leave to amend his complaint within thirty days of the date of the rescript. The order dismissing Rafferty's c. 93A claim is affirmed.

So ordered.