COMMONWEALTH OF MASSACHUSETTS
SUPREME JUDICIAL COURT

No. SJC-12347

BRIAN RAFFERTY,
Plaintiff-Appellant,

v.

MERCK & CO., INC.,
Defendant-Appellee,

and

SIDNEY RUBENSTEIN,

Defendant.

ON APPEAL FROM A JUDGMENT OF THE
SUPERIOR COURT FOR MIDDLESEX COUNTY

BRIEF FOR AMICUS CURIAE INTERNATIONAL ASSOCIATION OF DEFENSE COUNSEL IN SUPPORT OF APPELLEE

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October 10, 2017

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The International Association of Defense Counsel ("IADC") respectfully submits this brief pursuant to the Court's solicitation of amicus briefs issued on June 29, 2017.

STATEMENT OF INTEREST OF AMICUS CURIAE

The International Association of Defense Counsel, as amicus curiae, submits this brief in support of Appellee Merck & Co., Inc.

The IADC is an association of corporate and insurance attorneys from the United States and around the globe whose practice is concentrated on the defense of civil lawsuits. The IADC is dedicated to the just and efficient administration of civil justice and continual improvement of the civil justice system. The IADC supports a justice system in which plaintiffs are fairly compensated for genuine injuries, responsible defendants are held liable for appropriate damages, and non-responsible defendants are exonerated without unreasonable cost.

The IADC maintains an abiding interest in the fair and efficient administration of product liability actions. The IADC's Product Liability Committee consists of more than 900 members, publishes regular newsletters and journal articles, and presents educational seminars internally and to the legal community at large. The IADC has also participated as amicus curiae in several cases involving product

liability issues, including Kim v. Toyota Motor Corporation, No. S232754 (Cal.); Ramos v. Brenntag Specialties, Inc., et al., No. 8218176 (Cal.); Tincher v. Omega Flex, Inc., No. 17 MAP 2013 (Pa.); and T.H., A Minor, ETC., et al., v. Novartis Pharmaceuticals Corp., No. S233898 (Cal.).[1]

STATEMENT OF ISSUE PRESENTED FOR REVIEW

Where a brand-name manufacturer of a drug is responsible for labeling the drug and where a manufacturer of a generic version is required to use the same labeling, whether an individual who takes a generic version of a drug can hold the brand-name manufacturer liable for a failure to warn of possible side effects of the drug on the basis that the drug is labeled inaccurately.

STATEMENT OF THE CASE

For purposes of this brief, the IADC accepts the statements of the case and of those facts that appear

[1] Pursuant to Aspinall v. Philip Morris Cos., 442 Mass. 381 (2004), we state that Wilmer Cutler Pickering Hale and Dorr LLP represented the defendant in Kelly v. Wyeth, No. Civ. A. MICV200303314B, 2005 WL 4056740 (Mass. Super. Ct. May 6, 2005), which raised a similar issue. That representation concluded over eight years ago. No counsel for a party authored any portion of this brief, and no person other than the IADC or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. Although counsel for Merck, Richard Neumeier, Esq., was formerly an IADC member and now has emeritus status, Mr. Neumeier did not participate in the IADC's decision to submit a brief or the drafting of the IADC's brief in this case.

undisputed as set forth by the parties in their respective briefs to this Court.

SUMMARY OF ARGUMENT

The Court should reject Appellant's invitation to expand tort liability in the Commonwealth far beyond its doctrinal underpinnings to make drug manufacturers liable for injuries caused by drugs manufactured and sold by their competitors.

Tort law provides legal remedies for individuals injured by the negligent acts or omissions of others. In Massachusetts, a claim of failure to warn allows for recovery where a manufacturer has failed to "exercise reasonable care in warning potential users of hazards associated with use of the product," and the plaintiff is injured due to that failure to warn. Laaperi v. Sears, Roebuck & Co., 787 F.2d 726, 729 (1st Cir. 2010) (applying Massachusetts law). See also MacDonald v. Ortho Pharm. Corp., 394 Mass. 131, 135 (1985).

In cases such as this one, where a plaintiff has not purchased or used the defendant's product, but instead a product made by a third-party competitor, failure to warn claims fail for two reasons. First, as the Superior Court held, a manufacturer's duty to warn extends only to those individuals who are reasonably foreseeable users of the manufacturer's product. See H.P. Hood & Sons, Inc. v. Ford Motor

Co., 370 Mass. 69, 75 (1976); Carney v. Bereault, 348 Mass. 502, 506 (1965). Second, and independently, a manufacturer who did not make the drug the customer took has not performed any action that could be the proximate cause of the customer's injury.

The doctrinal reasons for the failure of Appellant's claim are supported by sound public policy. Product liability law exists not only to compensate for the plaintiff's injury, but also to make sure that that compensation is offset against the product manufacturer's income from the product. See Huck v. Wyeth, 850 N.W.2d 353, 378 (Iowa 2014) (noting that products liability law is designed to "place responsibility for the harm caused by a product on the party who profits from its manufacture and sale"). The rule sought by Appellant, however, would instead shift liability to a manufacturer who had no role in (and reaped no benefit from) the marketing of the supposedly injurious product. The fact that federal law preempts claims against generic drug manufacturers based on a drug's labeling, see PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011), does not justify shifting responsibility to a party that played no role in the plaintiff's injury. Besides being unfair and contrary to established principles of tort law, it would undermine the intent of Congress and the U.S. Food and Drug Administration ("FDA").

ARGUMENT

I. A PLAINTIFF WHO TOOK A THIRD-PARTY MANUFACTURER'S GENERIC DRUG CANNOT STATE A CLAIM OF FAILURE TO WARN AGAINST A BRAND-NAME DRUG MANUFACTURER

In order to succeed on a claim of negligent failure to warn against a manufacturer in Massachusetts, a plaintiff must show that he was "injured due to the failure of the manufacturer to exercise reasonable care in warning potential users of hazards associated with use of the product." Laaperi, 787 F.2d at 729. Recovery for a manufacturer's negligent failure to warn is limited to those individuals who are foreseeable users of the manufacturer's product. See Mitchell v. Sky Climber, Inc., 396 Mass. 629, 631 (1986) ("We have never held a manufacturer liable . . . for failure to warn of risks created solely in the use or misuse of the product of another manufacturer.").

Notably, Appellant did not proceed on a theory of negligent misrepresentation, likely because he would have been required to show that Merck should have foreseen that Appellant would reasonably rely on Merck's representations on the warning label for Proscar (a showing Appellant would be unable to make). See Capitol Indem. Corp. v. Freedom House Dev. Corp., 487 F. Supp. 839, 842 (D. Mass. 1980) ("Recovery for damages resulting from negligent misrepresentation is limited by a standard of foreseeability."). See also

Foster v. American Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994) ("There is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products."). Because Appellant chose to pursue a claim of failure to warn, his claim depends on "use of the product," not reliance on Merck's statements. Laaperi, 787 F.2d at 729 (emphasis added).

Appellant's claim fails because he is not a foreseeable user of Merck's product, and, in fact, is not a user of Merck's product at all. The legal consequence is twofold: Merck had no duty to warn Appellant, and Merck did not proximately cause his injury. Either conclusion is dispositive here.

A. Merck does not owe Appellant a duty to warn

As discussed in detail in Appellee's brief, Merck did not owe Appellant any duty to warn because Appellant was not a consumer of any Merck products and Merck did not undertake to make any representations to Appellant whatsoever. "Ordinarily, 'a manufacturer of a product, which the manufacturer knows or should know is dangerous by nature or is in a dangerous condition,' is under a duty to give warning of those dangers to 'persons who it is foreseeable will come in contact with, and consequently be endangered by, that product.'" MacDonald, 394 Mass. at 135, quoting H.P.

Hood & Sons, 370 Mass. at 75 (emphases added).

Merck is not the manufacturer of the generic finasteride that Appellant ingested. While Merck undoubtedly has a duty to warn foreseeable users of the products that it manufactures, see Mitchell, 396 Mass. at 631, it has no such duty to warn consumers of its competitors' products. See id. (noting that Massachusetts courts "have never held a manufacturer liable . . . for failure to warn of risks created solely in the use or misuse of the product of another manufacturer"). See also Carrier v. Riddell, Inc., 721 F.2d 867, 869 (1st Cir. 1983) (noting non-existence of Massachusetts cases "imposing liability upon a manufacturer (for failure to warn) in favor of one who uses the product of a different manufacturer").

Amicus will not repeat the multiple authorities supporting the Superior Court's decision, other than to note the recent decision from the U.S. District Court for the District of Massachusetts, In re Zofran (Ondansetron) Products Liability Litigation, No. 15-md-2657, __ F. Supp. 3d __, 2017 WL 3448548 (D. Mass. Aug. 8, 2017), which joined the chorus. Judge Saylor's well-reasoned opinion explains that "[t]he overwhelming majority of courts -- including all seven federal circuits to have addressed the issue -- have held that the manufacturer of a brand-name drug may

not be held liable for injuries caused by ingestion [of] its generic equivalent, regardless of the theory of liability." Id. at *6.

Judge Saylor also discussed the Fourth Circuit's decision in Foster, describing it as the "seminal case adopting the majority view" of innovator liability. 2017 WL 3448548, at *7. While Appellant ventures that the Fourth Circuit "made a critical assumption that generic drug manufacturers had an independent right and obligation to provide adequate warnings to their consumers, an assumption that was put to rest by Mensing" (Reply Br. 10), it is important to note that the Foster decision did not turn on such an "assumption," and it remains good law despite the Supreme Court's holding in Mensing. See Zofran, 2017 WL 3448548, at *8 (noting that "the great majority of courts have continued to follow Foster, notwithstanding the Mensing decision"); Foster, 29 F.3d at 171 (holding that "to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far"). Accordingly, the majority view remains "overwhelming and well-reasoned." Zofran, 2017 WL 3448548, at *16.

B. Merck was not the proximate cause of Appellant's injuries

Even if there were a duty from Merck to Appellant (and there is not), this claim would still fail for lack of causation. Massachusetts applies a proximate

cause standard in tort cases that is bound by the harm that is reasonably foreseeable from the negligent conduct. See Leavitt v. Brockton Hosp., Inc., 454 Mass. 37, 45 (2009) ("Liability for conduct obtains only where the conduct is both a cause in fact of the injury and where the resulting injury is within the scope of the foreseeable risk arising from the negligent conduct."). See also Stamas v. Fanning, 345 Mass. 73, 76 (1962) ("There are situations where it can be said, as [a] matter of law, that a cause is remote rather than proximate."). Section 10 of the Restatement (Third) of Torts, which this Court described as a "logical and balanced embodiment of the continuing duty rule" regarding duty to warn, Lewis v. Ariens Co., 434 Mass. 643, 648-649 (2001), states that "[o]ne engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller's position would provide such a warning." Restatement (Third) of Torts § 10, Products Liability (1998) (emphases added).

The "seller" in this case, however, is not Merck, but rather the third-party manufacturer of the generic finasteride that Appellant ingested. Merck is "engaged in the business of selling or otherwise

distributing" its own products, but it is not so engaged with the products of its competitors. It was, and continues to be, reasonably foreseeable to Merck that, when it developed and received FDA approval for Proscar's warning label, the Proscar label would be used to warn users of Proscar -- and no one else -- about the potential risks associated with using Proscar.[2]

Merck did not make the representation upon which Appellant may have relied; indeed, Merck made no representation to the Appellant whatsoever. If Appellant relied on any representation at all, it would be the representation made by the generic manufacturer of the finasteride that Appellant ingested. The fact that the generic manufacturer obtained the content of its finasteride warning label from Merck's Proscar warning label does not make the representation on which Appellant relied a representation made by Merck. Indeed, "[t]here is no

[2] In light of the overwhelming majority of courts that have held to the contrary, the existence of outlier cases in which courts have found that brand-name manufacturers owe a duty to consumers of the generic version of their drug fail to thrust Appellant's injuries into the realm of foreseeable risk associated with Merck's Proscar warning label, particularly given that only two state courts have adopted this position, and in one of those instances the state's legislature immediately acted to abrogate the court's decision. See Wyeth, Inc. v. Weeks, 159 So.3d 649 (Ala. 2014) (overturned by statute, Ala. Code § 6-5-530(a)); Conte v. Wyeth, Inc., 168 Cal. App. 4th 89 (2008).

legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer had no control." Foster, 29 F.3d at 170.

Merck neither manufactured the drug that Appellant ingested, nor made the representation upon which he relied, and therefore it cannot have been the cause in fact of Appellant's injuries. Moreover, because Appellant's injuries were in no way related to any Merck act or omission, those injuries were a harm that was completely unforeseeable to Merck. Accordingly, Appellant cannot, as a matter of law, show that Merck was the proximate cause of his injuries.

II. PUBLIC POLICY DOES NOT SUPPORT HOLDING BRAND-NAME DRUG MANUFACTURERS LIABLE FOR INJURIES CAUSED BY GENERIC DRUGS MANUFACTURED BY OTHERS

Sound public policy favors imposing tort liability (if any) on the party whose conduct is the proximate cause of the plaintiff's alleged harm; here, that is the manufacturer of the generic finasteride that Appellant ingested. See Huck, 850 N.W.2d at 377 ("Economic and public policy analyses strongly disfavor imposing tort liability on brand manufacturers for harm caused by generic competitors."). Indeed, product liability law is generally designed "to place responsibility for the

harm caused by a product on the party who profits from its manufacture and sale." Id. at 378. See also Johnson v. Supro Corp., 498 So.2d 528, 528-529 (Fla. Dist. Ct. App. 1986) (noting that "every theory of products liability . . . is based on the essential requirement that the responsible party is in the business of and gains profits from distributing or disposing of the 'product' in question through the stream of commerce"); Peterson v. Lou Bachrodt Chevrolet Co., 329 N.E.2d 785, 786 (Ill. 1975) ("One of the basic grounds supporting the imposition of strict liability upon manufacturers is that losses should be borne by those who have created the risk and reaped the profit by placing the product in the stream of commerce." (internal quotation marks omitted)).

Appellant's proposed rule, however, would flip this established legal rule on its head by shifting responsibility to a manufacturer who had no role in (and reaped no benefit from) the marketing of the supposedly injurious product. There are significant policy concerns associated with shifting such potential liability to brand-name manufacturers, "particularly where it is unclear what the impact of such a potentially enormous shift in liability may have on the development of new drugs." Zofran, 2017 WL 3448548, at *14.

Appellant's desired rule would also be fundamentally unfair and inconsistent with the congressional intent underlying the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetics Act. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. The Hatch-Waxman Amendments were enacted to "expand access to affordable generic drugs by reducing barriers to generic market entry," Huck, 850 N.W.2d at 356, and did so by allowing generic manufacturers to duplicate approved brand-name drugs and their labels. These amendments "emerged from Congress' efforts to balance two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." Abbott Labs. v. Young, 920 F.2d 984, 991 (D.C. Cir. 1990). Making brand-name manufacturers liable for harm that was not caused by their drugs will, however, have exactly the opposite effect. See Schwartz, Goldberg & Silverman, Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects, 81 Fordham L. Rev. 1835, 1870 (2013) ("Saddling 10 percent of a market with 100 percent of its liability is certain to create new and

significant financial pressures on brand-name drugs, the effects of which would harm health care consumers.").

Pursuant to the Hatch-Waxman Amendments, generic manufacturers can avoid the expenses associated with researching, developing, testing, seeking FDA approval for, and marketing new drugs, thereby allowing them to bring their drugs to market at lower prices. Given that the statutory scheme is designed to encourage brand-name manufacturers to continue to develop new and useful drugs, it strains credulity to argue that Congress also intended for brand-name manufacturers to bear all liability for injuries caused by name-brand and generic versions of their drugs.

Nor does the Supreme Court's preemption decision in Mensing warrant a different result. Federal law may well deal consumers of generic drugs an "unfortunate hand," 564 U.S. at 625, in that "a person injured by a generic drug cannot normally sue either the manufacturer of the product (that is, the generic manufacturer) or the creator of the label (that is, the brand-name manufacturer)." Zofran, 2017 WL 3448548, at *4. But that is the compromise that Congress struck in order to balance the incentives to research, develop, and obtain approval for life-saving drugs and to encourage the marketing of lower-cost generic versions. The impossibility of redress from

the third-party generic manufacturer due to federal preemption does not justify redress from an entity against whom the plaintiff cannot allege (much less satisfy) the elements of the tort in question, any more than would be the case were the generic manufacturer insolvent or otherwise judgment proof. The fact that Merck manufactures Proscar and is financially stable does not justify holding it responsible for the products of others. See Schwartz, supra, 81 Fordham L. Rev. at 1872 ("Compensation alone . . . is not a sufficient reason for establishing tort liability."). While Appellant may view the result in this case as "arbitrary and unfair" (Appellant's Br. 24), that is not a reason for this Court to drastically expand tort law beyond its underpinnings to allow failure-to-warn claims against brand-name manufacturers based on injuries they did not cause from products they did not make.

Rather, any objection to this lack of legal remedy is properly directed towards the structure of the federal statute and regulations governing drug labeling requirements and abbreviated new drug applications. The appropriate manner in which to address this lack of available legal remedy is through congressional or FDA action aimed at revising the applicable provisions that the Supreme Court interpreted in Mensing. See Huck, 850 N.W.2d at 380

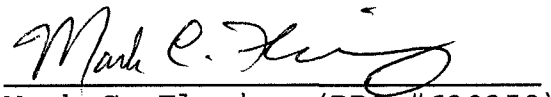
(finding that any "unfairness resulting from Mensing is best addressed by Congress or the FDA"). Indeed, one such change is potentially underway.[3]

CONCLUSION

For the foregoing reasons, this Court should conclude that a brand-name drug manufacturer may not be held liable for injuries caused by a version of the drug that is manufactured and sold by a third party.

[3] In response to the Court's holding in Mensing, the FDA proposed a rule that would allow generic drug manufacturers to update their labeling regardless of any such changes made by the brand-name manufacturer. See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (Nov. 13, 2013); 80 Fed. Reg. 8,577 (Feb. 18, 2015). This rule would "create parity among application holders with respect to these safety-related labeling changes by permitting [generic manufacturers] to distribute revised generic drug labeling that differs in certain respects . . . from the [name-brand drug's] labeling." Fed. Reg. 67,985. This would relieve the generic manufacturers of the "duty of sameness" discussed in Mensing, 564 U.S. at 616, potentially ending the federal preemption of claims against generic manufacturers based on their drugs' warning labels.

October 10, 2017 Respectfully submitted,



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CERTIFICATE OF SERVICE

I, Mark C. Fleming, hereby certify, under the penalties of perjury that on October 10, 2017, I caused true and accurate copies of the foregoing to be filed in the office of the clerk of the Supreme Judicial Court and served two copies upon the following counsel by electronic and overnight mail:

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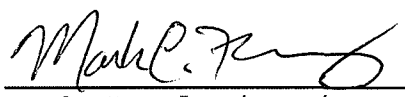

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MASSACHUSETTS RULE OF APPELLATE PROCEDURE 16(K) CERTIFICATION

I hereby certify that, to the best of my knowledge, this brief complies with the Massachusetts Rules of Appellate Procedure that pertain to the filing of briefs.

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