

Innovator Liability in Massachusetts: What is the fate of the learned intermediary doctrine?

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The Supreme Judicial Court's recent opinion in *Rafferty v. Merck & Co., Inc.*, 479 Mass. 141, 92 N.E.3d 1205 (2018) has led to a high volume of discussion about the implication of the SJC's decision to allow purchasers of generic pharmaceutical products to bring suit against the brand name manufacturer (or innovator) under certain circumstances. The *Rafferty* decision presents a host of concerns for defendants, including the fate of the learned intermediary doctrine in "innovator liability" claims in Massachusetts. This concern is raised by the court's willingness to look away from traditional product liability principles in place of a general negligence theory of recovery for innovator liability claims. "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 is responsible under a theory of products liability. See, e.g., *H.P. Hood & Sons, Inc. v. Ford Motor Co.*, 370 Mass. 69, 75, 345 N.E.2d 683 (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...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..." *Rafferty*, 92 N.E.3d at 1213.

In assessing the general negligence claim, the *Rafferty* decision speaks in terms that suggest a duty to directly warn consumers in innovator liability claims in Massachusetts, which stands in contrast to a traditional pharmaceutical product liability claim where the manufacturer's duty is to warn the prescribing physician, not the patient. *Rafferty* notes: "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, 131 S.Ct. 2567; *Mitchell v. Sky Climber, Inc.*, 396 Mass. 629, 631, 487 N.E.2d 1374 (1986)." (emphasis added). It is notable that the Massachusetts precedent cited by the court is not a case involving a pharmaceutical product, but rather one involving a piece of construction equipment. The court appears to be envisioning an innovator liability claim in Massachusetts as akin to any other product liability claim, despite the fact that a pharmaceutical product is at issue. *Rafferty* makes no mention of the fact that Massachusetts has adopted the learned intermediary doctrine where the allegation is a failure to warn of the risks of a prescription medication.

Rafferty's silence on the role of the learned intermediary doctrine in innovator liability cases leads one to question if the doctrine is being cast aside in the innovator liability context, or if it was simply overlooked. Concern is raised by the SJC's prior willingness to create an exception to the principal that a pharmaceutical manufacturer's duty to warn runs to the prescribing physician, not the patient/consumer. Of note, in *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65 (1985) the court was asked to determine if the manufacturers of oral contraceptives owed a direct duty to consumers to warn of the dangers inherent in their use. The court ultimately held that oral contraceptives bear "peculiar characteristics" which warrant a common law duty to warn users directly

of the their risks. 475 N.E.2d at 69. The *Rafferty* decision leaves open the possibility of another exception to the learned intermediary doctrine in the “peculiar” circumstance of a plaintiff being permitted to sue a defendant for general negligence even though the plaintiff did not use the defendant’s pharmaceutical product. The court is cognizant of the uniqueness of such a claim: “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.” *Rafferty*, 92 N.E.3d at 1215.

If the requirements of product liability are being cast aside, does the learned intermediary doctrine go with them? It should not. The learned intermediary doctrine in pharmaceutical product liability cases remains imbedded in Massachusetts law (and around the country), despite the rare exception carved out in *MacDonald*. See, e.g. *Liu v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 230 F.Supp.3d 3 (D. Mass. 2017) (applying learned intermediary doctrine in failure to warn claim regarding prescription medication Pradaxa). Creating an exception to the learned intermediary doctrine in the context of innovator liability would turn a blind eye towards the realities of the doctor-patient relationship, which were recognized by the SJC in *MacDonald* when it stated that “a patient’s involvement in decision-making concerning use of prescription drug necessary to treat a malady is typically minimal or nonexistent” 475 N.E.2d at 69. Even in the context of a generic prescription, the prescribing physician remains the true consumer of the warning and decision-maker. Accordingly, there is no good reason to abandon the learned intermediary for innovator liability claims in Massachusetts, claims which should be doomed in any event by the high burden of proof articulated in *Rafferty*.