Massachusetts Becomes the First State in the Country to Recognize a Unique Form of Innovator Liability Based on "Reckless" Conduct

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By Peabody & Arnold on March 21, 2018

Manufacturers of brand-named pharmaceuticals can now be sued in Massachusetts by plaintiffs who claim that they have been injured by a generic version of the branded drug. In an opinion released last week, the Massachusetts Supreme Judicial Court ("SJC") endorsed a unique cause of action against branded pharmaceutical manufacturers for injuries caused by a generic drug, where the manufacturer has engaged in "reckless disregard of an unreasonable risk of death or grave bodily injury." *See Brian Rafferty v. Merck et al.*, Civ. A. No. SJC-12347, (Mar. 16, 2018). *Rafferty* places Massachusetts in a decided minority of courts that have imposed any duty on brand-name pharmaceutical manufacturers to warn generic consumers.

Ever since the Supreme Court ruled in 2011 that federal drug regulations require preemption of state failure to warn claims by consumers of generic drugs against generic drug manufacturers, individuals who have sustained injuries as a result of ingesting a generic drug have been barred from obtaining compensation for their injuries from the manufacturer of the drug. *See PLIVIA v. Mensing,* 564 U.S. 604, (2011); *See also Mutual. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013). The *Rafferty* Court, sought to rectify what it perceived as a "public policy" issue, by doing what state and federal legislatures have opted not to do in the seven years since *Mensing*; it created a cause of action to provide generic consumers with a remedy for injuries sustained from generic drugs. However, because the current regulatory framework does not allow for recovery against generic manufacturers, the common law cause of action carved out by *Rafferty* targets manufacturers of brand-named medications or "innovators."

The *Rafferty* Court recognized that the imposition of liability on a brand name manufacturer for injuries caused by a generic drug is inconsistent with established product liability law:

> [U]nder…prevailing law, [the branded manufacturer] owes [the plaintiff] 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 that product.

(citations omitted) *Rafferty* at *4. The Court also acknowledged that there are significant policy concerns inherent in allowing negligent failure to warn claims against brand-name manufacturers in cases where the drug in question is a generic. Specifically, the Court cautioned that the breadth and uncertain scope of the standard for negligent failure to warn would provide broad latitude for plaintiffs to bring failure to warn claims and limited avenues for defeating such claims before trial. The court remarked, that brand-name manufacturers faced with such claims would be forced to shoulder the "significant cost not only of compensating injured consumers, but also of litigating their claims, meritorious or not." *Id.* at *7.

Nonetheless, *Rafferty* departed from established product liability law and carved out a cause of action

pursuant to which "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." *Id.* at *10. In other words, the manufacturer "will be held responsible for the resulting harm" where the manufacturer "*intentionally* fails to update the label on its drug to warn of an unreasonable risk of death or grave bodily injury" and "knows of this risk or knows of facts that would disclose this risk to any to reasonable person." *Id.* at11. The Court reasoned that "by limiting liability to circumstances where there has been reckless disregard of an unreasonable risk of death or grave bodily injury, [it] adequately address[ed]" policy concerns that have driven other courts to deny innovator liability." *Id.* at 12.

The full impact of the *Rafferty* carve-out on branded manufacturers will now rest largely on the trial courts' interpretation of the terms "*unreasonable* risk of death" and "grave bodily injury." If courts take a permissive approach and allow claims to make it through the pleading stage with a broad interpretation of these terms, branded manufacturers will undoubtedly be forced to shoulder the same unreasonable burdens that would have been present had the Court imposed liability for negligent failure to warn; namely the "significant cost not only of compensating injured consumers, but also of litigating their claims, meritorious or not." Some insight into just how "limited" the *Rafferty* carve-out will actually be construed should be available shortly, as the Court remanded *Rafferty* to the trial court with instructions that the plaintiff be granted leave to amend his complaint in 30 days if he "believes he can state facts sufficient to support" a recklessness claim.

