*~ This Month's 1st Article ~*

## Rafferty Recklessness: Supreme Judicial Court Limits, But Declines to Dismiss, Suit Against Pharma

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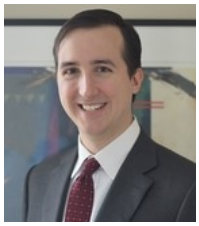

Breaking from the majority of jurisdictions in the United States, the Supreme Judicial Court has issued a ruling which leaves open the door for significant future litigation against brand-name pharmaceutical drug manufacturers. On March 16, 2018, the Supreme Judicial Court issued its decision in Brian Rafferty v. Merck & Co., SJC 12347. Judge Kenneth J. Fishman, Middlesex Superior Court, granted a Motion to Dismiss, and the Supreme Judicial Court, on its own initiative, transferred the case from the Appeals Court. The issue on appeal was "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." The Massachusetts Defense Lawyers Association, among others, submitted an amicus brief authored by Cetrulo LLP attorneys Lawrence G. Cetrulo, Kyle E. Bjornlund, Elizabeth S. Dillon, and Brian D. Fishman.

Under Federal law, manufacturers of generic drugs must include on their product a warning label which is identical to the label of the brand-name drug. Plaintiff Rafferty brought a common-law negligence claim and a 93A claim against Defendant Merck after suffering a side effect from use of a generic version of finasteride, which bore the warning label created by the Merck for its brand-name version of finasteride.

The Rafferty Court held that a user of a generic drug could not bring a negligent failure to warn claim against the brand-name manufacturer. The Court found that imposing liability for negligence on brand-name drug manufacturers for products which they did not create would impose unreasonable additional costs for products which the brand-name manufacturer no longer produces. Generally, these costs would not be incurred until after the brand-name manufacturer's patent monopoly expires, at which point the brand-name drug manufacturer will have suffered a precipitous decline in sales of its products. Further, the overall sales of generic drugs would likely far outweigh the total sales of the brand-name drug. And brand-name manufacturers would have no ability to share the costs of litigation with generic manufacturers, given that generic drug manufacturers are all but immune from suit. Therefore, since the brand-name manufacturers are not in the best position to bear these costs, the Court refused to recognize negligence liability against them because it would "impose on brand-name manufacturers an additional 'cost of production' for products that, in reality, they no longer produce." Rafferty v. Merck & Co., 479 Mass. 141, *8 (2018), citing Restatement (Second) of Torts, § 402A comment c.

However, because this would leave Plaintiffs with no route to recovery for any injuries suffered from use of generic drugs, the Court stated that while ordinary negligence might be excused, reckless behavior causing injuries would not be tolerated. Therefore, while a generic drug consumer cannot bring a general negligence claim against a brand-name manufacturer for failure to warn, "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." Rafferty, 479 Mass. 141, *10 (2018). The Rafferty court reached this result despite the fact that the plaintiff had not alleged recklessness in his complaint and despite the fact the issue had not been raised in the briefs. The Court remanded the case to the Superior Court, with instructions that he be granted leave to amend his complaint to add a claim for recklessness within 30 days.

In eliminating ordinary negligence, but preserving the possibility of bringing claims for recklessness, the Court sought to balance "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." Rafferty, 479 Mass. 141, *10 (2018).

At a minimum, this decision creates a new hurdle for pharmaceutical companies to overcome when seeking an early dismissal of claims brought by users of generic drugs, and it may allow Plaintiffs to proceed at least to the discovery stage against drug manufacturers with whom they have had no contact and from whom they have purchased no products if they are able to plead sufficient facts to set forth a claim for recklessness. While it seems improbable that Rafferty will have far-reaching effects outside of the world of pharmaceuticals, the high number of pharmaceutical companies who are at home or do significant business in Massachusetts will need to contend with the costs resulting from this decision.

Finally, the Court affirmed the motion judge's ruling dismissing the plaintiff's G.L. c. 93A claim against Merck. The Court concluded that "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 G.L. c. 93A to hold that such failure occurred 'in the conduct of any trade or commerce.'"