Massachusetts Creates First-In-Nation Recklessness Standard For Claims Against Brand-Name Drug Manufacturers By Users Of Generics

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March 21, 2018

In a case of first impression, the Massachusetts Supreme Judicial Court ("SJC") held in *Rafferty v. Merck & Co.*, No. SJC-12347 (Mar. 16, 2018), that the manufacturer of a brand-name prescription drug can be liable for reckless failure to warn a user of the drug's generic equivalent.

Plaintiff allegedly experienced sexual dysfunction during and after discontinuing use of generic finasteride, the equivalent of Merck's Proscar®. Plaintiff sued Merck, alleging its warning of the risk of sexual dysfunction failed to disclose the side effect could continue after stopping the drug. Although plaintiff never used Proscar®, he argued it was foreseeable to Merck that failing to update its warning would harm users of generic equivalents, since under the Federal Food, Drug and Cosmetic Act ("FDCA") generic drugs are required to use the same warning label as the brand-name drug.

After the trial court dismissed plaintiff's claim, the SJC granted direct appellate review to decide whether Massachusetts would recognize the doctrine of "innovator liability," under which the manufacturer of the original brand-name, *i.e.*, innovator, drug can be held liable for harm to users of generic equivalents. The question is of considerable significance because the United States Supreme Court has ruled that the FDCA preempts failure-to-warn claims against manufacturers of generic drugs, as they are unable to control the content of their warning labels. Thus, absent innovator liability, users of generic drugs—roughly 90% of the prescription drug market—have no recourse for harms caused by those products.

In its opinion, the SJC acknowledged the conflicting public policy concerns affecting innovator liability. Allowing innovator liability under a negligence standard would create "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." Moreover, such costs would be unusually burdensome because once a generic is introduced, the branded manufacturer's market share typically falls to about 10%, yet it would be required to bear the liability and litigation costs of the entire market. Despite these effects, the SJC asserted it was "difficult to accurately assess whether, and to what extent, this would have a chilling effect on [pharmaceutical] innovation."

On the other hand, recognizing innovator liability "would have undeniable benefits," including making drugs safer by giving branded manufacturers incentives to diligently update their labels even after generic equivalents were introduced, and affording generic users a remedy for harms caused by the drugs.

Ultimately, the SJC attempted to balance the conflicting policy concerns by holding 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." The court distinguished recklessness from mere negligence on two grounds: the "reckless conduct must be *intended*," and it "must involve a *substantially greater risk* than is required for ordinary negligence." Thus there must be a "conscious choice of . . . action, either with knowledge of the serious danger . . . or . . . of facts which would disclose this danger to any reasonable man." And there must be "a high degree of probability that substantial harm will result," or "the harm must be a probable consequence" of defendant's conduct.

Applying its new standard, the SJC vacated the dismissal of plaintiff's complaint and remanded to afford him the opportunity to plead a recklessness claim. The court did affirm dismissal of plaintiff's unfair or deceptive practices claim under Mass. Gen. L. ch. 93A, since Merck's labeling conduct did not occur in the course of any "trade or commerce" with respect to a plaintiff who did not use Merck's drug.

Notably, neither party argued for the recklessness standard recognized by the SJC or had any opportunity to brief the appropriateness of that standard. While the court likely believed it was creating only a limited avenue for innovator liability claims, plaintiffs' counsel can be expected to allege recklessness in virtually every case, and this prospect is heightened by *Rafferty*'s considerable ambiguities. Thus while the court defined recklessness as involving a "high degree of probability" of harm, or its being "a probable consequence," the court also spoke of an "unreasonable risk," the language of mere negligence. And although the court insisted recklessness requires risk of "death or grave bodily injury," the court permitted plaintiff to re-plead even though his claim involved a continuation of sexual dysfunction about which he had been warned.

Under *Rafferty*, brand-name manufacturers should expect an increase in litigation in Massachusetts. In light of the opinion's ambiguities, trial courts may also be reluctant to dismiss such claims at the pleading stage, forcing manufacturers to incur litigation costs at least through discovery and summary judgment, if not trial.

It is unclear whether other jurisdictions will now follow Massachusetts' lead. Until now, state and federal courts had overwhelmingly rejected innovator liability. The doctrine had been accepted by the high courts of just two states, California and Alabama, and the latter result was promptly reversed by the state legislature. But claims are pending before several courts, including the West Virginia Supreme Court, and the ostensible "middle ground" offered by *Rafferty* may prove tempting to some of those tribunals.

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