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2009 Massachusetts Avenue, NW
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202.588.0302 wlf.org

Deep Pocket Jurisprudence Swayed Massachusetts High Court in Pharma "Innovator Liability" Case

by Victor E. Schwartz

Rafferty v. Merck & Co., Inc., 92 N.E.3d 1205 (Mass. 2018) posed the Supreme Judicial Court of Massachusetts with a dilemma. Should the court follow the California Supreme Court's ruling in *T.H. v. Novartis Pharmaceuticals Corp.*, 199 Cal. Rptr. 3d 768 (2018), and impose liability on the manufacturer of a branded drug for harms caused by a competitor's generic product? Or should it follow the multitude of decisions, including that of the Iowa Supreme Court in *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014), and reject such a blatant transfer of liability from a responsible party to a third party?

The Massachusetts court struggled mightily to render a Solomonic decision. In attempting to do so, however, it awkwardly split the baby, ending up with an unjust and unwieldly result that will churn litigation costs and may encourage Litigation Tourism™—namely trips to the state by plaintiff lawyers seeking to avail themselves of the court's decision.

The Massachusetts high court fully understood that black-letter product liability law limits a manufacturer's responsibility to harms caused by a product it made or authorized. Nevertheless, the *Rafferty* court permitted an end-run around that standard by allowing a claim predicated on recklessness. The court never acknowledged that the prestigious American Law Institute (ALI), which literally created modern product liability law in its 1965 Restatement (Second) of Torts § 402A, came to understand over the next three decades that the vague standard it created became a litigation machine. For that reason, ALI adopted the Restatement of Torts (Third): Products Liability (1998) with a fundamental premise: have one set of rules for product liability.

The Restatement (Third) arose from a decade of study and development and the consensus of judges, law professors, and both plaintiffs' and defendants' counsel. It drew a hard line around product liability law; not only that product liability claims are to be brought only under product liability law, but that manufacturers were only to be responsible for products they made or authorized.

In *Rafferty*, the court recognized that completely open-ended, negligence-based law, with its broad and subjective foreseeability requirement, would be too extreme a measure for manufacturers of a branded drug whose generic competitor allegedly caused harm. The court understood that imposing liability for a copycat version of a drug it invented could chill a branded manufacturer's decision-making on future products. The opinion observed "the additional costs" of such a liability shift and noted that the uncertainty regarding the liability's scope and duration "would inevitably affect to some degree the financial incentives to invest in the research and development of new drugs." *Rafferty*, 92 N.E.3d at 1217. Further, the court acknowledged that "studies have shown that, on average, the process of developing and obtaining FDA approval for new drugs takes ten to fifteen years and costs $2.6 billion, and only a small fraction of compounds under development are ever approved." *Ibid*.

Victor E. Schwartz is Co-Chair of the Public Policy Group of Shook, Hardy & Bacon L.L.P., practicing in the firm's Washington, DC office. He is a Life Member of the American Law Institute.

Despite its clear grasp of the high stakes for branded companies, the court proceeded to subject the defendant to liability anyway. It was Rafferty's policy argument, unsupported by fact, that won the court's support: without tort law exposure, branded companies would have little incentive to improve their warnings. That argument does not hold water. Existing law provides significant fines and penalties for the failure of branded companies to inform FDA about a pharmaceutical product's serious adverse side effects—particularly when it acts recklessly. In fact, post-patent, generic companies, not branded companies, are in the best position to protect consumer safety because they control 90% of the market. They are subject to the same fines and penalties.

The court did attempt to cabin future litigation against branded drug companies to only the most extreme reckless behavior. In an effort to explain the stringency of its recklessness standard, the court referenced cases involving the duty of care landholders owe trespassers. Landholders' duty to trespassers is limited to refraining from willful and wanton misconduct. For example, a landholder would be liable for a trespasser's injuries if they were caused by a hidden spring gun the landowner set in his backyard.

In addition to analogizing its recklessness standard to the high bar trespassers must hurdle, the court explained that liability should be imposed on branded drug makers only if the plaintiff faced "unreasonable risk of death" or suffered "grave bodily injury." *Id*. at 1209. "Grave bodily injury" is not a standard tort-law term, so courts and juries in future drug-liability cases will have little guidance beyond *Rafferty* in interpreting it. Whether Rafferty faced "grave bodily injury" from Merck's alleged failure to warn is certainly open to dispute. The drug he took, finasteride, was prescribed for complications from an enlarged prostate. The generic version of the drug warned that its use in some cases might cause sexual dysfunction. Rafferty alleged in his lawsuit that the warning did not explain that the side effect could continue after he discontinued treatment.

No matter how well-intentioned the *Rafferty* court's efforts to set clear parameters for "recklessness" may have been, the term remains slippery and open to interpretation. Some Massachusetts lower court judges, moved by compassion for an injured plaintiff may deny branded drug defendants motions to dismiss on the ground that they did not engage in "reckless" conduct and let the emotion-filled claim be decided by a jury. That type of judicial decision making will force businesses that did not produce or sell the product at issue into a Hobson's choice: take a chance that the actual facts will prevail or settle.

Once one digests and sets aside all of the Supreme Judicial Court's sympathetic statements about the risks of prescription drug development and its sincere efforts to limit its holding, *Rafferty* boils down to yet another instance of *deep pocket jurisprudence*. The court believed the plaintiff had been wronged, and because the generic drug company had an absolute preemption defense, someone had to pay, and that someone was deep-pocketed Merck. To make the point clear, the court noted that decisions in a number of cases that ruled against innovator liability came down before the U.S. Supreme Court's decision in *Pliva v. Mensing*, 564 U.S. 604 (2011), which held that the product-liability failure-to-warn claims against generics were preempted. *Id*. at 1221.

In rejecting innovator liability in 2014, the Iowa Supreme Court invoked "deep pocket jurisprudence," condemning the blame-shifting legal theory as "law without principle."* The Massachusetts court should have adopted that same reasoning regardless of whether the liability standard involved negligence or recklessness.

Tort law builds by precedent. Massachusetts courts are now in the situation where plaintiffs can search for defendants who can pay even if they bore no practical responsibility for the injury. Are automobile manufacturers to pay for the cost of judgment proof drunk drivers? Are innocent companies to pay for harm when the real wrongdoer is bankrupt? Unfortunately, the Massachusetts court did not provide much guidance on these questions. It is now up to the state's lower courts to make sure they draw liability lines in the right places and not open the door to unprincipled litigation.

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* *Huck*, 850 N.W.2d at 380 (Iowa 2014)(quoting Victor E. Schwartz, Phil Goldberg & Cary 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, 1872 (2013)).

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