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Some in the legal profession may have been surprised by the Supreme Judicial Court's landmark decision in *Rafferty v. Merck & Co.* in 2018, imposing a duty on the manufacturers of brand-name drugs to warn consumers of the risk of their drugs' generic counterparts.

But Sharon lawyer Emily E. Smith-Lee knew from the start that she had a significant legal issue on her hands when she began representing Brian Rafferty in 2012.

In August 2010, a doctor prescribed Finasteride — originally sold by Merck under the name Proscar — to treat Rafferty's enlarged prostate. Shortly after he began taking the generic form of the drug, Rafferty began to experience side effects that only worsened when he weaned himself off it.

Rafferty was eventually diagnosed with hypogonadism and androgen deficiency, for which his treatment may continue indefinitely.

The generic form of the drug Rafferty took bore a warning label identical to Merck's label for Proscar.

Pursuant to the 1984 Hatch-Waxman amendments to the Food, Drug and Cosmetic Act, the manufacturer of a brand-name drug is solely responsible for ensuring that the warning label is adequate and accurately reflects the latest information about possible side effects. The manufacturer of a generic drug merely needs to ensure that its label mirrors that of its brand-name counterpart.

In 2013, Smith-Lee filed suit on Rafferty's behalf against his doctor and Merck, asserting claims of negligence for failure to warn and a violation of G.L.c. 93A, §9. A trial court judge granted Merck's motion to dismiss, and the SJC transferred the case from the Appeals Court on its own motion.

With a fair amount of pharmaceutical defense under her belt, Smith-Lee was well aware of the challenges in facing off against a company such as Merck.

"Sometimes you encounter an interesting and problematic piece of the law in the middle of the case, but we knew from the beginning what freight train was coming down the tracks," she says.

That train stopped for Smith-Lee and her client when the SJC agreed that Rafferty and other generic drug consumers should have some form of legal recourse against brand-name manufacturers.

By adopting the minority rule — recognized by only a handful of other jurisdictions — the court held that companies like Merck can be liable under a common-law recklessness claim if they intentionally fail to update a label despite knowing or having reason to know of any unreasonable risk of death or grave bodily injury.

For Smith-Lee, the victory was the logical outcome.

"Sometimes you believe you are right and hear the other side and adjust your lens a little bit," she says. "In this case, there was just no way I could get my head around the idea that under our tort law, no remedy exists for 80 percent of the people taking a drug."

Photos by Merrill Shea

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How did you approach the case, knowing you had a big issue on your hands?

We very intentionally did not bring a product liability claim and instead solely alleged a negligent failure to warn. Facing a growing tidal wave of decisions favoring the manufacturers in this category in federal court, we spent two years fighting the battle about remanding the case to state court after Merck removed it. We understood it was important that the state courts decide this issue.

What was the oral argument before the SJC like?

The stakes seemed so much higher and it felt like a higher level of gravity. There were quite a few amicus briefs submitted by industry-friendly organizations and just us on the plaintiff side.

But I knew things were going to be OK when 30 to 40 seconds into Merck's argument, Chief Justice [Ralph D.] Gants stopped their attorney and said, "Imagine if the facts were different and you manufactured a drug called thalidomide … ."

Did you have mixed feelings about the SJC ruling, since the justices closed the door on a failure to warn case but allowed common-law recklessness claims for plaintiffs?

Very little mixed feelings, as I am extremely proud of our work and the result. In the end, they split the baby to a certain extent. Although the opinion does not allow ordinary negligence, it still makes us one of three jurisdictions that does recognize some path to accountability for generic drug users. Things happen in steps, and I would take the result we got any day of the week.

Is it unfair to place the burden to warn consumers of generics on the makers of brand-name drugs?

Understand that all of the major pharmaceutical players are in both markets, with brand-name drugs and generic lines. There is not some community of generic drugmakers separate from brand-name makers. For every one instance of a brand-name manufacturer paying liability for another company, they will receive the same windfall with regard to one of their generics.

And yes, it is fair because [the brand-name manufacturers] are the only ones who can fix [the labels].

Though the SJC affirmed dismissal under Chapter 93A, the justices did so with leave to amend based on their ruling. What is the status of the case now?

We will be dismissing the case after reaching a confidential resolution. Somebody else can test the SJC position. I expect plaintiffs' lawyers are taking a hard look at their cases to see if they fit within the goalposts of the decision, and we will see [another case] the next time there is a clear, knowing failure to warn by a brand-name drugmaker.

Or I suppose it is up to the manufacturers, who could just start providing adequate warnings and then we wouldn't see any more cases.

— Correy E. Stephenson

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