VIEWPOINT

Legal Liability of Generic vs Brand Drug Manufacturers for Inadequate Product Labels

Marcia M. Boumil, JD, LLM
Department of Public Health and Community Medicine, Tufts University School of Medicine, Boston, Massachusetts.

Gregory Curfman, MD
Program on Regulation, Therapeutics, and Law (PORTAL), Brigham and Women's Hospital, Boston, Massachusetts; and Deputy Editor, *JAMA*, Chicago, Illinois.

Corresponding Author: Gregory Curfman, MD, Deputy Editor, *JAMA*, 330 N Wabash Ave, Chicago, IL 60611 (gregory.curfman@jamanetwork.org).

Massachusetts is the latest of state highest courts to address the issue of "innovator liability": brand-name pharmaceutical manufacturers who are exposed to legal liability for generic forms of their brand products that cause injuries to consumers. In *Rafferty v Merck & Co Inc* (2018),[1] the Massachusetts Supreme Judicial Court addressed a claim against Merck based on failure to warn of an adverse drug effect brought by a patient, Brian Rafferty, who took finasteride, a generic version of Merck's brand-name drug Proscar. Generic finasteride was prescribed to the plaintiff to treat an enlarged prostate. Almost immediately after starting the drug, Rafferty experienced symptoms of erectile dysfunction and decrease in libido, and despite weaning of finasteride, the symptoms persisted. The product label for finasteride warned of the potential adverse effect of sexual dysfunction but also reported that it would resolve if the drug were discontinued. Rafferty alleged that Merck had information in its possession that the adverse effect could persist even if the drug were discontinued and had even changed the label for Proscar in several non-US markets but failed to do so in the United States. The legal question in the case is: Should brand companies be held liable for harm resulting from a generic counterpart that they did not produce?

Generic manufacturers are required by law to maintain a label identical to the brand's label when marketing their drug.[2] A key feature of the federal law governing drug product labeling is that brand manufacturers must ensure that the label is adequate, accurate, and up to date, and generic manufacturers are obligated to use an identical label. The brand manufacturer is also obligated to monitor drug safety after receiving US Food and Drug Administration (FDA) approval to market the drug and to modify the label warnings when necessary as new safety data become available.

Why not sue the generic manufacturer? In *PLIVA Inc v Mensing* (2011),[3] the US Supreme Court held that a consumer of a generic bioequivalent of a brand-name product may not bring a claim against a generic drug manufacturer stemming from failure to warn of an adverse drug effect because the FDA controls the warning label and generic manufacturers have no authority to modify the label. Thus, legal action against the generic company was preempted. Furthermore, the US Supreme Court in *Mutual Pharmaceutical Co v Bartlett* (2013)[4] held that state law claims against a generic manufacturer alleging design defects based on inadequacy of the warning in the label are also preempted by the FDA regulations. In both cases, the patients harmed by adverse effects of generic drugs had no legal recourse based on the drug label's failure to warn of these adverse effects.[5] At this point, only Congress could change this situation by writing new law. Whether generic manufacturers should be expected to investigate the accuracy of the labels for the drugs they are marketing does not currently appear to be required by law. For example, in the case of *Rafferty v Merck & Co*, the generic manufacturer could have discovered that Merck had changed the label in a number of non-US markets.

In light of the FDA regulatory environment, a number of state courts have addressed the issue of whether a consumer injured by a generic drug should be able to bring legal action against a brand manufacturer that negligently, recklessly, or intentionally fails to warn of known adverse drug effects that cause injury. Massachusetts is the latest court to join a minority of courts holding that a brand-name manufacturer failing to update its warning label with relevant safety information may be held liable. The standard in Massachusetts is not one of mere negligence but requires recklessness or intentionality. The court justified its decision on the basis of public policy concerns for the safety of consumers while also considering the legal burden on brand-name manufacturers.

In December 2017, California became the first state to embrace the doctrine of innovator liability when the Supreme Court in *T.H., a Minor, etc, et al, Plaintiffs, and Appellants v Novartis Pharmaceuticals Corp*[6] held that a brand-name manufacturer incurs a duty to warn consumers that extends to its generic counterparts, even though the brand manufacturer did not produce the generic product. In this case, it was alleged that a mother's ingestion of the generic drug terbutaline to prevent preterm labor resulted in her twins developing autism. Holding that the brand-name manufacturer as innovator of the drug has a duty to warn consumers of the generic counterpart, the California court held that it was foreseeable that such consumers would rely on its label and the brand manufacturer was in the best position to warn of harmful effects and modify an outdated label. In reaching its conclusion, the court relied on the rationale of a previous California case, *Conte v Wyeth*.[7]

Garner v Johnson & Johnson et al[8] is another state decision from the Central District of Illinois allowing innovator liability for failure to warn of injury by a consumer of Johnson & Johnson's generic antibiotic counterpart, fluoroquinolone. In *Garner v Johnson & Johnson et al*, the plaintiff sued both the brand and generic manufacturers. The claim against the generic manufacturer was dismissed on the basis of FDA preemption under *PLIVA Inc v Mensing*, but the court denied a motion to dismiss as to Johnson & Johnson, holding that the brand has the "unilateral ability to strengthen the label," and

failure to do so resulting in injury can give rise to liability under state law. The decision stood, even though an overwhelming majority of courts confronting such claims have denied them. A similar Illinois decision in *Dolin v GlaxoSmithKline LLC* permitting innovator liability is currently on appeal to the Seventh Circuit.[9] And in *Kellogg v Wyeth*,[10] a Vermont federal district court held that under Vermont law, a brand manufacturer has a duty to maintain an adequate drug label. The court decided it was reasonably foreseeable that a physician would rely on a brand's label, even when, in this case, it was the pharmacist who substituted a bioequivalent generic. However, when the Alabama Supreme Court held that a brand manufacturer could be held liable for injuries caused by a generic counterpart, the Alabama legislature immediately countered with legislation overturning that decision. The vast majority of courts that have confronted this issue have declined to impose liability on the brand manufacturer. With more than 80% of today's prescriptions filled with generic drugs, courts have been reluctant to impose huge potential new liability without legislative approval.

Nevertheless, a limited number of states, including Massachusetts and California where drug innovation is vital to state economies, are concerned about public policy considerations for injured plaintiffs who have no recourse except from the brand manufacturer. In cases such as *Rafferty v Merck & Co Inc*, in which the brand manufacturer possessed information that might have led it to update the label—and failed to do so—such policy issues are compelling. An FDA rule proposed in 2013 that would have allowed generic manufacturers to update product labels to reflect new drug safety developments received significant push-back, and no final rule has been published to date. In the light of the FDA's failure to act, the state court opinions endorsing innovator liability are especially important.

Currently in most jurisdictions, both generic and brand companies are protected from legal liability stemming from failure-to-warn claims. Thus, it is a troublesome feature of current law that a patient harmed by a generic drug may have no legal recourse to pursue a failure-to-warn claim. Congress should fully consider this issue and fill the gap in the current legal framework through legislation.

ARTICLE INFORMATION

Published Online: July 23, 2018. doi:10.1001/jama.2018.8408

Conflict of Interest Disclosures: The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Disclaimer: Dr Curfman is Deputy Editor of *JAMA* but was not involved in any of the decisions regarding review of the manuscript or its acceptance.

REFERENCES

1. *Rafferty v Merck & Co Inc*. Massachusetts Supreme Judicial Court SJC-12347 (March 16, 2018).

2. Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Amendments), 21 USC §355j (1984).

3. *PLIVA Inc v Mensing*, 564 US 604, 131 S Ct 2567 (2011).

4. *Mutual Pharmaceutical Co v Bartlett*, 570 US 472, 133 S Ct 2466 (2013).

5. Boumil MM, Curfman GD. On access and accountability—two Supreme Court rulings on generic drugs. *N Engl J Med*. 2013;369(8):696-697. doi:10.1056/NEJMp1308368

6. *T.H., a Minor, etc, et al, Plaintiffs, and Appellants v Novartis Pharmaceuticals Corp*. Supreme Court of California S233898 (December 21, 2017).

7. *Conte v Wyeth*, 85 Cal Rptr 3d 299 (Cal Ct App 2008).

8. *Garner v Johnson & Johnson et al*. Illinois Central District Court Case No. 3:2018cv00067.

9. *Dolin v GlaxoSmithKline LLC*, 269 F Supp 3d 851 (ND Ill 2017), docketed in the US Court of Appeals for the Seventh Circuit, 17-3030.

10. *Kellogg v Wyeth*, 762 F Supp 2d 694 (D Vt 2010).