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Pharmaceutical Warnings: A Changing Landscape

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Can brand-name drug companies face failure-to-warn lawsuits from patients who take generic versions of their products? If the innovator stops making the drug, but generics continue to sell, is the brand-name manufacturer forever liable? How much control should generic manufacturers have over the drug labels on their products? How should the pharmaceutical industry warn the public of potential side effects when advertising their products directly to consumers?

These questions are being addressed by the U.S. Food and Drug Administration, and by courts across the country. The Seventh Circuit recently declined to weigh in on the issue of innovator liability, but the high courts of California, Massachusetts, and West Virginia have recently resolved the innovator liability issue in their states, and a federal district court in Massachusetts has applied the law of eight states in a multidistrict litigation.

Meanwhile, a group of generic manufacturers involved in another MDL are pushing back on false marketing lawsuits brought against them by Native American tribes, arguing they cannot be liable for the opioid epidemic on the basis of false marketing because they do not advertise their products. And, outside of the courtroom, several proposed changes to generic drug labeling and advertising could influence product liability preemption for generic drug manufacturers moving forward.

The Innovator Liability Theory in Failure-to-Warn Claims

The "innovator liability" theory in failure-to-warn claims arose in response to two United States Supreme Court preventing lawsuits against generic drug companies.[1] In *PLIVA Inc. v. Mensing*, the court held that the FDA's regulations that require a generic drug's label to mirror its brand-name counterpart preempt the generic drug manufacturer's state law duty to update the label and warn of newly discovered side effects.[2]

The high court found that it would be impossible for a generic manufacturer to meet its duty under state law while also complying with FDA regulations.[3] The court continued in *Mutual Pharmaceutical Company v. Bartlett* to hold

that patients' state-law design-defect claims that depend on a drug's warnings are preempted by federal law under Mensing when those patients' claims are asserted against a generic manufacturer and not the brand company.[4]

The bottom line from both of these cases is that generic drug manufacturers are insulated from liability for failing to meet certain duties requiring them to warn consumers of the potential side effects of their drugs. Under the innovator liability theory, brand-name manufacturers are responsible for injuries caused because of insufficient warnings on the labels of generic versions of their drugs. Several courts, including, most recently, the Seventh Circuit, have addressed the innovator liability theory, with varying outcomes.

State Supreme Court Decisions — Mixed Results in California, Massachusetts, and West Virginia

In the past year, the supreme courts of three states, California,[5] Massachusetts[6] and West Virginia,[7] have addressed innovator liability. In *T.H. v. Novartis Pharm. Corp.*, a lawsuit was brought on behalf of twin minors who allegedly sustained injuries in utero as a result of their mother's off-label use of a generic asthma medication to slow or stop premature labor.[8]

The California Supreme Court found under California state law that brand-name manufacturers have a duty to warn consumers of generic versions of their drugs for two reasons. First, the court stated, it was foreseeable that Novartis's failure to update the warning label could harm fetuses exposed to a generic version of the drug in utero.[9] Second, in the court's opinion, "public policy supports imposing a duty of care on brand-name manufacturers because the brand-name manufacturer is the only party with the practical and legal ability to warn about product risks."[10]

Even further, the court held that brand-name drug companies can face innovator liability even after they stop manufacturing or selling their drug if "the injury was foreseeable at the time the brand-name manufacturer held the NDA."[11] The court reasoned that because a successor drug manufacturer has to use the former manufacturer's warning label—or one at least as strong as the one used by the previous brand-name manufacturer—unless directed by the FDA, it was foreseeable that a successor could continue to use the label it inherited, even if it was deficient.[12]

In *Rafferty v. Merck & Co.,* the plaintiff took a generic form of Proscar, a drug used to treat benign prostatic hyperplasia.[13] After experiencing long-term side effects, Rafferty sued Merck, the manufacturer of Proscar, for negligence, failure to warn and unfair or deceptive acts.[14] As the Massachusetts Supreme Court noted, "As a general rule of products liability law…a manufacturer's duty of care runs to those who buy or use the product itself, not a different product."[15]

However, "Rafferty did not bring a products liability claim and [did] not contend that Merck owed him a duty to warn as a manufacturer," instead relying on general principles of tort law. The court held that brand-name manufacturers owe a duty to generic drug users not to act recklessly, but not a duty not to act negligently.[16]

Basing its decision on public policy grounds, the court wrote that there is "a certain irreducible minimum duty of care, owed to all persons—that as a matter of public policy cannot be abrogated: that is, the duty not to intentionally or recklessly cause harm to others."[17] Defining recklessness in this context as a brand-name manufacturer "intentionally fail[ing] to update the label on its drug, knowing or having reason to know of an unreasonable risk of death or grave bodily injury associated with its use," the court recognized that it is "in the minority of courts that have decided this issue" and the only court to set a standard of recklessness.[18]

Then, just as it seemed the innovator liability theory was becoming more accepted, the West Virginia Supreme Court rejected the theory. In *McNair v. Johnson & Johnson*, the plaintiff developed acute respiratory distress syndrome after taking a generic version of Levaquin, and filed a lawsuit claiming failure to warn and negligent misrepresentation.[19] The court determined he had no claim against Johnson & Johnson, stating: "[W]e decline to deviate from our traditional products liability law in order to extend the duty of brand manufacturers to those

allegedly injured by a competitor's product."[20]

Citing cases from the Fifth, Sixth, Eighth, Tenth, and Eleventh Circuits, the court noted that all federal circuit courts that have considered innovator liability have rejected innovator liability under the laws of different states.[21] The court also based its decision on a West Virginia statute governing failure-to-warn suits which refers to a "manufacturer or seller," reasoning that the statute "incorporates this Court's long-standing restriction of products liability to the manufacturer and seller of the allegedly injury-causing product."[22]

Federal Multidistrict Litigation — Rejecting Innovator Liability in Several States

A federal court in Massachusetts overseeing multidistrict litigation regarding GlaxoSmithKline's drug, Zofran, has dismissed nine plaintiffs' innovator liability claims in two decisions under the law of eight states.[23] In its 2017 decision, the court dismissed six plaintiffs' claims under Georgia, Indiana, Kentucky, New York, and Oklahoma law, noting that most but not all courts have rejected the innovator liability theory.[24]

The court's decision analyzed the law in each of the six states and stated that "for each of the jurisdictions, there is case law suggesting, often strongly so, that dismissal is appropriate."[25] Its 2018 decision recognized that "[s]ince the issuance of the Court's opinion on August 4, 2017, three state supreme courts (in California, Massachusetts, and West Virginia) have issued opinions on that topic," with California and Massachusetts allowing innovator liability and West Virginia rejecting it.[26] Still, after analyzing Connecticut, New Jersey, and Oklahoma law, the court dismissed the three plaintiffs' claims.[27]

Dolin v. GlaxoSmithKline LLC — The Seventh Circuit Declines to Decide Innovator Liability

Most recently, the Seventh Circuit overturned a jury verdict based on the innovator liability theory without deciding the legitimacy of the theory itself, making its decision on federal preemption grounds instead.[28] The jury had found GlaxoSmithKline liable for failure to warn because an individual committed suicide while taking the generic version of GSK's anti-depressant Paxil, which contained allegedly insufficient warnings on its label about suicide risk.[29]

Even though the decedent took a generic version of Paxil, the district court allowed the plaintiff to move forward against GSK with an innovator liability theory, finding that GSK held a duty of reasonable conduct for the benefit of the plaintiff.[30] In finding this duty, the court relied on the fact that under federal regulations, only GSK is allowed to cure defects in the drug's warning label. Since GSK was alleged to have been negligent with its version's design and warning label, this negligence would contribute to a risk of harm to the consumers of the generic version and any of its variants.

Finding that the FDA would have rejected a warning about increased risk of suicide in adult patients, and that GSK lacked new information that would have allowed it to add such a warning under FDA regulations, the court held that Wendy Dolin's state-law failure to warn claim was preempted by federal law.[31] Because the issue of federal preemption was "decisive," and noting that "Illinois courts have not yet considered" the innovator liability theory, the court declined to predict whether Illinois courts would impose a duty on brand-name drug manufacturers towards patients who take generic forms of their drugs.[32] Dolin filed requested rehearing and rehearing en banc, but those requests were denied.[33]

False Marketing Claims Against Generic Drug Manufacturers in the Opioid Crisis

Eight generic drug manufacturers recently filed motions to dismiss false marketing claims brought against them by Native American tribes in federal multidistrict litigation in Ohio in an attempt to hold them accountable for the opioid epidemic. The tribes claimed that "all manufacturers made false misrepresentations about opioids to unidentified prescribers and consumers."[34]

The manufacturers argued that the tribes' false marketing theory must fail, because the tribes failed to "plead facts both to show that each Generic Manufacturer engaged in promotional activity and to provide the specific details of the supposed fraud."[35] Indeed, generic companies generally do not advertise their products the way brand-name companies do, and the tribes could not "identify a single interaction between any Generic Manufacturer and any prescriber...a single false or misleading statement made by any Generic Manufacturer; or a single opioid prescription that was somehow written because of a false or misleading statement made by any Generic Manufacturer."[36]

Additionally, the generic defendants argued that the tribes' state law false advertising claims fail because they are preempted by federal law. Stating that FDA regulations require generic warnings to be identical to their brand-name counterparts, and citing Mensing and Bartlett, the defendants argued that "state law claims requiring generic drug manufacturers to communicate information beyond the content of their labels are impliedly preempted because, in doing so, generic drug manufacturers would violate federal law."[37]

Because the tribes did not allege that the generic manufacturers promoted generic opiates, they argued, the tribes' claims are based "only on the failure to disclose more than what is in the labels for those generic medicines" and are thus preempted.[38] The court has not ruled on the generic manufacturers' motion, but its decision will be significant in evaluating how false marketing claims against generic companies will be handled.

Potential Changes to FDA Regulation of Generic Drug Labeling

In 2013, the FDA proposed a rule that would have allowed generic drug manufacturers to put additional safeguards on their drugs and allow them to change their drug labels in the event of new developments regarding their drugs' safety.[39] After previously stating that the proposed rule would be issued in April 2018, the FDA decided not to include it in the Office of Management and Budget's July 20, 2017, or May 10, 2018, unified regulatory agendas, which list planned regulatory actions for the following year.[40] Though the proposed rule has not been permanently withdrawn, it is unlikely to be adopted in the foreseeable future.

The FDA is considering a different generic drug labeling rule, however. FDA Commissioner Scott Gottlieb has said that the agency is "looking for ways to keep generic drug labels up-to-date with the latest information about each medicine's safety and benefits."[41] Rather than allowing all generic drug manufacturers to alter the warning labels on their drugs, though, the FDA apparently wants to make sure generic drug labels continue to be updated after the brand-name manufacturer stops making the reference listed drug. Such a rule would not replace the 2013 proposed rule, but would address a different issue entirely.

Pharmaceutical Warnings: A Changing Landscape

For drug makers—brand-name and generic—pharmaceutical warnings and the way they are regulated and litigated are changing. Depending on the state, brand-name manufacturers may face failure-to-warn suits for generic versions of their products, even if they have stopped making their product. Meanwhile, generic companies may soon be forced to shoulder the responsibility of updating the warnings on drugs where the brand-name manufacturer stops making the reference listed drug, and they will soon learn if they can face false marketing claims, despite their lack of marketing. All pharmaceutical manufacturers should continue to pay heed to the courts and the FDA as they answer the questions brought by these developments.

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[1] PLIVA Inc. v. Mensing, 564 U.S. 604 (2011); Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013).

[2] Mensing, 564 U.S. at 618.

[3] Id.

[4] Mutual Pharmaceutical Company v. Bartlett, 133 S. Ct. at 2470.

[5] T.H. v. Novartis Pharm. Corp., 407 P.3d 18 (Cal. 2017).

[6] Rafferty v. Merck & Co., 92 N.E.3d 1205 (Mass. 2018).

[7] McNair v. Johnson & Johnson, No. 17-0519, --- S.E.2d ----, 2018 WL 2186550 (W. Va. May 11, 2018).

[8] 407 P.3d 18 at 22.

[9] Id. at 40.

[10] Id. at 47.

[11] Id. at 44.

[12] Id. at 41.

[13] 92 N.E.3d at 1211.

[14] Id. at 1213.

[15] Id. (internal quotations omitted).

[16] Id. at 1218.

[17] Id.

[18] Id. at 1209, 1220.

[19] 2018 WL 2186550, at *3.

[20] Id. at *8.

[21] Id.

[22] Id. at *10.

[23] In re Zofran (Ondansetron) Prod. Liab. Litig., 261 F. Supp. 3d 62 (D. Mass. 2017); In re Zofran (Ondansetron) Prod. Liab. Litig., MDL No. 1:15-md-2657-FDS, 2018 WL 2317525 (D. Mass. May 21, 2018).

[24] 261 F. Supp. 3d at 69.

[25] Id. at 80.

[26] 2018 WL 2317525 at *2.

[27] Id. at *4-6.

[28] Dolin v. GlaxoSmithKline LLC, No. 17-3030, --- F.3d ----, 2018 WL 4001208 (7th Cir. Aug. 22, 2018).

[29] Dolin v. SmithKline Beecham Corp. , 62 F. Supp. 3d 705, 710, 720 (N.D. Ill. 2014).

[30] Id. at 715.

[31] Dolin, 2018 WL 4001208, at *16-17.

[32] Id. at *25.

[33] Dolin v. GlaxoSmithKline LLC, No. 17-3030, Dkt. 71 (7th Cir. Sept. 20, 2018).

[34] Memorandum of Law In Support of Generic Manufacturers' Motion to Dismiss Plaintiff's First Amended Complaint at 6, In re National Prescription Opiate Litigation, No. 1:17-md-02804 (N.D. Ohio Aug. 31, 2018).

[35] Id. at 1-2.

[36] Id. at 1-2.

[37] Id. at 3.

[38] Id.

[39] Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985 (Nov. 13, 2013).

[40] Bronwyn Mixter, FDA's Generic Drug Labeling Rule Delayed Again, BNA Health Care Blog (Aug. 4, 2017); Office of Mgmt. and Budget, Executive Office of the President, Agency Rule List — Spring 2018, Department of Health and Human Services (May 10, 2018).

[41] U.S. Food and Drug Admin., Remarks from FDA Commissioner Scott Gottlieb, M.D., as prepared for testimony before a U.S. Senate Committee on Appropriations on FDA's Fiscal Year 2019 budget (April 24, 2018).
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