

Pharmaceuticals

Product Liability Preemption for Generic Drug Manufacturers—The Current Landscape (Corrected)

Recent cases suggest brand-name manufacturers are protected by the First Amendment when making truthful, promotional statements about off-label uses for their drugs, attorneys Christopher B. Essig, Schuyler Ferguson, and Jaime Simon say. The authors discuss recent rulings, as well as a pending Seventh Circuit case examining the “innovator liability theory” in failure to warn cases.



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Recently, pharmaceutical giant GlaxoSmithKline (GSK) filed an appeal of the trial judge's decision to deny the company judgment as a matter of law and a new trial in a wrongful death case.

The jury found GSK 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.

Even though the decedent took a generic version of Paxil, the court allowed the plaintiff to move forward against GSK with an innovator liability theory. But, as courts work through innovator liability cases, many recent proposals aim to change the way generic pharmaceuticals are labeled and advertised, which, in turn, could have an impact on the way failure to warn cases are litigated in the years to come.

I. The Innovator Liability Theory in Failure to Warn Claims

The Seventh Circuit will soon examine the “innovator liability theory” in failure to warn claims, as brand-name drug manufacturer GlaxoSmithKline (GSK) is appealing a key judgment in the Northern District of Illinois imposing innovator liability

on GSK. *Dolin v. GlaxoSmithKline, LLC*, Case No. 17-3030 (7th Cir. appeal docketed October 3, 2017). Under the innovator liability theory, brand-name manufacturers are responsible for injuries caused by insufficient warnings on the labels of generic versions of their drugs. In examining this issue, the Seventh Circuit will need to determine whether a brand-name company can be liable for damage caused by a drug it did not produce, but for which it controlled the content of the warnings.

A. SCOTUS Precedent Preempts Failure to Warn Claims Against Generic Manufacturers

Two cases from the United States Supreme Court, *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), set the stage for how patients who take a generic version of a drug will fare when they file a products liability lawsuit. In *Mensing*, the Court held that FDA regulations requiring 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. The Court found it would be impossible for a generic manufacturer to meet its duty under state law while also complying with FDA regulations. The Court continued in *Bartlett* to hold that state-law design-defect claims based 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. The bottom line from both of these cases is that generic drug manufacturers are insulated from liability, and logically so, for failing to meet certain duties requiring them to warn consumers of the potential side effects of their drugs.

B. The Loophole: Innovator Liability in California, Illinois, and Vermont

Even though patients have been unable to maintain product liability claims directed against generic drug manufacturers, they have been successful in some jurisdictions suing brand-name manufacturers for injuries arising from consumption of a generic drug under a theory of "innovator liability." Currently, only three states recognize the theory, including California, Illinois, and Vermont.

Conte v. Wyeth, a 2008 California case, started the trend of innovator liability theories. In *Conte*, a state appellate court considered a generic consumer's claim for negligent misrepresentation against a brand-name manufacturer. 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008). The plaintiff developed a neurological condition after consuming a generic drug for a significant period of time. She sued the brand-name and generic manufacturers alleging that the manufacturers' warnings failed to adequately warn of possible dangers from long-term consumption. The court held that the brand-name manufacturer had a duty of care not only to consumers of its own drug, but to consumers whose doctors will foreseeably rely on the brand-name manufacturer's warnings, even if the patient eventually takes the generic version of the drug.

Likewise, in *T.H. v. Novartis Pharm. Corp.* 199 Cal. Rptr. 3d 768, 770 (Cal. Ct. App. 2016), another California appellate court opened the door for a brand-name manufacturer to be liable under a negligent failure to warn claim where a patient consumed the generic counterpart to a brand-name drug. The T.H. court refused to follow other California courts, which had not held brand-name manufacturers liable for injuries caused by generics. According to the court, T.H. fell within a California Supreme Court-recognized exception for harm to which a defendant's product substantially contributes.

The key Illinois case addressing innovator liability is *Dolin v. GlaxoSmithKline LLC*, a Northern District of Illinois case currently on appeal to the Seventh Circuit. 2017 BL 324401 (N.D. Ill. 2017); *Dolin v. GlaxoSmithKline, LLC* Case No. 17-3030 (7th Cir. appeal docketed October 3, 2017). In *Dolin*, the jury found GSK, the brand-name manufacturer of Paxil, liable for negligence and fraudulent misrepresentation where the plaintiff's husband died shortly after taking paroxetine, the generic version of Paxil. In its decision denying summary judgment, the court recognized that GSK, in its capacity as the brand-name manufacturer, controlled the design and warning label for both Paxil and paroxetine because federal regulations dictate that a generic manufacturer use its brand-name counterpart's design and warning label. *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 716 (N.D. Ill. 2014). As a result, the court found that GSK had a duty of reasonable conduct for the benefit of the plaintiff. 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 the generic version's design and warning label, this negligence contributed to a risk of harm to consumers of the generic version and any of its variants.

Dolin was a significant departure from prior Illinois case law, which established that there is no duty for manufacturers to warn about the risks of a competing product. *Pluto v. Searle Laboratories*, 690 N.E.2d 619, 621 (Ill. App. 1997). In 2015, an Illinois appellate court even noted in dictum the numerous courts that have denied plaintiffs the opportunity to sue brand-name manufacturers after consuming the generic versions to brand-name drugs. *Guvenoz v. Target Corp.*, 30 N.E. 3d 404, 409 n.1 (Ill. App. 2015) ("The 'overwhelming' majority of courts have held that generic consumers may not sue the brand-name manufacturer."). Even more, the Sixth Circuit criticized the *Dolin* court's summary judgment decision in *In re Darvocet, Darvon, & Propoxyphene Products Liability Litigation*, 756 F.3d 917, 944-45 (6th Cir. 2014), stating that Illinois law requires plaintiffs to identify the supplier of a product and establish a causal connection between her injury and the product. The court also noted

that the Dolin court did not consider the difficulty for a brand-name manufacturer to guard against a non-foreseeable injury. Given the choice between an interpretation that expands liability and one that restricts it, the court found that the narrow path was the reasonable choice. Considering the judicial response, the Dolin decision seems to stand as an outlier in the grand scheme of Illinois product liability litigation.

Similar to the situation in Illinois, a federal district court in Vermont moved away from Vermont precedent by expanding liability to brand-name manufacturers for injuries to consumers of generic drugs. In *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010), the court addressed a negligent misrepresentation suit against a brand-name manufacturer. There, the plaintiff was diagnosed with tardive dyskinesia, the same condition as the plaintiff in Conte, after consuming the generic version of Reglan for four years. The court found that under Vermont negligence law, it was reasonably foreseeable that a physician would rely on a brand-name manufacturer's representations when prescribing a drug to a patient, even if the pharmacist eventually filled the plaintiff's prescription with a generic drug. Thus, the manufacturer's duty of care to physicians was not limited simply because the patient received the generic version of a brand-name drug.

In contrast, many states have enacted statutes to define the scope of permissible actions against manufacturers. See e.g., See La. Stat. Ann. §9:2800.52; Ky Rev. Stat. Ann. §411.300. For example, the Alabama legislature responded to *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 670-88 (Ala. 2014), an Alabama Supreme Court decision recognizing innovator liability by statutorily eliminating the theory altogether. See Ala. Code §6-5-530(a). Thus, there is a trend away from innovator liability.

II. The Future of Generic Drug Warnings

While state and federal courts throughout the country began to clarify how to address theories of innovator liability, there was a push by consumer advocacy groups for the FDA to provide a way for generic drug manufacturers to add safeguards by allowing generic manufacturers to change their drug labels in the event of new developments regarding their drugs' safety. For example, a proposed FDA rule, Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985 (Nov. 13, 2013), "proposed FDA rule", addressed generic drug labeling. This proposed rule was repeatedly pushed back until the agency finally announced that it expected the final rule to be published in April of 2017. To date, no such rule has been published, and under the new FDA Commissioner, Scott Gottlieb, it is unclear that this rule will be final any time soon.

In an opinion piece in the Wall Street Journal, Gottlieb tarnished the generic warnings rule, calling it a "political sop to the trial bar." According to Gottlieb, the rule would require generic manufacturers to "clutter" their labels with defensive warnings to avoid being plagued with failure to warn suits. In addition, Gottlieb referenced the American Enterprise Institute's Alex Brill to speculate that the legal fees incurred because of this regulation will add over \$5 billion to annual healthcare costs, with that number rising to \$8.6 billion by 2024. Commissioner Gottlieb's current efforts aim to work more generic drugs into the market to lower the price of drugs. Passing a rule that opens the door to imposing liability on generic drug manufacturers may counter his current efforts by serving as a deterrent for many generic manufacturers.

Meanwhile, restrictions are loosening on manufacturers' ability to communicate with doctors and insurance companies about off-label uses for their drugs. In 2012, the Second Circuit held in *United States v. Caronia*, 703 F.3d 149, 168 (2d Cir. 2012) that for the Federal Food, Drug and Cosmetic Act (FDCA) and FDA regulations to avoid infringing on the First Amendment, they must be construed "as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs" where the off-label use itself is lawful. Citing *Caronia*, a federal district court held in *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 224 (S.D.N.Y. 2015) that truthful, off-label communications are protected by the First Amendment. Outside the courtroom, Arizona recently became the first state to permit by statute "truthful promotion of an off-label use of a drug, biological product or device." See Ariz. Rev. Stat. Ann. §32-1997(a) (2017).

These developments beg the question: as brand-name manufacturers are given more latitude to speak about their products, will the rights of generic manufacturers follow? Even though the potential FDA rule granting generic drug-makers the ability to modify their warning labels appears to be dead for now, will those manufacturers, at some point, be given more leeway to speak about their products?

III. The FDA's Proposed Rule on Direct-to-Consumer Advertisements

In addition to label warnings, brand-name manufacturers are required to warn consumers of the side effects of their drugs in any Direct-to-Consumer (DTC) advertisements. The FDA recently released a proposed rule to change the disclosure requirements for pharmaceutical DTC ads. [Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements; Establishment of a Public Docket; Request for Information and Comments, 82 Fed. Reg. 160 (Aug. 21, 2017).]

The FDA proposed moving to a “limited risks plus disclosure strategy” in an effort to help consumers better understand drug side effects. Rather than listing every possible danger, this strategy would only require DTC advertisements to warn patients of “severe,” “serious,” and “actionable” risks. According to the FDA’s definitions, a “severe” risk is life-threatening, a “serious” risk could lead to hospitalization, and an “actionable” risk is “a risk the patient would know... or recognize... and can act upon to help mitigate the risk.” In addition to warnings about “severe,” “serious,” and “actionable” risks, DTC advertisements would be required to disclose that other risks and side effects exist and advise consumers to talk with their doctor and read the labeling for more information.

In effect, the FDA is simplifying DTC ads, trying to make them more consumer-friendly. But, as ads are simplified, it is difficult to determine how consumers will respond. Will consumers suggest the simplified DTC ads fail to provide adequate warning of the risks associated with a particular pharmaceutical? How will these changes impact generic pharmaceuticals? Although generic drug-makers benefit from the DTC advertising of the brand-name versions of a product, they rarely advertise their drugs to consumers directly.

IV. Pharmaceutical Warnings: A Landscape in Flux

For pharmaceutical manufacturers, brand-name and generic, there are a number of unanswered questions about the state of pharmaceutical warnings. In DTC ads, brand-name manufacturers may be able to provide fewer warnings. But brands also may face failure-to-warn liability for both their products, and, depending on the forum-court’s view of innovator liability theories, for generic pharmaceuticals as well. Currently, generic companies may not make additional or altered warnings on their drugs’ labels, even though it seemed just months ago that the FDA might create an avenue for them to do so. Nevertheless, recent cases suggest brand-name manufacturers are protected by the First Amendment when making truthful, promotional statements about off-label uses for their drugs. Given the current, shifting landscape, it is important to continue to monitor the courts and FDA as they answer these questions.

(Second from last paragraph corrected to note that generic companies may advertise directly to consumers but rarely do so).