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DRUG SAFETY LABELING: GENERIC VERSUS BRANDED

By: Louis Fogel & Peter H. Hanna

The proliferation of generic drugs largely has been hailed as an economic and consumer triumph. In 2013, more than 85% of all prescriptions in the United States were filled by generic drugs. Under FDA regulations, generic drugs must be chemically equivalent, have the same active ingredients, and be bioequivalent to their branded counterparts. However, the requirements for safety labeling on branded and generic drugs differ in important ways. Most notably, while a branded drug manufacturer is responsible for the accuracy and adequacy of its drug label, a generic drug company is responsible for ensuring that its warning label is the same as the label of the brand-name reference listed drug (RLD).

As the Supreme Court stated in *Bartlett v. Mutual Pharm*, “generic drug manufacturers have an ongoing federal duty of ‘sameness.’” In fact, under the Federal Food, Drug, and Cosmetic Act (FDCA) framework, a generic drug company may not alter its product’s safety labeling – even if a new side effect or safety issue becomes known — except to mimic changes made to the RLD’s labeling, or unless ordered by the FDA. Consumer advocates have contended that this “sameness” requirement for generic labeling could put consumers’ health at risk given that new drug safety issues are often not discovered until after a new drug has been sold to the public, or sometimes even after the branded drug is off the market.

Supreme Court Blocks State Claims Against Generic Drug Companies For Inadequate Safety Labeling

Despite the FDCA’s sameness requirement, consumers have attempted to sue generic manufacturers on state-law failure-to-warn and inadequate labeling claims. However, the United States Supreme Court has held that these state claims are preempted by federal law. For instance, in 2011, the Supreme Court ruled in *PLIVA v. Mensing* that the plaintiff’s failure-to-warn state law claims against generic manufacturers were preempted by the FDA’s prohibition on changes to generic drug labels. The Court in *PLIVA* acknowledged that it “makes little sense” to bar state law-based suits against generic drug makers while allowing the same exact claims to proceed against the brand name entities, but added that its duty was not “to decide whether the statutory scheme established by Congress is unusual or even bizarre.” Several Justices dissented, warning that the majority decision would “have troubling consequences for drug safety,” and could result in “[t]hree out of four patients in America [losing] . . . the right to sue for inadequate warnings.”

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Two years after PLIVA, the Supreme Court decided another case involving allegations of inadequate generic drug labeling. In *Bartlett v. Mutual Pharm.*, Karen Bartlett, a user of the generic version of Clinoril (the branded version of the anti-inflammatory drug sulindac) sued Mutual Pharmaceutical, a generic drug maker, after she suffered a rare hypersensitivity reaction resulting in disfigurement and blindness. After Mutual removed the case to federal court, a New Hampshire jury found Mutual liable on Bartlett's state law design-defect claim, and awarded her over \$21 million, a decision later affirmed by the Court of Appeals for the First Circuit. While acknowledging that Bartlett's case was "tragic and evoke[d] deep sympathy," the Supreme Court nonetheless overturned the verdict, finding that "it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label."

Outcry Among Consumer Advocates

The decisions in PLIVA and *Bartlett* made clear that generic drug makers are typically not liable for failing to disclose potential risks on their safety labels that are not listed on RLD labels because federal law does not permit generic drug makers to update their warnings independently. By extension, generic drug companies would not be liable for inaccurate, out-of-date, or misleading safety warnings on their drug labels, provided that they were also found on the RLD label.

Consumer advocates have raised a number of concerns with this regulatory scheme. They contend that generic drug makers may have a reduced incentive to be vigilant about updating product hazards. Also, consumer advocates argue, this problem may be exacerbated in situations where the generic entrant pushes the branded drugs out of the market, because the "innovator company" would be more likely to monitor new reports of adverse effects and undertake additional research to update RLD labeling.

Moreover, even if a generic drug company becomes aware of safety concerns with its product, it would be unable to update the warning label immediately without running afoul of federal law. If a generic drug maker is first to discover a safety problem, unknown to the branded drug maker or the industry at large, the generic company could notify the FDA, but it would then have to wait for the FDA and branded drug maker to implement labeling changes before the generic drug's labeling could follow suit. Unlike brand name drug manufacturers, who can update drug labeling via a "changes being effected" (CBE) supplement without waiting for the FDA to review the new safety information, generic drug makers may change their labels only to match an updated RLD label or to follow the FDA's instructions — as part of their "ongoing federal duty of 'sameness.'"

FDA's Efforts To "Create Parity" Between Generic and Branded Drug Makers Are Challenged and Delayed

The FDA has tried to address this labeling conundrum, but with little success thus far. In November 2013, largely in response to the Supreme Court decisions in PLIVA and *Bartlett*, the FDA proposed a rule that would require generic drug companies to submit — just like brand name drug makers — a "changes being effected" (CBE-0) supplement to revise labeling of generic drugs. A CBE-0 supplement would serve to reflect and distribute new safety information in advance of the FDA's review of the labeling change, regardless of whether the revised labeling differs from the RLD labeling. In announcing this proposed rule, the FDA emphasized the public health benefits and also stressed that the new rule would "create parity" between brand-name drug makers and generic drug companies.

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The FDA's proposed rule came under immediate and extended scrutiny from both policymakers and generic drug companies. They pointed out that the new rule would run contrary to the FDCA's requirement that a generic drug have labeling that "is the same as the labeling approved for the listed drug." The proposed rule has also been criticized as undermining the legislative intent of the Hatch-Waxman Act, which sought to strike a balance between encouraging innovators to create new drugs and providing expeditious entry into the market for generic alternatives. Another criticism of the proposed rule is that it could result in a situation where the warning label for a generic version of a drug differs in material respects from the warning label for the same, bioequivalent branded drug.

In addition, the Generic Pharmaceutical Association (GPHA) has argued that the new rule would have a negative economic impact on consumers. It published a white paper in early 2014 warning that the FDA's proposed rule change could increase product liability litigation to such an extent that consumer spending on generic drugs would increase by \$4 billion. Moreover, in a separate survey of 450 medical professionals, the GPHA found that 81% of those surveyed believed that FDA approval should be required prior to generic drug safety label changes, while 68% doubted they would even have the time required to keep current with labeling changes that would occur under the new FDA rule.

The FDA initially intended to publish its final rule in 2014, but announced last November that "a great deal of public input from various stakeholders during the comment period on the proposed rule" would delay finalization of the rule until late 2015.

Generic Consumers' Product Liability Claims Against Branded Drug Makers Often Fail

In light of the protection that the FDCA's sameness requirement affords to generic drug makers for mislabeled or inadequately labeled generic drugs, plaintiffs' lawyers have also attempted to bring suit against the brand name drug manufacturers — even when the underlying injury resulted from consumption of the generic, rather than the branded version of a given drug. Most commonly, consumers of generic drugs seeking to assert claims against brand name drug makers have chosen to advance negligent misrepresentation or related claims sounding in tort. However, the majority of these claims have been rejected by courts across the country.

A leading decision addressing this type of claim is the 1994 case of *Foster v. American Home Products*, in which the plaintiff asserted a negligent misrepresentation claim against the brand name drug maker when an infant died after ingesting the generic version of the prescription drug Phenergan. The Fourth Circuit Court of Appeals affirmed the district court's dismissal of the claim, holding that "there is no legal precedent for using a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products, over whose production the name brand manufacturer has no control." The court emphasized the unfairness of such a basis for liability, explaining that it "would be especially unfair when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising." In the 20 years since the Fourth Circuit ruling in *Foster*, the decision has proven to be a roadblock to generic consumer claims against branded drug makers. Indeed, in 2013, in *Guarino v. Wyeth*, the Eleventh Circuit Court of Appeals observed that the "overwhelming national consensus — including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question," have essentially followed the logic of *Foster*, i.e. that "a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product."

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Nevertheless, some courts have questioned the reasoning in *Foster*. For example, in *Conte v. Wyeth*, a California appellate court in 2008 held that a brand-name drug maker could be liable for injuries suffered by a consumer who purchased a generic form of the branded drug if the injuries were foreseeably caused by negligent or intentional misrepresentation by the brand-name drug maker. The Court explained that “[a]s the foreseeable risk of physical harm runs to users of both name-brand and generic drugs, so too runs the duty of care.” The Court was also unmoved by the “fairness” argument that the *Foster* court found compelling, asking: “[W]hat is unfair about requiring a defendant to shoulder its share of responsibility for injuries caused, at least in part, by its negligent or intentional dissemination of inaccurate information?” Ultimately, the *Conte* court concluded that “[t]he fact that Wyeth did not manufacture or sell the [generic drug that the plaintiff] . . . ingested does not relieve Wyeth from its general duty to use due care in disseminating product information to those it knows or should know are likely to be harmed as a result of their physician’s reliance on that information.”

More recently, in an August 2014 decision in *Wyeth v. Weeks*, a majority of the Alabama Supreme Court found the *Foster* court’s “fairness” reasoning to be flawed, and concluded that under Alabama law, “a brand-name-drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company.” However, several Alabama Supreme Court justices submitted dissents questioning the majority’s reasoning, one going as far as saying the decision went against the “overwhelming national consensus” and a “mountain of authority.”

The Effect on Consumers

Where does this all leave consumers of generic drugs who suffer injuries as a result of inadequate drug safety labels?

First, consumers have limited recourse against generic drug manufacturers since federal law requires generic drug makers labels to mimic branded drug maker labels. However, a generic drug maker does not have complete immunity for inadequate labeling – even a generic drug company will be liable for failing to timely implement a change to its warning label that the RLD has already adopted.

Second, while some generic labeling consumer claims against branded drug makers have been successful, those cases are rare, and often involve allegations of negligent or intentional misrepresentation by the branded drug maker in the first instance.

Third, the FDA’s proposed new rule on generic labeling faces significant hurdles, including both substantive and economically-based criticisms. Although the various stakeholders in the safety labeling discussion seem to agree that the proper regulatory framework must put public health and patient safety issues first, the path to that destination remains fraught with uncertainty.

ABOUT THE AUTHORS



LOUIS E. FOGEL

Louis E. Fogel is a partner in the Chicago office of Jenner & Block and assists clients in sophisticated patent litigation matters across industries including pharmaceuticals, biological drugs, medical devices, chemicals and computer electronics. He counsels clients in all aspects of patent litigation, advises clients in connection with Hatch-Waxman Act litigation and analyzes patents for validity and infringement purposes. He also has experience with patent counseling and negotiating and drafting settlement agreements. He received his law degree from the University of Chicago Law School, his PhD in chemistry from the University of Chicago, his Master's Degree in Chemistry from the University of Wisconsin and his B.A. in chemistry, Phi Beta Kappa, from Hamline University.



PETER H. HANNA

Peter H. Hanna is a senior associate in the Chicago office of Jenner & Block. Mr. Hanna has litigated in many complex patent cases across a broad array of diverse technologies, from pharmaceuticals and medical imaging devices to semiconductors and tablet PCs. An electrical engineering graduate of Cooper Union for the Advancement of Science and Art, he received his law degree, *magna cum laude*, from Benjamin N. Cardozo School of Law, where he served as articles editor of the *Cardozo Law Review*.

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