New Jersey Law Journal

VOL. 215 - NO 5 MONDAY, FEBRUARY 3, 2014 ESTABLISHED 1878

IN PRACTICE

# PRODUCTS LIABILITY

# Plaintiffs Without a Remedy: Federal Preemption and Generic Pharmaceuticals

## The FDA is attempting to eliminate this legal anomaly

**By Martin P. Schrama and H. Matthew Taylor**

The expansion of the pharmaceutical industry as a whole has spawned a commensurate increase in pharmaceutical manufacturer liability litigation. However, recent developments in the pharmaceutical industry and the controlling legal standards have given rise to a legal anomaly. Based upon a legal loophole created by the interplay between federal and state law, a valid claim against a brand-name pharmaceutical manufacturer cannot be maintained against a generic pharmaceutical manufacturer—despite the fact that the pharmaceutical product is exactly the same.

### Generic Medications in the United States

The Federal Food, Drug and Cosmetic Act (FDCA) requires manufacturers of pharmaceutical medications to gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce. A new brand-name drug requires the manufacturer to submit a new-drug application (NDA) to the FDA. The NDA application process is lengthy, demanding, and highly regulated.

The process of approving generic drugs is simpler. Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the "Hatch-Waxman Act," to govern the generic application and processing procedures. Under the Hatch-Waxman Act, a generic drug may be approved without the same level of clinical testing if the generic drug is identical to the brand-name drug in several ways. Specifically, the proposed generic drug must be chemically equivalent to the approved brand-name drug; it must be the "bioequivalent" (sharing an identical absorption rate) to the approved brand-name drug; and it must share identical labeling with the approved brand-name drug. In fact, federal regulations currently prohibit generic manufacturers from making any unilateral changes to a drug's label, instead requiring the label to remain consistent with the brand-name drug.

Over the past decade, health insurers, large employers and major healthcare providers have led the switch to generic drugs, due to their significantly lower cost—often about 80 percent less than the brand-name equivalent. The use of generic prescription medications continues to proliferate. Last year, 84 percent of all prescriptions in the United States were dispensed as generics, with some states requiring pharmacists to dispense the generic version of a drug unless a doctor affirmatively specified otherwise. Studies show that the use of generic medications reduced U.S. health-care spending by $1 trillion over the past decade, saving $193 billion in 2011 alone. Due to these cost-cutting benefits, consumers are increasingly prescribed generic versions of otherwise well-known brand-name medications. Based on this growing influx of generic medications into the market place, the legal system's treatment of generic drugs, particularly in the context of product liability and personal injury claims, continues to evolve.

### United States Supreme Court Decisions

The United States Supreme Court recently decided two cases involving generic drug manufacturer liability. In *Pliva, Inc. v. Mensing*, 131 S.Ct. 2567 (2011), the Supreme Court considered whether a manufacturer of metoclopramide, the generic version of Reglan®, a drug designed to speed the movement of food through the diges-

*Schrama and Taylor are members of Stark & Stark's complex litigation practice group, located in Lawrenceville.*

tive system, could be held liable under state tort law for failing to provide an adequate warning label on the medication. The plaintiffs had taken generic metoclopramide and alleged that the long-term ingestion of the drug had caused their tardive dyskinesia, a serious and irreversible nervous system disorder. The plaintiffs alleged that the FDA-ordered black box warnings were insufficient and that the manufacturers of meoclopramide failed to warn of the known dangers of the drug, despite the "mounting evidence" that long-term use carried a far greater risk than that indicated on the label.

In its defense, the generic manufacturers argued that federal law preempted the state tort claims. More specifically, the generic manufacturers argued that the federal labeling requirements prevented them from complying with the state tort duty-to-warn laws. The Supreme Court agreed with the generic manufacturers and found that the FDA regulations, which require brand-name and generic warning labels to be identical, imposed an "ongoing federal duty of 'sameness'" that prevented generic manufacturers from altering the warning label (and thus prevented them from complying with the arguably heightened label warning standard required by state law). The Supreme Court rested its decision on principles of federal preemption, ultimately deciding that it was impossible for the generic manufacturers to comply with both state and federal law, since federal drug regulations, as interpreted by the FDA, prevented the generic manufacturers from independently changing their safety labels. Interestingly, the court noted that, from a plaintiffs' perspective, finding preemption in the case "made little sense" and that federal drug regulation had dealt the plaintiffs that happened to use the generic rather than the brand-name pharmaceutical, an "unfortunate hand."

The next controlling Supreme Court case, decided only two terms later, was *Mutual Pharmaceutical Co. v. Bartlett*, 133 S.Ct. 2466 (2013), which involved a generic manufacturer of sulindac, a nonsteroidal anti-inflammatory drug (NSAID), commonly known as Clinoril®. In *Bartlett*, the plaintiff developed an acute case of toxic epidermal necrolysis after ingesting sulindac, which caused burns over nearly 65 percent of her body and nearly blinded her. The plaintiff brought a design-defect claim pursuant to state law, which imposed a strict liability standard against the manufacturer of an unreasonably dangerous product. The Supreme Court determined that the design-defect claim was tethered to the manufacturers' duty to warn the consumer about the possibility that the product was unreasonably dangerous. Thus, the Supreme Court followed its holding in *Mensing* and concluded that the state design-defect claim was preempted by federal law. Again, the plaintiff was left without a state tort remedy, or at least not the same remedy that would have been available had the claims been brought against a brand-name manufacturer.

### New Jersey State Court

These decisions have had a significant impact on plaintiffs in New Jersey state court. For instance, in the case of *In re Isotretinoin Litigation (Accutane)*, 2013 N.J.Super. LEXIS 1834 (Law Div. June 28, 2013), the Superior Court interpreted and applied the *Mensing* and *Bartlett* holdings to bar the plaintiffs' claims. In the *Accutane* cases, the plaintiffs alleged multiple state causes of action against the manufacturers of the generic version of Accutane®, including defective design, failure to warn, negligence, breach of warranties and misrepresentation. The court interpreted all of those state law claims as, at their core, failure-to-warn causes of action and found they were preempted under *Mensing*. As such, the plaintiffs' state law causes of action against the generic manufacturers were dismissed in their entirety.

### Conclusion

In the wake of the recent Supreme Court cases, plaintiffs are left with two inescapable realities. First, the current FDA regulations insulate generic drug manufacturers, as opposed to brand-name manufacturers, from state law product liability causes of action. Second, plaintiffs are left without a remedy to pursue injuries caused by generically produced medications that suffer from design defects and fail to provide adequate warnings of unreasonable danger. As such, and as of right now, it is essentially impossible for an individual to pursue a product liability cause of action against a generic manufacturer for injury caused by that medication.

However, the FDA has taken a cue from the Supreme Court in an attempt to eliminate this legal anomaly. On Nov. 13, 2013, the FDA promulgated a proposed rule, which would allow generic manufacturers to unilaterally change the label of a generic medication. This regulation could serve to create parity between brand-name and generic manufacturer obligations and liabilities, and essentially avoid the federal preemption concerns expressed by the Supreme Court in *Mensing* and *Bartlett*. For now, however, there is no way to tell what the final form of the FDA's proposed rule will be and how the judiciary will interpret that rule. ■