Generic pharmaceutical drugs are versions of brand-name counterparts with one major difference: they typically cost a lot less. By FDA regulation, the two have the same active ingredients, dosage forms and strengths, and routes of administration. And while federal law generally regulates pharmaceutical approval, states can regulate pharmaceutical distribution. Why is this significant? All states permit pharmacies to substitute generic drugs for the brand name equivalent, and some states require substitution in certain circumstances. But a generic pharmaceutical company cannot change the brand company’s product label, so a person’s ability to sue a drug manufacturer is limited to the brand company who created the label.

I. Background

Generic drug makers receive this protection for one important reason: they do not control the content of the clinical trial information on their product labels. The FDA requires brand-name manufacturers seeking approval for a new drug to submit an accurate and adequate label for any new drug with the drug application, including clinical trial information. In contrast, generic manufacturers file abbreviated applications and are required to mirror the approved drug’s label, with minor exceptions. And unlike generic manufacturers, brand-name manufacturers can propose changes to their drug labels in response to new information. Part of the benefit of our generic pharmaceutical system is the ability for abbreviated applications to rely on the clinical trial information that a brand company researched and compiled. On the flip side, however, generic manufacturers are generally stuck with whatever safety information the branded drug manufacturer includes or omits.

For that reason, the Supreme Court held in 2011 that people cannot bring failure-to-warn suits against generic drug makers because of a constitutional principle called preemption: when a federal law provides guidance and regulates requirements, that federal law governs over state law, including tort law. For example, failure-to-warn claims brought against generic drug makers under state law, if successful, would impose duties on them to implement different, stronger warning labels even though they could not do so under federal law.

Two years later, the Supreme Court applied this same reasoning to bar people from bringing design-defect claims against generic drug makers, reasoning that generic manufacturers cannot redesign safer products while complying with FDA restrictions. The Court concluded that if it required a generic manufacturer to make its drug safer, which it might ordinarily order as a remedy in a design-defect lawsuit, that ruling would effectively require the manufacturer to start from scratch and redesign the drug and/or the drug’s label. Yet under the generic pharmaceutical regulatory framework, any changes to the drug—the active ingredient, dosage form, etc.—could render the drug a “new” drug rather than a generic one. Therefore, the Court held that plaintiffs cannot bring state design defect claims against generic drug makers because these claims are also preempted by the FDA’s labeling requirements.

II. After the Supreme Court Cases
What will happen next? In both of these cases, the Supreme Court emphasized that it’s up to Congress and the FDA to change the law if they are so inclined. Some members of Congress took up this invitation in 2013 and asked the FDA to promulgate regulations that allow generic manufacturers to update their drug labels. The FDA investigated the issue and promulgated proposed rules, but upon consideration and after feedback, the rule was officially withdrawn in September 2017. This withdrawal likely indicates the FDA has backed off from allowing liability for generic drug manufacturers.

III. Recent Impacts

For these reasons, two recent state court cases held that brand name manufacturers may be liable for failure to warn claims even where a patient exclusively used a generic version of the pharmaceutical at issue. Although most states have not yet extended the Supreme Court’s 2011 rule expressly in this way, these cases signal that there is a growing number of states that are willing to move in this direction.

The boundaries of federal preemption are also being tested in a case currently before the Supreme Court—the Court granted certiorari in Merck Sharp & Dohme Corp. v. Albrecht earlier this year to consider the issue of whether a state-law failure-to-warn claim against a brand-name manufacturer is preempted when the FDA previously rejected the drug manufacturer’s proposed warning language. Court-watchers expect a hearing to be held before the end of the current term.

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[5] See id. (“[G]eneric drugs’ can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA.”).
[7] Id. at 626.
[8] See Mutual Pharm. Co., 555 U.S. at 475 (“Under the Supremacy Clause, state laws that require a private party to violate federal law are pre-empted and, thus, are ‘without effect.’”) (citing Maryland v. Louisiana, 451 U.S. 725, 746 (1981)).
[12] See Mutual Pharm. Co., 555 U.S. at 493; PLIVA, Inc., 564 U.S. at 626 (“As always, Congress and the FDA retain the authority to change the law and regulations as they so desire.”).

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