Client Alert.

June 23, 2011

Generic Drug Makers Protected from Failure to Warn Claims

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In a surprising decision that could affect thousands of pending lawsuits, the Supreme Court held today that federal law preempts failure to warn claims against generic pharmaceutical companies. Justice Thomas delivered the 5-4 opinion. The Court found it was impossible for a generic company to comply with federal law requiring the generic label to be the same as the brand label, while also changing its label to include heightened warnings required by state law.

Emphasizing that "impossibility" revolved around whether a private party could "independently do under federal law what state law requires of it," the Court analyzed the three existing avenues for effecting label changes—implementing CBE revisions, writing "Dear Doctor" letters, and petitioning the FDA for a label change. On the first two, all nine justices agreed that generic companies are prohibited from effecting unilateral label changes through either the CBE process or "Dear Doctor" letters.

The opinions diverged regarding the third avenue—a company's ability to petition the FDA for a label change. Justice Sotomayor, writing for the dissent, would have imposed such a duty on manufacturers, requiring them to show that the FDA would not have approved the proposed label change. She offered three ways to prove impossibility through the discovery process: (1) the FDA rejected a proposed label change; (2) the FDA had not responded to a request for a label change; or (3) the FDA had considered evidence but chose not to require a label change. The majority ridiculed this proposed process, comparing it to a "Mouse Trap game" necessary to effect a label change. Instead, a company's decision to petition the FDA "is not a matter of state-law concern," and there is no need for a court to second-guess what the FDA could or would have done.

The Court pointed out that its opinion was consistent with the result in *Wyeth v. Levine*, its 2009 decision holding that failure to warn claims against brand name pharmaceuticals are *not* preempted. Key to distinguishing *Levine* is the fact that CBE label revisions and "Dear Doctor" letters *are* available to brand name companies under federal law. Recognizing the potential unfairness resulting from different remedies for generic and brand name plaintiffs, the Court nonetheless refused to "distort the Supremacy Clause in order to create similar preemption across a dissimilar statutory scheme."

According to the dissent, generics make up 75 percent of all drugs taken in the United States. Those consumers are now without a remedy for inadequate warnings. Therefore, this decision may stimulate changes to the FDA regulations on what generics are required to do.

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