February 27, 2008

Riegel, Kent, and Levine: The Supreme Court Confronts FDA Preemption

In a trio of cases, the Supreme Court is clarifying a doctrine critical to products-liability suits against manufacturers of prescription drugs and devices: the defense of FDA preemption. The FDA increasingly asserts, and courts increasingly agree, that private claims are preempted where they seek to impose requirements on pharmaceutical companies that are inconsistent with FDA standards. The Supreme Court's three cases address preemption in the context of (1) medical devices, (2) so-called "fraud on the FDA" allegations, and (3) FDA-approved prescription drugs.

Medical Devices – *Medtronic v. Riegel*. Last week, the Supreme Court held in an 8 to 1 opinion that federal law preempted a state-law suit alleging that a patient was injured by a device (in this case, a catheter) that had received FDA premarket approval. The FDCA expressly preempts state-law requirements "different from, or in addition to, any [federal] requirement applicable . . . to the device." In a previous case, *Medtronic v. Lohr*, the Court held that state-law suits are not preempted by FDA review of devices for "substantial-equivalence" – in which the FDA determines only that a medical device is substantially equivalent to a predicate device. But in *Riegel*, the Court held that the more rigorous pre-market approval – in which the FDA spends approximately 1,200 hours reviewing the device's safety – does impose federal "requirements" that preempt conflicting requirements under state law.

In addition, the Court held that the FDCA preemption provision applies to jury verdicts in common-law tort suits: "State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." In fact, the Court suggested that state tort suits would actually undermine FDA regulation more seriously than would a state's creation of a competing drug safety agency: "A state statute, or a regulation adopted by a state agency, could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA: How many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm? A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court."

Fraud on the FDA – *Warner-Lambert v. Kent*. On Monday, the Supreme Court (with Chief Justice Roberts recused) heard argument on whether a state may permit juries to determine whether a manufacturer committed "fraud on the FDA." Michigan law prohibits product liability suits over FDA-approved prescription drugs unless the plaintiff can show that the manufacturer withheld information from the FDA that is material to the product's availability on the market. Other states, including Texas, New Jersey, Utah, and Arizona, have statutes that similarly limit liability or damages absent fraud on the FDA (or analogous company conduct).

In a previous decision, *Buckman*, the Supreme Court held that federal law preempts a state-law cause-of-action based on fraud on the FDA. In *Kent*, the Solicitor General's office stated at oral argument that the Court should reach the same result where fraud-on-the-FDA is an exception to a defense: "[W]here the State is essentially telling companies what they must or must not be telling FDA, . . . there's just an obvious intrusion [into] FDA's ability to administer its own approval process." A ruling in the case will likely come this summer.

Prescription Drugs – *Wyeth v. Levine*. In January, the Supreme Court agreed to consider whether and to what extent federal law preempts state-law suits alleging that a drug's FDA-approved labeling nonetheless failed adequately to warn of a drug's risks. The plaintiff alleged that she was injured because the FDA-approved labeling of an intravenous drug did not disclaim a certain method of injecting the drug; the FDA had approved this method of injection. Covington & Burling LLP authored an amicus brief, on behalf of PhRMA, urging the Supreme Court to take the case. The brief observed: "Pharmaceutical companies face an unprecedented number of state-law suits in which plaintiffs seek to revisit FDA decisions about a drug's labeling. These lawsuits encourage manufacturers to include warnings that are scientifically unsupported, discourage physicians and patients from using beneficial drugs, and deter the development of new drugs that would enhance patient health and safety."

The Supreme Court recently agreed to take the case, which will be heard in the fall of 2008. The case could affect many pending pharmaceutical suits. For example, in a brief requested by the Supreme Court, the Solicitor General proposed a broad rule of preemption, and suggested that state law "claims are impliedly preempted by the FDCA [when] they challenge labeling that FDA approved, after being informed of the relevant health risk, based on its expert weighing of the risks and benefits of requiring additional or different warnings." Much of Justice Ginsberg's dissent in *Riegel*, and several of the Justices' questions during the oral argument in *Kent*, appeared to foreshadow the drug preemption issues that the Court will consider in *Levine*.

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