SMITH ANDERSON
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Client Alert

PHARMACEUTICAL PRODUCTS LIABILITY UPDATE

In early 2008, the Supreme Court of the United States issued a pair of decisions in the pharmaceutical products liability area and granted certiorari (discretionary review) in another.

Riegel v. Medtronic, Inc.

The Supreme Court affirmed a federal appeals court's decision that when a medical device is given pre-market approval from the Food and Drug Administration ("FDA"), federal law preempts certain state law claims challenging the device's safety or effectiveness. In *Riegel*, Charles Riegel and his wife sued after a balloon catheter manufactured by Medtronic ruptured while Mr. Riegel was undergoing angioplasty. The catheter was a medical device that received pre-market approval from the FDA in a rigorous process similar to that undertaken for FDA approval of drugs. The Riegels brought several claims against Medtronic under New York state common law, including (1) negligence in the design, testing, inspection, manufacture, distribution, labeling, marketing and sale of the catheter; (2) strict liability; and (3) breach of express and implied warranties.

Finding that a federal law, the Medical Device Amendments of 1976 ("MDA"), preempted all of the Riegels' claims save negligence in manufacturing, a federal appeals court dismissed most of the Riegels' claims. The Supreme Court affirmed with an 8-1 majority holding that the MDA preempts many state common law claims challenging the safety or effectiveness of a medical device that has pre-market approval from the FDA.

The *Riegel* decision impacts medical device manufacturers in that it dramatically limits the individual claims challenging the safety or effectiveness of medical devices that can be brought against such manufacturers. However, the decision does not apply to other state common law claims not specifically at issue in *Riegel* nor to medical devices that enter the market through the less rigorous 510(k) process.

Although the majority opinion left open the possibility of similar preemption in cases against drug manufacturers, *Riegel* does not directly impact those claims. However, the Court has granted certiorari in *Wyeth v. Levine*, a case in which the issue of whether the FDA's approval of a drug preempts state common law product liability claims is squarely presented. The Court will hear argument in the *Wyeth* case sometime after October 2008 and will decide the case by the summer of 2009.

Warner-Lambert v. Kent

In another case, the Supreme Court failed to reach agreement on whether individual damage claims based on a claim that a drug manufacturer obtained FDA approval through fraud are barred by federal law. The Court issued an order indicating that the Justices had reached a 4-4 tie vote, which tie automatically affirms the Court of Appeals for the Second Circuit's decision. Because he owns stock in Pfizer, Inc., Warner-Lambert's parent company, Chief Justice Roberts did not participate in the case.

In *Warner-Lambert*, diabetes patients suffered liver damage while taking the drug Rezulin. Rezulin was approved by the FDA but withdrawn from the market three years later at the FDA's request. A federal appeals court had ruled the plaintiffs' claims could go forward. The Supreme Court's affirmance by tie does not set precedent for future cases. Thus, this issue remains unsettled, and a decision in *Wyeth* may not resolve it either, as it is unlikely the Court will address the status of lawsuits alleging that FDA approval was obtained by fraud in the context of that case.

Stay Tuned

As discussed above, next term the Supreme Court will take on the issue of federal preemption of state common law claims against drug manufacturers in *Wyeth v. Levine*. The Supreme Court will review the Vermont Supreme Court's rejection of Wyeth's defense that the FDA's approval for a drug preempted state common law product liability and failure to warn claims.

If the Court reaches the same conclusion it did in *Riegel*, most lawsuits for damages caused by FDA-approved drugs would be preempted. However, the future of *Warner-Lambert*-type claims (i.e., those alleging that FDA approval itself was obtained by fraud) will likely remain unsettled even after *Wyeth*.