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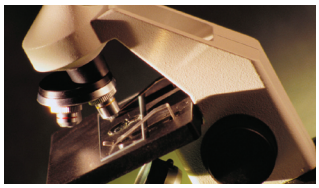

TWO DOWN, ONE TO GO: LAST LEG OF U.S. SUPREME COURT'S PREEMPTION TRILOGY HAS INDUSTRY'S FULL ATTENTION

By Steve Thomas and Ann Peper Havelka

The U.S. Supreme Court has been holding the pharmaceutical industry's attention for months – and the scrutiny will not be letting up any time soon. This spring, the Court decided two parts of a preemption trilogy that could have far-reaching implications for pharmaceutical and medical device manufacturers.

In *Riegel v. Medtronic, Inc.*, the Court held that state-law claims against manufacturers of medical devices subject to the Food and Drug Administration's (FDA) pre-market approval are preempted. *Riegel* appeared to generate momentum, or at least hinted at the possibility that the U.S. Supreme Court might be willing to adopt preemption in a broader context. Just two weeks later, however, the Court announced that it was deadlocked 4-4 and handed down a two-line *per curiam* decision in *Warner-Lambert Co. v. Kent*. This 4-4 split has no precedential effect but does leave standing the Second Circuit's opinion, which held that the implied preemption doctrine does not bar a fraud-on-the-FDA exception set forth in a Michigan statute that otherwise shields drug manufacturers from liability.

What do these two opinions mean? And what, if anything, do they tell us about how the Court may rule next term when it takes up a broader preemption issue in *Wyeth v. Levine*?

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Riegel v. Medtronic, Inc.

Riegel involved a product liability lawsuit against Medtronic for the alleged failure of a heart catheter, a Class III medical device that went through the FDA pre-market approval process in 1994. Under section 360 of the Medical Device Amendments of 1976, states may not

impose "any requirement" that is "different from, or in addition to" a federal requirement regarding the safety and efficacy of a medical device subject to FDA pre-market approval. The U.S. Supreme Court held that the pre-market approval process constitutes a "requirement" within the meaning of the Act. The Court then held that state tort law imposes additional duties of care on device manufacturers and that these "different or additional requirements" were expressly preempted by section 360.

The *Riegel* holding is limited to medical devices that have gone through FDA pre-market approval, which involves rigorous FDA review. Most Class III medical devices do not undergo pre-market approval but instead are approved under the 510(k) process, which addresses the approval of devices that are substantially equivalent to another device that was on the market before 1976. The U.S. Supreme Court has already held that section 360 does not preempt state tort law claims against the manufacturers of 510(k) devices. *See Medtronic v. Lohr*, 518 U.S. 470 (1996).

Riegel does not address the argument that state-law requirements could "parallel" federal requirements and therefore avoid preemption. In *Lohr*, the Court stated that section 360 does not expressly preempt states' "right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495.

Riegel's holding is premised on express preemption, and the Court interpreted the express terms of the Food, Drug, and Cosmetic Act to prevent state tort claims. Accordingly, this holding does not necessarily foreshadow the Court's thinking on implied preemption, the hot-button issue that the Court will address next fall in *Levine*. In addition, Congress could negate the impact of *Riegel* by revising the FDCA in response to the Court's holding. Shortly after the Court's ruling, Senator Edward Kennedy (D-Mass.) stated that Congress would take action, and Representatives Frank Pallone (D-N.J.) and Henry Waxman (D-Cal.) have drafted legislation that is expected to be introduced in Congress soon. According to reports, the proposed legislation would amend the FDCA to add a subsection stating, "Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State."

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Warner-Lambert Co. v. Kent

Kent involved Michigan plaintiffs who alleged injury as a result of taking Rezulin®, a prescription diabetes drug voluntarily withdrawn from the market in 2000. A Michigan statute bars personal injury suits against manufacturers of FDA-approved prescription drugs, but carves out an exception if the plaintiff can establish that the company deliberately withheld information from FDA that would have prevented the drug's approval.

The U.S. District Court for the Southern District of New York (Judge Lewis A. Kaplan) held that the exception in the Michigan immunity statute was preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) (holding that state-law fraud-on-the-FDA claims are barred by implied conflict preemption). The Second Circuit reversed, holding that

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Buckman was not controlling and that implied preemption did not foreclose the exception in the Michigan statute. Central to the Second Circuit's reasoning was its conclusion that the exception in the Michigan immunity statute did "not create a new cause of action for misleading the FDA." *Desiano v. Warner-Lambert*, 467 F.3d 85, 92 (2d Cir. 2007). The result left a split among the circuits (Second v. Sixth), and the U.S. Supreme Court granted *certiorari*.

Chief Justice John Roberts recused himself, likely due to his ownership of Pfizer stock. And the remaining justices deadlocked at 4-4. Further muddying the waters is the inability to determine how each of the justices voted, or why. In the case of a "tie vote," the U.S. Supreme Court does not disclose how the justices voted, and the *Kent* decision did not include a written opinion. Some take-aways from *Kent*:

- It has no precedential value given the 4-4 split.
- The Second Circuit's decision stands. The same is true of the Sixth Circuit's decision in *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), which reached the opposite result.
- The 4-4 split in *Kent* does not negate *Buckman*. Some plaintiffs' counsel, however, when examining the result in *Kent* alongside the 9-0 decision in *Buckman,* may sense a shift in thinking among the justices and begin viewing "fraud on the FDA" as a reopened path to liability. But the four justices who sided with the *Kent* plaintiffs may have simply bought into the Second Circuit's analysis, which viewed the issue in *Kent* as being very different from the issue in *Buckman*. If so, then *Buckman* stands strong, and *Kent* may have little impact beyond the Michigan immunity statute.

Riegel and *Kent* set the stage for Act III, as next term the U.S. Supreme Court will address the following question in *Wyeth v. Levine*: "Whether the prescription drug labeling judgments imposed on manufacturers by [FDA] pursuant to FDA's comprehensive safety and efficacy authority under the [FDCA] preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use." Pet. for Cert. in *Wyeth v. Levine*, O.T. 2007, No. 06-1249, p.i. *Levine* will be argued in October 2008.

FDA's position on preemption is clear. In fact, on May 14, 2008, Dr. Randall Lutter, Deputy Commissioner for Policy at the FDA, provided a statement for the record before the Congressional Committee on Oversight and Government Reform. Dr. Lutter stated that "FDA is concerned that state product liability lawsuits that challenge FDA's careful determination of safety, efficacy and appropriate labeling can have detrimental effects to public health in a number of ways, including limiting patient and doctor choices and decreased patient access to beneficial products, and increased confusion over warnings or statements that can deter the use of beneficial medical products." According to Dr. Lutter, "FDA believes that the important decisions it makes about the safety, efficacy, and labeling of medical products should not be second guessed by state courts." It is FDA's view that "both to protect the public health and as a matter of law, state law claims are preempted if they challenge a design or

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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."

Do *Riegel* and *Kent* provide hints about what may happen in *Levine*?

First, *Riegel* involved express preemption. *Kent* and *Levine* are implied preemption cases. The final tallies in *Riegel* (8-1) and *Kent* (4-4) may suggest that the Court is more comfortable finding preemption when interpreting an express congressional mandate.

Second, *Buckman* blocked fraud-on-the-FDA claims, but did not bar traditional state tort claims. If the *Kent* Court had held that the Michigan immunity exception was preempted, this would have precluded all Michigan plaintiffs' claims against pharmaceutical manufacturers. *Buckman* and *Kent*, taken together, may suggest that the Court is more apt to find preemption when plaintiffs will still have other state law claims to pursue. A favorable preemption opinion in *Levine* would seemingly extinguish the predominant claim (failure to warn) in prescription drug litigation.

Third, a number of preemption cases have resulted in 5-4 decisions. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996); *Cipollone v. Liggett Group Inc.* 505 U.S. 504 (1992). Some may interpret *Kent* to mean that a minimum of four justices favor a more restrictive view of implied preemption. Even so, it is important to remember that the missing vote in *Kent* was that of Chief Justice Roberts. Court watchdogs typically view Roberts as a pro-business Justice, someone who could tip preemption in Wyeth's favor if the Court is otherwise equally divided.

Riegel and *Kent* ultimately raise more questions than answers. In the end, all attention is sharply focused on next term – and *Levine*.

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