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Supreme Court Holds that State Tort Law is Expressly Preempted by Food, Drug and Cosmetic Act in Suits Involving FDA Approved Devices

On February 20, the Supreme Court of the United States in *Riegel v. Medtronic, Inc.*, No. 06–179, held that state law tort suits challenging the design, manufacture or labeling of medical devices approved for marketing under the FDA's Premarket Approval (PMA) process are preempted by the Medical Device Amendments of 1976 (MDA). The Court's decision resolved a long-festering Circuit split pitting the 11th Circuit (holding no preemption) against six other Circuits (2nd, 3rd, 5th, 6th, 7th, and 8th) all holding, to varying degrees, that the MDA preempts state tort claims involving devices approved by FDA under its PMA authority. Seven Justices joined in the Court's opinion written by Justice Scalia. Justice Stevens concurred in part and in the judgment, with Justice Ginsburg filing the lone dissent.

The Court's analysis was straight-forward. First, it held that PMA approval was device specific and as such, imposed specific labeling, design, and manufacturing requirements on the device's manufacturer. The Court emphasized that a device cleared under the 510(k) approval process (*see* 21 C.F.R. pt. 807) is not reviewed for safety and effectiveness and therefore, the process imposes no device specific requirements on the manufacturer. The opposite is the case with a PMA-approved device.

Second, the Court held that state common law claims also impose state law requirements on manufacturers of medical devices. Scalia viewed the FDA's regulations on this point as ambiguous, inconsistent, and not entirely helpful. He relied primarily on the nature of tort and the tort presupposes the existence of a duty which in turn forms the basis of a requirement.

Third, the Court concluded that any state-law based claim would be preempted to the extent that the state law imposes requirements that are "different from, or in addition to" the requirements imposed by federal law. §360k(a)(1). Thus, according to the Court:

"§360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements. *Lohr*, 518 U. S., at 495; *see also id.*, at 513 (O'Connor, J., concurring in part and dissenting in part). The District Court in this case recognized that parallel claims would not be pre-empted, *see* App. to Pet. for Cert. 70a–71a, but it interpreted the claims here to assert that Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements, see id., at 68a."

Finally, the Court in addressing Justice Ginsburg's dissent noted that whether the drug provisions of the Food, Drug, and Cosmetic Act impliedly preempt state law has not been decided . The Court has granted certiorari in two drug-preemptions cases. See *Wyeth v. Levine*, No. 06-1249, 76 U.S.L.W. 3391 (Jan. 18, 2008); *Desiano v. Warner-Lambert & Co.*, No. 06-1498, 76 U.S.L.W. 3154 (Sept. 25, 2007).

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