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## U.S. Supreme Court Finds Federal Preemption Applies in Medical Device Case

On February 20, 2008, *Riegel v. Medtronic*, 06-179 addressed federal preemption in the context of the Medical Device Amendments of 1976 (21 U.S.C. §360k, or "MDA") to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.* Justice Scalia authored the majority opinion:

- This case arises from the rupture of a balloon catheter, a Class III medical device which initially received premarket approval from the FDA in 1994. Plaintiffs sued the device manufacturer, asserting claims of negligence, strict liability, and breach of implied warranty. Both the District Court and the Court of Appeals found these claims were preempted under federal law.
- The Court took up two questions: (1) whether federal requirements exist as to the subject product such that it would trigger the MDA's express preemption provisions, and (2) whether the common-law claims were based on disallowed requirements "different from, or in addition to" the federal requirements.
- Among medical devices approved by the FDA, Class III medical devices undergo the most rigorous scrutiny, and enter the market through either a "510(k) process" which seeks to establish "substantial equivalence" to existing products or, for new products, a stricter premarket approval.
- Whereas in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court had previously held that that common-law claims of negligence and strict liability were not preempted by federal requirements that reflected

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"entirely generic concerns about device regulation generally," and that products marketed subject to 510(k) processes qualified as "an exemption rather than a requirement [allowing federal preemption]," here the Court held that premarket approval *does* impose "requirements" such that the MDA's provisions are implicated. "[P]remarket approval is focused on safety, not equivalence."

- Consistent with its holding in *Lohr*, the Court also held that common-law actions for negligence and strict liability do impose "requirements" that would be preempted by a finding of specific federal requirements governing medical devices. "Absent other indication, reference to a State's 'requirements' includes its common-law duties."
- The Court further rejected petitioners' arguments based on one FDA regulation [21 CFR §808.1(d)(1)], finding them contrary to both the *Lohr* holding and the MDA statutory provisions.
- Finally, the Court recognized, but declined to rule on petitioners' so-called "parallel claims" (such as a State's damages remedy for claims premised on a violation of FDA regulations).

Justice Stevens concurred in part with the opinion and concurred with the Court's judgment, recognizing that judicially-administered common-law rules create and define legal obligations; some of them unquestionably qualify as "requirements," properly invoking questions of preemption.

Justice Ginsburg dissented from the Court's decision, finding the Court's interpretation overbroad, a "radical curtailment of state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices." Justice Ginsburg further cited an inherent presumption against preemption, concluding that the Court's construction of MDA preemption has the "perverse effect of granting broad immunity to an entire industry that, in the judgment of Congress, needed more stringent regulation, not exemption from liability in tort litigation."

For the complete opinion, [click here](#).

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