

EDITORIALS



A Pivotal Medical-Device Case

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This spring the Supreme Court of the United States will decide whether premarketing approval of a medical device by the Food and Drug Administration (FDA) immunizes the manufacturer against product-liability litigation in state courts. This decision, we believe, is a matter of particular importance to patients and the medical community.

On December 4, 2007, the Supreme Court heard oral arguments in *Riegel v. Medtronic*.¹ In May 1996, Charles Riegel underwent coronary angioplasty in Albany, New York. During the procedure, the balloon ruptured, and advanced cardiac life support and emergency coronary bypass surgery were needed. Mr. Riegel and his wife subsequently sued Medtronic in a New York court, claiming that the device was defective and the labeling inadequate. Medtronic claimed, however, that any state lawsuit was preempted by a section of the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act.²

The 1976 law arose out of the Dalkon Shield disaster. Like all medical devices introduced before 1976, the Dalkon Shield intrauterine device underwent no premarketing assessment of safety or efficacy by any federal agency. In the wake of the thousands of deaths and serious injuries caused by the device, Congress took action, empowering the FDA to regulate all medical devices. To avoid conflict with state laws that, given the absence of any federal oversight, had been enacted to regulate medical devices, the 1976 law included a section that preempted certain state-law requirements that differed from federal (FDA) requirements with respect to the safety and efficacy of devices. This section, §360k(a), was used for two decades to prevent the enactment of state legislation that might conflict with FDA regulation.

In a 1996 Supreme Court case, however, Medtronic attempted to extend preemption beyond

the enactment of state laws to include all product-liability claims against medical-device manufacturers in state courts. In a Florida court in 1993, Lora Lohr and her husband had sought damages for an allegedly faulty pacemaker lead manufactured by Medtronic. The company argued that the Medical Device Amendments preempted any damages claims because the device had been approved for marketing by the FDA. In *Medtronic v. Lohr*,³ the Court's majority opinion, written by Justice John Paul Stevens, held that none of the Lohrs' damages claims were preempted by the 1976 law. Thus, in the *Lohr* case the Court ruled that FDA approval of a medical device did not preclude subsequent product-liability suits in state courts, and the Lohrs' lawsuit (in which a settlement was eventually reached) was allowed to proceed.

In *Riegel v. Medtronic* the company has resurrected the argument dismissed by the Court in *Lohr*. What, then, is the difference between the two cases? In *Lohr*, the pacemaker lead had been approved by the FDA in a "substantial equivalence" process in which, because the design of the lead was deemed to be "equivalent" to that of an existing lead, no further study of the safety and efficacy of the specific device was required. Furthermore, the existing pacemaker lead to which the new lead was judged equivalent had itself never undergone full premarketing assessment and had instead been "grandfathered." In *Riegel*, on the other hand, the angioplasty catheter had received premarketing approval from the FDA in accordance with current standards on testing for efficacy and safety. Medtronic argues that, given the rigor of the FDA approval process, any action at the state level, including tort litigation against the company, would represent a further requirement and thus be preempted under §360k(a) of the Medical Device Amendments. Medtronic ar-

gues, in effect, that the granting of FDA approval shields any device manufacturer from state tort liability.

Congress worked long and hard last year to reform the FDA in its mission to improve the safety of drugs and medical devices. Congressional scrutiny of the FDA raised serious questions about whether the agency has the authority and resources necessary to do its job. A recent report from the Office of Inspector General of the Department of Health and Human Services reinforced this concern.⁴ Thus, a question that the justices will address in *Riegel v. Medtronic* is just how reliable the FDA premarketing approval process is and how much weight to give it. For its part, the FDA in *Lohr* interpreted the Medical Device Amendments as providing no basis for the preemption of state lawsuits. However, in *Riegel*, the FDA has reversed itself and now interprets the same statute as allowing the preemption of state lawsuits.

The decision of the justices in *Riegel v. Medtronic* will be critical for patients' rights and will have enormous impact on manufacturers' responsibilities and the safety of medical devices. Whether drug manufacturers might enjoy the same immunity that device manufacturers are claiming is a question that will also soon come before the Court. Next month the Court will hear a case (*Warner-Lambert v. Kent*)⁵ involving the diabetes drug troglitazone, which was withdrawn from the market in 2000 because of liver toxicity. The Court will be asked to decide whether FDA premarketing approval of the drug preempts liability claims in state court.

Ultimately, we believe that the pivotal question for the justices in *Riegel v. Medtronic* resides in what is in the best interest of American society. Is it in the people's interest to shield medical-

device companies from product-liability claims? Would such a decision benefit patients by making more lifesaving medical devices available, or would there be adverse effects on the overall safety of devices? Is the FDA premarketing approval process sufficiently rigorous and comprehensive to justify immunization of the industry against tort claims? And if medical-device manufacturers are shielded from liability, what about drug manufacturers? Or would society be better served if patients retained their right to seek legal redress when they believed they had been damaged by a faulty medical device? In the long run, would this result in safer medical devices for patients?

If Congress later concludes that the Supreme Court has come to the wrong conclusion — that is, a conclusion that is too restrictive of patients' legal prerogatives and does not serve the public interest — Congress can then act to clarify the law and leave open the possibility that patients injured by devices or drugs can seek legal redress.

But by rejecting Medtronic's plea for immunity, the Supreme Court can act now to protect patients. From time to time, the Court agrees to hear a case that may have major, even momentous, implications for health care. *Riegel v. Medtronic* is such a case.

1. Donna S. Riegel, Individually and as Administrator of the Estate of Charles R. Riegel, Petitioner, v. Medtronic, Inc.
2. 1976 Medical Device Amendments, 21 U.S.C. § 360c et seq., to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.
3. *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).
4. The Food and Drug Administration's oversight of clinical trials. Washington, DC: Office of Inspector General, Department of Health and Human Services, September 2007. (Document no. OEI-01-06-00160.)
5. *Warner-Lambert Co., LLC, et al., Petitioners, v. Kimberly Kent, et al.*

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Survival after Tachyarrhythmic Arrest — What Are We Waiting For?

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Approximately 225,000 out-of-hospital cardiac arrests occur annually in the United States. It is a little-known fact that at least double that number of cardiac arrests occur in hospitalized patients.¹ Survival after cardiac arrest due to ventricular tachycardia or ventricular fibrillation requires

prompt defibrillation, regardless of the setting in which it occurs.^{2,3} Therefore, it is clear that timely defibrillation in the hospital is an important determinant of the quality of cardiovascular care.

If out-of-hospital cardiac arrest from ventricular tachycardia or ventricular fibrillation occurs