Riegel v. Medtronic may leave no remedy for patients injured by FDA-approved medical devices

The coming U.S. Supreme Court decision on preemption is a matter of great importance to patients and the medical-legal community.

Mary Bedard

At issue in *Riegel v. Medtronic* (2d Cir. 2006) 451 F.3d 104, *cert. granted* [(U.S. June 25, 2007) (No. 06-179) 75 U.S.L.W. 3690] is whether patients injured by a medical device may sue device makers through state law when the Food and Drug Administration has already approved the device. The Supreme Court granted certiorari in *Riegel* on June 25, 2007, after the Second Circuit United States Court of Appeals affirmed the district court's ruling that Riegel's claims were preempted in the case.

Background: A catheter bursts

Charles and Donna Riegel sued Medtronic, Inc. for injuries Charles Riegel sustained when the Medtronic Evergreen Balloon Catheter burst during an angioplasty procedure, which required advanced life support and an emergency coronary bypass procedure. Riegel has since passed away, but his wife alleges that the catheter had design flaws and misleading label instructions. Medtronic moved for summary judgment arguing, inter alia, that the Riegels' claims were preempted because the FDA had approved the catheter under its premarket approval or PMA process.

The PMA process is codified in the 1976 Medical Device Amendments (MDA) (21 U.S.C., § 360c et seq.) to the Federal Food, Drug, and Cosmetic Act (FDCA) (1 U.S.C., § 301 et seq.), which significantly broadened the FDA's authority to regulate medical devices. Section 360k(a) is the specific provision at issue in *Riegel*. It provides that no state may establish any requirement that is different from or in addition to any federal requirement that relates to the safety or effectiveness of a medical device.

The 1976 law arose out of the Dalkon Shield disaster. Prior to 1976, medical devices did not undergo a premarket assessment of safety or effectiveness by any federal agency. After thousands were seriously injured by the Dalkon Shield, an intrauterine device, Congress took action, empowering the FDA to regulate all medical devices. In order to prevent any conflict with state laws that had been enacted to regulate medical devices due to the absence of federal oversight, the 1976 law included a section 360k(a) that preempted certain state-law requirements that differed from FDA requirements with respect to the safety and efficacy of devices.

In 1996, 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 *Medtronic v. Lohr* (1996) 518 U.S. 470, Plaintiffs Lora Lohr and her husband sought damages in Florida for a faulty pacemaker manufactured by Medtronic. Medtronic argued that the MDA preempted any damages claims because the device had been approved for marketing by the FDA. The majority held that state law defective design claims were not preempted although the FDA approved the device for marketing under the substantial equivalence process defined in section 510(k); the MDA did not broadly preempt all state or local requirements that are equal to, or substantially close to, requirements imposed under federal law; claims were not preempted to the extent that they alleged that the manufacturer negligently failed to comply with duties equal to, or substantially identical to, federal requirements; and claims based on allegedly defective labeling and marketing were not preempted. Lohr was allowed to proceed in her case and settlement was eventually reached. In *Riegel*, Medtronic has resurrected the argument dismissed by the Court in *Lohr*.

Preemption affirmed in *Riegel*

The district court in *Riegel* granted summary judgment finding that the Riegels' claims, except for those based on negligent manufacturing and express warranty, were preempted. The Riegels appealed the ruling but the Second Circuit affirmed in a 2-1 decision, holding that (1) the PMA process imposes device-specific requirements rendering 360k(a) applicable and (2) the design and labeling claims were device-specific and warranted preemption. (*Riegel, supra,* 451 F.3d 104, 106.) The Second Circuit found that manufacturers would be in a vulnerable position if such claims were not preempted because they would be required to comply with federal regulations but still be liable

even when in full compliance, noting that the claims did not rest on the premise that the device was not in compliance with FDA standards but that in its approved form, the device was defective.

Justice Rosemary Pooler dissented, observing that two significant aspects of preemption were overlooked. (*Id*. at 127.) First, there is a presumption against preemption and second, there was a lack of congressional intent. Thereafter, the Riegels filed a petition for certiorari, which was granted, and oral argument heard by the Court on December 4, 2007.

The United States filed an amicus brief supporting Medtronic. The Chamber of Commerce of the United States of America, CropLife America, et al., The Washington Legal Foundation, the Product Liability Advisory Council, Inc. and The Advanced Medical Technology Association, et al. also filed amicus briefs in support of Respondent.

Amicus briefs were filed on behalf of Petitioners by New York, et al., The Public Health Advocacy Institute, et al., Edward M. Kennedy, et al., The Consumers Union of United States, Inc., The American Association of Justice and Public Justice, and AARP, et al.

Petitioners' arguments *against* preemption

Petitioners contend that the MDA does not explicitly mandate preemption and that the Court previously held in *Lohr* that the MDA does not preempt state-law damages claims. Petitioners argued that the PMA does not create device-specific requirements and that common law duties that apply to their claims are not specific to the device. Petitioners additionally argued that the only recourse for those injured by medical devices is through state law tort claims since no federal law provides an independent damages remedy.

At oral argument, Allison Zieve, an attorney for Public Citizen who represents the Riegels, tried to convince the justices that federal law allows suit against Medtronic in state court. Several of the justices were reluctant to accept the idea that a jury may be allowed to second-guess the FDA's approval process with respect to safety and effectiveness. Justice Anthony M. Kennedy pointed out that the FDA is "specifically charged with weighing the risks against the probable benefits," and in a state case, the jury would in essence be tasked with the same thing that the FDA is required to do.

Justice Antonin Scalia agreed with this concern: "What's going on is simply one jury has decided that in its judgment, there was a safer device that should have been used; and because of the judgment of that one jury, the manufacturer is placed at risk in selling a device that scientists at the FDA have said is okay. I find that extraordinary." He then stressed that in *Lohr*, the jury was not revisiting the same inquiry made by the FDA.

When asked by Justice Ruth Bader Ginsburg how the PMA process differs from FDA drug approval, Ms. Zieve responded that for drugs, the FDA approval is a defense on the merits but not preemptive of claims. Justice Scalia expressed skepticism that States are free to enforce additional requirements on drugs beyond those approved by the FDA – he seemed to think preemption would prevent States from enacting requirements on drugs. In sum, Justice Scalia seemed unconvinced that the Congress intended to allow additional requirements with respect to medical devices indicating that he seemed to believe that Congress wanted the FDA to regulate medical devices without interference from state regulators or courts.

Respondent's arguments *for* preemption

Medtronic argued for the Court to find preemption, contending that the PMA process does impose device-specific requirements. It claims this is so because of the substantive evaluation of the device and prohibition of a later modification that could affect its safety or efficacy. It further argued that *Lohr* supports its position because the PMA process is more thorough and comprehensive than the section 510(k) process subject in *Lohr*.

At oral argument, Medtronic's counsel, former Solicitor General Theodore Olson, now of Gibson, Dunn & Crutcher, argued that Congress made the decision to trust the FDA with balancing safety and effectiveness and that state laws would only make the process more burdensome and confusing. Justice Ginsburg pointed out that the same argument could be made about new drugs, but Congress failed to expressly preempt tort claims for drugs. Rather, she stated that it could be argued that preemption provision in section 360k(a) was meant only to preempt state pre-market approval procedures that might conflict with the FDA process.

In response to inquiry by Chief Justice John G. Roberts about newly discovered safety concerns that were not before the FDA during the PMA process, Mr. Olson stated that the process is on-going with reporting requirements. Thus, the FDA could later revoke the PMA. Respondent agreed that a negligent manufacturer claim where a manufacturer failed to comply with the PMA requirements would not be preempted by section 360k(a). Justice Ginsburg expressed concern that once a device is approved, there were no incentives to improve devices.

Deputy Solicitor General Edwin Kneedler argued for the United States claiming that in addition to Medtronic's arguments, a contrary finding would interfere with the FDA's expertise in balancing health risks with the benefits of medical devices. His concern was that States would be able to impose conflicting requirements to which Justice Ginsburg again inquired why, if that is so important, no such express preemption was required for drugs. Mr. Kneedler tried to argue that the discrepancy was due to the differences between drugs and devices until Justice Scalia offered that the provisions were enacted by different Congresses.

Conclusion

An important twist in this case is the FDA's reversal on its opinion on preemption. Until 2004, the agency took the position that there was no preemption of state law tort claims, but it changed its position that year. The decision in this case is without a doubt a matter of importance to patients and the medical community. While a majority of the Court seemed to support the view that Congress intended that the FDA regulate medical devices and that juries should not have the opportunity to second-guess that agency's decision-making process, the Court's decision will finally resolve federal and state appellate court division over the issue. If the Court acts to protect patients, then Medtronic's plea will be rejected. Otherwise, patients will no longer have any independent damages remedy for injuries caused by medical devices in the future. Then it is up to the Congress to act.


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