

## The Medtronic Case

### U.S. Supreme Court Rejects Medical Device Lawsuit Based on State Common-Law



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In a decision of importance to makers of FDA regulated medical devices, the U.S. Supreme Court affirmed on February 20, 2008, that a device that met the FDA's premarket standards, and that had premarket approval from the agency, was exempt from state law and regulation regarding safety and effectiveness, including common-law, as provided by the Medical Devices Amendments (Act) of 1976 (MDA).

In *Riegel v. Medtronic, Inc* (No. 06-179), 451 F. 3d 104, the Court – in an 8-1 decision – ruled that the pre-emption clause of the MDA (21 U.S.C. §360k) precludes common-law claims that challenge the effectiveness or safety of medical devices that were specifically approved by the FDA. The majority opinion in *Riegel* was written by Justice Antonin Scalia.

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In 1999 Charles and Donna Riegel filed a lawsuit against Medtronic in the U. S. District Court for Northern District of New York after a Class III medical device – an Evergreen Balloon Catheter marketed by the respondent – burst in Charles Riegle's coronary artery during an angioplasty procedure in 1996. Riegel survived the incident, but died in 2004 before the Riegels' lawsuit was adjudicated. And it should be noted that the Evergreen Balloon Catheter was contraindicated for use in a patient like Riegel, who had a diffusely diseased and heavily calcified coronary artery. Further, contrary to the product's warning label, Riegle's doctor overinflated the catheter.

The FDA granted Medtronic premarket approval (PMA) of the catheter in 1994. The Riegels claimed that the device violated New York common-law in that it was improperly designed, labeled, and manufactured. The trial court "held that the MDA pre-empted the Riegels' claims of strict liability; breach of implied warranty; and negligence in design, testing, inspection, distribution, labeling, marketing, and sale of the catheter." Secondly, the district court ruled "that the MDA pre-empted a negligent manufacturing claim insofar as it was not premised on the theory that Medtronic violated federal law." Thirdly, the district court held "that the MDA pre-empted Donna Riegel's claim for loss of consortium to the extent it was derivative of the pre-empted claims." The Second Circuit Court of Appeals affirmed those decisions.

The Supreme Court opined that the petitioners could not succeed in their common-law claims, which were based on New York law, because the state's requirements with regard to the catheter were different from, or in addition to, the requirements established by the FDA for the device, and thus the state requirements were pre-empted by the MDA. Furthermore, the Court was not persuaded by the Riegels' argument that Medtronic had duties under general tort law in that Title 21 CFR §808.1(d)(1) does not extend the MDA's pre-emption provisions to state or local requirements that are general in nature and which cover other products in addition to medical devices or which pertain to unfair trade practices in which the requirements are not limited to medical devices. The Court said this exception does not apply to PMA devices.

Justice Scalia made a strong distinction between devices that require FDA premarket approval, especially Class III devices, and those devices that are exempt from premarket approval because they meet the MDA's "substantially equivalent" standard [§360c(f)(1)(A)]. The FDA reviews products seeking entry into the market for substantial equivalence to another product already on the market by a procedure known as a §510(k) process. Products marketed before 1976 (pre MDA) were grandfathered by the MDA Act. (*Note*: most new Class III devices enter the market through the §510(k) process.)

In general, for §510(k) qualified devices, common-law claims of negligence and strict liability are not pre-empted by the MDA because they are generic, i.e., applicable to almost all medical devices [*SupCt, Medtronic Inc. v. Lohr, 1996*]. Devices that require premarket approval, said Justice Scalia, are subjected to specific federal safety review. Justice Scalia opined that, "While §510(k) is focused on equivalence, not safety ... premarket approval is focused on safety, not equivalence."

The Court held that if state common-law duties were excluded from the pre-emption provisions of the MDA, the exclusion would upset the cost/benefit balance that the FDA uses in deciding the trade-offs between safety and general effectiveness. State tort juries "see only the cost of a more dangerous design;" they are "not concerned with its benefits...." Some devices may carry more risk if they are designed to help more patients, and that is the information the cost/benefit studies provide. It may be inferred from the Court's opinion in *Riegel* that allowing tort law in each state to circumvent pre-emption for premarket approved medical devices would hamper innovations. Justice Ginsburg disagreed with that conclusion.

While the Court's ruling in *Riegel* supports federal pre-emption of FDA premarket approved (PMA) approved medical devices – in effect putting a short leash on state-based common-law lawsuits – it does not prohibit all federal or state lawsuits. Patients who are harmed by PMA medical devices may still sue in state and federal courts if the medical device was made, marketed, or sold without meeting the standards or requirements set by the FDA. As stated by Justice Scalia, "§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."

Equally important, the ruling neither loosens nor tightens the standards that the FDA applies to devices, nor does it diminish the agency's authority to remove devices or issue a recall after conducting investigations into incidents involving those devices, including the failure of the manufacturer to adhere to performance standards. The FDA may withdraw its approval of a medical device if it finds that a device is not effective, not safe [§360e(e)(1) and §360h(e)], or fails to conform to the premarket approval.

The court did not distinguish between medical devices used in hospital or clinical settings and those used as home medical equipment. *Riegel* sets a precedent for the circuit courts of appeal and state supreme courts, some of which have ruled differently on this subject in the past (e.g., 11<sup>th</sup> CirCtApp. in Atlanta and the Illinois Supreme Court).

## **Insurance Impact**

It is important to understand that this case impacts only a narrow cluster of medical device claims and lawsuits, specifically those involving PMA devices, with most devices not entering the market through the PMA process. In 2005, the FDA authorized the marketing of over 3000 devices under § 501(k), the alternative to the PMA process, but granted PMA to only 32 devices. On the other hand, even though there is a limited segment of the market (low frequency), the potential severity of these claims is very high, seeing high reserves, high jury values and certainly high legal costs.

This ruling may eventually reduce the cost of insurance for medical devices that are FDA approved, which could affect the retail cost of the products. However, it may increase liability for medical care providers who use devices that cause harm since protected manufacturers are more likely than not to avoid joint liability. But that is only speculative at this time.

## **Conclusion**

Justice Ruth Bader Ginsberg voiced the lone dissent from the majority's opinion. Justice Ginsburg said that Congress had not intended to radically curtail common-law lawsuits. Justice Scalia responded that it is not the job of the Court to "speculate upon Congressional motives." The senate sponsor of the 1976 law, Edward Kennedy, said Congress never intended to grant the manufacturers immunity from these lawsuits. A key member of the House panel that brought the bill to the House floor, Henry Waxman, concurred. Their hindsight, however, is not in the text of the MDA, Justice Scalia observed. Will Congress let the Court's interpretation stand, or will it amend the MDA?



**Footnotes:**

1. *The MDA Act was a response by Congress to the inability of the common law tort system to manage the risks associated with dangerous devices, foremost of which was the Dalkon Shield IUD.*
2. *The doctor who performed Riegel's angioplasty exceeded the pressure limits warned on the label during inflation of the catheter. It was at the higher pressure that the catheter burst.*
3. *Congress did not apply a pre-emption clause to the entire Food, Drug, and Cosmetic Act as it did to the Medical Devices Amendments (Act) of 1976. That distinction was used by Justice Scalia to challenge Justice Ginsburg's dissenting opinion in the Riegel case.*