News Release

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COURT URGED TO UPHOLD PREEMPTION OF SUITS INVOLVING MEDICAL DEVICES

(Riegel v. Medtronic)

The Washington Legal Foundation (WLF) this week urged the U.S. Supreme Court to rule that federal law preempts state-law product liability suits challenging the design or labeling of medical devices that have been determined to be safe and effective by the Food and Drug Administration (FDA).

In a brief filed in *Riegel v. Medtronic, Inc.*, WLF argued that Congress mandated such preemption when it adopted the Medical Device Amendments of 1976 (MDA), which established a rigorous Premarket Approval process (PMA) for all new medical devices. WLF argued that state court judgments against a device manufacturer that are based on a determination that the device is either defectively designed or deficiently labeled would undermine the PMA process by calling into question FDA's decisions mandating specific product designs and labels.

"WLF agrees with the court below and the great majority of appeals courts that have held that Congress's intent to preempt such suits is spelled out in a federal statute, 21 U.S.C. § 360k(a)," said WLF Chief Counsel Richard Samp after filing WLF's brief. "But quite apart from that provision, we submit that the MDA impliedly preempts many common law causes of action because they stand as an obstacle to the accomplishment of Congress's purposes in establishing the medical device approval process in 1976," Samp said.

The case before the court involves Charles Riegel, a resident of New York who claimed to have suffered injury during heart surgery involving use of a catheter manufactured by Medtronic. The catheter burst while the doctor undertaking the surgery was inflating it in an effort to open one of Riegel's clogged artery. In his suit against Medtronic, Riegel asserted that the catheter was defectively designed and inadequately labeled and that those deficiencies caused his injuries.

The district court dismissed the case on the ground that it was preempted by § 360k(a), which prohibits States from imposing "any requirement" with respect to a medical device that is different from a requirement imposed on the device by FDA. The U.S. Appeals for the Second Circuit in New York affirmed that decision. The Supreme Court has agreed to review the Second Circuit's decision.

In its brief urging that the appeals court be affirmed, WLF argued that when Congress prohibited States from imposing "any requirement," it intended the ban to cover not only positive state law (*i.e.,* law imposed by means of statutes and regulations) but also requirements imposed against the manufacturer through court judgments in state-law tort actions. WLF argued that such judgments impose "requirements" (in the sense of a rule of law that must be obeyed) just as assuredly as do state statutes or regulations.

WLF also argued that, quite apart from arguments based on § 360k(a), the appeals court decision could be affirmed on the alternative grounds that Riegel's claims are *impliedly* preempted by the MDA. WLF noted that when FDA approves a PMA for a new medical device, it does so subject to a requirement mandating the precise design and labeling for the device. The manufacturer has no option to change the design and labeling unless it gets explicit authorization from FDA to do so. If a state jury later determines that the PMA medical device was defectively designed or inadequately labeled, it in effect is ordering the manufacturer to change the design or labeling -- placing the state requirements in direct conflict with FDA requirements. WLF argued that under established rules governing preemption, that conflict requires a finding that the state court action is impliedly preempted by the FDA requirements.

WLF noted that the position it espouses does not leave injured patients without remedies. For example, they are still free to pursue other, non-preempted remedies against the manufacturer, such as that the device was manufactured negligently (*i.e.,* not in conformance with the FDA-approved design), or that the manufacturer breached an express warranty. Alternatively, they can pursue remedies against others who may be responsible for the injuries, such as their physicians, WLF argued.

The Washington Legal Foundation is a public interest law and policy center with supporters in all 50 States. WLF devotes a significant percentage of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.