News Release

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Court Urged To Uphold Preemption Of Suits Involving Medical Devices

(Medtronic v. Stengel)

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 *Medtronic, Inc. v. Stengel*, WLF argued that Congress mandated such preemption when it adopted the Medical Device Amendments of 1976 (MDA), which established a rigorous Pre-Market 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 further argued that plaintiffs should not be permitted to avoid preemption by asserting, as did the plaintiffs here, that the device manufacturer violated its duty to file safety reports with FDA and that their state-law tort action merely seeks recovery under a cause of action that precisely "parallels" the federal requirement.

In its 2008 *Riegel* decision, the Supreme Court held that a provision in the MDA, 21 U.S.C. § 360k(a), expressly preempts product liability claims that challenge the design or labeling of a medical device that was approved for marketing under FDA's rigorous PMA process. *Riegel* stated, however, that § 360k(a) creates a narrow "parallel claim" exception to preemption – *i.e.*, the common law claim is not preempted if it seeks to impose state requirements that precisely parallel the requirements imposed on the device by federal law. The *en banc* Ninth Circuit held in this case that the state-law claim asserted by the plaintiffs – that the device manufacturer failed to submit to FDA safety reports that federal law required it to submit – fell within *Riegel*'s "parallel claim" exception and thus was not preempted. WLF's brief urged the Supreme Court to review (and ultimately overturn) the Ninth Circuit decision.

"Review is warranted in order to resolve the deep circuit split regarding the preemptive scope of § 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 common law causes of action of this sort 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 Richard Stengel, a resident of Arizona who suffered debilitating injuries after his doctor implanted in his abdomen a "pain pump" manufactured by Medtronic. All agree that the negligence claims he initially asserted against Medtronic are

preempted under *Riegel*. But he later sought to amend his complaint to assert that Medtronic breached a continuing duty under federal law to monitor the device's post-approval performance and to report to FDA "any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product." He contended that this alleged federal violation constituted actionable negligence under Arizona law. The district court dismissed the complaint on preemption grounds, but the Ninth Circuit reversed, ruling that the complaint fit within *Riegel*'s "parallel claim" exception to preemption. Medtronic has asked the Supreme Court to review that decision.

In its brief urging that review be granted, WLF argued that the "parallel claim" exception is limited to state claims that are parallel to a federal requirement imposed specifically on a PMA medical device by FDA at the time that it approves the device for marketing. WLF noted that the federal requirement on which Stengel is relying – a requirement to file periodic post-approval safety reports with FDA – is not device-specific but rather applies generally to all device manufacturers. WLF argued that the Ninth Circuit's contrary interpretation robs *Riegel* of all vitality and would allow plaintiffs' attorneys to evade preemption in every product liability suit.

WLF also argued that the Court's 2001 *Buckman* decision requires a finding that Stengel's claims should be dismissed on an additional ground: *implied* preemption. WLF noted that the FDCA includes a provision explicitly barring private parties from filing suit to enforce federal law. WLF argued that the lawsuit is, in essence, an effort to enforce the FDCA and as such is impliedly preempted.

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. It filed its brief on behalf of itself and the Allied Educational Foundation.

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.