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DRI Files Amicus Brief Seeking Supreme Court Review in *Medtronic v. Stengel*

CHICAGO – (June 12, 2013)— Supporting Medtronic's position, DRI- The Voice of the Defense Bar has submitted an amicus brief seeking Supreme Court review in *Medtronic v. Stengel*. The core issue is the preemptive effect of the federal Medical Device Amendments of 1976 (MDA) to the federal Food, Drug, and Cosmetic Act.

Medtronic's pain pump is a medical device that infuses prescription medication through a catheter to relieve severe spinal pain. Richard Stengel brought several state causes of action in Arizona state court against Medtronic Incorporated for injuries allegedly sustained from his use of the pain pump.

After Medtronic timely removed the case to the United States District Court for the District of Arizona, it moved to dismiss under Federal Rule of Civil Procedure 12(b)(6) on the ground that all of plaintiffs' claims were barred as a matter of law by the express preemption provision of the Medical Device Amendments (MDA). The District Court granted Medtronic's motion to dismiss and denied plaintiffs' motions.

Subsequently, a three-judge panel of the Ninth Circuit affirmed. The panel explicitly held that plaintiffs' claims were expressly preempted, with the failure-to-warn claim being the one possible exception. The panel also recognized that to the extent that plaintiffs' failure-to-warn claim sought to enforce federal regulations governing the reporting of product complaints to the FDA, that claim was barred under a straightforward application of *Buckman Co. v. Plaintiffs' Legal Comm*., which prohibits private plaintiffs from usurping the FDA's exclusive authority to enforce its own regulatory scheme.

The majority concluded that most state law claims involving medical devices were preempted unless they asserted that the state requirements were identical to federal requirements governing medical devices. Because plaintiffs in *Medtronic v. Stengel* alleged additional requirements, the panel majority determined that their claims were preempted. At the same time, the panel majority "acknowledge[d] that there is a division among the circuits whether state failure-to-warn claims are preempted by *Buckman*."

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The Ninth Circuit then granted rehearing en banc and, on January 10, 2013, reversed. Judge W. Fletcher wrote the unanimous opinion, which began by stating that there is a presumption against the federal preemption of state laws that "operate in traditional state domains" like health and safety. The court stated that its sister circuits have uniformly held that tort claims that "parallel" federal requirements (rather than impose different or additional requirements) are not preempted by the MDA—either expressly or impliedly.

The court held that Medtronic had a "continuing duty to monitor the product and to discover and report to the 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." This, according to the Ninth Circuit, was parallel to an Arizona state law negligence-based duty to warn patients (or their physicians).

The en banc *Stengel* decision is open to criticism, and its holdings conflict with those of the Supreme Court and other circuits. For example, the Supreme Court has explained that because the MDA preempts only state laws that impose duties "different from, or in addition to" those imposed by federal law, a state law cause of action only survives if it imposes duties that are "identical" to those imposed by federal law. The en banc Ninth Circuit simply did not address the degree of identity required to assert a state law claim that is not "different from, or in addition to" federal law duties as 21 U.S.C. § 360k(a) requires.

DRI added its voice to the en banc proceeding, raising concerns about undermining Congressional intent in enacting the MDA and watering down the Supreme Court's controlling precedent regarding the preemptive reach of the MDA.

DRI argued that medical device manufacturers need a national set of standards to follow, rather than forcing them to navigate 50 state legislatures with 50 different court systems. As the United States Supreme Court has recognized on more than one occasion, preemption of state law claims advances that objective.

DRI's amicus brief was prepared by DRI members Eric J. Magnuson, Shareholder, and Scott M. Flaherty, Associate, at Briggs and Morgan in Minneapolis. To access the brief, click here.

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