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Medtronic Preemption Case Turned Away By Supreme Court

By **Greg Ryan**

Law360, New York (October 01, 2012, 8:10 PM ET) -- The U.S. Supreme Court on Monday declined to take up a challenge to the Fourth Circuit's finding that malfunctioning medical devices are in violation of federal law only if they do not meet performance standards established by the U.S. Food and Drug Administration, a decision that clarified the court's 2008 Riegel ruling.

The high court denied a writ of certiorari from plaintiff Sherry Walker, who appealed a Fourth Circuit decision in January affirming that the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act preempted a suit linking a Medtronic medical device to her late husband's death.

Walker had claimed that because Medtronic's SynchroMed pump, a component in a system used to deliver medication for patients who require chronic infusions, had failed to operate in accordance with the terms of its premarket approval, her claims were consistent with federal requirements and therefore were not preempted.

A majority of a three-judge panel found otherwise, noting that the terms cited by Walker — that an internally implanted pump should maintain its delivery accuracy between plus and minus 15 percent — were not actually part of the formal performance standard for governing the ongoing performance of a medical device as mandated by the provisions of the FDA regulatory process.

Because Walker conceded that the 15 percent rule was not part of the formal performance standard required by the FDA, the panel found that her common law claims would seek to impose requirements above and beyond those of the FDA, which is preempted by the MDA.

The decision helped clarify the standard set by Riegel v. Medtronic, which held that a state requirement would be preempted by the MDA if it would create liability for medical device manufacturers who make the class of devices requiring the greatest federal oversight for failing to comply with standards beyond the FDA's requirements.

An attorney for Walker, Christopher Brinkley of the Masters Law Firm LC, said he was not shocked by the Supreme Court's rejection of certiorari, given how few cases it handles every term.

"I'm very disappointed because of the potential harm it leaves open for consumers for all premarket approval devices," Brinkley said.

An attorney for Medtronic, Andrew Tauber of Mayer Brown LLP, said he "was not surprised, but nevertheless pleased, that the court left the decision below undisturbed."

The dissenting Fourth Circuit judge, U.S. Circuit Judge Albert Diaz, argued that the requirement cited by Walker was in fact a formal FDA standard, not an “aspirational figure” as treated by the majority opinion. If that were the case, Walker's claims would not be preempted because they would be in keeping with federal requirements for the Medtronic device.

The dispute dates back to 2003, when physicians implanted the SynchroMed pump in Walker's husband, Arnold Walker, to deliver medication to treat his chronic back pain.

The pump functioned for approximately 2 years, but in June 2005, Walker died from an overdose of the drugs used to treat his pain. An expert for the plaintiff later claimed that the SynchroMed pump had most likely malfunctioned and overinfused Walker's body with hydromorphone, which caused his death.

Walker is represented by Christopher Brinkley of the Masters Law Firm LC.

Medtronic is represented by Andrew Tauber of Mayer Brown LLP.

The case is Walker v. Medtronic Inc., case number 11-1418, in the U.S. Supreme Court.

--Editing by Lindsay Naylor.