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4th Circ. Tosses Suit Over FDA-Approved Medtronic Device

By **Lana Birbrair**

Law360, New York (January 25, 2012, 8:35 PM ET) -- The Fourth Circuit on Wednesday upheld a finding that federal law preempted a suit against Medtronic Inc. when its device allegedly malfunctioned and caused a man to die because the device in question received U.S. Food and Drug Administration premarket approval.

In a split decision, a three-judge panel upheld a West Virginia federal court's decision that the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act preempted a suit brought by Sherry Walker against Medtronic after her late husband died while being treated with a Medtronic medical device.

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.

The majority opinion 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 plus and minus 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 Fourth Circuit decision helps clarify the standard set by the 2008 U.S. Supreme Court's decision in Riegel v. Medtronic Inc., 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.

In this case, the panel found that because the Medtronic device had been tested before sale and found to be in compliance with the FDA's premarket approval, the malfunction of an FDA-approved device does not necessarily violate the rules set by the MDA.

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.

In a dissent, 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.

“If manufacturers are not held accountable for having their devices perform as approved by the FDA, they will have little incentive to ensure that potentially deadly devices function properly,” Diaz said.

Representatives for Medtronic declined to comment on the suit. Representatives for the plaintiff were not immediately available for comment Wednesday.

Judges Allyson K. Duncan, James A. Wynn Jr. and Albert Diaz sat on the panel for the Fourth Circuit.

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

Medtronic is represented by Andrew E. Tauber, David M. Gossett and Brette L. Steele of Mayer Brown LLP.

The case is Walker v. Medtronic Inc. et al., case number 10-02219, in the U.S. Court of Appeals for the Fourth Circuit.

--Editing by Andrew Park.