

# Fourth Circuit Clarifies Scope of Federal Preemption for Requirements Governing Medical Devices

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The United States Court of Appeals for the Fourth Circuit recently affirmed a West Virginia federal district court's holding that a plaintiff's common law tort claim was preempted by the 1976 Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). Under the MDA, certain medical devices, known as Class III devices, are required to receive premarket approval from the Food and Drug Administration ("FDA"). The MDA also allows the FDA to condition a grant of premarket approval on a requirement that a device meet certain performance standards. The establishment of a performance standard is a formal process that requires publication in the Federal Register and providing interested parties with an opportunity to comment. The MDA expressly preempts state medical device regulations that are "different from, or in addition to, any [federal] requirement."

In a 2008 United States Supreme Court case, *Riegel v. Medtronic, Inc.*, the Supreme Court determined that the terms of a Class III device's premarket approval are considered to be a federal requirement and that a common law tort claim premised on different or additional requirements is preempted by the MDA. But, the Supreme Court recognized one situation in which a plaintiff's common law claims would not be preempted under the MDA--specifically, when "state duties 'parallel,' rather than add to, federal requirements," such as when claims are premised on a violation of FDA premarket approval terms or a formal performance standard.

In *Walker v. Medtronic, Inc.*, No. 10-2219 (4th Cir. Jan. 25, 2012), the plaintiff claimed that the Medtronic SynchroMed Pump--a Class III device, which is designed to deliver pain medication--failed to operate in accordance with the terms of its premarket approval. Specifically, the Technical Manual for the Medtronic device--which was approved by the FDA during the premarket approval process--specified that the device was supposed to operate with a plus or minus 15 percent accuracy rate. The plaintiff argued that her common law negligence, strict liability, and breach of warranty claims regarding the device's alleged failure to operate within the 15 percent accuracy rate paralleled the federal requirements for the device and, therefore, should not be preempted. The Fourth Circuit, however, determined that "[a]n alleged deviation from manufacturing performance specifications for a device that has received premarket approval is not the same thing as noncompliance with the FDA or its regulations," nor had the 15 percent accuracy rate been promulgated as a formal performance standard. Therefore, the Fourth Circuit upheld the district court's decision to dismiss the case because the plaintiff's claims were preempted under the MDA. This decision further clarifies the *Riegel* "parallel duties" exemption and affirms that the malfunction of a medical device does not necessarily mean that the malfunction violates the MDA.