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Recent Supreme Court Decision Bars Product Liability Claims Involving FDA-Approved Class III Medical Devices

In a decision that will limit product liability lawsuits, the U.S. Supreme Court ruled this week that product liability claims against manufacturers of Class III medical devices are barred where the devices have undergone and passed the Food and Drug Administration's pre-market approval process.

Under the Supreme Court's February 20th decision in Riegel v. Medtronic, product liability claims under state law conflict with, and are thus barred by, federal law regulating products that are required to undergo and achieve FDA pre-market approval.

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Case Background: Riegel v. Medtronic, Inc.

Plaintiff Charles Riegel underwent coronary angioplasty in 1996. The Medtronic catheter used during the surgery ruptured, causing a life threatening heart block.

The Medtronic catheter, a Class III medical device, is defined as a product that supports or sustains human life, and thus presents a potential unreasonable risk of injury. To ensure the device's safety, federal law requires that certain Class III devices undergo a thorough FDA pre-market approval process (which takes, on average, 1,200 hours). Once the FDA has given the device its stamp of approval, the manufacturer must produce the device according to the approved design, manufacturing processes and labeling.

Mr. and Mrs. Riegel brought several state law tort claims against Medtronic, including claims for strict product liability and negligence. Because the Medtronic catheter had received pre-market approval, the question before the Supreme Court was whether the Medical Device Amendments of 1976 (MDA) preempted the Riegel's state product liability claims. The MDA expressly prohibit states from establishing any requirement "(1) which is different from, or in addition to, any requirement under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]."

The Supreme Court held that because the FDA approval process is specific to the

device itself, rather than to all medical devices generally, it is a federal "requirement," and that a manufacturer such as Medtronic is not allowed to deviate from the specifications in its approval application. Because product liability claims brought under state law seek to hold manufacturers liable for products that had been approved by the FDA, these suits would establish a requirement which is different from that of the MDA. Because this is not permitted, the Court ruled that the MDA preempt state claims such as strict liability and negligence for those Class III medical devices that go through the pre-market approval process.

The Court did note, however, that where a manufacturer departs from the FDA requirements, injured consumers could sue under state law. In these situations, the state law remedy would not differ from the federal requirement because it would be premised on a violation of FDA regulations.

Implications of this Case to Covered Manufacturers and Beyond

Under *Medtronic*, manufacturers of Class III medical devices authorized under the FDA's pre-market approval process will eventually face fewer product liability claims. Although the decision seemingly takes much pressure off these medical device manufacturers, the Supreme Court clearly stated that the preemption protection only extends to manufacturers that abide by the approved design.

Clearly, the dust has hardly settled on this opinion; however, some members of Capitol Hill have already vowed to legislate against this decision. Additionally, the Supreme Court is expected to rule on two more cases this term on related preemption issues.

Although the decision itself only applies to a narrow category of medical devices, the Court's discussion of the MDA may have ancillary application to other federal statutes with similar preemption language. For example, the Meat Inspection Act, like the MDA, prohibits states from making requirements in addition to or different from federal requirements applicable to meat establishment operations. While the Supreme Court did not directly address this federal statute in its opinion, other courts may be convinced to apply that analysis to bar state tort claims in this or other similar federal laws.

If you have questions regarding the impact of this decision on your business, please contact a member of Reinhart's Product Liability Team.