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Medtronic Win In 10th Circ. A Break For Device Cos.

By **Sindhu Sundar**

Law360, New York (April 22, 2015, 2:42 PM ET) -- The Tenth Circuit decision rejecting off-label marketing claims over Medtronic Inc.'s Infuse bone graft device cements the notion that medical devices are generally immune to injury claims if they have weathered federal regulators' pre-market approval process, a finding that helps defendants get such suits dismissed earlier in the litigation before the expensive discovery stage.

The appeals court found that plaintiff Patricia Caplinger's claims are preempted even though they involved an off-label use for the product, reasoning that Congress had intentionally worded its preemption provisions broadly, without carving out exceptions for "the manner of use" of devices that have gone through the rigorous pre-market approval process.

The decision is the latest in a line of federal court rulings to consider the thorny issues of preemption in light of landmark U.S. Supreme Court cases including Riegel, and it reinforces defendants' arguments that PMA-approved devices are shielded from design defect and failure-to-warn claims. The court had held in Riegel v. Medtronic in 2008 that plaintiffs are restricted from bringing state law claims about the safety or effectiveness of a device preapproved by the FDA.

But the appellate panel's explicit rejection of off-label marketing claims, which it supported with a detailed reasoning about Congress' intent, can help device makers try to get similar suits against them tossed at the motion to dismiss stage, rather than the later summary judgment phase, helping them evade costly and potentially drawn-out discovery battles, attorneys say.

"This body of law that we have now with PMA-approved devices provides a rare opportunity for defendants to get cases dismissed at the motion to dismiss stage, and avert any additional discovery for PMA-approved devices," Matt Keenan of Shook Hardy & Bacon LLP said.

"PMA-approved devices are unique from others, given the safety and effectiveness showing that manufacturers have to make to the regulatory body," he said.

Plaintiffs in pharmaceutical and device injury litigation have lately focused their complaints on alleging that a particular drug or device was marketed for an unapproved use and that the FDA's approval only concerns their approved uses.

Caplinger had argued in this case that even if there were no parallel federal law claims to her state law claims — as required by Supreme Court rulings including Riegel — her state tort claims should still be

able to survive preemption because they concern an off-label use. The Tenth Circuit's ruling deals a blow, at least within its jurisdiction, to that line of argument, attorneys say.

"The off-label use claim used to be an opportunity for plaintiffs to carve out some life for these suits, to say that manufacturers affirmatively took on some additional duty because they did something beyond what the regulatory framework required them to do, by marketing an off-label use," Keenan said.

"But this opinion really goes a long way to say that those types of attempts to create exemptions will not be allowed," he added.

Some plaintiffs attorneys agree that the Tenth Circuit handed defendants an important tool to thwart discovery, though some say it is possible that other appellate courts could diverge from its view on off-label marketing claims.

"For plaintiffs who are attempting to craft complaints in the jurisdiction of the 10th Circuit, this ruling has made it hard," said Paul Slager of Silver Golub & Teitell LLP. "But the 10th Circuit has a reputation for being a more business-friendly court than other circuits, so it remains to be see if other circuits will have the same business-friendly interpretation."

Caplinger is represented by Allison M. Zieve and Scott L. Nelson of Public Citizen Litigation Group, and James W. Dobbs of Rhodes Dobbs & Stewart PLLC.

Medtronic is represented by Andrew E. Tauber and Daniel L. Ring of Mayer Brown LLP, and Scott M. Noveck, formerly of Mayer Brown, and Michael K. Brown, James C. Martin, and Lisa M. Baird of Reed Smith LLP.

The case is Patricia Caplinger v. Medtronic Inc., case number 13-6061, in the U.S. Court of Appeals for the Tenth Circuit.

--Editing by Jeremy Barker and Emily Kokoll.
