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Riegel Loophole Keeps PMA Device Cases Afloat, Barely

By **Greg Ryan**

Law360, New York (July 17, 2013, 9:40 PM ET) -- The U.S. Supreme Court ruled five years ago that federal law preempts most allegations targeting medical devices that have received pre-market approval. Medical device makers now face fewer lawsuits because of the ruling, as was expected, but plaintiffs have exploited a loophole in the decision to sustain a small category of claims over the products.

The court held in Riegel v. Medtronic in February 2008 that plaintiffs cannot challenge under state law the safety or effectiveness of a device preapproved by the U.S. Food and Drug Administration, if the device is marketed in the approved form. The decision sparked outrage from Democrats in Congress, who tried to undo the ruling by introducing bills that ultimately went nowhere.

One lawmaker who co-sponsored the failed legislation, Rep. Frank Pallone Jr., D-N.J., said at the time that the decision “denied victims any legal recourse and gave medical device makers blanket immunity for the life of a product.” While that assessment has held true for many plaintiffs, a tiny subset has escaped preemption by pleading state-law claims that paralleled federal requirements — a type of allegation the Supreme Court said it would not address.

That statement, which came in the last paragraph of the majority opinion in the Riegel case, has kept alive litigation against manufacturers of preapproved devices. In the five years since the decision, plaintiffs have attempted to squeeze their allegations through that “parallel claims" valley, and though they have met with more failure than success, they have discovered a handful of routes that allow them to survive preemption bids, attorneys say.

Although the landscape may not look anywhere near as plaintiff-friendly as it did before Riegel, the ground ahead seems pretty stable, according to attorneys.

“I never really expected the plaintiffs would just go away,” Reed Smith LLP counsel James Beck said. “The one thing I was not expecting was that the courts would have made as much of parallel claims as they have.”

The plaintiffs with the best shot at fitting through the loophole are those alleging a device suffered from a manufacturing defect, attorneys say. If an implanted device does not meet the specifications the FDA set out when it approved the product, a plaintiff can easily make the case that the manufacturer violated a state-law duty that does not add on to federal requirements, they say.

“If you have a manufacturing defect, it is almost guaranteed to be recognized as a parallel claim,” Shook Hardy & Bacon LLP partner Matthew Keenan said.

Other stabs at parallel claims have met with mixed success, including allegations based on an FDA warning letter to a manufacturer. The alleged violation of federal law is right there in writing, but even the FDA says the letters are not final actions. And plaintiffs run into difficulty showing how the violations in the letter relate to the particular devices they've used, attorneys say.

“The trouble is a lot of FDA warning letters don't have a causal relationship with a particular plaintiff's claim, or they have a technical detail that doesn't have a state-law analog,” Beck said.

Similarly, while some courts have found that state-law claims that a manufacturer promoted its device for off-label uses are preempted, others have maintained that the allegations can parallel federal requirements, since the product's purported use falls outside the FDA-approved indications.

In the end, the off-label claim route is a limited one, according to Kaye Scholer LLP counsel Angela Vicari. Plaintiffs pursuing these claims must find a state-law analog to the Food, Drug and Cosmetic Act, since the federal law cannot be enforced by anyone but the government. And to funnel an off-label violation into a fraud claim, plaintiffs must show that the manufacturer actually promoted the product in a fraudulent way, rather than simply pointing out that physicians are prescribing the devices for off-label uses, she says.

“Even if you're able to get past the pleading stage, you have your work cut out for you,” Vicari said.

Riegel is not the only case plaintiffs suing device makers have to worry about, either. The Supreme Court's 2001 decision in Buckman v. Plaintiffs' Legal Committee held that state-law claims that a company defrauded the FDA while seeking pre-market approval for a device are preempted by federal law. In addition, plaintiffs in the post-Riegel era have fallen victim to the high court's so-called Twombly-Iqbal standard, as courts have held they failed to make their claims detailed enough.

Still, the Riegel ruling isn't likely to kill off the litigation, according to attorneys, who say the status quo is likely to hold for the foreseeable future.

Experts view a legislative reversal of Riegel as unlikely, since lawmakers' attention has drifted to other perceived court-induced inequities. Three years after it decided Riegel, the Supreme Court all but barred state-law product liability claims against generic-drug manufacturers, in a case known as Mensing.

As with Riegel, lawmakers introduced legislation in response to the decision. But it appears Mensing may actually spur regulatory action, as the FDA indicated earlier in July that it planned to propose a rule that could once again allow plaintiffs to sue generics makers over their warning labels.

“That's taken all of the air out of the room, leaving Riegel on very solid footing,” Keenan said.

--Editing by Kat Laskowski and Melissa Tinklepaugh.