

3rd Circ. Gives 'Hybrid' Med Devices New Liability Shield

By Emily Field

Law360 (March 6, 2018, 9:20 PM EST) -- The Third Circuit recently ruled that a patient with a so-called hybrid hip replacement can't bring negligence claims against Smith & Nephew because they are preempted by federal law, giving device makers a legal shield for products composed of parts with various levels of regulatory approval.

The appeals court in its published opinion tackled whether claims by Walter and Vivian Shuker over a hip replacement system made by Smith & Nephew PLC were preempted by the Federal Food, Drug and Cosmetic Act. The panel in a case of first impression addressed a medical device system made of components classified differently by the U.S. Food and Drug Administration. At issue for the first time in an appellate decision was whether the panel should analyze preemption — when federal law bars state law claims — at the component level or at the system level.

Ultimately, the panel concluded that preemption should be analyzed at the former level, basing its decision on the grounds that the FDCA defines a device as not just a finished product, but also as any device component. The FDA also takes the stance that the preemption analysis must be conducted at the component level, the panel said in upholding a lower court's decision to dismiss the couple's negligence, strict liability and breach of implied warranty claims.

"[The decision] marks a step forward in clarifying the law on the component question," John DeBoy of Covington & Burling LLP said in an email. "Some federal district courts have applied an analysis similar to the Third Circuit's, while others have taken the position that express preemption doesn't apply in claims arising from the interaction of mixed-class components."

The decision is "substantively" favorable for makers of medical devices, as the holding should prevent plaintiffs from dodging express preemption — when a federal law is written to explicitly preempt state law — in "at least some" cases involving mixed-class components, according to DeBoy.

"It will be interesting to see if other circuits follow the Third Circuit's lead on this issue," DeBoy wrote in an email.

DeBoy did caution that the ruling may not necessarily lead to all cases involving components of mixed classes being dismissed on preemption grounds, noting that the panel explained that alleged warning defects in the non-Class III parts might not implicate express preemption.

Class III devices pose the greatest risk and are subject to more scrutiny from the FDA than other classes. Those must go through a premarket approval process where the manufacturer has to submit details on the device's safety and efficacy. In contrast, other classes go through the more lenient 510(k) approval process and aren't subject to the same requirements as Class III devices.

Walter Shuker had total hip replacement surgery in 2009, and some components of the system, such as the one that replaced the top of his thigh bone, were Class II devices, according to the opinion. But one component, the metal liner, was Class III, the panel said.

Almost two years after the operation, Shuker had to have surgery to remove the system after he developed increasing pain and discomfort due to metallic debris, according to the opinion.

Under the FDCA, state law claims over Class III devices or components are preempted when the claims impose additional requirements to the federal ones.

While the panel upheld the dismissal of Shuker's claims of negligence, strict liability and breach of implied warranty on preemption grounds, it disagreed with the lower court that other claims were also preempted by federal law.

On the couple's state law claims on the company's off-label promotion of the metal liner, which was only FDA-approved for use in a different system, the appeals court found that those claims ran parallel to federal law and didn't impose additional requirements, and thus weren't preempted.

Lower courts in other circuits have held differently than the Third Circuit on this issue, finding that there has to be a state law barring off-label promotion for there to be a parallel claim. Those courts have held that no states have such a law and therefore the issue falls under the FDA's purview, said Alana Bassin of Bowman and Brooke LLP.

The disparate rulings could lead to a circuit split on the question of whether off-label promotion claims are preempted by federal law, lawyers suggested.

"It continues to be this unresolved issue and it is a hollow victory because [the opinion] still allows [plaintiffs] to sue," Bassin said.

The ruling highlights an unsettled area of law that may require the U.S. Supreme Court to step in and find one way or another whether state law claims regarding off-label promotion are preempted, according to Bassin.

--Editing by Pamela Wilkinson and Breda Lund.