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7th Circuit panel clears way for lawsuit over prosthetic hip

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A woman who contends she was injured by the device that replaced her right hip should be allowed to pursue her claims against the device's maker, a federal appeals court has held.

The 7th U.S. Circuit Court of Appeals on Thursday revived a lawsuit brought by 56-year-old Margaret Bausch, who claimed that her prosthetic hip was manufactured in violation of federal safety standards and, as a result, she should be allowed to pursue a claim for damages under Illinois law.

The court reversed U.S. District Judge Samuel Der-Yeghiayan's decision to dismiss the suit, concluding that the federal judge erred in holding that Bausch's common law claims were preempted by federal law.

In its opinion, the three-judge federal panel pointed out that the central issue in the appeal was whether federal law preempts product liability claims against manufacturers of complex medical devices where a patient claims that she was harmed by the manufacturer's violation of federal law.

"That statement of the issue may be a little startling. The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive," Judge David F. Hamilton wrote. "Nevertheless, manufacturers in this case and in others have asserted this theory of defense."

Bausch alleged that the prosthetic hip was implanted in her body six days after the U.S. Food and Drug Administration informed the defendants — Stryker Corp., HOC, and Stryker Ireland Ltd. — that a component of the hip system was "adulterated" and that the companies' manufacturing processes failed to comply with federal standards.

The device implanted in the woman failed, requiring surgical removal and replacement of the product and leading to a host of serious and painful medical problems, the woman claimed. The defendants later recalled a component of the hip replacement system bearing the same catalogue number as the one that had been implanted in Bausch's body.

The 7th Circuit said the manufacturers' preemption defense theory "tries to stretch the Supreme Court's decisions in this field beyond the boundaries that were made clear in those decisions."

The court cited U.S. Supreme Court rulings in *Medtronic Inc. v. Lohr* [1996] and in *Riegel v. Medtronic Inc*. [2008].

The court pointed out that the manufacturers' hip implants are treated as "Class III Medical Devices" under the federal Food, Drug, and Cosmetic Act and therefore are subjected to a rigorous pre-market

approval process. In *Riegel*, the court noted, the Supreme Court held that lawsuits brought under state law against medical device manufacturers who obtain the full federal "premarket approval" are preempted by section 360k(a) of the Medical Devices Act when liability is premised on violations of state law requirements that are in addition to or different from federal requirements regulating the devices.

However, the panel held, "Neither case held that state lawsuits premised on violations of federal law are preempted … In fact, the Court's opinions in *Lohr* and *Riegel* expressly left the door open for state law claims based on violations of federal law."

"Just as a plaintiff in an auto accident may use the other driver's speeding violation as evidence of negligence, plaintiff Bausch claims that she was injured by Stryker's violations of federal law in manufacturing the device implanted in her hip," Hamilton wrote. "It remains to be seen whether she can prove those allegations, including causation and damages. But if she can prove those allegations of harm caused by violations of federal law, her claims under state law would not impose on defendants any requirement 'different from, or in addition to, any requirement' imposed by federal law."

Chief Judge Frank H. Easterbrook and Judge Daniel A. Manion joined in the panel's 33-page decision. *Margaret J. Bausch v. Stryker Corporation, et al.*, No. 09-3434.

The panel, which directed that the action be sent back to the district court for further proceedings, also concluded that the district court abused its discretion by dismissing the action with prejudice and denying Bausch leave to file an amended complaint.

Chicago attorney Joshua L. Weisberg of Rapoport Law Offices P.C. argued the case before the 7th Circuit on behalf of Bausch.

In a prepared statement, Weisberg said the decision "will go a long way toward eliminating an injustice that has gained too much traction in the lower courts in the last few years."

"People who suffer harm from defective medical devices manufactured in violation of federal regulations should have remedies in court not only because this is fair, but also because it makes us all safer," he said.

Robert M. Connolly of Stites & Harbison in Louisville, Ky., argued the case on behalf of Stryker.

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