

Hips will be huge next year

Medical device makers face potentially massive claims.

BY AMANDA BRONSTAD

Soon after Maurice Brigham underwent surgery to implant a metal hip replacement, he started suffering from swelling, infection and pain. So he signed up for another surgery—this time, to remove the device, an ASR XL acetabular system—but infection prevented surgeons from removing the device.

The episode left the San Bruno, Calif., equipment operator bedridden, according to a lawsuit he filed on Aug. 30, 2010. The action names the hip implant's manufacturer, DePuy Orthopaedics Inc., and its parent company, Johnson & Johnson Services Inc.

His case is one of about 3,500 lawsuits filed against DePuy over its ASR hip implants, which the company recalled on Aug. 24, 2010. About 93,000 patients worldwide have had the devices implanted—one reason why plaintiffs' attorneys predict the litigation will be huge. "We're just at the tip of the iceberg," said William Trombetta, a professor of pharmaceutical and health care marketing at St. Joseph's University in Philadelphia. "We have a lot of huge issues here that are going to explode."

DePuy faces additional litigation over its Pinnacle acetabular cup system, another metal-on-metal hip implant, and cases are pending against another manufacturer, Zimmer Holdings Inc., over a device called a Durom acetabular component.

On May 6, the U.S. Food & Drug Administration, which regulates medical devices, ordered 21 manufacturers of metal-on-metal hip implants to conduct surveillance on their products and to assess the safety of the devices. DePuy, based in



HOT LITIGATION: Ellen Relkin "Not only wasn't it working well, it was literally out of whack due to the metal getting deformed because of this bad design," she said.

Warsaw, Ind., initiated a voluntary recall of all its ASR devices after fresh data in the United Kingdom indicated that the rate of patients who had to return to surgery within five years—the revision rate—was 12 to 13 percent. That was much higher than the industry standard, according to the FDA. DePuy recalled two devices: The ASR XL acetabular hip system, introduced to the U.S. market in 2005, and the ASR hip-resurfacing system, which was not sold in the United States.

More than 2,200 cases involving the devices are pending in a federal multidistrict proceeding in Toledo, Ohio. Another

1,000 are pending in state courts in California and 160 in New Jersey's state courts. Additionally, more than 300 lawsuits have been coordinated in Dallas in separate multidistrict litigation against DePuy over its Pinnacle device. And DePuy isn't alone. Zimmer faces dozens of lawsuits in federal multidistrict litigation in New Jersey involving its Duron implant, which it withdrew in 2008.

'EVERYONE STAYED FOR DEPUY'

This year, hip-implant litigation has been a top subject at conferences for the plaintiffs' bar across the country. Updates about the hip-implant litigation were scheduled during events in San Francisco, San Diego and Louisville, Ky., and during this month's Mass Torts Made Perfect, a retreat for plaintiffs' attorneys at the Bellagio Hotel and Casino in Las Vegas.

"People come and go, depending on the hotness of the litigation, in and out of those conferences, and everyone stayed

for DePuy and Pinnacle," said Richard Meadow, managing attorney of the New York office of The Lanier Law Firm. Meadow led the session on the Pinnacle litigation before a crowd of 400.

In the federal ASR litigation, more than 100 lawyers vied for four hours during a recent hearing for appointment to various plaintiffs' leadership committees, said Ellen Relkin of Weitz & Luxenberg in New York. She was named co-lead counsel. About 500 law firms are involved in the litigation, she said.

"Typically, there are several dozen firms that really specialize in phar-

maceutical and medical-device litigation," Relkin said. "But because this was recalled and there were people all over the country having problems, many different lawyers have taken on the case."

DePuy and Johnson & Johnson, based in New Brunswick, N.J., are represented by Robert Tucker of Tucker, Ellis & West in Cleveland, and by Susan Sharko, a partner in Drinker Biddle & Reath's Florham Park, N.J., office. They shared lead counsel roles in the Ortho Evra birth control MDL. Tucker declined to comment.

DePuy spokeswoman Lorie Gawreluk wrote in an e-mail to *The National Law Journal* that DePuy voluntarily recalled the ASR products in "the best interests of patients." She continued: "DePuy will defend itself against the allegations raised in these litigations and believes the evidence will show that the company acted responsibly."

On Dec. 7, the U.S. Judicial Panel on Multidistrict Litigation centralized the litigation over the ASR hip implant before U.S. District Judge David Katz in Toledo. The plaintiffs' executive committee is a six-member team co-chaired by Relkin and Steven Skikos of Skikos Crawford Skikos & Joseph in San Francisco. Thirteen lawyers sit on the plaintiffs' steering committee, four on a science committee, six on a discovery committee and two on a law-and-motions committee.

So far, DePuy has produced more than 7 million of the anticipated 18 million documents in the case, Relkin said. Plaintiffs' attorneys argue that the ASR was defectively designed or manufactured. "Not only wasn't it working well, it was literally out of whack due to the metal getting deformed because of this bad design," Relkin said.

The metal-on-metal design was intended to improve on the conventional hip implant, which uses a metal cup and polyethylene insert, according to Relkin. The ASR product was marketed for use in younger, more active patients—many of her clients are in their 40s and 50s, she said. "The idea of the metal-on-metal was it would last longer theoretically because of the harder surface," she said—over time, some of the polyethylene implants would wear away. But several patients who had the metal-on-metal devices surgi-

cally implanted have undergone additional surgeries to remove the implants.

In California's state courts, the cases are pending in a coordinated proceeding before San Francisco Superior Court Judge Richard Kramer. Leading the plaintiffs' attorneys is Michael Kelly, a partner at Walkup, Melodia, Kelly & Schoenberger in San Francisco and one of 13 members of the steering committee in that litigation.

'A LOT OF PEOPLE INJURED'

"The effect of this device has been so widespread, systematic and ruinous that the natural result is you have a lot of people injured and a lot of lawyers representing them," said Khaldoun Baghdadi, another partner at the firm.

In New Jersey, several plaintiffs' attorneys asked that the cases be moved out of Middlesex County, where Johnson & Johnson is based. They were coordinated in front of Bergen County Superior Court Judge Brian Martinotti in Hackensack, N.J.

Defense counsel have had limited responses in the case filings. In a master answer filed in the federal ASR case on April 7, attorneys for DePuy denied the allegations. They suggested that the alleged injuries could be due to pre-existing medical conditions or an "idiosyncratic reaction to the product."

In preparing its defense, DePuy might look at specific reasons why a certain hip implant failed—a patient's medical condition, perhaps, or an activity the patient was doing when the implant failed, said Beth Rose, a partner at Newark, N.J.-based Sills Cummis & Gross who represents medical-device companies but is not involved in the hip-implant cases.

Additionally, the company might argue that some risks and side effects are normal. "With any drug or device, there are risks or benefits and potential side effects and anticipated complications," Rose said.

Another defense attorney, Jack "Skip" McCowan, a partner at San Francisco's Gordon & Rees, questioned just how big the litigation could get. "I'd have to assume not every one of these implants is creating a problem," he said.

As of Oct. 6, 538 cases had been filed in the federal litigation over DePuy's Pinnacle implant, said Meadow of The Lanier Law

Firm, which moved to coordinate the cases. U.S. District Judge Ed Kinkeade in Dallas, who is hearing the Pinnacle cases, has stayed the proceedings until he can select lawyers for the lead counsel committees. Nearly 80 lawyers have submitted applications on the plaintiffs' side.

Meadow predicted that many more cases will arise, particularly since reports of problems with the Pinnacle have increased each year. But because this particular device has not been recalled, he anticipates a bigger fight with DePuy in these cases. "They're probably going to contest this a lot more strenuously than they do the ASR," he said.

DePuy has selected a separate legal team for the Pinnacle cases: Michael Powell, a Dallas partner at Locke Lord, and John Beisner of Skadden, Arps, Slate, Meagher & Flom. Powell did not return a call for comment. Beisner, co-chairman of Skadden's mass torts and insurance litigation group in Washington, represented Merck Inc. in the litigation over painkiller Vioxx.

When asked about the reason for a separate legal team, Gawreluk wrote: "Since these are two different products, the issues in the lawsuits will be different.

"Pinnacle is not subject to a recall, and the company stands firmly behind the device," she added. "Pinnacle has been cleared for sale by the FDA and regulators around the world and is backed by more than a decade's worth of clinical data that have consistently shown that Pinnacle is a safe and effective option for patients who are candidates for hip replacement."

To be sure, the hip-implant cases, while numerous, are far from certain. "It's not going to be the slam dunk for the plaintiff lawyers," said Trombetta, the St. Joseph's University professor, who has been hired by plaintiffs' attorneys as an expert. "You never know what's going to happen in front of a jury."

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