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# J&J Accused at Trial of Ignoring Pinnacle Hip Failures

By Jef Feeley and Sophia Pearson - Oct 22, 2014

To protect billions of dollars in sales, Johnson & Johnson (JNJ) ignored reports that the metal-on-metal version of its Pinnacle hip implants failed at alarming rates, a lawyer told jurors at the end of the first case to go to trial over the devices.

J&J's DePuy unit turned a blind eye to reports the hips had design flaws that prompted them to break down and then misled doctors about the implants' failure rates to protect sales, Mark Lanier, an attorney for a Montana woman who sued after complications forced her to have the device removed, said in closing arguments yesterday in Dallas federal court.

Kathleen Herlihy-Paoli, 58, claims the metal hips made by the unit of J&J, the world's largest health-care company, leached cobalt and chromium material into her bloodstream, causing an infection that required the devices to be surgically removed.

DePuy executives decided to continue "to sell these things while they knew people were getting hurt," Lanier said.

The case is the first of more than 6,000 over the Pinnacle hips to go before a jury. The devices weren't covered by New Brunswick, New Jersey-based J&J's $2.5 billion settlement of claims last year over another line of artificial hips known as ASRs. In that case, J&J recalled 93,000 ASR hip implants worldwide in August 2010, saying 12 percent failed within five years.

## 'Acted Appropriately'

"We are confident that the evidence shows that the company acted appropriately and responsibly in the development, testing and marketing of the product," said Mindy Tinsley, a spokeswoman for DePuy.

Lanier argued that J&J's marketing of the Pinnacle hip devices included "countless false representations" about the implants' durability. The company's advertising was part of an "incredible monetary machine that is behind" J&J's drive to increase its market share for the medical devices, Lanier told jurors.

The Pinnacle cases have been consolidated before U.S. District Judge Ed Kinkeade in Dallas for

pretrial information exchanges. Kinkeade also is presiding over Herlihy-Paoli's trial, which has lasted about eight weeks. A nine-person jury, which includes an engineer and a real estate lawyer, began deliberations yesterday.

J&J could face a punitive damages judgment if the jury finds it engaged in fraud or acted with malice in its design or handling of the hip implants.

## Earlier Settlement

The earlier ASR settlement aimed to resolve about 8,000 U.S. suits against DePuy and offered an average of about $250,000 for each surgery, plus related medical costs, officials said when the deal was announced in November 2013.

J&J agreed to pay as much as $1 billion to insurers who covered the medical costs of removing the recalled ASR hips. Those costs, along with other expenses tied to the drugmaker's push to resolve hip-implant cases, are likely to drive the agreement's price tag to more than $4 billion.

J&J stopped selling the metal-on-metal version of the Pinnacle hip in August 2013 after the U.S. Food and Drug Administration said it would require device makers to submit new versions of the artificial hips for pre-market approval.

J&J touted the metal-on-metal implants, first sold in the U.S. in 2000, as a design that would last 20 years and offer greater range of motion.

Herlihy-Paoli, a graphic designer, got two Pinnacle hips in 2009 and quickly began to complain of pain, according to court filings. She had the artificial hips removed in 2011, according to court papers.

## Cobalt, Chromium

Tests prior to the surgeries found the "implants had released dangerous levels of cobalt and chromium into her bloodstream," the woman's lawyers said in court filings. That caused an infection requiring removal of the device, according to her complaint.

J&J's lawyers countered during the trial that Herlihy-Paoli's ailments were caused by the position of the hips in her body and weren't linked to design flaws. Overwhelming evidence showed the implants were placed in a position that "made it impossible for them to function properly," Richard Sarver, J&J's lawyer, said yesterday in closing arguments.

"They don't want to know the truth because it destroys their case," Sarver said of Herlihy-Paoli and Lanier.

DePuy executives also disclosed the risks of the metal-on-metal hips to both FDA regulators and orthopedic surgeons, the company's lawyers told jurors.

"To say DePuy was ignoring the problem is not fair," Sarver said. "To suggest we hadn't done our homework on the metal-on-metal design is wrong."

The case is Herlihy-Paoli v. DePuy Orthopaedics Inc., 12-cv-04975, U.S. District Court, Northern District of Texas (Dallas).

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