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J&J to Pay \$120 Million in Its First Big Mesh Settlement

Markets

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Johnson & Johnson has made its first serious move to settle thousands of lawsuits filed by women who fault the company's vaginal-mesh inserts for their injuries, according to people familiar with the matter.

The medical-device maker agreed to pay more than \$120 million to resolve 2,000 to 3,000 suits alleging women suffered organ damage and were left in constant pain by mesh surgical inserts that eroded in their bodies, according to three people who asked not to be named because they weren't authorized to speak publicly about the settlement.

The company faces another 42,400 such cases, according to a regulatory filing. It's unclear what J&J's exposure will be after those suits are resolved through verdicts, settlements or dismissals because average payouts will vary based on the strength of cases.

"From time to time we have appropriately agreed to resolve some cases," Ernie Knewitz, a J&J spokesman, said in an e-mailed statement. "We will not discuss the terms, nor discuss our ongoing litigation strategy."

The settlements mark the first time J&J and its Ethicon unit have agreed to resolve a significant number of mesh cases. The company, which has settled only a handful of cases so far, has set aside an undisclosed reserve for those and other product-liability claims, according to its October filing with the Securities and Exchange Commission. J&J has said it doesn't consider the financial risk from the mesh cases to be material.

Total Expenses

The New Brunswick, New Jersey-based company reported \$141 million in total litigation expenses in 2015, down from \$1.2 billion in 2014 legal costs and \$2.2 billion in 2013, according to its filings.

<u>Clayton Clark</u>, a Houston-based lawyer who represents the settling women, declined to comment on the accord. The company has said it acted appropriately and responsibly in the development and marketing of the device.

J&J faces the most cases in the sprawling vaginal-mesh litigation, which began in 2011 and has encompassed at least 100,000 suits against more than a half-dozen device makers. Companies including Boston Scientific Corp. and C.R. Bard Inc. have settled some cases while setting aside more than \$1 billion to deal with claims over inserts, which bolster sagging organs and treat incontinence.

Women complain that Ethicon's inserts shrink once implanted, causing organ damage and constant pain.

J&J agreed in June 2012 to pull some lines off the market.

Join Talks

J&J has so far refused to join talks between plaintiffs' lawyers and other insert makers seeking a global resolution of sprawling litigation, said Carl Tobias, who teaches product-liability law at the University of Richmond in Virginia.

"J&J still has a ton of cases to deal with, but this settlement may encourage other lawyers to consider taking their offer," Tobias said.

The U.S. Food and Drug Administration in 2012 ordered J&J, Boston Scientific, Bard and other mesh makers to study rates of organ damage and complications linked to the implants after the companies faced a wave of lawsuits. The FDA this month tightened regulations governing inserts after finding they should be classified as higher-risk products when used to bolster sagging organs.

Juries in <u>Texas</u>, <u>New Jersey</u>, and <u>California</u> have found J&J and Ethicon liable for injuries tied to the inserts.

A Philadelphia jury last month ordered the device maker to pay \$12.5 million to a woman who said Ethicon's

Prolift mesh harmed her bladder. The company has won several trials, including a 2014 case brought in West Virginia over mesh used to treat incontinence.

Federal Judge

U.S. District Judge Joseph Goodwin in Charleston, West Virginia, was tapped in 2012 to oversee mesh cases in federal courts across the country. He's been pushing manufacturers to consider <u>settling</u>, Tobias said.

Marlborough, Massachusetts-based Boston Scientific faces 30,000 mesh suits, the company said in a November filing. In April, the device maker said it agreed to pay \$119 million to resolve almost 3,000 cases in its first substantial settlement.

Bard said in an October SEC filing that it faced 12,850 mesh suits after settling about 6,400 cases. The company agreed in August to pay more than \$200 million to resolve at least 3,000 cases, people familiar with the <u>accord</u> said at the time.

The case is In Re Ethicon Inc. Pelvic Repair System Products Liability Litigation, 12-MDL-2327, U.S. District Court, Southern District of West Virginia (Charleston).