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Bard Used Mesh Plastic Found Unfit for Humans by Supplier

By Jef Feeley & David Voreacos - Jun 26, 2013 11:39 AM ET

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CR Bard Inc. (BCR) sold vaginal-mesh devices made of a plastic that its manufacturer warned wasn't suitable for human implantation, according to unsealed court records.

Managers at Bard's Davol unit used a resin-based plastic made by a Chevron Phillips Chemical Co. unit to produce hernia-repair mesh after the material's supplier officially registered a warning that it shouldn't be permanently implanted in people, according to e-mails and documents in a lawsuit over Bard's implants. Plaintiffs suing Bard contend the same mesh was used in some of Davol's vaginal-mesh products.

Enlarge image

Johnson & Johnson said last year that it would stop selling four lines of vaginal-mesh implants after complaints and lawsuits about the devices. Photographer: Scott Eells/Bloomberg

In 2004 and 2007 e-mails filed in federal court in West Virginia, a Davol executive warned colleagues not to tell Chevron Phillips or other resin makers that the company was using the material in medical devices placed in humans.

Suppliers such as Chevron Phillips "will likely not be interested in a medical application due to product-liability concerns," Roger Darois, the Davol executive, now a Bard vice president, said in a March 2004 e-mail. "It is likely they do not know of our implant application. Please do not mention Davol's name in any discussion with these manufacturers."

Lawyers for thousands of women who blame Bard's Avaulta line of implants for their injuries said the files show Davol officials knew the resin-based mesh wasn't proper for human implantation and tried to cover up their use of the material.

Bard Statement

In a statement yesterday, Bard didn't respond to a question about its desire to keep the information from suppliers. Company officials declined to elaborate on the statement.

Bard, based in Murray Hill, New Jersey, faces a July 8 trial in Charleston, West Virginia, over claims its mesh device harmed Donna Cisson, 54.

"During the upcoming trial, Bard will provide all the relevant evidence for the jury to consider and

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render a decision, which will demonstrate that Bard acted appropriately in its acquisition of polypropylene resin," Scott Lowry, a Bard vice president, said in yesterday's e-mailed statement.

"We believe that the Avaulta polypropylene mesh implant is a safe and effective treatment for pelvic organ prolapse when used in accordance with its instructions," Lowry said. "To this day, after more than 50 years of use, polypropylene remains one of the most widely implanted and best materials for mesh products in medical applications in the human body."

Lowry didn't comment on the e-mails filed in federal court.

Judge's ruling

U.S. District Judge Joseph Goodwin ruled June 4 that the e-mails regarding the resin-based mesh raised "a genuine issue of material fact about whether Bard was aware its conduct was practically certain to cause injuries."

Lawyers for Cisson, who lives in Georgia, will use the e-mails in next month's trial over whether the Avaulta design was defective and Bard failed to warn of the risks. Cisson claims the device caused her pain, bleeding and bladder spasms that required follow-up surgeries.

She can seek punitive damages if jurors hold Bard liable for compensatory damages and find the company's conduct justifies the additional award, the court ruled.

Goodwin is overseeing 20,000 lawsuits against Bard, Johnson & Johnson (JNJ), Endo Health Solutions Inc. (ENDP)'s American Medical Systems, Boston Scientific Corp. (BSX), Coloplast Corp. and Cook Medical Inc. alleging injuries from vaginal mesh implants. The companies have denied wrongdoing in court filings.

Cisson's case will be the first against any of those companies to go to trial before Goodwin, who is coordinating the pretrial exchange of information.

Bellwether Trials

Three more "bellwether trials" involving Bard's vaginal inserts are scheduled before Goodwin after Cisson's case. The trials will be used to gauge the validity of the two sides' conflicting claims.

The women who sued contend erosion of the inserts, designed to shore up weakened pelvic muscles and treat urinary incontinence, can cause organ damage and bleeding and make sexual intercourse painful. They said the meshes, threaded in place through vaginal incisions, degrade and shrink over time.

U.S. Food and Drug Administration officials estimate that 300,000 women had pelvic organ prolapse surgery in 2010 and mesh was used in a third of the procedures. Agency data showed more than 250,000 incontinence surgeries for women that year, about 80 percent involving vaginal-mesh implants, the FDA said.

The agency last year ordered Bard, J&J and other mesh makers to make three-year studies of rates of organ damage, infection and painful sex linked to the devices after women's groups called for their removal from the market.

Sales Halted

J&J, based in New Brunswick, New Jersey, said last year it would stop selling four lines of vaginal-mesh implants after complaints and lawsuits about the devices. The company acted for

reasons unrelated to safety concerns, it said at the time.

A jury in Atlantic City, New Jersey, decided in February that J&J and its Ethicon unit must pay more than $11 million in damages to a woman who blamed the company's Gynecare Prolift implant for her injuries.

A California state court jury last year awarded $3.6 million to a woman who blamed Bard's Avaulta Plus implant for injuring her. It was the first such case to be tried in any court. The Avaulta inserts, sold in the U.S. since 2005, were pulled off the market last year.

A Bard official said in a January 2012 internal e-mail that, in response to the FDA ordering safety studies on vaginal-mesh devices, the company planned to pull Avaulta devices off the market that year.

'Business Decision'

The company "is simply making a business decision not to invest in clinical trials on this product," Brenda Hammans, a vice president, said in the e-mail.

In Cisson's case, the Georgia woman alleged the Avaulta device, inserted in May 2009, caused pelvic and rectal pain, bleeding and bladder spasms and required surgeries to remove.

Goodwin unsealed Bard documents and witness depositions about how its vaginal-mesh products were designed, tested and marketed. Cisson's lawyers fault Bard for not testing the mesh on people before selling it. Plaintiffs' lawyers obtained e-mails in the pretrial exchange of information with the company.

Medical companies have used polypropylene for years to make items such as sutures, catheters and artificial-heart components because the material is considered to be "biocompatible" and won't be rejected by the human body.

Safety Document

Cisson's lawyers said in court papers that Phillips Sumika, a Woodlands, Texas-based unit of Chevron Phillips Chemical, filed a required safety data document, called a "Material Safety Data Sheet," with the U.S. Occupational Safety and Health Administration about the Marlex polypropylene used in some Bard hernia and vaginal implants.

On the 2007 document's front page, Phillips Sumika put a "Medical Application Caution" about the product. Chevron Phillips is a petrochemical venture involving U.S. oil producer Chevron Corp. (CVX) and refiner Phillips 66. (PSX)

"Do not use this Phillips Sumika Polypropylene Co. material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues," according to the disclosure unsealed in Cisson's case.

"Do not use this Phillips Sumika Polypropylene Co. material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Phillips Sumika Polypropylene Co. under an agreement that expressly acknowledges the contemplated use," according to the warning.

Chemical Reactions

The caution stated that the resin-based plastic "may react with oxygen and strong oxidizing agents, such as chlorates, nitrates and peroxides." Cisson's lawyers said human bodies can produce such oxidizing agents and the reaction can cause the mesh to erode.

Despite the warning, officials of Cranston, Rhode Island-based Davol purchased Phillips Sumika's resin-based plastic from other companies that bought it in their own names, according to Cisson's lawyers. Davol used the material as the base for hernia-repair and vaginal-mesh devices, the attorneys said in court papers.

Darois, the Davol executive, told colleagues in a Nov. 27, 2007, e-mail that a Jarden Corp. (JAH) unit involved in the mesh manufacturing process refused to continue working on the material once it learned Phillips Sumika barred its use in medical devices.

Data Sheet

Managers at the Jarden unit "obtained a copy of Phillips MSDS data sheet which specifically discloses that this resin should not be used for medical implants," Darois said in the e-mail, referring to the material safety data sheet.

That prompted the company to renege "on a prior verbal commitment to supply one last run" of material used in the mesh, he said. Jarden's Shakespeare Co. subsidiary, based in Columbia, South Carolina, makes materials used in fishing line and other products containing polypropylene.

In another e-mail the same day, Jim Brann, now Bard's director of business development, told Darois and other company officials that Shakespeare's managers refused to continue working on the Phillips Sumika plastic even after Davol executives agreed to cover any resulting legal costs or damages.

The Jarden unit's officials "responded that under no circumstance, even with indemnity from us" would they produce another shipment of the mesh material, Brann said.

Alecia Pulman, a spokesman for Rye, New York-based Jarden, didn't immediately return a call and an e-mail seeking comment on the refusal to continue working with Bard's mesh. Jarden is the maker of Crock-Pot Slow cookers and Mr. Coffee machines.

Business Professor

Erik Gordon, a University of Michigan business professor, said the Avaulta case shows an abuse of the 510(k) process.

"The alleged conduct is unconscionable," Gordon said in an e-mail. "How can anyone ever trust a company that knowingly disregards safety warnings from its own supplier and covers up its conduct?"

The judge also unsealed Bard officials' and medical experts' pretrial testimony on the lack of human testing of the mesh before the company began selling it in the U.S. in 2005.

The mesh was cleared through the FDA's 510(k) system, which allows medical devices to reach the market without human testing if regulators decide they're similar to products already for sale. JNJ, Bard and other competitors already had vaginal-mesh inserts on the market when the Avaulta Plus insert Cisson received was approved in 2007, according to court filings.

Dozens Cleared

"The FDA cleared Bard's mesh devices after scrutiny of Bard's submission, including substantial biocompatibility testing, just as the FDA had already cleared dozens of other companies' mesh products made of polypropylene," Lowry, the Bard spokesman, said in the company's statement.

Jim Ross, a Salinas, California-based gynecologist who worked as a Bard consultant on the vaginal implants, testified in a deposition that he suggested clinical trials of the devices, to no avail.

“I felt at least a pilot study would have been good to do,” he said.

Ross said he and Bard officials concluded the vaginal-mesh technology was developing so quickly that a multiyear clinical trial wouldn’t be worthwhile.

“We were able to determine that it was going to cost several million dollars and there was no way that we could do it, collect the evidence, write it up and get it in publication for probably three to four years minimum,” Ross said. “The field was moving so rapidly” that the results would be outdated by that time, he said.

Clinical Trials

Melissa Johnson, a Bard manager involved in the marketing of vaginal-mesh implants, testified that doctors and company salespeople asked for clinical-trial results showing Avaulta was superior to competing implants.

“There wasn’t anything published that I was at liberty to provide,” she said.

Robert Orr, a Bard manager who helped oversee product research, said in a deposition that a company study of vaginal mesh in sheep didn’t yield needed data on its use in women.

“I would say it gives you an indication of how the body will incorporate it and the type of response that you will achieve,” Orr testified, referring to a clinical trial. “Does it totally simulate the clinical response? No, it’s not the whole product.”

The Bard consolidated cases are In re C.R. Bard Inc. Pelvic Repair System Products Liability Litigation, 2:10-md-02187, and Cisson’s case is Cisson v. C.R. Bard Inc., 2:11-cv-00195, U.S. District Court, Southern District of West Virginia (Charleston).

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wrestler79 1 day ago

Bard has already lost $3.5 million in one suit, J&J has lost $11 million in another suit, which if you add the cost of their high priced attorney and expert witnesses I am sure the amount that J&J loss is close to $20 million. Lets face it they have a loser for a case and even the best legal defense in the country could not save J&J. When are the board of directors from these companies going to force them to own up to the fact that they sold a product that was horrible and have caused irreparable harm to thousands of women? When is the court of public opinion going to start to turn on these companies and their profits begin to drop? J&J tries to portray themselves as the "Family Company" with all their baby products, but look at the damage it has done to the mothers and grandmothers and with a cavalier attitude as in the last case blame the victim? Awesome defense!

2 Likes Like Reply

Ransomexx 1 day ago

I wonder what business consulting group made these decisions. The QA group would clearly and loudly say no go. CEOs are generally too stupid to make these decisions, having come from an alien world. CEOs should go back to being MDs instead of having a background in marketing or law or aeronautical engineering..

Like Reply

tarltonp 1 day ago

"The Jarden unit's officials "responded that under no circumstance, even with indemnity from us" would they produce another shipment of the mesh material..."

Good for Jarden! Seeing one article after another about senior corporate executives willing to cause any amount of misery to their fellow human beings in the pursuit of profit and personal gain, it brings some hope to see the occasional sign that there are still some companies and some senior executives that recognize their responsibility to operate their businesses in the context of a responsible moral and ethical framework.

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