Company lied to FDA about breast implant safety, ex-employees say

by Gardiner Harris, *The New York Times*

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Two former employees of a major manufacturer of silicone breast implants said in sworn depositions in 2003 that the company for years made defective implants that were prone to rupture and hid this information from customers and federal regulators.

One employee, John C. Karjanis, who from 1996 until 1998 was manager of product evaluation for the company, the Mentor Corp., said some top executives instructed him to destroy reports detailing the high rupture rates and poor quality of some types of implants because the products "are in the customers." He also said the implants were sometimes contaminated with fleas.

The two former employees were deposed as part of a lawsuit in Greene County, Mo., brought by a woman who claimed that Mentor implants had made her ill. The suit was dismissed. The depositions were provided to The New York Times last week by the National Research Center for Women and Families, a nonprofit group in Washington that opposes silicone implants.

Josh Levine, Mentor's president and chief executive, would not comment on the employees' specific accusations. In a

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Commentary:

An FDA advisory committee recently recommended that Mentor once again be allowed to implant their silicone time bombs into women's bodies. (For the last few years silicone implants have been used only for reconstructive surgery like in breast cancer patients, while cosmetic surgeons had to settle for less realistic but much safer salt-water implants.)

But the only reason Mentor's implants were approved by the FDA advisory committee is because of the low rate of rupture -- implants from a rival company were rejected because of their higher failure rate.

Now it turns out that two ex- employees have sworn in depositions that Mentor was wildly underestimating the number of implant ruptures ... which means that the FDA committee approved them specifically based on the company's lies about their safety.

A whistleblower who worked in Mentor's

employees' specific accusations. In a written statement, Levine said the company believed that a criminal investigation of Mentor by the Food and Drug Administration that began in 1998 "included allegations from these two former employees." He added, "Mentor cooperated fully with the FDA, and the investigation was closed in 2002 without any further action."

The FDA's investigation looked into accusations that Mentor falsified records, hid defective implants and knowingly used contaminated silicone. No charges were filed.

In 1998, Mentor also entered into a judicial consent agreement with the FDA, a serious regulatory step, to correct deficiencies in its manufacturing processes "that could potentially affect the safety and quality of the breast implants," the agency said at the time.

The agency, which in 1992 limited the use of silicone implants to reconstructive surgery, usually after cancer, is now using data provided by Mentor to help it decide whether to allow their use in cosmetic surgery.

Citing a very low rupture rate reported by Mentor, a federal advisory panel voted 7-2 in April to approve Mentor's application. The panel rejected an application from Inamed, Mentor's rival, in part because Inamed reported a higher rupture rate among its implants than Mentor did. The companies, both based in Santa Barbara, Calif., have roughly equal shares of the U.S. market for silicone breast implants.

Dr. Diana Zuckerman, president of the National Research Center for Women and Families, said the depositions suggested

complaint department says that the real rate of patient complaints was nearly three times that reported by the company, because they only counted those complaints accompanied by a signed form allowing the company to inspect the ruptured implants after they were removed. And we haven't even gotten to the part where faulty implants were hidden behind factory ceiling tiles so that the inspectors didn't know how many bad ones were being thrown out. Or how frequently the implant packaging was literally infested with fleas.

You know, ladies, they make these great push-up bras now that will just smash your breasts together and shove them up towards your neck so they look huge.

Seriously, though, while some people find it hard to get too worked up about women who are dumb enough to go under the knife so their boobs look better, being somewhat superficial does not give corporations the right to lie to you about inserting highly dangerous materials into your body.

Being maybe just a little too worried about your looks should not be punishable by having your entire immune system shot to hell.

=Madeline Zane=

Commentary:

I'll believe the FDA gives a damn about people's health when each and every Mentor executive who knew about this is locked away for life.

Until that happens -- and of course, it never will happen -- I'll know the FDA is only

that the low rupture rate that Mentor has reported to the FDA might not be accurate.

"Mentor employees said under oath that their company significantly underreported implant problems," Zuckerman said. "Mentor's new statistics also seem questionable. Are Mentor implants so much better than their competitors' in terms of rupture rates, or are they providing misleading or false information?"

The safety of silicone implants has been vigorously debated for years. A number of women's groups say they are prone to rupture -- usually without the woman's knowledge -- and cause long-lasting health problems.

In 1999, the Institute of Medicine, an arm of the National Academy of Sciences and the nation's most prestigious medical advisory group, said there was no evidence that silicone implants caused major diseases. Plastic surgeons say that silicone implants are safe and should be more widely available to women undergoing cosmetic breast augmentation. Most of the 250,000 breast augmentations done in the United States each year use saline implants -- plastic bags filled with water that can slosh during activity. Patients and doctors say silicone implants feel more natural and look better.

Dr. Richard D'Amico, a co-chairman of the breast implant task force of the American Society of Plastic Surgeons, called the depositions by the former Mentor employees "old news."

"Our confidence in the data presented remains absolutely high," D'Amico said. FDA officials refused to comment, saying

about pretending to protect people's health, when it's really always all about the money.
=Angry Annie=

only that the application is under review.

Karjanis, the former product evaluation manager, worked for Mentor from July 1996 to September 1998. He left the company voluntarily. The other employee who was deposed, Cynthia Fain, supervised the company's complaint unit. She worked for Mentor for more than three years and was fired in 1996 or 1997, she said. Both were deposed under oath as a result of subpoenas.

In his deposition, Karjanis said that Mentor never met basic quality standards for implant manufacturing while he was there and that its supplier might have sent the company contaminated silicone. He also said that the implants' packaging was sometimes infested with fleas, which came in contact with the surface of the implants.

He added that workers on the company's factory floor would sometimes store defective implant parts above ceiling tiles so managers and inspectors would not realize how often the plant failed to make the parts properly.

Karjanis said that while he was at Mentor, some manufacturing executives made efforts "to get an acceptable disposition of materials through fraudulent means." In one example, an operations manager tried to get him to approve implant parts that had been poorly made.

"In reviewing the documentation, I found that the documents had been falsified," Karjanis said. "And in confronting him and asking him to come back to my office, I remember his literal statement was, 'I almost got it past you.'"

Fain said that Mentor greatly

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underreported implant rupture rates to the federal authorities. Like Karjanis, she said the company suppressed a report finding that some models of the company's implants had a high failure rate.

Fain said Mentor received about 6,000 complaints of ruptured implants in each of her three years there. In its recent filing with the FDA, Mentor said that it received a total of 8,060 rupture complaints from 1985 to September 2003.

One reason for the discrepancy, Fain said, was that Mentor disregarded rupture complaints if patients had failed to sign a form allowing the company to inspect their extracted implants.

Karjanis and Fain signed nondisclosure agreements as part of their depositions. Neither could be reached for this article.

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