

Suture infections spur new lawsuits

Plaintiffs say products made them gravely ill

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A medical manufacturer has been hit with a new flurry of lawsuits in connection with an infection outbreak allegedly caused by contaminated surgical sutures.

In two class-action suits filed earlier this month, seven surgical patients in California and Nevada charged that they had suffered raging infections because the Johnson & Johnson subsidiary Ethicon Inc. allegedly distributed sutures contaminated with infectious bacteria.

One suit was filed in Superior Court in San Francisco, and the other in U.S. District Court in New Jersey, where Ethicon has its headquarters.

The patients charged that they became gravely ill because Ethicon had sold millions of its trademark Vicryl dissolving sutures in 1994 even though the products had been contaminated during processing in a breakdown-prone sterilizer unit.

The company has denied its products caused anyone to become ill.

Sixteen people who suffered infection have sued Ethicon since The Examiner published "Outbreak," a series of stories about a sterilizer breakdown at an Ethicon plant in San Angelo, Texas, and its aftermath.

The stories quoted lawsuits and U.S. Food and Drug Administration records indicating that more than 100 patients in California and eight other states had blamed Ethicon sutures for fierce post-surgical infections, many caused by *staphylococcus* and a rare bacteria related to tuberculosis.

Months after problems were first noted in the sterilizer, the FDA prodded the firm into issuing a voluntary recall for 3.6 million of the sutures, federal records show.

But more than 70 percent of the sutures were not recovered, according to the FDA. And starting shortly after the sutures were first distributed, patients began complaining that the sutures had made them ill.

Some lawyers and patients contend it is likely that there were many others across the country who suffered infections and never learned the cause of their mysterious ailments.

Company says sutures were safe

In letters to Congress and in lawsuits, Ethicon has acknowledged problems with the sterilizer unit, but contended that all the sutures it sold were safe. Since the incident, the firm has made confidential settlements with 22 victims who blamed the sutures for their infections, according to public records.

In the new suits, the patients accused the firm of seeking to conceal the risks posed by the sutures. They claimed they never would have known that sutures caused their medical problems but for the nationwide publicity that followed The Examiner's stories in February.

Infection victims from around the United States continue to come forward because of the stories, said Sacramento lawyer Wendy York, who filed the lawsuits.

"This was one of the most ineffective recalls I have ever seen," she said.

She said she filed dual class-action complaints in hopes of improving victims' chances of prevailing.

Bay area plaintiffs

The San Francisco lawsuit was filed by four women patients from the Bay Area who said they were felled by serious infections after routine procedures in 1994 and 1995.

They are: Ann Boylan, who underwent abdominal surgery at Kaiser Hospital in Hayward; Susan Ronnow, who had back surgery at Daly City's Spine Care Medical Group; Mary Grace O'Nyon, who had a sinus operation at Seton Medical Center in Daly City, and Elivra De la Rosa, who had open-heart surgery at Washington Hospital in Fremont.

De la Rosa's infection occurred in her leg, where surgeons removed a vein for use in the procedure. Her daughter, Erma, said her 65-year-old mother had no problems with the heart surgery. But she said the leg infection caused her to lose 30 pounds within two weeks of surgery. Five years later, she still suffers health problems, the daughter said.

"Sometimes, my mother is at the point where she just wants to die," she said.

The federal complaint was filed by Iris Mazaroff, who had breast surgery at Brookside Hospital in San Pablo; Richard Meyers, who underwent ulcer surgery in Columbia Sunrise Hospital in Las Vegas, and Sandra Lawrence, who had back surgery at John Muir Hospital in Walnut Creek.

Lawrence, 29, a medical researcher, said her incision refused to heal for months after her 1994 operation, and at one point she was rehospitalized with a 104-degree fever.

Her illness forced her to drop out of graduate school and left her unable to work for a year, she said. Doctors had no explanation about the cause for the infection, she said, but she became suspicious when she read The Examiner's stories.

"Just like all the other people who read the paper, I said, 'Hey - I had surgery in 1994' - so I went to get my medical records," she said. "They used the same sutures on me."