

OUTBREAK: EXAMINER INVESTIGATIVE REPORT: UPDATE

Lawsuits fly against maker of sutures alleged to be tainted

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In Oakland, a retired engineer dies after surgery to repair a broken leg. Doctors blame a raging infection they can neither explain nor control.

In Oklahoma, a rancher is infected after heart bypass surgery. He spends months in the hospital, but doctors can't cure him. After four years, infection kills him.

In New York City, a policeman develops an unexplained chest infection after heart surgery. He has an emergency operation to drain his wound. Doctors give him anti-infection drugs in such massive doses that his kidneys begin to fail. Five years later, his chest remains so sensitive, even wearing a shirt is excruciatingly painful.

Ever since his 1995 operation, retired NYPD officer Joseph Grieco said he puzzled over what caused the post-operative infection that shook his life. So did the families of rancher Tom Schroeder and engineer Robert "Pete" Miller, whose lives infections claimed.

But now, because of stories published in The Examiner, they believe they have their answer. The infections, they think, occurred because surgeons unwittingly sewed them up with sutures contaminated with infectious bacteria during a factory mishap in 1994.

"My daughter in California saw your stories," Grieco said. "That's how I found out what happened to me."

These patients are among 53 U.S. infection victims who have come forward in response to "Outbreak," an Examiner report that first disclosed a nationwide infection outbreak linked in lawsuits and federal records to contaminated sutures sold by the medical supply giant Ethicon Inc., a \$1.2 billion subsidiary of Johnson & Johnson.

The series, published in February, told how Ethicon had distributed some 3.6 million of its trademark Vicryl dissolving sutures after they were processed in a breakdown-prone sterilizer unit at a Texas factory.

Although the U.S. Food and Drug Administration later prodded Ethicon into recalling the suspect sutures, 2.7 million were never recovered, federal records show.

And because the FDA did no follow-up investigation, it has been left to individual victims to try to unravel the mystery of the outbreak.

The Examiner's report led Rep. Pete Stark, D-Hayward, to call for reform of FDA recall procedures. The stories also provoked an unusual outpouring of concern from patients and their families.

In the months since the stories were published, the newspaper received more than 300 inquiries from as far away as Monaco, most from infection victims. Lawyers mentioned in the articles said they, too, received an unusual number of inquiries.

"It has snowballed," said Sacramento lawyer Wendy York, who has filed four lawsuits on behalf of infection victims since the stories were published.

Out-of-court settlements

Since the 1994 incident, Ethicon has reached out-of-court settlements with 22 patients who blamed sutures for their ailments, court records show.

But the firm insists its products are safe and never made anyone sick. Spokeswoman Susan Odenthal has pointed out that post-operative infections are common.

Indeed, The Examiner was called by many infection victims whose medical records did not support the notion that the Ethicon sutures from the 1994 incident were responsible for their illnesses. Other cases were inconclusive.

But the newspaper identified 53 new cases involving victims whose operations involved suspect sutures, and whose post-operative infections resembled those of other known victims.

They included two fatalities: Schroeder, 80, of Freedom, Okla., whose death certificate blamed infection; and Miller, 80, who died of a staph infection, according to court records.

If it is proved that contaminated sutures were responsible for the injuries and deaths, Ethicon ought to be hit with whopping financial penalties, Stark said.

"The bottom line is that these people knew about the contamination in May and they didn't do anything until September," he said.

"When you have a company as big as Johnson & Johnson, \$100,000 isn't going to trouble them. So, if in fact people were harmed or killed by this, I hope (the victims) get billions.

"It's the only thing these guys understand."

"This has totaled me"

Among the other cases:

- * Mary Lou Doyle, bedridden for 18 months after an infection following hip replacement at Santa Rosa Memorial Hospital in 1994.

"I have 13 grandchildren and I've always been a very active person," she said. "This has totaled me."

- * Chicago graduate student Chris Alger, who was hospitalized twice due to an infection following 1994 heart surgery at Alta Bates Hospital, Berkeley.

"I was never the same afterward," she said. "I felt I had walked over hot coals and came out the other side."

- * Berkeley retiree James Rhoda, infected after a neck operation, also at Alta Bates.

"He was so sick, I had a doctor say, 'I think you might want to consider pulling the plug,' " said his daughter, Karen Hill.

- * Las Vegas police executive Richard Meyers, who suffered peritonitis and gangrene after an infection that followed ulcer surgery in 1994.

"The whole situation has been devastating to my wife and family," he said. "My son joined the Marines rather than going to college because we had to spend his college fund on medical bills."

- * Mark Ziegler, who required treatment in a hypobaric chamber to treat the infection he suffered during stomach surgery at Doctors Hospital in Pinole.

"I lost 60 or 70 pounds," he said. "I looked like a concentration camp victim."

A variety of operations

Of the new infection victims, 32 are women and 21 are men.

Ten became infected after heart surgery, 10 after breast surgery, including mastectomies, and eight after operations on the back or neck. But a wide range of other surgeries involving the use of dissolving sutures are represented: knee and hip replacements, hysterectomies, face lifts, hernia repairs.

Of the new group of victims, 29 have already filed lawsuits against Ethicon, while most of the rest said they had asked lawyers to investigate their claims.

Ethicon Inc. is the world's largest manufacturer of surgical sutures.

Court records and FDA documents state that, in March 1994, Ethicon scientists at a plant in San Angelo, Texas, noted malfunctions in a new system for sterilizing synthetic Vicryl sutures, which dissolve in a patient's wound. In May, after repeated problems, Ethicon shut the equipment down.

But the firm made no move to recall any sutures until September, after FDA inspectors learned of the sterilizer breakdown and prodded the firm into action, according to the records.

The recall was only partially successful: About 2.7 million of the suspect sutures were never retrieved, according to the FDA. Harold Pellerite, an FDA official, said he presumes the sutures not retrieved in the recall were used in operations.

Ethicon contended the risk of infection was so slight that there was no reason for doctors who had used the sutures to warn patients, a company memo shows.

The FDA decided against asking the U.S. Centers for Disease Control and Prevention to track the possible threat to public health posed by the sutures. It wasn't warranted, a spokeswoman said.

Nevertheless, court records show that by 1996, 24 patients in California and eight other states had sued Ethicon, claiming that contaminated sutures had given them fierce post-surgical infections, many caused by *staphylococcus* and a rare bacteria called *mycobacteria fortuitum*, which is related to tuberculosis.

FDA reports

Lawyers and patients familiar with the incidents say they believe there were many more infections that never resulted in lawsuits.

FDA reports obtained via the Freedom of Information Act cited more than 83 patients who had blamed contaminated Ethicon sutures for post-operative infections in the two years after the recall.

The FDA reports were edited so that names, locales and key details could not be learned.

For many people whose lives had been rocked by infections, the "Outbreak" stories were the first they had ever heard about contaminated sutures. Some seized on the sutures as the explanation of their medical problems.

Said Sandy Lawrence, who has sued Ethicon over a grievous infection that followed back surgery at Walnut Creek's John Muir Medical Center:

"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. They used the same sutures on me."

Legal hurdles

But infection victims must surmount a series of hurdles before they can get their cases to court. Some potential claims have stalled because victims were unable to prove the suspect sutures were used in their operations.

For example, a woman contacted The Examiner about her elderly father, who according to medical records died of infection in 1995, two months after heart surgery at a San Francisco hospital.

The victim's case closely resembled other suture cases, but medical records did not state whether Vicryl sutures were used. Without that evidence, lawyers were reluctant to investigate her case, the woman said.

Other infection victims found their cases had legal problems even though they could prove Vicryl was used in their surgeries.

Medical records show that in December 1994, a surgeon used Vicryl while operating on the neck of Lee Fish, a retired Modesto contractor. Fish soon developed a raging staph infection that has left him wheelchair bound.

But in 1995, long before he heard about the contaminated sutures, Fish hired a lawyer to pursue a medical malpractice lawsuit against his hospital. The suit went nowhere, but Fish said lawyers tell him courts may not permit a second action over the same matter.

Other patients said they couldn't find an interested lawyer. The family of Schroeder, the Oklahoma rancher, said lawyers didn't want to pursue a wrongful death suit when the victim was 80.

A formidable opponent

Even if they get into court, the patients face a formidable opponent in Ethicon, which has made a skilled San Francisco attorney, Charles Preuss, legal quarterback for sutures cases nationwide.

No suture case has ever gone to trial. But in pre-trial actions, Ethicon has denied its product was responsible for infections and aggressively sought to limit or challenge evidence. It sought to suppress evidence about both the sterilization failure at the Texas factory and the recall. And if patients' hospital records were ambiguous about what sutures had been used, it asked that the cases be dismissed, contending the infection must have had some other cause.

Nevertheless, some lawyers have been willing to give it a go. Earliest off the mark has been York, a 32-year-old Sacramento lawyer who in 1995 sued Ethicon on behalf of four women who had suffered infections after breast surgery at a clinic in Lafayette.

Ethicon made confidential settlements of those complaints.

When new cases emerged, York was eager to take them on.

"A lot of harm"

"I look at this as a way to civilly prosecute a corporation that has caused a lot of harm to a lot of people," she said. Ethicon "has to be held accountable," she said.

York has already filed suits in New Jersey and California. To handle what she anticipates will be a legal fight that will last years, she has associated with three law firms experienced in class-action litigation - two in Sacramento and one in Newark, N.J., near Ethicon's corporate headquarters.

York also has established an "Ethicon Suture Victims" Web site, at www.suturevictims.com, with information on the controversy.

"I'm hearing from attorneys from New York and Florida who think they have Vicryl sutures cases, too," said York.

Another lawyer with an intense interest in the suture cases is Joseph Olsen, 71, of San Jose, who said he is investigating claims on behalf of six infection victims.

To Olsen, the Ethicon cases are personal. He said he is a post-operative infection victim himself. After open-heart surgery at San Francisco's Kaiser Hospital in 1995 he said he had a coughing fit, and his badly infected incision broke apart, exposing the inside of his chest to full view.

"You could actually see my heart beating," he said. "It was scary as hell."