

### ***3 new lawsuits blame sutures***

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## **Court actions claiming wrongful deaths filed in S.F., East Bay**

By **Lance Williams**

Staff Writer

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The families of a San Francisco school counselor, a San Jose homemaker and an Oklahoma rancher - each killed by infections after routine operations - have filed wrongful death lawsuits against Ethicon Corp., the world's largest manufacturer of surgical sutures.

In the suits, the families claimed their loved ones died because surgeons unknowingly sewed them up with sutures allegedly contaminated with infectious bacteria during a processing mishap at an Ethicon factory in 1994.

The complaints regarding the deaths of William Carpenter, retired counselor at Potrero Hill Middle School, housewife Virginia McMillan, and Tom Schroeder, a cattle rancher from Freedom, Okla., were contained in lawsuits filed last month in San Francisco and Alameda County courts.

The three new lawsuits were filed on behalf of 52 surgical patients who said they had suffered grievous injuries because their doctors unknowingly used contaminated sutures in operations.

More than 100 patients in California and 15 other states have sued Ethicon in connection with infections that they blame on breakdowns in a new sterilizer system at an Ethicon plant in San Angelo, Texas, court records show.

Four fatalities have been blamed on the sutures in lawsuits.

Ethicon has denied that its products made anyone ill. Spokeswoman Susan Odenthal said she wasn't aware of the new lawsuits and had no comment on them.

Many of the victims who have sued said they were alerted to the contamination incident - and, thus, to the alleged cause of their maladies - by "Outbreak," a 1999 Examiner series on the sterilizer breakdown and its aftermath.

The stories quoted lawsuits and U.S. Food and Drug Administration records indicating that months after problems were first noted in the sterilizer unit, the FDA in September

1994 prodded Ethicon into issuing a voluntary recall for 3.6 million of the firm's trademark Vicryl dissolving sutures.

But more than 70 percent of the sutures were not recovered, according to the FDA. Meanwhile, surgical patients around the country began blaming Ethicon sutures for fierce post-surgical infections, many caused by *staphylococcus* and a rare bacteria related to tuberculosis.

### **Acknowledging problems**

In letters to Congress and in response to 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.

Earlier lawsuits have focused solely on alleged contamination of Ethicon's dissolving Vicryl sutures, the products that were the subject of the September 1994 recalls.

But one of the new lawsuits filed in Alameda County contended that Ethicon also shipped out contaminated sutures made of silk and another synthetic, Prolene.

In February 1994, the company voluntarily recalled 2,600 packages of Ethicon's prolene and silk sutures, according to the lawsuit filed by Sacramento lawyer Wendy York on behalf of eight California patients.

The suit contends that those sutures, like the Vicryl ones subject to the later recall, had been contaminated during processing and caused the patients to suffer serious postoperative infections.

The lawyer said the foil packages containing the silk and prolene sutures had been improperly sealed, leading to fears that the products were contaminated.

### **Recent incidents**

And while earlier lawsuits had focused on patients who suffered infections in the 18 months after the 1994 sterilizer breakdown, a new suit in San Francisco Superior Court involves patients who became ill as late as 1998, more than three years after the incident.

San Jose lawyer Joseph Olsen said he believes some hospitals and surgery centers don't follow a strict first-in, first-out policy on use of sutures, which are advertised as having a shelf life of five years.

"There could be today, after all these years, some sutures that are contaminated in doctors' offices and hospitals, and that's what scares me," Olsen said.

According to the complaints, the three patients who died all had operations involving the dissolving Vicryl sutures. Carpenter, the school counselor, was admitted to Kaiser Hospital in San Francisco in October 1995 for replacement of a heart valve.

Except for his heart problem, the 72-year-old retired educator was in good health and was planning a party to celebrate his 50th wedding anniversary, said his daughter, Cici Bonfiglio.

But a few days after he came home from the hospital, Carpenter was staggered by a staph infection, she said. He was rehospitalized, but doctors were never able to knock the infection down. He died two months after the operation.

Bonfiglio said Carpenter's death hit her family particularly hard because her daughter, who was 10 years old at the time, had blamed herself for her grandfather's death.

"For a long time, my daughter thought she killed him - she had a cold, and she had shared an orange juice with him the day he came home from the hospital," she said. It was only after reading The Examiner series that the family came to believe the sutures were responsible, she said. Her daughter no longer blames herself, Bonfiglio said.

"She said, 'Mom, I didn't kill him,' " she said.

Schroeder, the Oklahoma rancher, had heart surgery at an Oklahoma City hospital in 1994 at age 75. Four days after the operation, the former rodeo cowboy's chest burst open from a serious staph infection, medical records show.

He lived four more years, but was an invalid frequently subject to infections that required urgent care, said his daughter, Carlene Culver of Ashland, Kan. He died in January 1998.

"The doctor said, 'You know, he's got an infection, and we just can't figure out why,' " Culver said.

McMillan, 48, had a heart valve replacement at San Jose's Good Samaritan Hospital in June 1994. She also suffered a serious infection and ultimately succumbed, according to the lawsuit.