Recipients of Faulty Heart Valve: Put Novel Liability Issue to Test: Lawsuit: Can those implanted with the life-saving--but potentially fatal--Shiley device win damages even if there has been no physical harm? Their case is to go to trial this year.

February 16, 1992 | SONNI EFRON | TIMES STAFF WRITER

IRVINE — The artificial heart valve clicks 60 times a minute. Some patients find the mechanical heartbeat soothing, audible proof that their lifesaving valve is working.

To John Civatte, who was implanted with a potentially defective Shiley heart valve in 1986--just nine months before the manufacturer pulled the device from the market--the ticking sounds like a time bomb.

"Imagine if you had a piece of dynamite strapped to your chest, you didn't know how long the fuse was and you didn't know if the fuse was lit," the 31-year-old salesman said. "Could you be comfortable?"

Bill Wallace said he has nightmares in which his valve stops ticking. Wallace, 40, of Chino said he began having anxiety attacks last summer after his cardiologist called to tell him that his valve was the type that has been blamed for more than 250 deaths.

The good news, the cardiologist said, was that the risk of his valve breaking is tiny--less than 1% per year, according to the manufacturer, Shiley Inc. of Irvine.

The bad news was that two-thirds of such fractures are fatal.

Wallace's wife asked the doctor whether there are any early warning symptoms.

"Unfortunately, there aren't," the doctor told them. "The only symptom is instant death."
Civatte and Wallace are among about 400 patients suing Shiley, alleging fraud and emotional distress—not because their valves have failed but because they must live with the fear that they might.

The mammoth product liability case is expected to come to trial later this year in Orange County Superior Court, posing a novel legal and ethical question: Is a person implanted with a lifesaving but flawed device entitled to compensation even if there has been no physical harm?

Other states have rejected such claims, but a California appeals court ruled in 1990 that Shiley patients could sue if they could prove fraud by the manufacturer.

That ruling could have wider implications for other product liability suits. It raises the possibility, for example, that women with Dow Corning Wright silicone breast implants who have not suffered health problems but want the implants removed might also seek damages.

Unlike breast implants, however, the risk of surgery to replace heart valves—even a potentially faulty one—have until recently been deemed unacceptably high. Mortality during open-heart surgery averages 3% to 5%.

Shiley says that is much higher than the risk of valve failure, which it estimates at about 0.07% per year. Implant patients are vastly more likely to die of complications, heart disease or other causes, which claim 5% of patients each year, Shiley spokesman Robert Fauteux said.

For years, plaintiffs' attorneys have complained that Shiley has grossly understated the risk of valve fracture. This month, a new study published in the Lancet British medical journal indicates a higher rate of fracture than most studies have shown.

The study followed 2,303 Dutch patients implanted with Shiley valves and found that the actual incidence of fractures over eight years was four to eight times higher than Shiley's estimates.

For the first time, researchers concluded that patients with some types of valves should consider replacement surgery.
Shiley and its corporate parent, Pfizer Inc. of New York, are still reviewing the Lancet data, but Fauteux said the firm's independent medical panel has seen a preliminary version of the Dutch study and does not recommend removal for U.S. patients.

"We think that (patients) need to recognize that all medical devices and medical products have risks as well as benefits," he said. "That includes the valves they have that are saving their lives. The important thing is that they put the various risks they face into some perspective that makes those risks commensurate with reality."

"It's not that we're not sympathetic," Fauteux added. "It's just that we think they ought to achieve a realistic understanding of the risks by talking with their doctor."

"We never, ever said that people who have Shiley heart valves haven't had an improvement in their condition," said Minneapolis attorney Bruce A. Finzen, whose firm represents about 370 patients with intact valves who are suing Shiley. "But there are other valves out there that would make them feel just as good and would not expose them to the risk of fracture."

But patients such as Civatte and Wallace said they no longer trust Shiley, feel betrayed by their doctors and are considering having their Shiley valves removed, even against medical advice.

"I feel like I've got something in my heart that could break right now or break on the way home--today, tomorrow, or a year from now," Wallace said. "Sometimes I think it might be better for me to take the chance and live a worry-free life. . . .

"I've tried to block it out, but I just can't. I get on a freeway and traffic gets stopped, and I think, 'What am I going to do if I have a problem right now and I can't get off the freeway?'

One of the few U.S. cardiac surgeons who has removed functioning Shiley valves from healthy patients is Dr. Cecil Vaughn of Phoenix.

"I did it after a lot of soul-searching and review of the data," Vaughn said. He performed successful replacement surgery on three patients who told him that they could no longer bear to live with the device. All three survived.
Vaughn tells patients that the risk of death during such surgery is about 5%. He said if patients understand the risks, the choice should be theirs.

As the toll of fracture deaths mounts, and more data about the Shiley valves becomes available, Vaughn said, some cardiologists are also beginning to reconsider.

"If I had it in my chest, I'd have it out," Vaughn said.

The Shiley heart valve story began when several valves fractured even before the federal Food and Drug Administration approved them for sale in 1979. The devices were recalled three times before they were removed from the market in 1986, after about 86,000 valves had been implanted in patients worldwide.

Since then, Shiley has been lambasted by the FDA and a congressional committee; sued repeatedly; accused of misleading regulators; submitting confusing or even fraudulent data, and ignoring or concealing manufacturing defects. The company has denied all wrongdoing.

Last fall, Pfizer sold all of Shiley's assets, leaving the company as a shell to handle the litigation and conduct research to try to discover a method for predicting valve fractures. At the moment, no such method exists.

For years, Pfizer has reached out-of-court settlements with patients whose valves have broken, or their survivors. But with just two exceptions, the company has refused to settle fear-of-fracture suits.

In an about-face, last month the company announced a proposal under which it would spend up to $205 million to settle the hundreds of anxiety lawsuits.

But the three major law firms handling the anxiety cases all recommended that their clients reject the offer. So has the head of a support group for Shiley patients.

The offer of $2,000 to $4,000 per patient would not even cover psychological counseling to deal with the anxiety, they said, let alone the $40,000 to $60,000 it costs to replace a valve.
One Miami law firm is demanding $100,000 for each of its 250 fear-of-fracture clients.

Wallace and Civatte each said they will reject Pfizer's offer and take their chances with a jury.

"To me, $4,000 is a piddly amount for having to live with the anxiety of possibly dying," said Wallace, who also said he cannot understand why Shiley did not withdraw the valve from the market sooner.

"They took seven years--seven years--before they recalled the product. . . . I'm angry that they let it go on so long," he said.

Elaine Levenson, who organized the patient group, said: "When these valves were implanted in us, we were told it would improve the quality of our lives, but we don't feel that we're living a quality life."

Levenson was also cool to Pfizer's offer to spend $75 million for research at Shiley's Heart Valve Research Center in Irvine.

"We've got a Shiley valve in us that could fracture at any time," she said. "Why would we trust Shiley to do the research?"

While they wait for their cases to come to trial, Wallace and Civatte said, they struggle daily not only with fear but also with feelings of anger and betrayal.

Civatte must travel on his job. When he checks into a hotel, he said, the first thing he does is scout out the nearest medical transport helicopter.

"The further I get from a trauma center, the less I sleep at night," Civatte said. And he worries that if his valve failed, he might not even have time to call help.

"My valve is in the aortic position," he said. "If it fractured, I would feel like a drowning man. My lungs would fill with fluid. . . . I would be unconscious in three, maybe four minutes."
"Can Shiley tell me how to increase my chances of survival in the unlikely event of a valve failure?" he asked. "Nobody can."

Civatte began seeing a psychiatrist after several trips to the emergency room with symptoms that seemed terrifyingly similar to a valve fracture but turned out to be anxiety attacks.

The counseling, he said, "made me realize that my fear was real." He also takes an anti-anxiety drug.

"Can someone please tell me how to live a normal life?" he said. "That's the question that we all want answered."

History of Shiley Heart Valves

1969--Dr. Viking O. Bjork, a Swedish surgeon, implants the first Bjork-Shiley heart valve at Karolinska Hospital in Stockholm.

April, 1979--Pfizer Inc. acquires Shiley along with the new Bjork-Shiley 60-degree Convexo-Concave heart valve, which has just received Food and Drug Administration approval for marketing in the United States.


April, 1984--Shiley begins new inspection procedures. Since then, none of the approximately 8,100 60-degree heart valves manufactured have reported strut fractures.

September, 1984--Despite assertions by Public Citizen and even Shiley's own admissions that the 60-degree valve may be failing, the FDA reiterates that its benefits outweigh the risks.

January, 1990--Latest figures indicate that of the 86,000 valves implanted worldwide, 391 reported strut fractures. A California appellate court rules that patients whose valves have not fractured can sue for emotional distress if they show that Shiley fraudulently withheld information about problems with the valves.
February, 1990--The state appellate court rules that heart valve recipients may sue Shiley for fraud even if their own heart mechanisms have not malfunctioned, provided that plaintiffs prove that the company acted in a fraudulent and deceitful manner.

December, 1991--Pfizer announces its intention to sell most of the product lines of trouble-plagued Shiley; the company will retain the Shiley Heart Valve Research Center as well as legal responsibilities for defective heart valves.

January, 1992--Pfizer announces a proposal to spend up to $205 million to settle hundreds of lawsuits arising from its valves, which have been blamed for more than 250 deaths; reaction from plaintiffs' attorneys was chilly. They said that would net only about $2,000 to $4,000 each for their clients.

Researched by DALLAS M. JACKSON / Los Angeles Times

Defective Heart Valve

About 55,000 patients worldwide are implanted with an artificial heart valve blamed for more than 250 deaths. How some of the valves have fractured.

Bjork-Shiley Convexo-Concave valve. Fracture: When strut breaks, tilting disc cannot open and close properly to control blood flow.

Where it's Placed in the Heart: Artificial valve replaces diseased natural valve.

Source: Shiley Inc.

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