An estimated 25 million Americans have one kind of medical implant or another. However an analysis of implant recalls over 10 years show that the average number of recalls per year was 40 and by 2001, the number rose to 117.

The FDA regulates the implant industry, but many products reach the market with insufficient clinical testing, followed by very little oversight.

By law, the FDA is supposed to inspect medical-device manufacturing plants every 2 years, but according to an August 11, 2002, report by the Star-Ledger, "it visits U.S. plants on average once every five years, and overseas plants once every 13 years."

In addition, of the 3,500 proposed medical devices reviewed by the FDA in 2001, the Ledger determined that 98% were approved under an expedited process that requires no clinical testing.

Implants include heart valves, pacemakers, stents, hip and knee joints, orthopedic plates and screws, and breast enhancements. However, devices recalled most often have been heart related implants which made up nearly 40% of all recalls during the 10 year period between 1992 and 2002 investigated by the Ledger.

Perhaps the most infamous recall case on record involves the Bjork-Shiley Convexo-Concave mechanical heart valve. Shiley, Inc manufactured the valves and Pfizer purchased Shiley in 1979.

The product came on the market in 1979, and was recalled in November 1986, after the struts that held the device in place began fracturing.

When the strut breaks, the heart contracts and explodes, and without emergency surgery, the person can die within minutes. Due to fear and anxiety arising from the risk of a fracture at any moment, the injury to patients is lifelong.

According to the August 17, 1995, New England Journal of Medicine, by December 31, 1994, "564 complete strut fractures had been reported to the manufacturer, approximately two thirds of which were fatal."

The JAMA article also noted that there was no reliable diagnostic methods to detect valves that may be at risk for strut fracture.
As of April 1, 2003, according to CBS News, approximately 12,000 people had filed claims for wrongful death and personal injury in a class-action lawsuit against Pfizer. Under the terms of a settlement agreement, CBS said victims could receive somewhere between $500,000 and $2 million, depending on age, income, and family status. At the time of the settlement there were an estimated 40,000 living heart valve recipients.

Early on when lawsuits were filed, Pfizer insisted on secrecy agreements. Corporations in products liability cases often insist that material turned over in litigation be kept confidential, even when the product is dangerous and remains on the market.

As a result of the secrecy agreements in this case, crucial information about the valves was not revealed to doctors or the FDA, and patients continued to receive the implants long after the company detected the defects. Federal law requires a company to report a known hazard and in this case, the secrecy fostered the evasion of laws designed to protect consumers.

It later became known that company inspectors had found poor welds on the valves, but rather than throw them out, they ordered the valves to be ground down and polished to look smooth, after which they were sold all over the world.

As it turns out, employees at the factory intentionally filled out paperwork to disguise the practice of polishing over the cracks and an internal memo that surfaced, written by a supervisor, complained about the policy that disguised cracked valves.

As more documents turned up, one showed that in 1980, Dr Viking Bjork, whose name helped sell the valves, had written to Pfizer demanding corrective action and threatened to publish cases of valve failures.

In response, a Pfizer executive telexed Dr Bjork and said: 'ATTN PROF BJORK. WE WOULD PREFER THAT YOU DID NOT PUBLISH THE DATA RELATIVE TO STRUT FRACTURE.' His reason for holding off was: 'WE EXPECT A FEW MORE.'

In 1990, a Congressional report concluded that the company had "aggressively marketed the device despite internal knowledge of serious problems in the manufacturing and quality assurance procedure."

Had the dangers with the valve been known, thousands of deaths and injuries, as well as the related economic costs, could have been avoided because doctors would
not have implanted the valve in thousands more patients.

In March 1992, the FDA instructed Shiley to notify physicians that the risk of fracture could be five times higher than previously thought.

"When a critical device such as a heart valve is found to have a problem that could result in death or serious injury, FDA has an obligation to see that doctors and patients are notified so that they can consider the new information in deciding on a course of action," said FDA Commissioner David Kessler, MD at the time.

The FDA also told Shiley to send letters to patients who received the faulty device to inform them of the increased risks. By that time, the FDA had already received about 350 reports of fractures among the roughly 82,000 valves implanted worldwide.

Some patients were advised to undergo explantation, to remove the defective valve and replace it with another valve. However, explantation was a risky procedure for which few patients were eligible.

The conduct by Pfizer of suppressing the fact that the valves were defective eventually came under intense scrutiny by the Department of Justice and a Congressional oversight committee.

According to the charges in a lawsuit filed by the DOJ under the False Claims Act, Pfizer-Shiley made false statements to the FDA to obtain approval of the valve, and again later to keep the product on the market. Specifically the DOJ said Shiley:

- falsely asserted the valve caused fewer blood-clotting complications than other models
- falsely asserted a series of manufacturing changes had corrected a serious design defect
- did not provide FDA with all the data it had concerning fractures during testing
- argued - to keep marketing the valve after the problem became evident - that the fracture risk was outweighed by the purported blood-clotting advantage, which did not prove to be as significant as represented to FDA
- rebuilt scrap valves
- rewelded valves an excessive number of times
- polished, rather than rewelded, cracked valve struts
• falsified employee identification numbers on cards attached to bags of reworked valves, including more than 3,000 "baggie cards" with inaccurate identification numbers.

In a 1994, Pfizer agreed to pay $10.75 million to settle the false claims case. The company also agreed to pay for medical costs the government had incurred, or would otherwise incur in the future, through Medicare, Medicaid, CHAMPUS, federal hospitals, or other programs due to fracture or replacement of the valve.

The DOJ announced the settlement on June 30, 1994, and estimated its total value to be close to $20 million.

The settlement also brought to a close a case that the Congressional Subcommittee on Oversight and Investigations had been following for years. Since the late 1980s, the Subcommittee had been investigating the shortcomings of the FDA, and the implant industry, in medical device regulation and had zeroed in on the heart valve case.

According to the committee, despite the occurrence of fractures during clinical trials, the FDA approved the valve after a short premarket approval process. The Subcommittee said that the FDA had been unable, or unwilling, to critically and independently assess clinical data and that instead, the agency relied upon an "Honor System" which trusted the company to report problems with the valves.

Although there was an aggressive campaign to locate valve recipients, the General Accounting Office determined that only about 14,000 patients were located; which means the defective valves remain implanted in thousands of patients.