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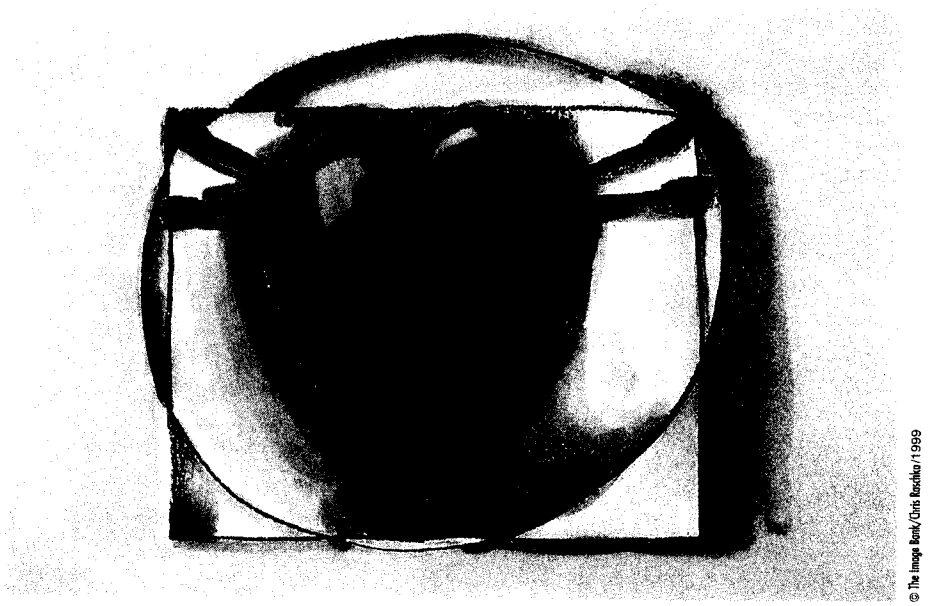

Defects and Deceptions — The Bjork-Shiley Heart Valve

Despite extensive engineering analysis, bench and *in vitro* testing, and clinical trials, the behavior of medical devices cannot be entirely predicted under conditions of commercial use. While extensive testing greatly increases the probability that the device will perform safely and effectively, it cannot capture the range of conditions experienced in actual use. Instead, commercial use should be regarded as a second clinical trial, with patients having the right to be informed of any significant changes in performance results data.

As discussed in [1], the Safe Medical Devices Act of 1990 implicitly incorporates this concept, by establishing a registry and tracking provision for notification of patients with Class III medical devices, implants whose failure is likely to cause serious harm to the patient. The Act also authorizes post-marketing surveillance of devices about which questions have arisen concerning their safety.

Despite conscientious testing programs, new defects often appear, some serious enough to require withdrawal of the device. The Starr-Edwards caged-ball heart valve originally used a ball made of silicone elastomer, which absorbed lipids from the blood. This caused cracking, swelling, and abnormal wear, resulting in its withdrawal from the market. More suitable materials for the ball were found, and the valve is still in use. Other caged-ball valves featured a cloth cover for the cage struts to promote tissue

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ingrowth. However, the cloth abraded before this could occur, causing a variety of serious problems. These are only two of many examples of heart valves that were promising but were found to have unacceptable defects after being put on the market and implanted in patients.[1]

Heart valves like these, where new and substantial defects appear after being introduced into the market, are clearly defective, and there is little controversy about their withdrawal. Their performance falls substantially below the standard predicted from testing and clinical trials. Similarly, minor problems that do not significantly affect the valve's function do not result in it being designated as defective. For example, some patients complained that the Bjork-Shiley Convexo-Concave (C/C) heart valve made too much noise and caused them to be embarrassed in social situations.[2] But where is the line between these two poles, where devices cross over from being acceptably safe, to being defective and needing to be withdrawn? How serious does the defect have to be, and what characteristics of the defect are important, for deciding whether it should be withdrawn from the market?

It is tempting to set a threshold of failure — say 1% — to define "defective." Is any device that has a greater than 1% failure rate sufficiently defective to require discontinuation? Based on my conversations with individuals in government and industry who are familiar with the case, a majority would have said that a 1% failure rate would not disqualify a medical device. Yet the C/C valve was withdrawn despite having a failure rate that even its harshest critics did not place above half of that 1% level. Was the valve improperly withdrawn or are there other factors to consider? Are there other factors besides failure rates that should influence what counts as an unacceptable failure rate?

While I cannot answer this question in a general way, an examination of the Bjork-Shiley heart-valve case suggests that other factors were considered in the development of a consensus that the valve was defective and should be withdrawn. By examining a brief history of the Bjork-Shiley C/C valve and then discussing the factors that critically influenced the judgment that it was defective, I have reached the conclusion that the failure rate and the technical characteristics of the C/C valve alone were not responsible for its withdrawal. A number of critical ethical issues made the difference. I believe that if Shiley and its later owner, Pfizer, had responded to the problem in an ethically acceptable way, the valve could still be on the market.

[1]Both of these examples are discussed in [2].

[2]In a survey of 35 patients with C/C valve, about half reported that they were disturbed by the sound of the valve. See [3].

Mechanical Heart Valves[3]

The development of mechanical heart valves is one of the success stories of contemporary medicine. Many people with diseased heart valves become seriously disabled and soon die unless a prosthetic valve can be installed. The first mechanical heart valves were implanted in 1960, and since then their use has grown rapidly. Today over 40 000 Americans receive artificial heart valves each year [2, p. 410].

Shiley, Inc., later a subsidiary of Pfizer, was a pioneer in the development of mechanical heart valves. In 1974 the company developed a radial spherical (R/S) valve, consisting of a disk held in place by two wire struts, allowing it to swing open and closed in response to blood flow. The struts are welded to a metal ring, which is covered with a cloth sewing ring for attachment to the heart. In 1979 Shiley introduced a similar valve, the 60° Convexo-Concave (C/C), which it believed would improve blood flow through the valve. In this valve, the inlet strut was an integral part of the metal ring and only the outlet strut was welded. A C/C valve that opened to 70° was also manufactured, but it was not approved for sale in the U.S.

How serious does the defect have to be, and what characteristics of the defect are important, for deciding whether it should be withdrawn from the market?

Blood clots (thromboses) caused by the presence of artificial heart valves are a serious problem and are responsible for the greatest percentage of complications that occur. Because the movement of blood is obstructed by the valve, there are areas of relatively stagnant flow where clots can form. They may form on the valve, preventing it from fully opening or closing, or they may break free and cause strokes, heart attacks, and other serious complications. Drugs to "thin" the patient's blood and reduce clotting are an essential part of the treatment of

[3]Some of the material in this section is taken from other articles I have written on this topic [4], [5].

implantees, but there is a limit to their ability to reduce the incidence of thromboembolism (TE): blood clots that break free and lodge in an artery, cutting off blood flow to tissues or organs. Shiley's 60° C/C valve, which appeared to allow better blood flow and promised a lower incidence of TE, was regarded as a significant improvement in heart-valve technology.

Strut Fractures in the C/C Valve

A fracture of the outlet strut of a 60° C/C valve occurred during clinical trials in 1978, and as more of the valves were implanted, other reports of similar fractures began to reach Shiley. While the number was not large in relation to the number of valves implanted, the fact that all the fractures were similar —occurring at the point where the outlet strut was welded to the ring — strongly suggested that a design or manufacturing problem was responsible for the failures. There had been a few fractures of the inlet strut of the similar radial-spherical (R/S) valve, but a welding change was made in 1975 and no further fractures occurred.

When both legs of the outlet strut of the C/C valve fracture, the disk falls out of its ring, resulting in unrestricted blood flow through the heart. Without a valve to close one end of the chamber, contractions cannot force blood out of the heart. This is a form of heart failure, and it requires immediate open heart surgery. Depending upon the location of the valve in the heart, the person has anywhere from a few minutes — if it is an aortic valve — to one or two hours to live [2, p. 175]. About two-thirds of the persons who experience valve failure die, and many survivors have serious complications ([6]; also [2, appendix]).

The symptoms resulting from valve failure are similar to those of other forms of heart failure, and unless an autopsy is performed, it is usually not possible to determine that valve failure was the cause of death. Obviously, there are hidden or unreported fractures, and one of the controversial issues in the case is the estimated number of fractures. By 1993 the number of reported deaths by fractured heat valves was 386. However, the Public Citizen Health Research Group, an organization founded by Ralph Nader, estimated that the actual number of deaths was 50% higher than actually reported [6, p. 48].

Subsequent studies in the Netherlands added to this controversy. Twenty-two patients elected to have their Bjork-Shiley C/C valves explanted because epidemiological data (age, size of valve, opening angle, and position) indicated they were at risk for strut fracture [7].[4] In some patients there were additional indications for reoperation, such as the presence of moderate cardiac impairment or other cardiac complaints unrelated to the valve. There was no diagnostic or clinical indication in any patient to suggest a valve defect.

The mean age of the 8 women and 14 men who chose valve explantation was 51 (26-68). Two patients had two valves replaced, making a total of 24 explanted valves. Ironically, one of the patients had previously survived a strut fracture of a 29-mm 60° mitral valve. Nondestructive examination of the valves was performed stereoscopically and with a scanning electron microscope to evaluate their structural integrity. Examination of the valve struts with a scanning electron microscope revealed no evidence of surgical mishandling in either implantation or explantation.

A total of eight 60° and sixteen 70° valves were explanted. The 70° valves have been shown to be more susceptible to strut fracture, particularly the larger sizes (29 mm). An earlier study showed mitral valves of this size to have the greatest risk of failure, a cumulative risk after eight years of 17.4% [8]. In contrast, the estimated failure rate for the 60° valves is less than 0.5% per year. Larger sizes of the 60° valve have a greater risk of fracture as well. The 70° valves were never approved for sale in the United States, and Shiley has been criticized for marketing them abroad when questions of their safety prevented them from being approved in the U.S.

Results of the Study

The results of the study of these twenty-four valves are breathtaking. *Seven of them (29%) had single-leg fractures (SLF): one leg of the outlet strut had already broken.* Two others showed characteristics of incipient fatigue failure (one was already cracked; the other showed intrusions and extrusions). *Counting these two and the seven instances of SLF, 37.5% of the valves were in various stages of strut fracture.* These fractures cannot be seen with the naked eye, but are easily detected at 25× magnification. Unless microscopic examination is undertaken, these fractures will not be noticed.

These new numbers place the risk of fractured valves orders of magnitude higher. They reinforce the position of those who have held that the actual number of fractures is far higher than what is reported. For example, 4 of 13 aortic valves had single leg fracture and one had a cracked strut. "This finding supports our hypothesis that, owing to the lethal character of the failing aortic valve strut, fractures remain under-reported; few such patients reach hospital and necropsy [autopsy] is rarely done" [7, p. 11]. As a result of this new

[4]For a discussion of [7], see [5].

study, suggesting that the fracture rate is far higher than originally expected, the Public Citizen Health Research Group increased its estimate of the number of deaths to "at least 1500" [9].

Shiley's Recalls

Soon after the C/C valve was introduced into commercial use in 1980, Shiley began to receive reports of fractures of the outlet strut. Between 1980 and 1986 Shiley/Pfizer initiated several voluntary recalls of the C/C valve and tried to identify the cause of the problem. This was difficult because of the small rate of failure. Although the failure rate was higher for large diameter valves, the reported failure rate for all sizes of valves was still much less than 1% per year. To reproduce failures in the lab would have required unrealistically long periods of testing. Consequently, scientists and engineers at Shiley had to construct hypotheses about the failures based upon the relatively meager data available and test them by reintroducing the valve back into the market [2, p. 374]. For example, one theory of failure was based on how the strut was bent before welding. New manufacturing techniques were instituted, and as new valves became available, Shiley recalled the old ones and replaced them, accompanied by "Dear Doctor" letters to surgeons that minimized the problem.[5]

Unfortunately, the failures continued despite several changes, and new explanations for the failures were put forward. Each one resulted in new methods of manufacturing or quality control and the replacement of "old" valves with new. The Food and Drug Administration (FDA) became increasingly concerned about Shiley's actions. Finally, Shiley withdrew the valve from the market voluntarily in the face of FDA movement toward an involuntary withdrawal. Ironically, Shiley may have finally hit upon the correct theory, for its last batch of valves appears to have had no known failures.[6]

Shiley's Combined Mortality Defense

When Shiley withdrew the valve from the market in 1986, the failure rate for its 60° C/C valve sold in the U.S. was estimated to be below 1%. Was this less than 1% failure rate enough to establish that the valve was defective and should be withdrawn from the market? Shiley argued that it was not, because the small failure rate is offset by the valve's superior performance in preventing TE. Most deaths (50%) of patients with valve implants are caused by the underlying heart disease of the patients. Another 30% of deaths are also unrelated to the artificial valve. The remaining 20% of deaths are caused by valve-related problems. TE is responsible for about half of valve-related deaths (10% of the total) and the rest are caused by anticoagulant hemorrhage, infection, leaks around the valve, and mechanical failure.

The fact that all the fractures were similar strongly suggested that a design or manufacturing problem caused the failures.

David Schoenfield prepared a report for Shiley in which he analyzed the performance of several artificial heart valves and concluded that "the overall combined mortality from thrombosis, embolism and strut fracture with the 60° C/C valve does not differ appreciably from other mechanical heart valves." Shiley claims that this reflects the improved design characteristics of the C/C valve in reducing the incidence of thrombosis and thromboembolism, and Schoenfield agrees [11]. Although Schoenfeld makes a strong case, his conclusion is not universally accepted. An important part of Shiley's conflict with the FDA concerned whether or not the data supplied by Shiley really established its claim of reduced TE. The issue is a statistical quagmire, and for my purposes it is more useful to assume that Shiley's claim was correct — that the C/C valve has a higher mechanical failure rate, which is offset by improved reduction of TE deaths — and examine what that means for the question of its defectiveness. If one cause of death is balanced by a roughly equal reduction in another cause of death, does this mean that the valve is not defective and should have remained on the market?

Ethical Dimensions of Defectiveness

If one looks at this defense from a utilitarian ethical perspective, it has a good deal of force. Utilitarianism, based on the work of Jeremy Bentham (1748-1832) and John Stuart Mill

[5]This issue is discussed in [10].

[6]At the hearing Shiley claimed that there had been no fractures in valves manufactured since April 1984; statistically, there would have been 11 fractures based on previous rates [2, p. 374].

(1806-1873), holds that the ethical choice is the one that results in the maximum amount of good consequences and minimizes the bad ones for all affected.[7] If the balance of good and bad consequences — utility — is the same for the C/C valve and other valves on the market, then the C/C valve is no more defective than any other. Forcing it off the market would be unfair and discriminatory, using a different standard for the C/C valves than the rest. If this were the only ethical dimension of the problem, Shiley would have a good case (assuming that the statistical analysis of TE reduction is correct).[8]

Utility is only one of several competing ethical traditions, however. Another major tradition, deontology, is derived from the thought of Immanuel Kant (1724-1804).[9] This tradition emphasizes respect for the individual as an autonomous person with the freedom to choose. Any ethically acceptable decision must take into account this concept of the individual. People should not be viewed as "means" to achieve a (good) end, but as "ends in themselves" (i.e., as autonomous moral agents). Whereas utilitarianism emphasizes the totality of good and bad consequences that accrue to individuals, deontology focuses on the intrinsic worth of individuals as free, rational beings. The language of rights is most at home in deontology, for rights protect individuals from intrusion by others. For Kant, individuals have a right to choose, as long as their choices treat others as free, autonomous choice-makers as well.

From a deontological standpoint, Shiley's defense is much less persuasive. While the balance of good and bad consequences may be the same, the effect on individual autonomy is not. Consider Shiley's program of making changes in their valve and testing whether those changes were effective by sending out modified valves to be implanted in patients. In effect, Shiley was conducting a clinical trial of their modified valve, but neither the surgeons nor the patients were afforded the ethical protections, particularly informed consent, associated with a clinical trial. Shiley's "Dear Doctor" letters to the surgeons minimized the problems with the valves and based the statistical evidence on reported fractures, ignoring the issue of hidden fractures. Most observers regard them as misleading. Patients were not informed of the valve's history or modifications; they were enlisted as research subjects without their knowledge or consent.

In a similar way, the Food and Drug Administration was also misled in order to prevent its taking action against Shiley. A 1990 FDA report concluded that there was "information that supports a belief that Shiley, Inc. has engaged in a continuing scheme to interrupt, deflect, and misdirect FDA's regulation of the Shiley Convexo-Concave heart valve." This was carried out by failing to reveal material information about the valve's performance, delaying reports of the defect to FDA, and making manufacturing and quality control changes (discussed above) without advising FDA and without their approval [15].

All of these practices are designed to interfere with the autonomous choices of surgeons, patients, and the FDA. Withholding information, providing misleading information, and preventing others from finding out what they need to know were direct attacks on the ability of these groups to make rational choices. Had they known the truth about the C/C valve, surgeons might have chosen another valve, patients might have refused to have a possibly defective valve implanted in them, and the FDA might have moved against Shiley more quickly. Shiley's efforts were designed to prevent surgeons, patients, and the FDA from making decisions that would have an adverse effect on the company's marketing of the C/C valve. As such, those efforts were clearly wrong from a deontological standpoint.

It is important to see that patients may have agreed with Shiley that the overall risk —fracture and TE — was the same for different valves, but that does not mean that each patient (or surgeon) would have given equal weight to the possibility of fracture and the reduction of TE. Many patients have chosen to have their C/C valves explanted because they did not want to live with the uncertainty of a possibly defective heart valve. For them, the reduction in TE is not an acceptable trade-off for the risk of fracture, and they would not choose it. In fact, it was important enough for them to take the risk of additional open-heart surgery with its 1-4% mortality rate and the pain and discomfort it brings.

Another factor contributed to the view that the Shiley valve was defective. The failures were all alike: they were not random component failures that can be expected with any device. There was clearly a mistake in the design and/or manufacturing of the valve, and therefore a presumption that it could be fixed. Shiley obviously believed this, too, but it did not want to discontinue marketing the valve while seeking a solution (hence the "earn as you learn" characterization). By working on changes while still marketing the valve, Shiley was treating surgeons and patients simply as a means to its marketing program and not acknowledging their right to make informed choices about participating in it.

Had Shiley not engaged in these deceptive

[7] There is another discussion of this approach in [12].
[8] For a critique of Shiley's statistical claim, see [6, p. 22-24].
[9] For an introductory discussion of these ethical traditions, see [13] and [14].

practices, it is possible that it could have kept its valve on the market. There is a risk that taking the valve off the market to determine what the problem is and how to fix it would result in not being able to successfully remarket the valve. But the Starr-Edwards caged-ball valve, mentioned earlier, which experienced early failures, was successfully redesigned and reintroduced into commercial use. Removing a product from the market to fix a problem is not an automatic kiss of death.

Defective Ethics

Was the C/C valve defective? Yes, but not simply because a small percentage fractured. What made the valve defective was the unethical practices that surrounded its marketing and development. A heart valve is a social as well as a material artifact, and the quality of its social relationships is as significant as its technical features. The valve cannot be considered apart from the company that makes it and determines what will be done when things go wrong. The same valve in the hands of a company that took its ethical obligations more seriously might not be defective, because what determines if it is defective is, in part, the quality of its relationships with patients, the medical community, and federal regulators. If the quality of those relationships at Shiley had been better, the valve might well have survived. Thus the valve must be regarded as a social artifact, not simply a material one. A heart valve with a small failure rate that is hidden from patients, surgeons, and the FDA is a defective device. Defects in both aspects of the C/C valve contributed to its being defective.

The concept of "defective device" is analogous to that of "approved device," in that both must meet socially defined criteria. A device that has been approved by FDA for commercial use is one that has certain technical features, as well as having passed all the regulatory requirements to secure the approval. A device that is technically capable of approval will not be approved if the manufacturer fails to meet the FDA requirements. Similarly, a heart valve whose small failure rate is surrounded by deceptive practices that substantially violate the rights of patients, surgeons, and the government agency whose job is to insure that medical devices are safe and effective, is a defective valve. For the purpose of determining defectiveness, the valve cannot be considered apart from its context,[10] the ethical relationships the manufacturer has with the major stakeholders — patients, surgeons, the FDA and, ultimately, Congress.

The Shiley heart-valve case is an instructive one. Because the defect in the valve was not so serious that it clearly had to be withdrawn, Shiley chose to continue to market the valve while trying to fix it. The company might have been successful had it not engaged in a pattern of deceptive practices. Perhaps if Shiley had realized that a medical device can be defective for ethical reasons, it might have chosen a different response to the small but persistent rate of fracture that developed in its heart valve.

[10]The analysis I am suggesting takes its inspiration from Arnold Pacey's *The Culture of Technology* [16], where he argues that an understanding of technology must include not only its technical features but also the cultural and organizational ones [16, p. 6].

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