M ost readers of “Twenty-Five-Year Experience With the Björk-Shiley Convexo-concave Heart Valve: A Continuing Clinical Concern” in this issue of Circulation have not heard of the valve.1 Many elements of its story parallel those of cerivastatin2,3 and rofecoxib,4 but with a twist: Recalling a heart valve may entail greater risks than leaving a possible “time bomb” in place. The Björk-Shiley story raises many questions about balancing the benefits of drugs and devices with their risks to public safety. For example:

- Why was the device approved by the Food and Drug Administration (FDA) when catastrophic failure occurred in premarket trials?
- Once marketed, why was the device not withdrawn when catastrophic failures continued to occur?
- Why did the FDA approve engineering modifications when the failure mechanism was unknown (see Table 2 in the original article)?
- Were the expert scientists assembled by Shiley to discover the mechanisms of failure and devise diagnostic methods to identify patients at risk of failure as tainted as Circulation believed them to be?
- What is the scientific basis and optimal medical process for recommending removal of devices when the risks of doing so are high?
- Should the court have insisted that only large-volume, low-risk institutions remove them?

See p 2850

My Involvement
My personal involvement began when a lawyer for Shiley, Inc, with a biostatistical degree read our account of the Braunwald-Cutter heart valve and wanted to understand why the University of Alabama at Birmingham and the Mayo Clinic decided to prophylactically remove every one.5 Subsequently, I served on scientific panels, spearheaded a multi-institutional effort to quantify the risks of prosthesis explant,6 and suggested ways to use this information for the tough decision making ahead.7

The Björk-Shiley Heart Valve
The Björk-Shiley heart valve, developed by Shiley, Inc, in collaboration with Dr Viking Björk of Sweden, was one of the earliest low-profile tilting-disc prostheses. These early models were prone to thrombosis, however.8 To reduce this tendency, the company developed a convexo-concave disc called the BSCC valve (the original was plano-convex) that washed better in the bloodstream, reducing the potential for thrombus formation.

The BSCC disc was constrained within the device by inlet and outlet struts. The inlet strut was integral with the prosthesis flange, but the outlet strut was welded to it (see Figure 1 in the original article). There were a limited number of flange sizes; the 31- and 33-mm label sizes used 29-mm flanges. (Nevertheless, the risk of outlet strut fracture [OSF] increased incrementally according to label size [see Table 2 in the original article].)

Catastrophic Failure
During the premarket trial, catastrophic failure occurred from OSF. Shiley and others assumed the welds were responsible because many fractures occurred in their vicinity.9 As Wieting and colleagues demonstrated,10 however, the apparent cause was “transient (<0.5 ms) outlet-strut-tip impacts due to closing disc over-rotation that [had] almost ten times the force of disc opening.” These induced “[outlet strut] base bending stresses [were] beyond the strut wire’s fatigue endurance limit.” Elucidation of the failure mechanism did not occur during the continued manufacture of the valve but awaited “development of computer-controlled pulse duplicators and [outlet] strut strain gauging.”10

OSF, then, requires an unusual hemodynamic state; prosthesis geometry, fit-up conditions, and materials susceptible to this state; and enough occurrences of outlet tip loading to cause fatigue-induced fracture. A slight increase in outlet strut clearance introduced in April 1984 apparently eliminated the problem (see Table 2 in the original article).10

Where Was the FDA?
Before their removal from the market, ~86,000 BCSS valves were implanted worldwide. Where was the FDA during these 7 years? Much has been made of incomplete and false manufacturing documentation and corporate misconduct by Shiley and its parent company, Pfizer. Yet the FDA accepted Shiley’s assertion that the first valve failure was a fluke, with lowered risk of thrombus more than compensating for OSF,
and approved a series of engineering changes when the mechanism of OSF was still unknown. Was the FDA more interested in supporting a device manufacturer than in protecting the public? After all, other prostheses were available for life-threatening valvular disease.

Self-Regulation
In the era of the BSCC prosthesis, no comprehensive valve implant registry existed. Inferences about the incidence of OSF have been derived mainly from implant cards.11 A contribution of the Björk-Shiley story was emergence of postmarket surveillance programs and comprehensive patient registries. (Although privacy legislation may thwart such registries, they have already proven valuable for rofecoxib.)12 Postmarketing surveillance is based on industry self-regulation, which Fontanarosa et al call into question.13 Until this system is restructured, they note, “the United States will still be far short of having an effective, vigilant, and trustworthy system of postmarketing surveillance to protect the public.” Although I agree, the present surveillance mechanism mirrors our professional self-regulation!

Industry (Shiley, Pfizer, HealthSouth, Enron) has not developed a viable mechanism for dealing with “bad news,” the disclosure of which often leads to the demise of the company. Because honesty cannot go unpunished, the business counterpart of “survival of the fittest” is to ignore, suppress, hide, or falsify bad news. In medicine, we are learning that the least-fruitful approach to reducing human error is finding and punishing culprits.14 A culture of culpability leads to defensiveness that undermines efforts to change systems and implement mechanisms to prevent errors or detect and correct them before harm results. As long as the emphasis is on culpability, industry will always minimize bad news and maximize good news.

Are there alternatives to internally funded surveillance? One could imagine a system of both initial clinical trials and subsequent surveillance, supported by pooled industry funds or taxes on drugs and devices, that would dissociate public safety from both product development and marketing.9 The FDA could do this as an expanded internal activity or as a sponsoring agency. Alternatively, a new agency could be formed. An advantage of the latter 2 suggestions is that industry-sponsored clinical trials would give way to a new sponsoring mechanism that is scientifically distanced from industry and conflicts of interest.

Role of Professional Journals
Although belatedly, Shiley and Pfizer deserve credit for assembling a well-respected group of scientists focused on 1) understanding the mechanisms of OSF, 2) discovering and testing acoustic15 and imaging methods16 to identify patients at risk of OSF, 3) identifying device, manufacturing,17 and, to a limited extent, patient factors18 that increase the likelihood of OSF, and 4) evaluating the clinical epidemiological risks versus benefits of removing the device.7,19 As a participant in this process, I was unaware of pressure from Shiley or Pfizer to suppress “bad news” or withhold data and scientific evidence.

Because our studies resulted in new knowledge, we were keen on publishing them. The response of some journals, including Circulation, was that our manuscripts would not be reviewed because, despite the list of reputable authors, the study had been sponsored by Shiley or Pfizer, and most authors had been paid by them for their services. As an author, I believed the journal editors were saying, “You are a respected scientist, but because a manufacturer has sponsored your study, you have been duped and we don’t believe you!”

Indeed, it is disturbing that many manuscripts submitted to journals are ghostwritten by industry, yet have highly published authors on their bylines.20 I can understand, then, the editors’ skepticism—and 10 to 15 years ago, their tolerance was probably lower than it is in the present era of industry-sponsored research that exceeds that of NIH-funded research.

If, however, we discredit all research performed or sponsored by industry, then we are discounting the work of thousands of serious scientists who have discovered, developed, and tested drugs and devices that even critics can scarcely deny have improved our health. Throwing out the baby with the bath water is not an acceptable or fair solution. Full disclosure of all authors and their roles may be part of the answer, but for authors, full access to data and their analysis is essential. A journal with which I am associated imposes 2-year sanctions on authors who violate journal policies, a practice that merits consideration for curtailing ghostwriting.

Weighing Life and Death
The Björk-Shiley story teaches us that no group or entity knows best how to make life-and-death decisions—not medicine, not the public, not journalists, not lawyers, not the courts. Do the math: 8% (see Table 6 of Blot et al) of 86 000 patients is 6880 deaths if all BSCC valves had been removed, given the observed reoperative risks. If the remaining 22 000 patients were to all undergo reoperation, then this would translate into 1760 deaths. Although universal recall has been advocated, the reoperative risks outweigh deaths from OSF. The court correctly recognized that reoperations should be confined to patients at greatest risk of OSF.1

Medical decision making is impeded by the lack of an accurate test predictive of future OSF and the lack of patient-level, detailed clinical data that together may more accurately identify those most vulnerable to OSF. Even if better models were available than that presented in Table 6, how should they be used? The problem is a tough one.2 Death and serious morbidity attributable to reoperation occur shortly after surgery, whereas the risk of OSF smolders over a long period. How does one weigh short-term reoperative risks against a small long-term gain from explant?

Physician recommendations and patient decisions would be easier if risk were lower, as they were for the Braunwald-Cutter prosthesis.8 On the one hand, those patients were younger and had fewer cardiac and noncardiac comorbidities than the remaining BSCC patients. On the other hand, the Braunwald-Cutter reoperation experience occurred 20 years ago, before advances in oxygenators, myocardial treatment, and imaging modalities. The achievement stemmed in part from high-volume environments and intensive efforts to avoid or catch errors.
It is unlikely that this could be repeated today without concentrating the recall effort in a few highly experienced centers committed to exceeding the standard of care.

**Could It Happen Again?**

It is happening again. All of the elements of the Björk-Shiley story remain in place, although the recent controversy over withdrawing drugs from the market presents fewer tough decisions than replacing a functioning prosthetic valve. The take-home imperatives from the Björk-Shiley story are as follows:

- Do not approve devices that fail during premarket testing until the failure mechanism is understood and corrected and premarket testing is repeated. Once marketed, immediately withdraw failing devices until the cause is understood and corrected and efficacy of the correction is verified by new testing.
- Stringently control, evaluate, and monitor engineering changes in approved marketed products, particularly changes aimed at solving failures whose mechanisms are incompletely understood.
- Incorporate expected key patient variables in designing postmarket registry and surveillance programs to facilitate epidemiological outcome assessments. This may require amending privacy legislation to permit surveillance and direct notification of at-risk individuals.
- For device recalls that will incur substantial risk, identify centers of excellence committed to removing them with minimal complications.
- Penalize authors and companies that submit articles that conceal their true authorship or that deny authors complete access to all data and analyses. The penalty may be a ban on publishing in that journal or a consortium of journals for over withdrawing drugs from the market presents fewer tough decisions than replacing a functioning prosthetic valve.

**Conclusion**

Attrition by age during the next 25 years will reduce the population of patients with a BSCC valve to 0. A fitting tribute to those who lost their lives from the failure of their device and the failure on numerous levels to protect them against harm would be a well-reasoned, scientifically sound device and drug approval, surveillance, and alerting system.

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