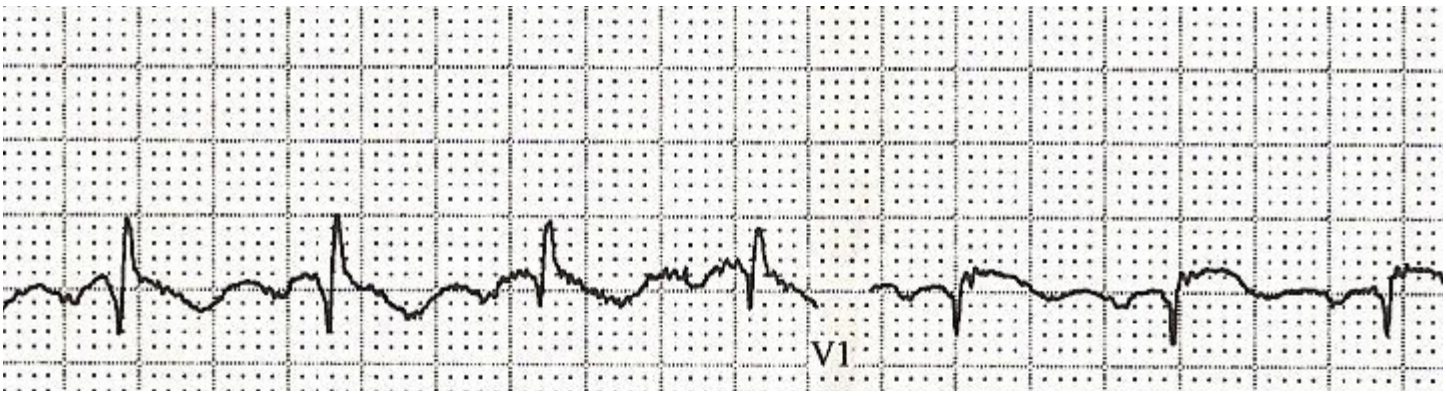
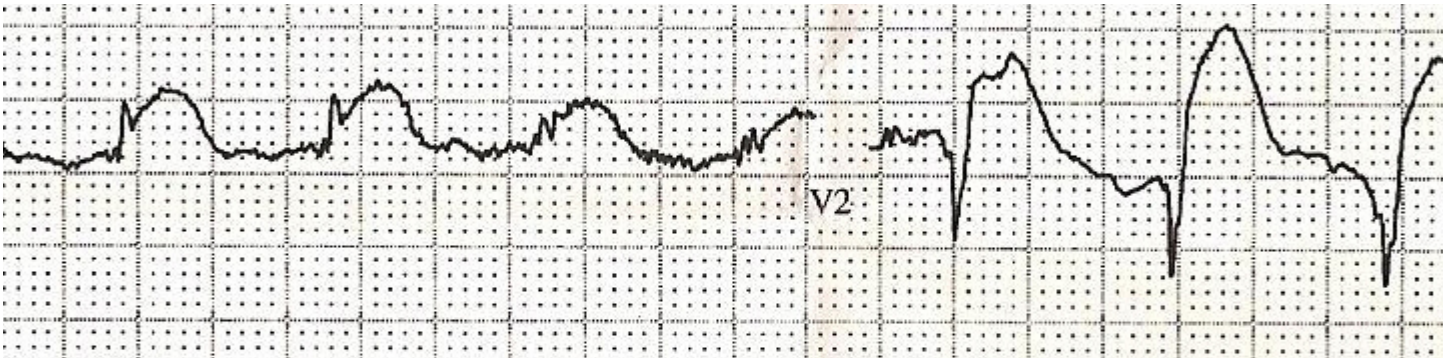


HEART SICK

HAZARDOUS HEART DEVICES AND THE IMPORTANCE OF LITIGATION



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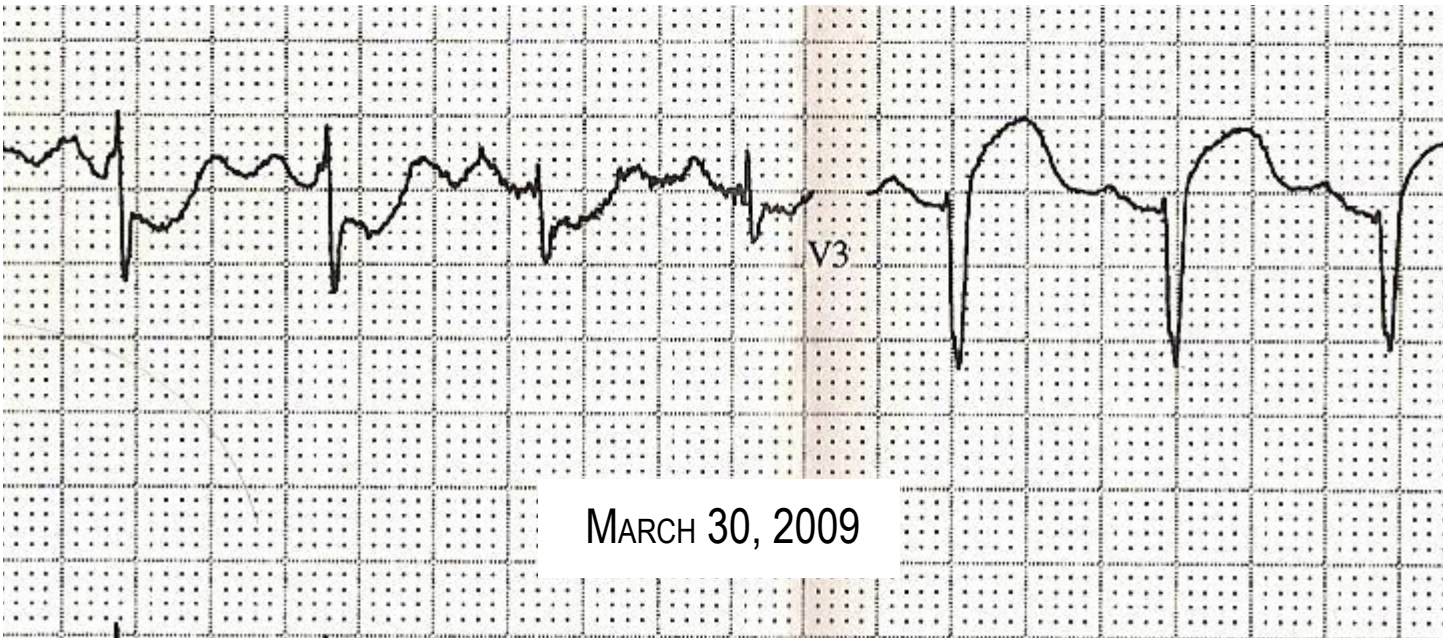
BY AMANDA MELPOLDER

EDITED BY JOANNE DOROSHOW



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HEART SICK

Hazardous Heart Devices and the Importance of Litigation

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For more information, contact:

Center for Justice & Democracy
90 Broad Street, Suite 401
New York, NY 10004
Phone: 212/267-2801
Fax: 212/459-0919
centerjd@centerjd.org
www.centerjd.org

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Hazardous Heart Devices and the Importance of Litigation

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By Amanda Melpolder

Edited by Joanne Doroshow

Designed by Daniel Albanese

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HAZARDOUS HEART DEVICES AND THE IMPORTANCE OF LITIGATION

EXECUTIVE SUMMARY

Heart disease is the number one killer in the United States. Medical device companies have invested billions of dollars developing devices to repair and protect the heart. While saving many lives, heart implants are also among the most dangerous and recalled medical implants ever made.

Because of medical risks, heart implants are not always removable even if the device fails or is later recalled. Sometimes devices are recalled long after manufactures were aware of problems and tens of thousands of devices are implanted in patients, forcing them to live with ticking time bombs in their chests.

Time and again, medical device companies have shirked their responsibilities to ensure the safety of heart devices. Some heart devices have been placed on the market without adequate clinical testing. This has been with the acquiescence of the FDA, a troubled agency that has repeatedly been unable to oversee properly this hazardous industry.

Only through litigation were many of these patients or their families compensated, did the public learn how dangerous some of these devices were, and ultimately, was the public protected. This report tells the story of some of these devices.

HEART VALVES

Björk-Shiley Convexo-Concave Artificial Heart Valve

- Only on the market for seven years, Shiley (later bought by Pfizer) marketed the Björk-Shiley Convexo-Concave Heart Valve with a shoddy design and manufacturing defects, which caused the device to fracture. When finally withdrawn from the market in 1986, it had caused hundreds of deaths and the valve continued to kill and injure patients while creating sheer terror for patients living with this implant.
- A congressional committee found that Shiley intentionally tried to obstruct government knowledge and oversight of design and production defects and misled the medical community, causing even more deaths. It also found serious questions about the FDA's willingness and ability to protect the public.
- Although the company initially insisted on confidentiality upon settling lawsuits, ensuring that future victims never learned of these defects, many victims did

receive compensation. The company also paid the government $10.75 million to settle civil claims. As a result of lawsuits, critically important information eventually came to light about this tragic episode.

Heart Valve Problems Have Continued

St. Jude Medical's Silzone valve, which went on sale in 1998, was recalled in 2000, because the valve's silver coating caused it to leak, resulting in many injuries and death.

ENDOVASCULAR GRAFT STENTS

- This stent is a treatment for abdomen aortic aneurysms (rupture of the main artery taking blood from the heart). While there are safe treatments for this condition, the endovascular graft stents manufactured by Medtronic and Guidant were not safe and caused many injuries and deaths.
- In 2003, a Guidant unit, Endovascular Technologies, plead guilty to 10 felonies and paid a large fine for failing to notify the FDA about device malfunctions and patient deaths.

ARTIFICIAL PACEMAKER AND DEFIBRILLATORS

- Pacemakers are a two-part heart implant (generator and leads) that keep the heart in regular rhythm. Pacemakers have been subject to hundreds of recalls over many years. Defibrillators, which also regulate the heartbeat, can also deliver electric shocks to accomplish this.
- Pacemaker failures have included: fracturing of the leads (wires) causing problems like perforating the aorta or shocking the patient; battery failures; and moisture buildup, which has caused the device to fail.
- In 2005, at the encouragement of two well-respected cardiologists, the *New York Times* broke the story about a Guidant defibrillator that was short-circuiting at a rate of about once a month. Three years earlier the company had changed its manufacturing process to correct the problem but never told doctors and continued to sell its defective inventory. Patients died and the FDA kept this information from the public for many months.
- Both victims and taxpayers (via state Attorneys General suits) have received compensation from litigation, and lawsuits uncovered important information about this episode.

In the 2008 case *Riegel v. Medtronic*, the U.S. Supreme Court immunized from liability companies that manufacture defective heart devices. This decision leaves heart patients with no legal recourse should they be injured, and removes the most significant and effective financial consequence to a company for choosing to keep a dangerous heart device on the market. Legislation to remedy this situation is currently before Congress.

HEART SICK

HAZARDOUS HEART DEVICES AND THE IMPORTANCE OF LITIGATION

CENTER FOR JUTICE & DEMOCRACY

BY AMANDA MELPOLDER, EDITED BY JOANNE DOROSHOW

INTRODUCTION

> *As the widow [Kathleen Gohde] bent toward Allan Gohde's coffin in July [2005], she was startled by a loud beeping coming from his chest. The source of the noise was an implanted Guidant Corp. defibrillator, the same model that was linked to the death of a 21-year-old man [in] March. Both men died after their defibrillators failed to deliver a life-saving jolt to their hearts. As it turns out, the beeping that Gohde heard was a signal of a device malfunction, and if it hadn't sounded, the family might never have known why he died.*[1]

It's hard to imagine a story more chilling than Kathleen Gohde's. Each year, over 100,000 defibrillators are implanted in patients. These stopwatch-sized devices are reliable for most people, monitoring an irregular heartbeat and if necessary, delivering a 700 volt electric shock to restore a heart to proper rhythm.[2] But thousands of these devices have failed over the years, like her husband Allan's whose defibrillator had apparently short-circuited and killed him. This was despite the device undergoing an FDA approval process that is supposed to ensure safety. And if some scientists are correct, the next-generation of heart defibrillators, which are using novel and untested technology, foretell even more deaths because they will not be sufficiently tested in humans first. Dr. Robert Hauser of the Minneapolis Heart Institute Foundation warned bluntly, "The consequences for the patient could be catastrophic."[3]

Medical device companies have invested an untold amount of time and billions of dollars developing medical devices that repair and protect the heart. Defibrillators alone are a $5 billion market.[4] Heart disease is the number one cause of death in the United States, killing nearly 900,000 Americans each year, according to the American Heart Association. Many of these medical devices like heart valves, aortic stents, pacemakers and defibrillators have undergone incredibly important technological advancements in the past 30 years. These devices have saved lives and protected patients for decades, but at the same time they are among the most dangerous and recalled implants ever made. But like the defective Guidant's defibrillator implanted in Allan Gohde's heart, a good number of these devices have failed with tragic results.

Charles Riegel was another such patient. When he suffered a heart attack in 1996, his doctor performed an angioplasty and inserted a Medtronic Evergreen Balloon catheter into his blocked coronary artery. During the procedure when the catheter's balloon was expanded to restore blood flow to his heart, it burst requiring an emergency heart bypass to save his life. Riegel sued Medtronic, the maker of the catheter, over the design, manufacture and labeling of the device.

Riegel died in 2004, but his widow pursued his case all the way to the U.S. Supreme Court.[5] However, in a devastating blow to heart patients everywhere, the court ruled in 2008, that medical device companies like Medtronic that manufactured Riegel's defective device were completely immune from liability. The only requirement for immunity was that this device complied with the requirements of the federal Food and Drug Administration (FDA), no matter how flawed the device's approval process or the existence of subsequent problems.[6] In effect, this case, *Riegel vs. Medtronic*, removed the most significant and effective financial consequence to a company for choosing to keep a dangerous heart device on the market.

One year later in March 2009, the same Supreme Court seemed to contradict many of its own findings in *Riegel*. In *Wyeth v. Levine*, the Court ruled that drug companies were not immune from liability for injuring or killing patients with unsafe drugs. The Court determined that lawsuits were critical for both supplementing the FDA's efforts to ensure drug safety and compensating those who are injured, especially given the FDA's "limited resources to monitor the 11,000 drugs on the market."[7]

The same reasoning should apply to the risky medical devices considered in *Riegel*. But until Congress changes the law to correct this decision,[8] companies like Medtronic are benefiting. In January 2009, a federal court dismissed over 1,000 lawsuits brought by victims of another Medtronic defibrillator flaw, this one involving the defective Sprint Fidelis lead (the wire that connects the heart to the defibrillator) that fractured causing

electrical shocks in the patient. The judge said, "The court recognizes that at least some plaintiffs have suffered injuries from using Sprint Fidelis leads, and the court is not unsympathetic to their plight [but] the court simply cannot provide a remedy."[9]

By the time the Sprint Fidelis lead was recalled in October 2007, it had already been implanted in over 200,000 people. In February 2009, Dr. Robert Hauser and another cardiologist released a study saying that this lead was "still functioning in only 88 percent of the patients studied three years after being implanted," a failure rate "significantly higher than previously known."[10] While Medtronic refuted those numbers, in March 2009, it admitted that the faulty lead had resulted in at least 13 deaths and 2,200 serious injuries.[11]

Incredibly though, according to Dr. Hauser, the Sprint Fidelis lead was not properly "vetted by the FDA for safety and effectiveness before being launched in the United States."[12] In fact, while dangerous heart devices like defibrillator leads are supposed to be carefully studied in humans before being widely approved, the FDA has sometimes approved medically hazardous heart devices that have not undergone this extensive process, allowing companies to "piggyback onto an application of an existing device."[13]

As another example of how the *Riegel* decision has left injured patients no recourse, in February 2009, the Wisconsin Supreme Court reluctantly dismissed a case brought by a man with a Medtronic defibrillator – this one with a failing battery.[14] In dismissing the case, concurring Justice Ann Walsh Bradley wrote:

> I write separately in order to express my concern that the United States Supreme Court's interpretation of the 1976 Medical Device Amendments does not adequately protect the safety of the citizens of Wisconsin. With one stroke of a pen, it has diminished the states' traditional authority over the development of the common law and substituted instead mandatory adherence to a regulatory standard that may be substandard. I do not believe that such adherence was mandated by the express language of the amendments, although I acknowledge that I am bound by the Supreme Court's interpretation.[15]

And what about the impact of *Riegel* on the public's health and safety as a whole? A former FDA drug reviewer interviewed for *Frontline* said, "The FDA is wholly dependent on trust, on trusting that the company is providing all the truth all the time that the company is not hiding information, the company is not covering up information, the company is not changing information."[16] This trust completely breaks down when a company's profit motive, driving it to maintain sales and market share, works counter to public safety, instead motivating companies to keep important information about deaths and injuries related to FDA-approved products from the government, doctors and patients.

This report shows how, time and again, manufacturers of medical devices for our most important organ, the heart, have violated this trust all with devastating results for patients. In many cases, the FDA could do little or nothing to help until it was too late for the victims. Only through litigation were these patients or their families compensated, and in many cases, only then did the public learn how dangerous some of these devices were, and ultimately, was the public protected.

SPECTACULAR HEARTBREAK – ARTIFICIAL HEART VALVES

> *Imagine 55,000 people engaged in a massive version of Russian roulette, all of them walking around with medical equivalent of time bombs embedded in their hearts. Not all of these time bombs will go off, not even most of them, but some of them will, and in the best tradition of Russian roulette, not one of them knows whose turn it will be next.*
>
> Herbert Burkholtz, *The FDA Follies*[17]

Only on the market for seven years, the saga of the Björk-Shiley Convexo-Concave (BSCC) Heart Valve's shoddy design and construction, which made the device prone to fracture, is one of the most tragic stories of a medical device company's irresponsibility and the FDA's failures. The defective valve resulted in hundreds of deaths, and while it was finally withdrawn from the market in 1986, it continued to kill and injure patients with these implanted devices. Public Citizen estimated that by 1993, approximately 900 deaths had occurred as a direct result of these fractures, and at least one additional death was resulting from the defect every month.[18]

Shiley "continually provided the medical community with incomplete and misleading information regarding the number of strut fractures and the severity of the problem," which "prematurely cut short the lives of hundreds of implantees."

This tragedy was so severe that it led the U.S. House Subcommittee on Oversight and Investigations to conduct a year-long investigation into the BSCC valve. The committee published a report in February 1990, that found Shiley production slipshod, and concluded that the company intentionally tried to obstruct government knowledge and oversight of the BSCC valve's failures, and Shiley "continually provided the medical community with incomplete and misleading information regarding the number of strut fractures and the severity of the problem," which "prematurely cut short the lives of hundreds of implantees."[19] Congress was equally critical of the FDA, saying the episode raised serious questions "about the FDA's willingness and ability to fulfill its regulatory mandate to protect public health when faced with companies that profit from the manufacture and sale of medical devices."[20]

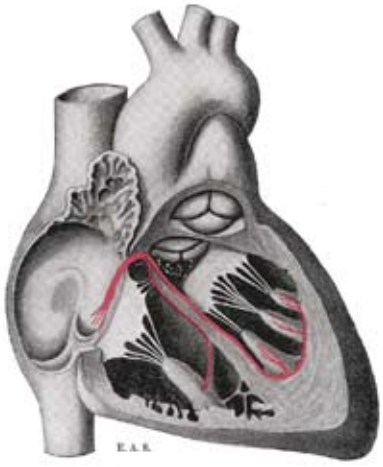
By the time it was withdrawn, 86,000 valves had been implanted patients worldwide, with close to 400 known failures resulting in over 250 deaths – although that number is considered to be vastly understated. Approximately two-thirds of known failures have resulted in death.[21] Lawsuits resulted in class actions, settlements in the hundreds of millions and over $10 million paid to the federal government itself.[22]

History of the Björk-Shiley Convexo-Concave (BSCC) Heart Valve

Mechanical heart valves, first developed in the 1950's, are used to replace diseased or deformed valves. In 1966, Donald Shiley, an American engineer, founded Shiley Inc., a small medical device company in Irving California. With the help of Swedish surgeon Dr. Viking O. Björk, Shiley developed and manufactured the first Björk-Shiley heart valve.[23] In 1976, Shiley changed their design and developed a new version of their valve – the BSCC heart valve. Shiley claimed this valve was an improvement over its earlier valve because it decreased the incidence of blood clots.[24] The valve was a complicated device, as described in one news report:

> [The BSCC valve] consists of a flexible disk installed in a half-dollar-sized metal ring, which is in turn surrounded by another ring that is sewn into the heart. The disk, which replaces the damaged heart valve, opens to let blood flow through as the heart beats, and then closes, making a tiny but audible clicking sound. It is held in place by two wire holders called struts. The problems have occurred in struts that break or fracture, allowing uncontrolled blood flow through the heart.[25]

The BSCC valve was developed the same year that Congress passed the Medical Device Amendments of 1976 – a new law that for the first time required pre-market approval of medical devices.[26] As a result, the new BSCC heart valve was one of the first devices to undergo the FDA's new pre-market approval process.



In February 1978, while the BSCC valve was still being tested, Shiley reported the first BSCC valve strut fracture to the FDA,[27] but told the agency that the fracture was an anomaly.[28] This was untrue. In April 1979,[29] the FDA approved the BSCC valve with a 60° opening[30] after only reviewing it for five and half months.[31] A second fracture occurred in July 1979, (the company was informed of this a month later) demonstrating that the device fracture had not been an anomaly, but the company delayed telling the FDA. Because the pre-market approval process was new and "relatively undefined" the regulations had not yet been implemented. However, the company was clearly not being forthright with basic information to the FDA and the medical community. For example in 1979, the company was aware of a total of three strut fractures that had occurred in patients, but the company delayed reporting these to the FDA for many months[32] and only mentioned two strut fractures in the "Dear Doctor" letters Shiley sent out to cardiovascular surgeons.[33]

In March 1979, Pfizer acquired Shiley Inc. for about $63.9 million in stock.[34] During later litigation, Wayne Runnells a welder who had worked for Shiley stated in an affidavit,

"after Pfizer took over the company, things changed and it seemed that the company's efforts were concentrated strictly on more production and not quality control."[35]

Between 1979 and 1984, the company made "numerous manufacturing and quality control changes designed to solve the strut fracture problem"[36] including several recalls. Many of these changes were not reported to the FDA so the agency could evaluate whether these were responsive to the problem, even though this was a requirement under as yet unfinalized pre-market approval regulations.[37] Moreover, the company told doctors that the changes had worked even though they hadn't.[38] In fact, even the company engineers admitted they "still had not located the source of the engineering problem."[39]

In 1983, George Sherry a Shiley engineer alerted the company's CEO of his concerns with the welding, quality control and manufacturing. But it wasn't until he went public in 1984 with his concerns, assisted by Public Citizen's Health Research Group that the public learned of the valve's "slipshod production process," including use of uncertified welders, poor weld quality, introduction of contaminants, and improper rewelding.[40] Sherry left Shiley because he was unable to "persuade the company to make manufacturing changes."[41] He said his bosses brushed off his protests over a three-year period, deriding him as a 'nitpicker' who was 'not a team player.' Even after resigning 'in total frustration' in September 1983, he said he worked for months with a Pfizer task force looking into his charges but ultimately decided that his quest for remedial action was futile."[42]

Shiley employees testified to witnessing employees getting drunk and high while on the job, and that they would polish over cracks rather than have the valve rewelded.

The following month another former Shiley employee, Larry Hamilton who had been a manager of quality control came forward and said "inspectors frequently found flaws in welds holding together crucial parts of the device. A typical valve had to be sent back for inspection four or five times before it passed quality control." Hamilton also said that the technicians were not properly trained and that the devises were "prone to manufacturing flaws which [led] to failures"[43] and he was unsuccessful in his attempts to improve the quality control of the product.[44] During later litigation, other former Shiley employees testified to witnessing employees getting drunk and high while on the job, and that they would polish over cracks rather than have the valve rewelded.[45]

The BSCC Heart Valve Finally Withdrawn from the Market

The FDA failures were also significant. The agency not only moved too slowly, it "failed to heed the warnings and reports of product failures" from its own internal reports, failed to monitor the company properly, and failed to help notify doctors and patients ("allowing the firm to control the type and nature of the information, much of which was misleading and confusing to the practitioners") among other things.[46] In January

1984, the FDA was aware of 73 incidences of strut failure that had resulted in 58 deaths, but the FDA's Cardiovascular Post Market Surveillance Committee voted not to withdraw the BSCC valve's pre-market approval from Shiley. However, in June of the same year, the FDA sent Shiley a letter informing the company that the agency would take action if it could not prove the valve's safety.[47]

Later that year, Public Citizen's Health Research Group urged the FDA to remove the BSCC heart valve from the market.[48] At the time there were 91 worldwide cases of strut fractures that resulted in 64 deaths out of the 80,000 valves that had been distributed.[49] In January 1985, once again the Public Citizen Health Research Group issued another warning on the BSCC heart valve, this time published in the *New England Journal of Medicine*.[50]

Dr. Sidney Wolfe of the Health Research Group said, "Shiley wait[ed] until enough dead bodies piled up to pull these valves off the market."

In October 1985, Shiley recalled roughly 200 large sized 60º BSCC heart valves that had not yet been implanted in patients. At least 2,700 of the recalled valves had already been implanted in patients and at the time of the recall the company had no suggestions for what these patients should do.[51] Of the recall, Dr. Sidney Wolfe of the Health Research Group said, "Shiley wait[ed] until enough dead bodies piled up to pull these valves off the market," and the recall was "too late and [was] not broad enough because they're not recalling smaller valves, which have also fractured…any cardiac surgeon who implants any of these valves is begging for a malpractice suit."[52]

In November 1986, "faced with mounting lawsuits," Shiley announced that it would voluntarily remove the valve from the market.[53] Indeed, while still publicly insisting it did nothing wrong, Shiley's parent company Pfizer began quietly settling lawsuits brought on behalf of patients or the families of those who were killed by the BSCC valve. In fact, Pfizer made sure that neither the FDA nor other patients learned of some of the most serious evidence of misconduct by the company, or the extent of the fracture problem so other patients' heart problems could be properly diagnosed before they were killed. They did this through the use of court-enforced protective orders, whereby the company required that documents obtained by lawyers and their clients "be kept secret as a condition of allowing the lawyers to pursue their cases."[54]

The first such protective order was signed after depositions taken in a 1987 case, revealed that, "Shiley employees were disguising their practice of polishing over cracks by falsely filling out paperwork. The slips of paper would say one worker had identified a cracked valve, another had rewelded it and a third had polished it."[55] Attorneys also uncovered employee 2832, a "phantom welder" who would sign off on the re-welded faulty valves. In truth there was no employee 2832. It was a "dummy number that everyone knew to use for re-welding that was not occurring" and "[f]or more than

a year, [the attorneys] tried to persuade Shiley to allow them to share their findings with the F.D.A., but the company refused."[56]

Fred Barbee, whose wife Carol died after the valve fractured and killed her in 1988, testified in Congress about learning that "Pfizer had settled many lawsuits involving valve fractures, requiring promises of confidentiality in return. Moreover, because of these secrecy agreements, Mr. and Mrs. Barbee and the doctors in the hospital they went to when the valve fractured were unaware of the Shiley valve's fracture problem. The doctors misdiagnosed Mrs. Barbee's problem, treating her for a heart attack rather than a fracture, and she died."[57]

In a letter to Congress, Mr. Barbee wrote:

> FDA approval did nothing but provide the vehicle to make this deadly product available to her doctor. I have certainly learned that FDA approval is no guarantee of safety of a product. Instead, I have learned that the FDA lacks staff and financial resources to even begin to monitor completely all of the vast products, which fall within its jurisdiction. I have also learned that the tort system in our country provides a vehicle to keep manufacturers of all types of products honest, and that the award of punitive damages in those cases where manufacturers act unscrupulously has the effect of deterring other manufacturers from engaging in similar misconduct.[58]

The secrecy only continued. In December 1990, "the lawyers asked the F.D.A. to implore the court to lift the secrecy order [regarding employee 2832]. A month later, Alan L. Hoeting, director of the F.D.A. office of enforcement, wrote the lawyers, saying, 'Despite my sympathy,' with your efforts, 'for various reasons the agency should not participate in that effort.' He did not elaborate."[59] However, that same month, the FDA issued a report concluding it had "'identified information that supports a belief that Shiley Inc. has engaged in a continuing scheme to interrupt, deflect and misdirect the F.D.A.'s regulation of the Shiley Convexo-Concave heart valve.' The report included several examples of court protective orders that it said hobbled the agency in its investigation of the valve."[60]

In February 1992, the British medical journal the *Lancet* published a Dutch study, which reported that the BSCC heart valves were five times more likely to break than previously estimated.[61] The Public Citizen Health Research Group urged the FDA to take action on this new information.[62] A month later the FDA increased its warning on the heart valve and suggested that patients who had received certain models of the valve should consider replacement surgery. This was a reversal of the FDA's previous position, which had been that the replacement surgery was far more risky than the possibility of the valve breaking.[63]

The BSCC Heart Valve Litigation History

While publicly insisting it did nothing wrong, Pfizer clearly recognized that patients or the families of those who were killed by the BSCC valve deserved to be compensated. In December 1991, while Pfizer sold off most of Shiley's assets, the company set aside funds to cover the litigation compensation.[64]

However, Pfizer continued to refuse to pay any compensation to those living with implanted devices, which could fail at anytime, that is, until August 1992, when a Cincinnati court approved a global class action settlement against Pfizer. The case involved 55,000 class action members. However, the settlement was not without controversy, because Pfizer would pay only $2,000 to $4,000 to patients whose valves had not yet failed. The purpose of the settlement was to allow the patients to consult a cardiologist. As one lawyer put it, "there isn't any non-invasive method [short of open-heart surgery] right now known to detect an incipient fracture." [65] Some attorneys called this offer "grossly inadequate," explaining "This matter does nothing to compensate for their primary element of damage, which is their stark terror that their valve may malfunction at any moment and kill them." The company also said it would "guarantee compensation to patients 'in the unlikely event of valve fracture.'"[66] However, two thirds of those fractures kill the patient.[67]

"This matter does nothing to compensate for their primary element of damage, which is their stark terror that their valve may malfunction at any moment and kill them."

In November 1992, a new challenge to the settlement was raised as a result of a "disclosure published in the *New York Times* that fractures have been found in three out of 57 Shiley heart valve patients who have undergone a new diagnostic process funded by Shiley Inc. and its parent Pfizer Inc., rais[ing] fundamental questions about the fairness, adequacy and reasonableness of the settlement of the class action suit brought against Shiley and Pfizer on behalf of Shiley heart valve recipients."[68]

Public Citizen also strongly objected to the settlement.[69] Indeed, an estimated 1,000 patients opted out of the settlement to pursue their own litigation[70] and a few months later 333 of these patients settled with Pfizer in California for much higher compensation - $40,000 to $300,000, depending on their circumstances.[71] However, challenges to the global settlement, estimated at $215 million, were unsuccessful.[72]

More individual cases by patients who chose not to be part of the class action suits continued. In July 1993, Ruth Barillas' case was the first case to go to trial. Barillas had a BSCC heart valve implanted in 1980, and more than a decade later, after learning of the dangers of the potential failure of the valve, she attempted to have the heart valve replaced. During her open-heart surgery the doctors found too much scar tissue around the valve and determined that she could not have the valve safely removed.[73] In Baril-

las' testimony she described her heart valve as a "ticking time bomb" and said, "sometimes I dream that I explode and at the same time I explode I say, 'Oh, my valve.'"[74] During her trial, another BSCC valve recipient died after her heart valve ruptured.[75] In early September 1993, just as the jury was about to begin its deliberations, Shiley confidentially settled its case with Ruth Barillas along with 258 other cases including five cases with trial dates.[76]

"Sometimes I dream that I explode and at the same time I explode I say, 'Oh, my valve.'"

In 1994, Pfizer agreed to pay the government $10.75 million to settle civil claims by all agencies of the federal government, including Medicare and the Veterans Health Administration, over the valve. The government claimed that the FDA approval of the BSCC heart valve "was based on false statements made by Shiley" and that the company later made further false statements to keep the mechanical valve on the market."[77]

The company admitted no liability and continued to insist there was no basis for people with functioning valves to recover damages. However, as a result of lawsuits, critically important information came to light that the company had deliberately withheld from the FDA, and thousands of people have been compensated for one of the most frightening corporate misdeeds in this nation's history.

Later Heart Valve Problems

With the Bjork-Shiley heart valve history firmly etched in the minds of the medical device industry, one would think that artificial heart valve debacles would be a thing of the past. But tell that to Nelson Baez. Nelson's wife Linda had a diseased heart valve and needed an artificial one. The first one was implanted in 1999. That one failed. A second one was implanted five months later. That one failed too. Finally, a third one was implanted in 2000. Within a month, she was dead.[78]

Unbeknownst to Linda, Nelson or her doctors, the Silzone valve manufactured by St. Jude Medical had gone on sale in 1998, with no clinical trial and big problems. It was recalled in 2000, because the valve's silver coating caused it to leak.[79] Yet, after Baez's second valve failed, the company had assured her concerned surgeon that there were no problems with the valve. As reported by the *Newark Star Ledger,* the surgeon testified in a deposition connected to Nelson's lawsuit against the company:

"I don't even want to face them.… They don't care. These people don't have a heart."

> Richard D'Agostino, who inserted both of the two silver-coated valves that would go bad, said he called a company representative immediately after the second operation. "There is something peculiar about this silver" was the

> upshot of what I was trying to drive home in the conversation, the Massachusetts surgeon said in a deposition. The sales rep called back within an hour. "He said they were not aware of any problems with the valve," D'Agostino said.[80]

In fact, both the company and the FDA maintain that they acted properly as the company faced over 100 more lawsuits by patients injured by this valve. Regarding his lawsuit, which later settled for an undisclosed amount, Nelson Baez could hardly stand the pain of it. As he put it, "I don't even want to face them.…They don't care. These people don't have a heart."[81]

BLEEDING HEARTS – AORTIC STENT GRAFTS

One of the most serious heart problems concerns aneurysms in the aorta, the bodies' largest artery and main supplier of blood, which is pumped out of the heart. Aneurysms are "weakened and bulging area in the aorta" that can burst or rupture and can lead to death. And while aneurysms can be anywhere along the aorta, most occur in the abdomen, called abdominal aortic aneurysms (AAA). According to one medical website, "Each year, physicians diagnose approximately 200,000 people in the United States with AAA. Of those 200,000, nearly 15,000 may have AAA threatening enough to cause death from its rupture if not treated… Fortunately, especially when diagnosed early before it causes symptoms, an AAA can be treated, or even cured, with highly effective and safe treatments."[82] However, not all treatments have been safe or effective.

As part of its 2002, investigative series on dangerous medical implants, the *Newark Star Ledger* featured a retired truck driver named Ed Gilleon, who in 2000, was implanted with an AneuRx Medtronic's endovascular stent graft, a device used to treat AAA.[83] Around the same time as Gilleon's operation, the FDA had issued a Public Health Notification warning the public of concern over "reports of approximately 25 aneurysm ruptures" and other serious problems that had occurred with the device.[84] But the FDA's warning came too late for Gilleon. As his subsequent lawsuit alleged, the company had "purposely downplayed and understated the health hazards and risks associated with AneuRx."[85]

"I know any jarring motion or any bend could kill me; that is what I live with every day"

Gilleon described to the *Newark Star Ledger* that three months after his operation, he started experiencing intense pain. His doctors soon discovered that the device had dislodged and moved down through his bloodstream, eventually causing significant blockage in his kidneys. Doctors were forced to implant another stent graft to save his life, but were unable to remove the migrated device. "'I know any jarring motion or any bend could kill me; that is what I live with every day,' said Gilleon. 'I have no feeling in my right leg and buttocks because of the nerve damage. I take morphine to dull the pain. It's unimaginable what this has done to me. I used to enjoy life. But I am very limited in what I can do now.'"[86]

At the same time the FDA issued its notice about problems with the Medtronic's AneuRx System endovascular graft stent, it issued a similar warning about a Guidant's Ancure endovascular graft stent.[87] However, Guidant's warning noted,

> The company reported to the FDA that they had failed to report many device malfunctions and adverse events, including severe vessel damage associated with problems with the deployment of the device. There were also manufacturing changes that were not properly reported to the FDA. The manufacturer told FDA that an internal audit revealed problems with their complaint handling

system, manufacturing quality systems, documentation procedures and training.[88]

The FDA sanctioned neither manufacturer.[89] But in 2003, a Guidant unit, Endovascular Technologies, pleaded guilty to 10 felony counts and agreed to pay $92.4 million to settle criminal and civil charges of failing to notify the FDA about device malfunctions and patient deaths related to AAA stent grafts. After the plea, Guidant entered into a corporate integrity agreement, or C.I.A., with the Department of Health and Human Services, agreeing to comply with all regulations and reporting requirements of the FDA as well as government health care programs like Medicare.[90] However, as this report later discusses, Guidant's "compliance" left something to be desired.

WHEN HEARTS MISS A BEAT – PACEMAKERS AND DEFIBRILLATORS

The American Heath Association describes a permanent artificial pacemaker as an implanted device in two parts (the generator and leads) that keeps the heart in regular rhythm. The leads are made of wire and are inserted through blood vessels. The battery-powered device "send[s] electrical impulses to the heart to help it pump properly. An electrode is placed next to the heart wall and small electrical charges travel through the wire to the heart."[91] A defibrillator, on the other hand, is more complicated as it not only regulate the heartbeat but can also "deliver an electric shock to help restore a normal heartbeat to a heart that's beating chaotically and much too fast."[92]

"The complexity that we see in the devices we're releasing is so much greater than it was even two years ago…so the opportunity for problems goes up."

The technology in these devices has advanced exponentially over the last few decades. As one Medtronic executive said in 2000, "The complexity that we see in the devices we're releasing is so much greater than it was even two years ago…so the opportunity for problems goes up."[93] But the opportunity for problems has been exacerbated by the irresponsible actions of some heart implant manufacturers, needlessly costing many thousands of lives. What's more, the FDA's actions or inactions have often contributed substantially to the casualty count.

In 2002, investigative reporters with the *Newark Star Ledger* published a three-part series on the medical implant industry. They found during the prior ten years, "573 recall notices covering more than two million implants were issued for lapses such as mislabeling, structural failure or manufacturing error." The most common recall was for heart implants such as pacemakers and defibrillators, which the journalists discovered to be nearly 40 percent (roughly 800,000 devices) of device recalls.[94]

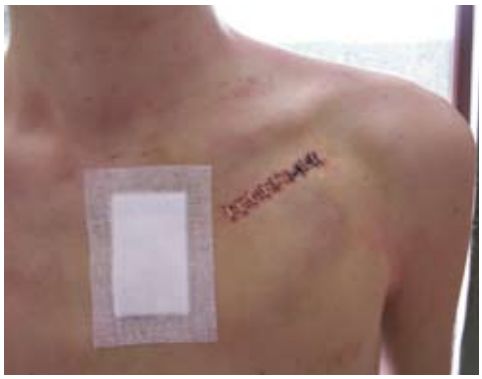
The paper noted, "Under the FDA's de facto honor system, the reporting of problems with medical implants is left to the companies, and often companies are reluctant to admit mistakes and to recall products." Moreover, "even when devices are subjected to the FDA's most rigorous pre-market approval screening," like heart implants, "problems that threaten the health of patients are allowed to slip through the system's many cracks."[95] In fact, the FDA, "subjects pacemakers and defibrillators to no special oversight, allowing most to be placed on the market without requiring clinical testing as long as they are 'substantially equivalent' to previously marketed devices. When it comes to ridding the market of defective products, the FDA relies on the industry to police itself."[96]

Often by the time manufacturers do recall a heart implant, the problems are severe and many unwitting patients can do nothing about it because of the risk of additional heart

surgery to remove the device outweigh the chance the device will fail. So patients are left with ticking time bombs in their chests, which can fail at any moment.

Pacemakers

Millions of people live productive lives with artificial pacemakers. Hundreds of thousands are implanted each year. Like defibrillators, pacemakers are implanted and regulate slow or fast heartbeats. But the safety record of pacemakers has much to be desired. Subject to hundreds of recalls over the years, pacemakers are among the most dangerous heart devices on the market. The following are just a few examples of some pacemaker problems in recent decades.



- Mid-1980s: "In 1984, one of the Medtronic [pacemaker] models was recalled by the federal government. That same year, Metronic paid $3 million to the federal government to cover Medicare costs involved" for the recall of the company's model 6972 heart pacemaker lead, which was marketed from 1980 to 1984.[97] Some members of Congress chastised both Medtronic and the FDA for pacemaker failures that year.[98]

- 1992: The General Accounting Office issued a report that "14 other models, with the same technological characteristics as the recalled model [above], remained on the market." According to the GAO, "the remaining leads have demonstrated a 'wide range of failure rates,' from zero to eight percent or higher after three to seven years following implantation,"[99] higher than the FDA's level of acceptable risks. The GAO said, "The health risks associated with defective pacemaker leads are real. . . . Indeed, their failure could prove fatal" and "urged doctors to closely monitor patients who have the implants," but neither the GAO nor the FDA "recommended removal of any of the devices, given the cost involved and the additional risks associated with any surgery, particularly on the elderly."[100]

- 1994: Pacemaker leads manufactured by Telectronics Pacing Systems were recalled. Because the wires could "fracture, protrude through the polyurethane insulation, through the right atrial appendage, and perforate the aorta."[101] This wasn't the only problem for this company's leads. The *Newark Star Ledger* reported, "12 percent to 25 percent of the company's Accufix J-Lead pacemakers manufactured from 1987 until 1994, had failed.…More than 45,000 of the company's pacemak-

ers were implanted worldwide, including some 25,000 in the United States. At least 18 heart patients died, 32 were injured and thousands of others were forced to undergo potentially dangerous surgery to replace the leads. The company agreed to a $62 million settlement of a class-action suit brought by patients and the survivors of those who died."[102]

- 2005 July: Guidant, in the midst of a major scandal over its defibrillators (see below) admitted that "nine of its older pacemaker models were prone to failing" because "a component used to seal the pacemakers could degrade, allowing moisture to build up and causing the devices to fail." The company said that "some patients might need to have the units replaced." This alert covered "28,000 pacemakers made from November 1997 to October 2000."[103]

- 2005 September through 2006: Again, Guidant announced that, "two of its widely used pacemakers, the Insignia and the Nexus, had experienced a small number of failures because of two types of malfunctions." This alert followed an inspection by the FDA of company's operations. The *New York Times* reported, "Among other things, the inspectors noted that the company had received the first report of a failure of the Insignia device in November 2003, and that 'the products continue to be distributed and users have not been informed of a potential no-output failure mode.' … In addition, Guidant said it had received additional reports of failure involving two devices that were the subject of an earlier recall, the Contak Renewal and Contak Renewal 2. According to Guidant, there have been a total of three reports of deaths associated with the devices.[104] Recalls continued. In January 2006, Guidant recalled another 19,300 pacemakers because of a problem with a potential leak in a seal, which could allow moisture into the device. This leak could create "serious health consequences" for the patients.[105]

Defibrillators

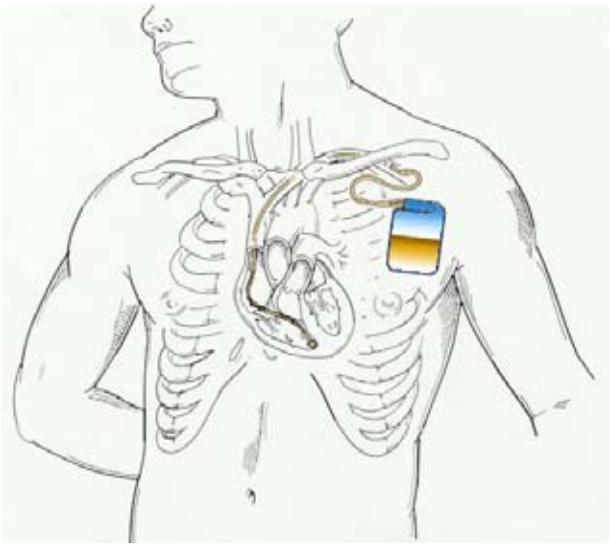
There is much more to the Guidant story than voluntary recalls of its pacemakers. The biggest story began in March 2005, when 21 year-old Minnesota student Joshua Oukrop died on a biking trip when his implanted Guidant Ventak Prizm 2 Model 1861 defibrillator short-circuited.[106] In May 2005, his doctors, longtime Minneapolis cardiologists Dr. Robert Hauser and Dr. Barry Maron, met with Guidant officials to discuss the college student's death. The company did not deny that their device malfunctioned and caused his death. They admitted to at least 25 other cases of similar if non-lethal malfunction. The doctors learned, apparently, that this information had been reported to the FDA, but it had not been fully disclosed to the public, which infuriated both doctors.[107]

Dr. Maron said during his meeting with Guidant he had warned the company that withholding the safety information was "the biggest mistake [the company would] ever make." He also said that company officials had put doctors in "an untenable situation ethically and morally by withholding information about the device."[108] Both doctors felt compelled to go to the media with the information.[109] They soon tipped off the *New York Times*.

Shortly thereafter, the *New York Times* reported on Oukrop's tragic story. The reporters described how three years earlier, the company had changed its manufacturing process to correct problems with the Giudant's Ventak Prizm 2 Model 1861 defibrillators but never told doctors, patients or the public.[110] When the company realized that the *New York Times* was about to publish an article about their product, Guidant issued an advisory to doctors.

He had warned the company that withholding the safety information was "the biggest mistake [the company would] ever make.

According to the top Guidant executives interviewed in the article, the company did not alert physicians earlier because it believed the failure rate was low in the 24,000 implanted devices. However the company continued to recommend to doctors "that the unit not be replaced."[111] In fact, the *New York Times* discovered in early June 2005, that the manufacturers continued to sell defective devices for months after it changed the way it manufactured the device – dumping its remaining inventory on unsuspecting doctors and patients."[112] Within days of that story, the company announced a recall of not only Model 1861, but also two other Guidant units that had also repeatedly short-circuited (about 29,000 devices), which had failed in at least 26 cases and at least two deaths. The company also announced it would provide free replacements, which could cost up to $25,000."[113]



Still more recalls followed, involving tens of thousands of additional devices that were found to be defective for a variety of reasons.[114] By September 2005, nearly 80 percent of Guidant's heart products were under recall or warning advisory.[115] It should be noted that this entire incident took place while the company was under special obligation to report device problems stemming from its 2003 plea agreement over its failure to disclose problems with defective aortic aneurysms stents.[116] Senator Charles Grassley (R-Iowa) later began a congressional investigation into whether

Guidant's behavior regarding heart devices violated this agreement.[117]

Some also blamed the FDA for being far too passive on this issue. Within days of the *New York Time's* first article about the Ventak Prizm 2 Model 1861 defibrillator, the FDA met with Guidant.[118] However, the FDA did little. Even after the company issued its recall, the agency "did not take a position on whether the devices should be replaced" in patients.[119] "The FDA should have been able to alert us [doctors] that there was a problem with this Guidant device," Hauser told one newspaper.[120]

The FDA had in its possession company reports that these devices were short-circuiting at a rate of about once a month

In fact, the FDA's actions were quite problematic. In July 2005, the FDA finally issued its own warning against at least 100,000 of the manufacturer recalled defibrillators, stating that the devices could cause serious injury or death if they malfunctioned.[121] But the FDA had known for months of Guidant's 1861 defibrillator problems, keeping the information secret from doctors and the public. Even finding out what the FDA knew and when they knew it had not been easy. In September 2005, the *New York Times* reported on records it had obtained through a Freedom of Information Act request,[122] with which the FDA had originally refused to comply claiming the information constituted company "trade secrets."[123] After an appeal, the documents were finally released to the newspaper, and showed that in February 2005, the FDA had in its possession company reports that these devices were short-circuiting at a rate of about once a month.[124] The agency not only failed to alert physicians, but did not issue an alert until the news media started covering the story, by which time Joshua Oukrop had died.

"When a regulatory agency official says 'There is a lot of stuff going on under the table,' how can Americans rest easy?"

Shortly after the latest *New York Times* article, Senator Chuck Grassley (R-Iowa) and Representative Edward J. Markey (D-Mass.) both issued statements criticizing the FDA for failing to publicly disclose problems about heart implants.[125] The U.S. Senate Finance Committee asked the FDA to release information about the Guidant products recently recalled.[126] Grassley, then the committee chair, inquired why the FDA typically kept post-approval product-safety reports confidential.[127] Senator Grassley said the FDA [had] not handled the defibrillator safety issue well, noting "Senior FDA officials acknowledged to [his] staff that the Center for Devices and Radiological Health needed to do a better job…When a regulatory agency official says 'There is a lot of stuff going on under the table,' how can Americans rest easy?"[128]

Lawsuits against Guidant began. In November 2005, Guidant confidentially settled the lawsuit brought by Joshua Oukrop's family.[129] In October 2006, two Texas victims settled confidentially with the company.[130] In September 2007, 36 Attorneys General settled lawsuits against the company for $16.75 million.[131] Florida Attorney General

Florida Attorney General Bill McCollum said, "We have a responsibility to the citizens of our state to protect them from less-than-responsible corporate behavior, and I believe this settlement makes a positive contribution towards that protective effort."

Bill McCollum said, "We have a responsibility to the citizens of our state to protect them from less-than-responsible corporate behavior, and I believe this settlement makes a positive contribution towards that protective effort."[132] And in December 2007, Boston Scientific (which acquired Guidant in 2006) agreed to pay up to $240 million to settle more than 8,550 claims in the consolidated Minnesota federal Multi-District Litigation (MDL) against the company.[133] This supplemented its earlier agreement to pay $195 million to settle over 4,000 claims in the MDL. Guidant had by that point recalled at least 300,000 defibrillators and pacemakers for flaws in its devices.[134]

Importantly, the lawsuits also continued to uncover information. In a document connected to the Texas case, Dr. Richard N. Fogoros who had consulted with Guidant just before the defibrillator flaws became public, "noted that Guidant had a clear conflict of interest [by not disclosing the device defects] that would naturally lead [the company] to disclose product failures only when absolutely necessary."[135] Said another doctor in a letter to Guidant released in the Texas case, "I am not critical of Guidant's device problems – these devices are so complex, issues are expected. I will not, however, work with a company that put profit and image in front of good patient care and honesty in device manufacturing."[136]

"I will not, however, work with a company that put profit and image in front of good patient care and honesty in device manufacturing."

CONCLUSION

Heart devices are among the most dangerous medical devices on the market today. Continuing responsibility for ensuring the safety of these devices rests squarely with device manufacturers. However, as this report shows, time and again companies have shirked their responsibilities to patients, doctors, and the government – sometimes with the acquiesce of the FDA. This has resulted in a huge casualty count, as well as constant terror by those forced to live with defective heart devices because of the great health risks presented by their removal.

When in *Riegel v. Medtronic*, the U.S. Supreme Court closed the courthouse door to patients with dangerous medical devices like heart implants, telling victims they had no recourse against these manufacturers or any opportunity to be compensated, the Court decided to place blind faith trust in the FDA – a troubled agency that has repeatedly been unable to oversee properly this hazardous industry.

In the 2009 decision *Wyeth v. Levine*, the Supreme Court observed the "longstanding coexistence of state and federal law and FDA's traditional recognition of state-law remedies," noting that "the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." It said, "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." Moreover, they "serve a distinct compensatory function that may motivate injured persons to come forward with information." Certainly the same is true for defective medical devices. As Senator Ted Kennedy (D-Mass.), Chairman of the Senate Committee on Health, Education Labor and Pensions, put it "[i]n enacting legislation on medical devices, Congress never intended that FDA approval would give blanket immunity to manufacturers from liability for injuries caused by faulty devices."[137] For the sake of heart patients everywhere, Congress' need to fix the *Riegel* decision could not be more urgent.

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