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ABIOMED Crisis Response Strategy

Clinical Trials for AbioCor, the Artificial Heart

Part One

Introduction

Sara Goldstein, lead corporate communications specialist for ABIOMED, sat in her office in December 2002 and pondered the unpleasant events her company had been struggling with since early that year. Beginning in the 1990's, ABIOMED, based in Danvers, Massachusetts, developed and sold the BVS 5000, a temporary medical assist device that assisted the functioning of the human heart. During 2001 and 2002, the company began testing its new product, the AbioCor artificial replacement heart, in FDA-approved clinical trials involving human volunteers. In the context of many developments during these clinical trials, in October 2002, Irene Quinn, the widow of the fifth implant recipient, had brought charges against ABIOMED, the hospital that performed her husband's surgery, and the IPAC (Independent Patient Advocate Council) who had advised her husband. She alleged that they were made to sign misleading, deceptive, and incomplete informed consent papers and that their patient advocate, Dr. Cassarett, had failed to advocate for them, ask questions, or negotiate on their behalf.¹ Now it was December and ABIOMED's investors were getting restless.

Goldstein's challenge was to coordinate ABIOMED's media response to the present litigation with the guiding principles and ethics established by her company's leadership team in January 2001. Her response had to appeal to multiple, complex groups of stakeholders. Since ABIOMED was a publicly traded company (ABMD), the impact of Goldstein's communication choices would be measured in the stock price and shareholder feedback. Other

quantitative metrics such as the number of new patient inquiries and the number of new implants, would be indicative of her success. Qualitative measures could also be used, including shareholder response at the annual meeting and correspondence from shareholders, surgeons, patients, employees, and the public. Another possible metric could be the success or failure of ABIOMED's defense in the pending lawsuit that had been brought against them.

The goal of the company was to survive long enough to complete the clinical trials and bring the product to market. Although the surgeons, scientists, organizational leaders and others who had worked for decades on the AbioCor were motivated by their mission to help people who suffer from heart disease, regulatory and financial reality remained. ABIOMED had to demonstrate the product's effectiveness through a structured clinical trial and secure FDA approval before its cash ran out. Bud Frazier, the Texas Heart Institute surgeon who had worked to develop the heart since 1985, quoted St. Augustine when he said, "We try to live in the City of God, but we must live in the City of Man." Ultimately, we have to worry about costs."²

Hearts Have Come a Long Way

In 2002, the AbioCor was the most advanced and comprehensive artificial heart – the most recent product stemming from a long history of heart assist technology development. In the 1950's and 60's, the heart-lung machine, replacement valves, implantable pacemakers, and the intra-aortic balloon pump (IABP) were invented. In the 1970's and 80's, human heart transplants became feasible, a balloon catheter was

used to treat coronary artery disease, and external and implantable ventricular assist devices entered clinical trials. The 1990's saw the approval and use of implantable assistive devices, such as ABIOMED's BVS 5000, which replaced the functioning of one or both ventricles in a human heart that is failing but potentially recoverable. Other companies manufactured devices similar in function to ABIOMED's BVS 5000.³

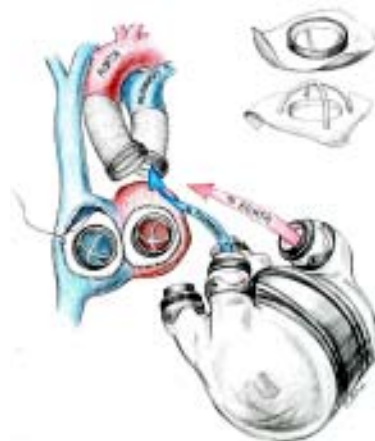
Two completely artificial hearts other than the AbioCor had been implanted in human beings, one in 1969 by Dr. Liotta, which sustained the patient for a few hours, and the other in 1982 by Dr. DeVries⁴, called the Jarvik-7. The Jarvik-7 had a large external power source the size of a refrigerator, which made mobility difficult and caused infection where the power source entered the patient's body. It was implanted in several volunteers, including retired dentist Barney Clark, before being recalled by the FDA in 1990.⁵ Another artificial heart that was in the process of being developed at Pennsylvania State University was purchased by ABIOMED in 2000.⁶ As of December 2002, the AbioCor was the only artificial heart currently approved for testing in human beings.



2001 AbioCor⁹



Implanted AbioCor¹⁰



Connecting the AbioCor¹¹



1969 Liotta⁷



1982 Jarvik-7⁸

For patients with unrecoverable heart function, there were three options: death, transplant, or artificial replacement. The estimated need for 100,000 transplants in the US each year far outstripped the available 2,000 donor hearts. Due to an exclusive patent on the type of plastic used in the AbioCor and the long lead times required for product development and approval, the AbioCor had the potential in the near future to be the only complete replacement heart available to serve this annual demand.

AbioCor Clinical Trials

Beginning in 2001, the AbioCor had been implanted into seven human volunteer test subjects in the initial clinical trial, which was approved by the United States Food and Drug Administration under an Investigational Device Exemption. Fifteen volunteers in total were required to complete the trial and permit ABIOMED to begin petitioning the FDA for formal manufacturing approval. Each of the volunteers had been thoroughly screened and met the main criterion of having only a 70% chance of not living longer than thirty days. The clinical goal of the implant procedure was to double the life of the volunteer to sixty days. Eventual loss of life was expected, considering the critically ill condition of the volunteers.

Patients volunteered for the trials for a number of reasons. Some hoped to extend their lives possibly beyond 60 days and were willing to take a chance on their quality of life with the AbioCor. Others were willing to extend their lives at all costs, even if that meant a reduced quality of life. Most, if not all, recipients wanted to help others by participating in a study which had the potential to save millions of lives in the future. The altruistic motivation of donating the last few months of one's life to scientific study is a deeply personal one. The first volunteer, Robert Tools, a former science teacher, participated in the study in order to give back to science and help others.¹²

Six implants were performed in 2001, and one was performed in April 2002 (see timeline).

Timeline of Surgeries¹³

Surgery Number	Patient name	Surgery Location	Date of Surgery	Date of end-of-life, if applicable	Length of life with the AbioCor
1	Robert Tools	Jewish Hospital of the University of Louisville	July 2, 2001	November 30, 2001	151 days
2	Tom Christerson	Jewish Hospital of the University of Louisville	September 13, 2001	Not applicable as of December 2002	14 months and ongoing as of December 2002
3	Bobby Harrison	St. Luke's Episcopal Medical Center of the Texas Heart Institute	September 26, 2001	February 15, 2002	137 days
4	Anonymous	UCLA Medical Center	October 17, 2001	December 14, 2001	57 days
5	James Quinn	Hahannemann University Hospital of Drexel University College of Medicine	November 5, 2001	August 25, 2002	289 days
6	Anonymous	St. Luke's Episcopal Medical Center, Texas Heart Institute	November 27, 2001	November 27, 2001	None, patient did not survive surgery
7	Anonymous	Jewish Hospital in Louisville	April 10, 2002	April 10, 2002	None, patient did not survive surgery

A Design Change

Late in 2001, autopsies of three of the recipients suggested that the cause of death was related to blood clots in the AbioCor which had dislodged and caused a fatal stroke. ABIOMED stepped back briefly in February 2002 to reevaluate and improve the AbioCor so that the best possible device could be used with the next patient. The part thought to be contributing to the clotting was removed. Although Goldstein states that the clinical trials were never officially halted¹⁴, the press characterized the clinical trials as having officially resumed on March 6, 2002.¹⁵ Only one transplant, however, took place for the remainder of 2002, on April 11, but the patient did not survive surgery. Since that date, ABIOMED had not found any volunteers for new implants that fit its criteria.

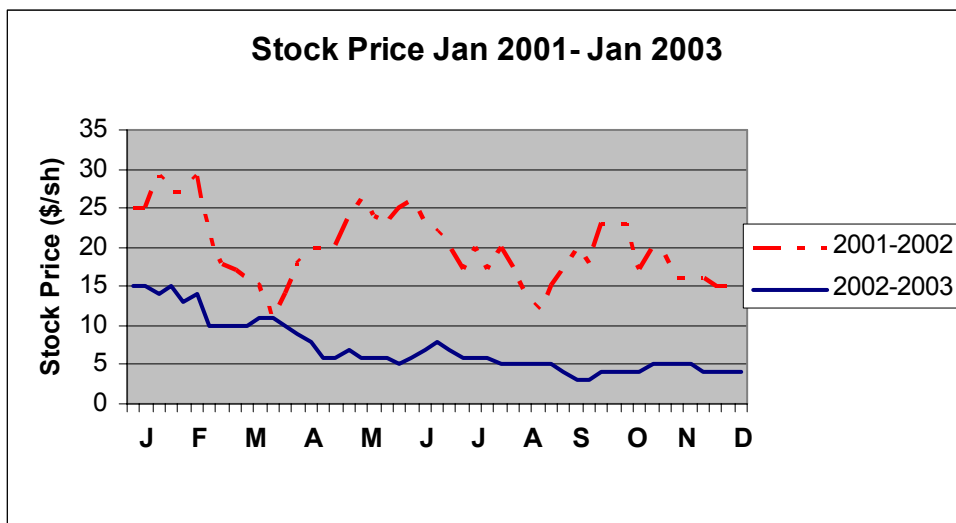
By December 2002, six of the seven test subjects had passed away over the course of the two years that the study had been underway. One flagship patient, Tom Christerson, still survived after more than a year at home, living a moderately active life.

A major roadblock to establishing the viability of the AbioCor throughout the clinical trials was the severe health complications of the volunteers; that is, the patients not only had unrecoverably failing hearts, but other life-threatening medical conditions as well. For example, several had gastrointestinal disorders that prevented

them from taking the blood thinners recommended for use with the AbioCor. Other conditions complicated recovery and a clear demonstration of the effectiveness of the AbioCor implant. Good science involved clearly isolating variables so that the actual effect of the AbioCor could be more accurately determined. In fact, Tom Christerson, the only AbioCor patient still surviving in December 2002, was also the only volunteer who did not have other complicating conditions; his heart had been damaged solely by the drugs he had taken for lung cancer treatment.¹⁶

After March 2002, the company appeared to employ a stricter set of health criteria on new volunteers. ABIOMED seemed to be looking for other patients like Mr. Christerson, who did not have other conditions, and may have been more likely to survive for longer periods with a higher quality of life. Goldstein denied that standards had changed, however, and stated that doctors, not ABIOMED, were responsible for screening patients.¹⁷

Some investors were impatient. Bill Frain, a large investor in ABIOMED, said, "I think they're being overly ethical. They're being so cautious that they're hurting themselves."¹⁸ Investor confidence was waning and the stock price was falling. Multiple articles in popular publications predicted continued loss of investor confidence were the study to remain stalled by the lack of new transplant operations.¹⁹



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Stakeholder Analysis

ABIOMED had to balance many potentially inflammatory issues in crafting its corporate communications response during this period. Among the concerned parties were the patients participating in the clinical trial and their families, the company's shareholders and employees, the doctors and hospitals donating services, the medical community at large, those who suffered from heart disease, the FDA, and the media.

The primary claim of the patient and his family²¹ on ABIOMED's communication policy during this grueling experience was that patient privacy be protected. ABIOMED chose to give first priority to the patient's wishes regarding the release of identifying information and changes in medical condition. No patient was required to give a public appearance. This policy was at odds with the desires of the public, which would have preferred up-to-the-minute information about the status of patients. Similarly, the doctors and hospitals would have preferred to have more jurisdiction over the communication of patient condition than ABIOMED chose to give them, since they had much to gain in the way of reputation and status.

As a public company, ABIOMED's shareholders had conflicting needs. They felt entitled to frequent updates regarding the condition of patients, yet they wanted ABIOMED to maximize its value over the long run. People who owned stock in companies that research and manufacture medical devices, however, did know that a long-term view was required. In addition, investors in medical device companies may have had some of the same altruistic motives as did the scientists and surgeons themselves.

Even those shareholders who were motivated to invest primarily by the promise of financial gain wanted the trials to succeed, even if that meant less frequent and less complete updates on patient condition. The fact that these clinical trials were being performed on human subjects made ABIOMED legally vulnerable and created a situation whereby infallible ethical

standards were synonymous with value creation. Any misstep in this area could lead to a legal disaster and loss of shareholder value. ABIOMED maintained a similar fiduciary and ethical responsibility to the employees that entrusted the company with their time and talent.

Other stakeholders included a) heart disease sufferers, who wanted the clinical trials to be a success but also wanted up-to-the minute information upon which to judge their own future options, b) the media, who wanted as much information as possible, and c) religious groups that may have been concerned with the moral repercussions and obligations associated with extending the life of a human being. ABIOMED was also accountable to the FDA, which required communication in confidence and in accordance with government regulations.

Pre-Litigation Communications Strategy

In December 2002, Goldstein had the opportunity to draw on an extensive ethical foundation that had been established by ABIOMED's leadership team early in 2001, prior to the start of the trials.

ABIOMED's corporate strategy and communications strategy were mutually supporting. Whereas corporate strategy is a company's plan for how it intends to evolve from its current competitive situation to a more robust competitive advantage, communications strategy considers and optimizes the use of all available media, through both words and deeds, to portray a unified message that acts in the service of the corporate strategy. ABIOMED's corporate strategy was to obtain clean experimental results and FDA approval without the cost and time investment of additional clinical trials and without unnecessarily jeopardizing patient health. The message which supported the corporate strategy was, "We put patients first." Chosen media channels included the criteria by which potential patients were screened, direct communication to shareholders, website design and implementation, and the

creation of the Independent Patient Advisory Council (IPAC).

Goldstein summarized the communications strategy designed by ABIOMED leadership as follows:

“What steers our strategy is really a respect for patient privacy. At times we don’t say things that are in our best interest...saying less rather than more...we look to the doctors and hospitals to do that. We let the clinical people lead. The big paradox is, how do you stick to such a stringent policy and still make people aware of how successful you are?”²²

Patient Selection

Patient selection criteria were crucial not only to the soundness of the clinical trials but also to reinforcing ABIOMED’s message. The company referred to the survival of a patient for sixty days after surgery as an “important milestone”.²³ Because patients participating in the trials had irreparably damaged hearts, had a 70% chance or greater of complete heart failure within thirty days, and were ineligible for transplant, ABIOMED could claim with a reasonable degree of certainty that if a patient were to survive for more than sixty days that his or her life expectancy had been doubled. This statement framed the patient’s trial experience in a beneficial context and placed expectations in perspective.

Direct Shareholder Communication

Investor communication through letters and conference calls was utilized in an effective manner to position ABIOMED as an ethical authority. On August 6, 2001, two days before its annual meeting, CEO Dr. David M. Lederman released a letter to the company’s stakeholders explaining the company’s communications policy. The letter explicitly addressed all major stakeholders and explained that while ABIOMED respected the public’s need for information, it was not willing to compromise the integrity of the study, the viability of the company, or the patient’s quality of life by divulging personal information:

“Dear shareholders, employees, clinical partners and their patients... our information policies for the clinical trial have been the subject of substantial discussion in the media...we developed communications policies for our clinical trials that put the patients first...personal detail and change in medical status...[should not be] broadcast in a play-by-play manner reminiscent of a sporting event... Public curiosity, and the appeal of what is admittedly a fascinating human interest story, does not constitute a right. It certainly cannot override the privacy right of the patient and his family.”²⁴

The document continued by addressing and refuting several arguments against this policy. It indicated that the company had secured the support of medical journalists for its information policy and concluded with a message to the shareholders:

“As shareholders...we understand that you need to be, and should be, kept informed of our progress...We are using our experience to minimize trial delays and maximize probability of success. We look forward to communicating with you on a timely basis as we reach important milestones and other significant events in the clinical trial and urge you to evaluate opinions on our progress based on what is in the overall interest of the patients. By focusing on the patients in this trial, we help ourselves succeed.”²⁵

This document set the tone for the annual meeting and provided definitive responses to public concerns. Dr. Lederman both created transparency with regard to the corporate policy and preserved the opacity of the trials themselves.

Website

The ABIOMED website was an important link to both the investment and medical communities. ABIOMED posted all press releases to the site and prominently featured

the following company statement, which served as a protective disclaimer, which is fairly standard practice for a publicly traded company:

"This ABIOMED, Inc. web site contains information and representations about future plans, events, developments and performance that are forward-looking statements...Investors and other visitors to our web site are cautioned that all such forward-looking statements involve risks and uncertainties...Actual results, events, developments and performance may differ materially."

Investors and other visitors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date that each such statement was posted to this web site...The Company undertakes no legal obligation to post the results of any revision to any forward-looking statement that may be made to reflect events or circumstances after the date posted in this web site, or to reflect the occurrence of unanticipated events."²⁶

The company did not want to be held liable for withholding critical information about the success or failure of the trials that may have affected shareholder value. ABIOMED wanted investors who understood and believed in their long-term strategy, rather than investors who planned to sell their stock at the first sign of a failure.

Updates regarding the progress of the trials were provided via press releases posted to the website. In line with company policy, personal information was not released about a patient without his consent. In the event of a patient's death, personal, empathetic statements were issued directly by the CEO:

"ABIOMED's sincerest condolences go out to this patient's family," said Dr. David M. Lederman, ABIOMED's Chief Executive Officer...Events of this kind are unavoidable in any

clinical trial involving surgical intervention with such gravely ill patients; that does not make them easier to accept. At the same time we are resolved to move forward..."²⁷

"Because of the courage of these medical pioneers, we are learning a great deal and are progressing toward our goal of making life-saving heart replacement technology available to hundreds of thousands of patients with terminal heart disease."²⁸

Independent Patient Advisory Council (IPAC)

In addition to the effective utilization of print and electronic media and timely public appearances, ABIOMED took actions that quietly cemented their communications strategy: patients come first. The most critical of these was IPAC, which was the result of a twenty-year consultation process involving medical ethicists, lawyers, and the medical community. ABIOMED created the IPAC and endowed it with an irrevocable trust. IPAC was instructed to advise patients and to advocate on their behalf with no consideration for the financial interests of the parent company. The forward-thinking IPAC was the first of its kind in clinical trials and had the effect of firmly establishing company credibility as well as providing some element of legal protection.

The Litigation

Irene Quinn's husband, James Quinn, was implanted with the AbioCor on November 6, 2001 at Hahnemann University Hospital of Drexel University Medical Center in Philadelphia, Pennsylvania. He survived almost ten months but suffered a fatal stroke on August 25, 2002. Two months later, in October 2002, his widow filed the suit against AbioMed, Hahnemann Hospital, and Quinn's IPAC patient advocate.

The Boston Herald reported that the Quinns thought the pump would save Mr. Quinn's life and that it was not made clear to them that the device was experimental. Mrs.

Quinn said that her husband had come to regret having the device implanted and that he had “no quality of life.” The informed consent form had been designed by ABIOMED for use by the hospitals performing the surgery, but George Annas, a lawyer and bioethicist at the Boston University School of Public Health, said that Hahnemann Hospital watered down the consent form, and made the surgery sound less threatening by taking out words like ‘experimental.’²⁹

Mrs. Quinn did not sue the surgeon, because she said that her husband loved him, even though it was the surgeon’s legal responsibility to obtain informed consent, and not that of ABIOMED, the hospital, or the patient advocate.³⁰ Informed consent suits had previously been won only when allegations were made that the surgeon had not obtained consent, so in December 2002 there was no precedent for success in suits such as the one Mrs. Quinn brought. The ABIOMED informed consent form was posted on its website:

Excerpts from Informed Consent Form³¹

Why I am Being Considered as a Candidate for the Study

I understand that I have a heart condition that is considered end-stage and that patients with a condition such as mine typically die within a short period of time. I also understand that, in the judgment of my physicians, there are no currently available medical or surgical alternatives that would have a reasonable chance of extending my life.

This Study is Experimental

I understand that the implantation of the AbioCor Implantable Replacement Heart is an experimental surgery which is undergoing initial evaluation in patients such as myself. I understand that if I am implanted with an AbioCor Implantable Replacement Heart, I may be the very first human patient, or one of the first human patients, to undergo such surgery.

This Study Involves Complex Surgery and Permanent Replacement of the Natural Heart

I understand that the implantation of the AbioCor Implantable Replacement Heart will involve the removal of the two main pumping chambers of my heart (right and left ventricles). The pumping unit of the AbioCor device is placed in the space in my chest where my heart’s ventricles were and is intended to take over the pumping function of my ventricles. I understand it will never be possible to put my natural heart back in my chest.

Conclusion

Much was at stake for ABIOMED, regardless of the legal outcome of the suit. This negative publicity occurred during a difficult time for ABIOMED: the design change made early in 2002, followed by the delay of new implants and the inability of the company to find new volunteers healthy enough to survive after having had an artificial heart implanted, in addition to the dragging economic conditions that had plagued the entire country since September 2001, had all contributed to dropping stock prices throughout 2002.

Reputation management was clearly one part of Sara Goldstein’s comprehensive strategy. The consequences of her decisions, however, reached far beyond the maintenance of a public image. She related her motivations for working with ABIOMED and her experience of the present challenge: “It’s challenging but rewarding. [We’re] creating a whole new path. It’s the first trial of its kind, and the first fully implantable heart ever. And we’re really protecting patients. The company itself is not very large – just under 300 employees. There’s only me [in the corporate communications department]. I work under the VP for strategic planning and policy, and I work very closely with the CFO and CEO. [When

I look back on this part of my career], I think I'll see that I played a large role [in participating in bringing the AbioCor to market]."³²

Investor confidence, and, indeed, the FDA's confidence, in ABIOMED during the coming months could determine the company's future. Successful completion of the trials would have determined, at least for the time being, the viability of the artificial heart as a therapeutic, life-extending alternative for over 100,000 people a year. In contrast to typical "better mousetrap" new product development, the surgeons, scientists, and organizational leaders at ABIOMED had devoted decades of their lives to the development and testing of this product because they believed in its promise. ABIOMED's crisis communications response to the threat to investor confidence and the confidence of the public, the medical community, the patients, and the FDA had to ring true, and had to allow ABIOMED to continue the trials so that it could achieve its goal of bringing the AbioCor to market.

¹ "Artificial Hearts: Quinn v. AbioMed, Inc. Artificial-Heart Patient's Widow Sues Manufacturer, Health Care Providers." *Medical Devices Litigation Reporter*: November 1, 2002.

² "Artificial Heart has a Weaker Pulse; A Lull in Transplants This Year Raises Questions About AbioCor's Financial Prognosis." *Houston Chronicle*: September 23, 2002.

³ <http://www.AbioMed.com>.

⁴ <http://www.AbioMed.com>.

⁵ Burling, Stacey. "New Artificial Heart Human Trials Announced." *Philadelphia Enquirer*: January 31, 2001.

⁶ Ibid

⁷ Reprinted by permission of AbioMed. Publicly available image. <http://www.AbioMed.com>.

⁸ Reprinted by permission from AbioMed. Publicly available image. <http://www.AbioMed.com>.

⁹ Reprinted by permission from Jewish Hospital/University of Louisville.

<http://www.Heartpioneers.org>.

¹⁰ Reprinted by permission from AbioMed. <http://www.abiomed.com>.

¹¹ Reprinted by permission from Jewish Hospital/University of Louisville.

<http://www.Heartpioneers.org>.

¹² Burling, Lori. "Widow of First Artificial Heart Patient Speaks at Science Exhibit." *Associated Press*: November 16, 2002.

¹³ As condensed and extrapolated from AbioMed press releases, <http://www.AbioMed.com>

¹⁴ Sara Goldstein, phone interview by author, January 13, 2003.

¹⁵ "ABIOMED ISO Certification Received For AbioCor Implantable Replacement Heart: Patient Enrollment in Clinical Trial Set to Resume." *AbioMed Press release*: March 6, 2002.

¹⁶ Ackerman, Todd. "Artificial Heart has a Weaker Pulse; A Lull in Transplants This Year Raises Questions About AbioCor's Financial Prognosis." *The Houston Chronicle*: September 23, 2002.

¹⁷ Pope, Justin. "Artificial Heart company tries to reassure investors as tests drag on." *The Associated Press*: December 18, 2002.

¹⁸ Ibid

¹⁹ "AbioMed misses deadline for marketing artificial heart." *The Associated Press*: December 9, 2002; Pope, Justin. "Artificial Heart company tries to reassure investors as tests drag on." *The Associated Press*: December 18, 2002; Ackerman, Todd. "Artificial heart has a weaker pulse; A lull in transplants this year raises questions about AbioCor's financial prognosis." *The Houston Chronicle*: September 23, 2002.

²⁰ Compiled from publicly available information supplied on www.Hoover.com

²¹ All patients to date have been male.

²² Sara Goldstein, phone interview by author, January 13, 2003.

²³ "Four AbioCor Patients Have Attained Sixty-Day Milestone." *AbioMed press release*: January 4, 2002.

²⁴ "AbioMed CEO Explains Company Policy For Initial Human Trial of AbioCor Replacement Heart." *AbioMed press release*: August 8, 2001.

²⁵ "AbioMed CEO Explains Company Policy For Initial Human Trial of AbioCor Replacement Heart." *AbioMed press release*: August 8, 2001.

²⁶ AbioMed web site, home page, May 2, 2002

²⁷ "AbioCor Implant Performed at Jewish Hospital: Patient Does Not Survive." *AbioMed press release*: April 11, 2002.

²⁸ "First Patient Enrolled in AbioCor Clinical Trial Dies." *AbioMed press release*: November 30, 2001.

²⁹ Lasalandra, Michael. "Suit May Jeopardize FDA OK for AbioMed." *Boston Herald*: October 17, 2002.

³⁰ Ibid

³¹ "Informed Consent Form." *AbioMed website*, www.abiomed.com

³² Sara Goldstein, phone interview by author, January 13, 2003.