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THIS IS NOT AN ARBITRATION MATTER. ASSESSMENT OF DAMAGES HEARING IS NOT REQUIRED.

IRENE QUINN as ADMINISTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF JAMES QUINN AND IRENE QUINN, in her own right, **5716 Delancey Street** **Philadelphia, PA 19143** **Plaintiff,** **v.** **ABIOMED, INC.** **22 Cherry Hill Drive** **Davers, Massachusetts 01923** **and** **TENET HEALTHCARE CORP.** **3820 State Road** **Santa Barbara, CA 93105** **and** **DREXEL UNIVERSITY/MCP HAHNEMANN UNIVERSITY** **245 N. 15th Street** **Philadelphia, PA 19102** **and** **HAHNEMANN UNIVERSITY HOSPITAL** **245 N. 15th Street** **Philadelphia, PA 19102** **and** **DAVID CASSARETT, M.D.** **245 N. 15th Street** **Philadelphia, PA 19102** **Defendants.**	:	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY** **October TERM, 2002** **NO.: 001524** **JURY TRIAL OF TWELVE (12) PERSONS DEMANDED** **COMPLAINT/CIVIL ACTION**

COMPLAINT / CIVIL ACTION

Plaintiff Irene Quinn, in her own right and as Administrator and Personal Representative of the estate of James Quinn, claims of the defendants, both jointly and severally, a sum in excess of One Hundred Thousand Dollars ($100,000.00) in compensatory and punitive damages, upon causes of action whereof the following are true statements:

1. Plaintiff Irene Quinn ("Mrs. Quinn") was the wife of James "Butch" Quinn ("Mr. Quinn") and is the Administrator and Personal Representative of the estate of James Quinn and has an address of 5716 Delancey Street in Philadelphia, Pennsylvania.

2. Defendant Abiomed, Inc. ("Abiomed") is a developer, manufacturer and marketer of medical products designed to assist or replace the pumping function of a failing heart. Abiomed's AbioCor Implantable Replacement Heart (the "artificial heart") has been and is currently being implanted in subjects as part of an initial clinical trial (the "experiment") conducted under an Investigational Device Exception from the United States Food and Drug Administration.

3. Defendant Tenet HealthCare Corp. ("Tenet") is a nationwide provider of health care services and owns or operates 116 acute care hospitals, including defendant Hahnemann University Hospital.

4. Defendant Drexel University/MCP Hahnemann University (the "University") is the largest private medical school in the nation and was formed through the consolidation of the Medical College of Pennsylvania and Hahnemann University.

5. Defendant Hahnemann University Hospital (the "Hospital") is a 618 bed teaching facility and specializes in, among others, cardiac and transplantation services. It is affiliated with the University and is part of Tenet.

6. Defendant David Cassarett, M.D. ("Dr. Cassarett") was the Patient Advocate for the Quinns who was being paid by Abiomed for his services in the experiment. At all times mentioned herein and material hereto, Dr. Cassarett was an agent, servant, representative and/or employee of Abiomed.

7. Mr. Quinn was a 52 year old retired baker and grandfather of five children whom he had raised with his wife of thirty years, Irene Quinn.

8. In September 2001, Mr. Quinn was diagnosed with congestive heart failure.

9. Mr. Quinn's physician at the Hospital informed the Quinns that Mr. Quinn would not live another six months.

10. Mr. Quinn's physician recommended that he schedule an appointment with Dr. Samuels ("Dr. Samuels"), who was conducting a clinical trial on the Abiomed Artificial Heart.

11. In October 2001, Dr. Samuels met with the Quinns and informed them that Mr. Quinn would most probably die within a week to thirty days, that he was not eligible for a heart transplant, and that there was an artificial heart being used in a research study that offered Mr. Quinn a therapeutic alternative.

12. At the time, Abiomed had already begun enrolling subjects in its nationwide "clinical trial" for its artificial heart. This was an experimental, implantable, battery powered heart replacement device in the infant stage of development.

13. In order to participate in the study, subjects had to have an Eighty Percent (80%) likelihood of dying within thirty days on optimized medical management as predicted by Abiomed's AbioScore mortality prediction tool.

14. Upon information and belief, the protocol for the clinical trial called for a control group of subjects who, under the Abio Score prediction tool, also had a likelihood of dying within thirty days but who did not receive an artificial heart.

15. In July, 2001, the experiment began with one subject at Jewish Hospital in Louisville, Kentucky.

16. In September 2001, Abiomed announced that it expected, consistent with its plan, at least five patients would be implanted with its artificial heart before the end of 2001.

17. The experiment was designed to advance medical science in order to make artificial hearts a commercial therapeutic alternative for patients who suffered from ailments which afflicted Mr. Quinn.

18. In order to make such advancements, defendants knew they had to conduct experiments on human beings.

19. Because this was the first experiment of its kind regarding the Abiomed artificial heart and because of the prior history of experiments with artificial hearts, defendants knew or should have known that the benefits of participating in such an experiment were minimal to the subject and the risks of suffering extreme pain and suffering and ultimate death were great.

20. In addition, defendants knew or should have known that subjects such as Mr. Quinn were extremely vulnerable and, because of what is known as “the therapeutic misconception,” would believe that enrolling in such a trial was in their best therapeutic interest.

21. Contrary to what defendants, through their agents, told Mr. Quinn, this artificial heart was not at that time a therapeutic alternative and the only reason Mr. Quinn or any subject should volunteer for such an experiment would be to serve as a martyr for the greater good.

22. In essence, the subjects in this experiment would be human guinea pigs who are poked, prodded, injected and tested in order to advance medical science and the profits and reputations of Abiomed, Tenet, the University, the Hospital, and the other individuals associated with the experiment.

23. The defendants, through their agents, represented to the Quinns that they would work to set up a trust fund for Mrs. Quinn, which would be available to her following the experiment.

24. The defendants, through their agents, represented to the Quinns that there would be 24 hour nurses available to Mr. Quinn after the surgery for the remainder of his life.

25. The defendants, through their agents, represented to the Quinns that, as a result of the operation, Mr. Quinn stood to have a good quality of life.

26. The defendants, through their agents, represented to the Quinns that, because Mr. Quinn was a volunteer, he would incur no medical expenses.

27. At various times, defendants presented the Quinns with an informed consent document governing the experiment. (See copy of Consent to Take Part In a Research Study attached hereto and incorporated herein as Exhibit "A.")

28. For publicity purposes, defendants would present Mrs. Quinn other consent documents, sight unseen, for her to sign prior to appearing in front of the cameras and the press.

29. Such documents and discussions concerning such documents were materially misleading, deceptive and incomplete.

30. While the Quinns were assigned Dr. Cassarett as their "patient advocate" to assist them in the informed consent process, Dr. Cassarett failed to advocate for the Quinns. Indeed, at the informed consent conference, Dr. Cassarett made no demands and asked no questions of the investigators.

31. As a result of the misrepresentations and misconceptions described above, the Quinns agreed to the artificial heart transplant because they believed it was their only viable therapeutic alternative, and it would prolong Mr. Quinn's life in a meaningful and productive manner.

32. On November 5, 2001, in a ten hour operation, Dr. Samuels performed the world's fifth implantation of Abiomed's artificial heart on Mr. Quinn.

33. Mr. Quinn immediately began experiencing pulmonary distress as his lungs filled with fluid and he required an external oxygen machine.

34. On November 11, 2001, the first recipient of the artificial heart suffered a serious stroke.

35. On November 27, 2001, a sixth artificial heart recipient did not survive the surgery.

36. On November 30, 2001, Abiomed reported that the first recipient of the artificial heart had severe abdominal bleeding and died.

37. On December 12, 2001, Abiomed reported that the fourth recipient of the artificial heart died.

38. On December 31, 2001, Mr. Quinn suffered a stroke.

39. On January 14, 2002, Mr. Quinn was released from the Hospital and transported to a nearby hotel.

40. While at the hotel, defendants failed to provide the twenty-four hour nursing and failed to provide adequate medical supervision, notwithstanding the fact that the defendants had promised and represented to the Quinns that they would provide these services.

41. Mrs. Quinn was forced to stop working in order to help care for her husband.

42. On January 23, 2002, Abiomed announced that Mr. Quinn had suffered a stroke and that future artificial hearts would be modified because of the strokes suffered by the first recipient and Mr. Quinn.

43. Abiomed modified the device by removing a plastic cage on a surgical cuff that attaches to the tissue of the recipient.

44. According to Abiomed, the cage was needed for testing on calves but was not needed for humans.

45. The defendants have also claimed that Mr. Quinn's stroke resulted from a blood clot that lodged in the right thalamus section of his brain and formed, in part, because the amount of anticoagulation drugs that he was taking was too low.

46. After Mr. Quinn's first stroke, he had difficulty with balance, a weakened left side, slurred speech and vision impairment.

47. By February 3, 2002, Mr. Quinn was readmitted to the Hospital because of breathing difficulties.

48. On February 15, 2002, the second recipient of the artificial heart died.

49. After being readmitted to the Hospital, Mr. Quinn could barely breathe and was in constant, unbearable pain with extreme burning sensations in his back and chest.

50. On March 6, 2002, Mr. Quinn was placed on a ventilator in order to breathe.

51. By June 2002, Mr. Quinn was still in the Hospital and the Quinns had become extremely dissatisfied with the experiment and the conduct of defendants; the Quinns thereafter terminated Dr. Casarett as their advocate.

52. At no time did the defendants plan or prepare for Mr. Quinn to return to his home and had no arrangement to pay for home nursing services for the Quinns. Indeed, the Quinns' home was ill-suited for Mr. Quinn's ultimate return with the artificial heart in his chest, a fact defendants, through their agents, later conceded should have been known by them before accepting Mr. Quinn as a subject.

53. Throughout the late spring and early summer of 2002, no medical reason required Mr. Quinn to stay in the hospital, yet he stayed because defendants could not agree on which

entity would be responsible for the costs involved in allowing him to live, and die, in his own home.

54. On August 23, 2002, Mr. Quinn suffered a massive stroke.

55. On August 25, 2002, defendants, through their agents, declared Mr. Quinn brain dead.

56. Thereafter, on August 26, 2002, defendants, through their agents, programmed the AbioCor heart to turn off.

57. Immediately after the AbioCor heart was turned off, and the day after he was declared brain dead, Mr. Quinn opened his eyes, sat up, extended his arms upward, closed his eyes, crossed his hands, lay back down and died.

58. Since the surgery and continuing to the present, Mrs. Quinn has received thousands of dollars of bills related to the experiment.

59. During the course of the experiment, these burdens created a terrible financial hardship on Mrs. Quinn.

60. Recently, Tenet Hospital has advised that these bills have been sent in error, and that she owes no money, yet the bills continue to be sent to Mrs. Quinn and she has been contacted by collection agencies.

61. During the course of the experiment, Mr. Quinn had no quality of life and his essential human dignity had been taken from him.

62. The Quinns would not have participated in the experiment if either had to do it over again.

63. The suffering of the Quinns and their severe emotional pain and distress were a direct result of the careless, negligent, reckless and intentional acts and misrepresentations of the defendants.

FIRST COUNT

PATIENT ADVOCATE MALPRACTICE – DAVID CASSARETT, M.D.

64. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

65. Dr. Cassarett is a physician and patient advocate and was the patient advocate for the Quinns with respect to the experiment.

66. Dr. Cassarett represented to the Quinns that he had experience as a patient advocate and led the Quinns to believe that he was capable of competently representing and advising them as to all aspects of the experiment.

67. As part of Dr. Cassarett's responsibilities and obligations, he was to advise the Quinns regarding the informed consent process including: all conflicts of interest of individuals and entities involved in the experiment, the risks associated with the experiment, the safety of the experiment, and whether it was in Mr. Quinn's best interest to participate, Dr. Cassarett also had the duty and responsibility to negotiate ongoing informed consent issues that might arise during the course of the experiment and to advise the Quinns with respect to end of life issues.

68. Dr. Cassarett was present at the informed consent conference but advocated no position for the Quinns and asked them only whether they had any questions.

69. Dr. Cassarett was negligent and/or failed to exercise the ordinary skill and knowledge employed by others in his field in that:

a. he failed to exercise the ordinary care, skill and diligence required of patient advocates;

b. he breached his fiduciary duty owed to the Quinns;

c. he failed to protect the interests of the Quinns with respect to the informed consent process;

d. he failed to act with respect to billing issues;

e. he failed to set up communications with the wives of other subjects;

f. he failed to protect the interests of the Quinns with respect to privacy issues; and,

g. he failed to disclose that he was getting paid by Abiomed.

70. As a direct and proximate result of the negligence and breach of fiduciary duty of Dr. Cassarett, the Quinns have been harmed and have suffered damages.

WHEREFORE, plaintiff claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Hundred Thousand Dollars ($100,000.00), punitive damages and delay damages pursuant to Pa. R.C.P. 238, interest and allowable costs of suit

SECOND COUNT

NEGLIGENCE

71. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

72. Defendants knew that this experiment served little therapeutic purpose and that the artificial heart was untested as to its safety and efficacy.

73. Defendants knew subjects like Mr. Quinn were vulnerable and would feel compelled to submit to the experiment without understanding the risks and limited benefits associated with participating.

74. Defendants' actions, as set forth above, were negligent in the manner in which they conducted the experiment asset forth above, as well as by:

a. failing to properly advise the Quinns as to the limited benefits and substantial risks of participating in the experiment;

b. failing to exercise reasonable care in the informed consent process;

c. failing to exercise reasonable care in allowing the experiment to fall out of protocol once Mr. Quinn moved to the Hawthorne and survived longer than sixty days;

d. failing to ascertain whether Mr. Quinn truly met the inclusion criteria of having an 80% likelihood of dying within 30 days;

e. failing to exercise reasonable care in preparing for end of life eventualities; and,

f. otherwise failing to exercise reasonable care in designing and conducting the experiment.

75. As a direct and proximate result of defendants' actions, as set forth above, Mr. Quinn, was caused to sustain serious, disabling and permanent personal and psychological injuries, as well as dignitary harm.

76. Mr. Quinn has sustained and makes claims for pain and suffering, permanent physical, mental and psychological injuries, dignitary harm, humiliation and embarrassment, wrongful life, and any and all the damages to which he is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, plaintiff claims of defendants and each of them respectively, jointly and severally, compensatory damages in excess of One Hundred Thousand Dollars ($100,000.00), punitive damages, and delay damages pursuant to Pa. R.C.P. 238, interest and allowable costs of suit injuries.

THIRD COUNT

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

77. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

78. Defendants, and each of them respectively, failed to obtain lawful informed consent of Mr. Quinn and Mrs. Quinn so as to afford them the opportunity to make an informed decision as to whether or not to participate in the experiment.

79. The lack of informed consent includes, but is not limited to:

a. understating the risks and overstating the benefits of the experiment;

b. failing to inform Mr. Quinn about the pain and suffering he would endure;

c. failing to inform Mr. Quinn that there were limited benefits to him as a subject;

d. failing to adequately disclose the extent to which the defendants knew about the risks of the experiment;

e. failing to adequately disclose the interests of Tenet, the University and the Hospital had in relation to the study;

f. allowing Mr. Quinn to believe that his participation was his best therapeutic alternative; and,

g. failing to inform Mr. Quinn about prior experience with this and other artificial hearts.

80. As a direct and proximate result of defendants' actions, inactions and misrepresentations as set forth above, Mr. Quinn was caused to sustain serious, disabling and permanent physical and emotional injuries.

81. Mr. Quinn has sustained and makes claims for pain and suffering, physical, mental and psychological injuries, dignitary harm, humiliation and embarrassment, wrongful life and any and all the damages to which he is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, plaintiff claims of defendants and each of them respectively, jointly and severally, compensatory damages in excess of One Hundred Thousand Dollars ($100,000.00), punitive damages and delay damages pursuant to Pa. R.C.P. 238, interest and allowable costs of suit.

FOURTH COUNT

INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

82. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein.

83. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused Mr. Quinn and Mrs. Quinn severe emotional distress.

84. The conduct of defendants in making false statements to Mr. Quinn and Mrs. Quinn, knowing they would rely on these statements in making his decision to participate in the experiment, has caused emotional harm and was extreme and outrageous.

85. As a direct and proximate result of defendants' actions, as set forth above, Mr. Quinn and Mrs. Quinn were caused to sustain serious, disabling and permanent emotional injuries and distress.

86. Mr. Quinn and Mrs. Quinn have sustained and make claims for pain and suffering, permanent physical, mental and psychological injuries, dignity harm, humiliation and embarrassment, wrongful life, and any and all the damages to which they are or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, Irene Quinn claims of defendants and each of them respectively, jointly and severally, compensatory damages in excess of One Hundred Thousand Dollars

($100,000.00), punitive damages and delay damages pursuant to Pa. R.C.P. 238, interest and allowable costs of suit.

FIFTH COUNT

COMMON LAW FRAUD/INTENTIONAL AND/OR NEGLIGENT MISREPRESENTATION

87. Plaintiff incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

88. Defendants made the following intentional and/or negligent misrepresentations and committed common law fraud in:

a. understating the risks and overstating the benefits of the experiment;

b. failing to inform Mr. Quinn regarding the pain and suffering he would endure;

c. failing to inform Mr. Quinn that there were limited benefits to him as a subject;

d. failing to adequately disclose the extent to which the defendants knew about the risks of the experiment;

e. failing to adequately disclose the interests of Tenet, the University and the Hospital had in relation to the study;

f. allowing Mr. Quinn to believe that this artificial heart was a therapeutic alternative;

g. informing Mr. Quinn and Mrs. Quinn that they would incur no bills related to the experiment;

h. informing Mr. Quinn and Mrs. Quinn that they would set up a trust to care for Mrs. Quinn after the experiment;

i. informing Mr. Quinn and Mrs. Quinn that they would provide 24 hour nursing care at all times after the artificial heart surgery; and,

j. informing Mr. Quinn that his quality of life would improve.

89. The intentional and/or negligent misrepresentations set forth above were done to induce Mr. Quinn to participate in the experiment.

90. The misrepresentations set forth above were done with the knowledge that the misrepresentations were false when made.

91. Mr. Quinn and Mrs. Quinn justifiably relied upon the misrepresentations set forth above in making the decision as to whether to participate in the experiment.

92. As a direct and proximate result of defendants' actions, as set forth above, Mr. Quinn and Mrs. Quinn were caused to sustain serious, disabling and permanent physical and emotional injuries.

93. Mr. Quinn and Mrs. Quinn have sustained and make claims for pain and suffering, permanent physical, mental and emotional injuries, dignitary harm, humiliation and embarrassment, wrongful life, and any and all the damages to which they are or may be entitled under the law of the Commonwealth of Pennsylvania.

94. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, Mr. Quinn and Mrs. Quinn have suffered severe physical and emotional injuries.

WHEREFORE, plaintiff claims of defendants and each of them respectively, jointly and severally, compensatory damages in excess of One Hundred Thousand Dollars ($100,000.00), punitive damages, and delay damages pursuant to Pa. R.C.P. 238, punitive damages, interest and allowable costs of suit.

SIXTH COUNT

NEGLIGENCE/STRICT PRODUCTS LIABILITY – ABIOMED

95. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

96. As set forth above, the first artificial heart implanted in Mr. Quinn was defective and/or negligently designed in that it contained a plastic cage needed for use in calves but not for humans.

97. As a proximate cause of such defective product and/or negligent design, Mr. Quinn sustained severe physical damage and was caused to undergo unnecessary surgical procedures.

WHEREFORE, plaintiff claims of defendants and each of them respectively, jointly and severally, compensatory damages in excess of One Hundred Thousand Dollars ($100,000.00), punitive damages and delay damages pursuant to Pa. R.C.P. 238, punitive damages, interest and allowable costs of suit.

EIGHTH COUNT

LOSS OF CONSORTIUM

98. Plaintiff hereby incorporates all of the above Paragraphs as if each were set forth in full herein.

99. As a result of the injuries sustained by Mr. Quinn, wife-plaintiff Irene Quinn has been deprived of the assistance, companionship, consortium and society of her husband, all to her loss and detriment.

WHEREFORE, plaintiff claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Hundred Thousand Dollars ($100,000.00),

punitive damages and delay damages pursuant to Pa. R.C.P. 238, punitive damages, interest and allowable costs of suit.

NINTH COUNT

SURVIVAL ACTION

100. Plaintiff hereby incorporates by reference the allegations in the above paragraphs as if they were set forth fully.

101. The plaintiff, as Administrator of the estate of James Quinn, brings this action on behalf of the estate of the James Quinn under and by virtue of the laws of the Commonwealth of Pennsylvania, 20 Pa. Cons. Stat.§ 3373 and 42 Pa. Cons. Stat. §8302.

102. As a direct result of the defendants' aforesaid acts and negligence, Mr. Quinn suffered and defendants are liable for the following damages:

a. Mr. Quinn's pain and suffering between the time of his surgery and the time of his death;

b. Mr. Quinn's dignitary harm;

c. Mr. Quinn's loss of retirement and Social Security income;

d. Mr. Quinn's other financial losses suffered as a result of his death;

e. Mr. Quinn's loss of enjoyment of life; and,

f. Mr. Quinn's wrongful life.

WHEREFORE, plaintiff claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of One Hundred Thousand Dollars ($100,000.00), punitive damages and delay damages pursuant to Pa. R.C.P. 238, punitive damages, interest and allowable costs of suit.

SHERMAN, SILVERSTEIN, KOHL, ROSE & PODOLSKY

By: _____
ALAN C. MILSTEIN
DEREK T. BRASLOW
Attorneys for plaintiff

DATE: _____