

SHERMAN, SILVERSTEIN, KOHL, ROSE & PODOLSKY

Alan C. Milstein

Derek T. Braslow

Attorney ID #s: 38387, 78994

4300 Haddonfield Rd.

Suite 311

Pennsauken, New Jersey 08109

(856) 662-0700

Attorneys for plaintiffs

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

BEVERLY H. SCHEER, individually and:

as Administrator and Personal :

Representative of the Estate of :

R. SCOTT SCHEER :

711 Pond View Way :

Downingtown, PA 19335 :

Plaintiff, :

vs. :

JAMES F. BURKE, M.D., :

Lankenau Hospital :

356 Medical Office Building, East :

100 Lancaster Avenue :

Wynnewood, PA 19096 :

and :

MICHAEL J. DUZY, D.O., :

380 Medical Science Building :

100 Lancaster Avenue :

Wynnewood, PA 19096 :

and :

SUSAN HEANEY, R.N. :

Main Line Heart Center :

100 Lancaster Avenue :

Wynnewood, PA 19096 :

**COURT OF COMMON PLEAS
PHILADELPHIA COUNTY**

JURY TRIAL DEMANDED

JULY TERM, 2003

NO.: 000375

COMPLAINT – CIVIL ACTION

PARTIES

1. Plaintiff Beverly H. Scheer was the wife of decedent R. Scott Scheer (“Scheer”) and duly appointed Administrator and Executrix of his Estate and is a resident and citizen of the Commonwealth of Pennsylvania residing at 711 Pond View Way, Downingtown, PA 19335.

2. Defendant James Burke, M.D., is an employee of Lankenau Hospital, the Principal Investigator for the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Clinical Trial (“ALLHAT”) and is in medical practice with Kelly Cardiovascular Group (Division of Cardiovascular Associates of Southeastern PA, PC), Lankenau Hospital, 356 Medical Office Building, East, 100 Lancaster Avenue, Wynnewood, PA 19096.

3. Defendant Michael J. Duzy, D.O., is an employee of Lankenau Hospital and an Investigator for ALLHAT and is in medical practice with Heart Care Associates Lankenau Hospital, with an address at 380 Medical Science Building, 100 Lancaster Ave, Wynnewood, PA 19096.

4. Defendant Susan Heaney, R.N., is an employee of Lankenau Hospital and the Clinical Research Coordinator for ALLHAT with an address at 100 Lancaster Avenue, Wynnewood, PA 19096.

5. Defendant Joseph T. Conroy, D.O., is in medical practice with Kelly Cardiovascular Group, (Division of Cardiovascular Associates of Southeastern PA, PC), Lankenau Hospital, with an address at 356 Medical Office Building, East, 100 Lancaster Avenue, Wynnewood, PA 19096.

6. Defendant Main Line Hospitals, Inc., is a Pennsylvania corporation including Lankenau Hospital and The Lankenau Institute for Medical Research with an address at 100 Lancaster Avenue Wynnewood, PA 19096.

7. Defendant George A. Reichard, Jr., Ph.D., is the Chairman of the defendant Main Line Hospitals Institutional Review Board with a location at 100 Lancaster Avenue in Wynnewood, Pennsylvania.

INTRODUCTION

8. On March 9, 1997, after seeing an advertisement for ALLHAT, Scheer contacted Lankenau Hospital and had a telephone screening with Nurse Heaney, Clinical Research Coordinator.

9. Nurse Heaney immediately sent Scheer literature regarding the study.

10. The ALLHAT materials stated, “This is a chance for you to join in a national research effort which could help people like you with high blood pressure or high cholesterol lead more productive and longer lives.”

11. The materials also represented the study would involve a high level of clinical oversight, stating: “In addition to your regular medical care, the information given by you at each visit will be looked at by other doctors working on this program...special laboratories will do your blood tests and look at your ECGs using the most up-to-date methods...as a participant in ALLHAT you will be asked to see your [ALLHAT] doctor for regular blood pressure check-ups at least every three months during the first year and every four months for the next four to six years...your doctor will send some information about your health to the ALLHAT Center in Houston, Texas...” and “your doctor will check some blood tests (about every 6-8 months) to be sure the drug is not giving you any side effects.”

12. ALLHAT distributed to its staff a Manual of Operations (“the Manual”) which instructed its staff how to recruit subjects for the study.

13. The Manual suggests how ALLHAT Clinic staff can respond to the comment, “I don’t want to be no guinea pig!” by explaining that “guinea pigs can’t say no” and saying that ALLHAT wants [patients] to “have all the facts they need to make an informed decision.”

14. The Manual suggests how ALLHAT Clinic staff can respond to the questions about side effects by saying “ALLHAT patients will get extra attention and will be followed more closely than in regular practice, in case they have a side effect or other problem.”

15. Similarly, the ALLHAT-MLH patient brochure proclaimed, “If you agree to help us, we promise to make every effort to safeguard your welfare and provide the best possible care for your high blood pressure and high cholesterol.”

16. Commenting on these representations, Dr. Borrer of the Office of Human Research Protection, in an August 5, 2002 letter to MLH-Lankenau, questioned how randomizing subjects could represent the best possible care.

17. In fact, ALLHAT’s own data reveals that the drug amlodipine resulted in a 38% increase in risk of heart failure particularly when compared to the results to those subjects on the diuretic.

18. Dr. Robert Califf, Chairman of the ALLHAT Safety Monitoring Board, later concluded that patients on amlodipine were much more likely to be hospitalized, and that amlodipine “obviously doesn’t protect against heart failure.”

19. On April 18 1997, Scheer signed the informed consent document to participate in the antihypertensive arm of ALLHAT-MLH. (See copy of informed consent document attached as Exhibit “A.”)

20. This document was misleading and materially deficient in that, among other things:

- a. it represented that the second or third line drugs would be “standard medications commonly used by doctors in treating high blood pressure”;
- b. it failed to state that one of the third line drugs used was hydralazine, a drug reserved for use in resistant hypertension and pre-eclampsia during pregnancy, not for normal male hypertension ;
- c. it failed to describe the possible adverse reactions to hydralazine up to and including drug induced lupus, tachycardia glomularnephritis, renal failure, anemia, and death;
- d. it overstated the benefits subjects would receive from participation; it describes participation in the experiment as “treatment,” and “regular medical care,” uses the phrase “your doctor” instead of “investigator or coordinator,” and uses the word “patient” instead of “subject”;
- e. it states that the risks “were rarely serious” and included only “...rashes, stomach upset, drowsiness, tiredness, weakness, impotence, headache, dizziness and cough which might be related to the medicines”;
- f. it states “Most people who take these drugs do not have any side effects at all...Other risks and discomforts which might occur include bruising, bleeding, and a slight risk of infection from drawing blood”;
- g. it states “If your blood pressure has not been adequately lowered by your assigned ALLHAT drug, you may be given a second or even a third line drug to lower it to the desired level” and states “your doctor will explain to you any side effects that these medications have”;
- h. it fails to state subjects on amlodipine would not be receiving the usual sequence of care in common practice for hypertension management which is a diuretic

plus a beta blocker, a beta blocker plus a diuretic or an ACE inhibitor plus a diuretic; it fails to state that subjects on amlodipine would have a greater risk of myocardial infarction than patients on beta blockers and that the risk would increase along with the increase in dosage; and

i. it fails to include edema as a potential adverse reaction to amlodipine and hydralazine which could lead to permanent tissue damage, venous insufficiency and death from thromboembolism or hemorrhage.

21. On May 19, 1997, Scheer was presented with an informed consent document to participate in the cholesterol-lowering arm of ALLHAT-MLH.

22. This document was materially misleading and deficient in that, among other things:

a. it failed to describe potential serious adverse reactions from taking the drug pravastatin;

b. it overstated the benefits subjects would receive from participation; and

c. it describes participation in the experiment as “treatment,” and “regular medical care,” uses the phrase “your doctor” instead of “investigator or coordinator,” and uses the word “patient” instead of “subject.”

23. On April 21, 1997, Scheer rated his health as “very good” and a “90” on a 0 to 100 scale.

24. Scheer was randomized to the blind drug amlodipine and given dose # 1 (2.5 mg/day).

25. On May 19, 1997, Scheer’s blood pressure was 3 points above goal with an average reading of 138/92.

26. While the ALLHAT protocol states, “The therapeutic goal is to achieve blood pressure control on the lowest possible dosage of the first-line drug,” Dr. Duzy increased the blind drug to dosage #2.

27. At that time, Scheer’s Cholesterol was 193, his Triglycerides were 111, his HDL was low at 36, and his LDL value was 135. He was randomized to Pravastatin 40 mg daily.

28. On June 19, 1997, Scheer’s blood pressure met the ALLHAT goal with an average blood pressure of 118/89.

29. Scheer reported that the increased dosage of the blind drug made his ankles swell “as Calan had done.” Nurse Heaney noted in the chart that he had a “weak pulse” and “ankle edema.” Dr. Duzy wrote, “continue dose #2” though he did not know which blind drug Scheer was taking and did not know whether the edema Scheer was experiencing was from one of the blind drugs or from an underlying condition.

30. On July 30, 1997, Scheer’s blood pressure was still at the ALLHAT goal with an average blood pressure of 119/83. Nurse Heaney performed a physical exam and on the medical records Dr. Duzy wrote, “Continue same meds.”

31. On November 4, 1997, Scheer’s blood pressure was 2 points above goal with an average blood pressure of 118/91.

32. Though the ALLHAT protocol states, “The therapeutic goal is to achieve blood pressure control on the lowest possible dosage of the first-line drug,” Dr. Duzy increased the blind drug to dosage #3.

33. Scheer thereafter complained to ALLHAT personnel of muscle aches in his biceps, triceps and back.

34. Though The Manual states that “if a patient reports diffuse muscle pain, or pain in two or more unrelated muscle groups, a creatinine kinase test should be obtained locally,” no such creatinine test was performed.

35. Though the ALLHAT Protocol requires that clinic visits occur every three months during the first year and every four months thereafter, as much as eleven months would elapse between certain visits.

36. On April 2, 1998, Nurse Heaney performed a physical exam and noted Scheer’s blood pressure was at goal with an average reading of 119/88; Scheer was not examined by a physician. Nurse Heaney did note that Scheer had +1 ankle edema but she did not discuss the +1 ankle edema with any other physician or the Regional Coordinator.

37. On October 1, 1998, Scheer was examined by Dr. Duzy who noted Scheer had a weak pulse and + 2 peripheral edema. Dr. Duzy made the notation, “Right eye getting cloudy.” While the ALLHAT Pravastatin information sheet includes as an adverse event the progression of cataracts, Dr. Duzy failed to report the adverse event and failed to warn of the risks of continuing to ingest pravastatin.

38. Also on October 1, 1998, Dr. Duzy made the decision to add hydralazine to the blind drug contrary to the indications in the protocol, and to the standards of good medical care. Scheer remained on hydralazine for 33 months.

39. The 1997 Physicians’ Desk Reference for hydralazine lists edema as an adverse reaction and states, “whenever adverse reactions are moderate to severe, it may be necessary to discontinue the drug.” In addition, long term ingestion of the hydralazine (over 12-18 months) increases the risk for toxicity and hydralazine-induced lupus.

40. On December 22, 1998, Nurse Heaney examined Scheer and noted his blood pressure was at goal with an average of 119/75, but that he had a “weak pulse” and +1 pitting

edema. Nurse Heaney noted, "Continue same meds per Dr. Duzy." Scheer was not examined by a physician in that visit or in any visit for the next eleven months.

41. On May 27, 1999, Nurse Heaney sent the blind drug by Federal Express.

42. On August 18, 1999, Nurse Heaney sent pravastatin and hydralazine to Scheer by Federal Express.

43. On November 19, 1999 Nurse Heaney sent the blind drug, pravastatin, and hydralazine by Federal Express.

44. On March 14, 2000, Nurse Heaney examined Scheer and noted his blood pressure was 3 points above goal with an average blood pressure of 120/92. She also noted "increase hydralazine to 50 mg. BID per Dr. Mike Duzy." Scheer was not examined by a physician.

45. On March 7, 2001, Scheer's blood pressure was at goal with an average of 118/82. Though the ALLHAT Summary of Required and Actual Patient Visits and Laboratory tests submitted to the Office of Human Research Protection reflected that the protocol schedule for Visit #16 called for Laboratory Tests of K, glucose, and creatinine, no such tests were ordered.

46. Though Scheer's ECG was "abnormal" with a "left axis deviation" and a "non-specific T wave abnormality, these abnormalities were not investigated.

47. On June 16, 2001 Nurse Heaney sent pravastatin by Federal Express.

48. For the period leading up to July 4, 2001, Scheer was tired and didn't eat much. He had difficulty trying to exert himself when playing tennis with his daughter. He fell asleep at the dinner table. He had red dotted rashes on his legs and feet, which were swollen. He had a cough with sputum that he attributed to postnasal drip from sinusitis.

49. On July 5, 2001, Scheer had blood tests that revealed abnormalities including an elevated BUN (at 68 mg/dl) and elevated creatinine at (5.8 mg/dl).

50. On Monday, July 9, 2001, Scheer went to see Edward Stadtmauer, M.D., Associate Professor of Medicine, Hematology-Oncology Division. After conducting preliminary labwork, Dr. Stadtmauer recommended Scheer discontinue the hydralazine.

51. On July 10, 2001, Scheer called ALLHAT to report that he was discontinuing the hydralazine per his hematologist's instructions.

52. He reached Clinical Research Coordinator Susan Heaney and reported the discontinuation of hydralazine, related his symptoms, and verbally described his University of Pennsylvania abnormal lab results which indicated renal insufficiency.

53. Nurse Heaney stated she told Scheer "just to keep in touch. . . [and] to send the results of the labs he was going to have next week."

54. Though the protocol lists decreased renal function as a study endpoint, and despite the knowledge that Scheer was severely anemic, had renal insufficiency, had symptoms of hydralazine-induced lupus with glomerulonephritis, and had symptoms of a hypersensitivity reaction to Pravastatin, Nurse Heaney sent the blind drug by Federal Express to Scheer on July 12, 2001, continuing to treat Scheer as an ALLHAT subject.

55. On July 12, 2001, Dr. Stadtmauer advised that Scheer's creatinine had gone down to 5.5 mg/dl after stopping the hydralazine.

56. On July 15, 2001, Scheer was shuffling when he walked and had periodic episodes of staring into space. He was coughing blood. He seemed like he was "in a fog" and had a fever and went up to bed. In the early evening, Scheer collapsed and fell to the floor where his wife found him unresponsive. Scheer died from a pulmonary embolism, a consequence of drug induced lupus and end stage rapidly progressing glomerulonephritis brought on by the continued ingestion of hydralazine.

57. On July 18, 2001 Beverly H. Scheer called ALLHAT to report that her husband had died. When James Burke returned the call, Mrs. Scheer asked him how long her husband had been on hydralazine. Dr. Burke replied, "A month or maybe a couple of months." On July 24, 2001, he called back to report that Scheer had been on hydralazine since October 1998.

58. On September 24, 2001, the minutes of the MLH IRB state: Notification of death of patient SCHSC "involved serious adverse event or product problem."

COUNT I - WRONGFUL DEATH

59. Plaintiff incorporates by reference the above paragraphs as if fully set forth at length herein.

60. At all times mentioned herein and material hereto, the defendants, and each of them respectively, jointly and severally, were charged with the professional responsibility of rendering proper care and treatment to Scheer, of properly and carefully examining him in order to determine his condition and eligibility for the ALLHAT trial, of properly and carefully administering the ALLHAT protocol in a careful and prudent fashion, and of assuring that proper medical care and attention were provided during all periods of time during which he remained under said defendants' care and treatment.

61. As a result of the careless, negligent and reckless conduct of the defendants, Scheer was caused to suffer excruciating and agonizing pain and discomfort and ultimately died as a result of defendants' conduct.

62. Defendants together, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel, medical assistants and employees were careless, negligent and reckless in:

- a. failing to properly and adequately evaluate Scheer's condition and eligibility for the ALLHAT trial;
- b. failing to properly diagnose Scheer's condition subsequent to the administration of the ALLHAT medications;
- c. failing to perform proper and adequate testing for his condition;
- d. failing to properly and adequately treat his condition;
- e. failing to properly and adequately care for his condition;
- f. failing to provide and afford proper and careful medical care and treatment;
- g. failing to perform proper and careful medical practices and procedures in accordance with the standards prevailing in the community in which defendants practiced at the time;
- h. failing to properly care for his condition under all of the circumstances;
- i. caring for Scheer in a negligent and improper manner;
- j. failing to properly monitor his condition both prior to and subsequent to the delivery of the ALLHAT medications;
- k. failing to inform Scheer of all the risks of the ALLHAT medications so as to afford him with the opportunity to make an informed decision as to the ingestion of said medications;
- l. failing to properly and timely observe, discover, diagnose, treat and care for his condition;
- m. failing to conform to the standard of care and treatment prevailing in the medical community in which defendants practiced at the time in conducting ALLHAT;

n. failing to exercise reasonable care under all of the circumstances, in accordance with the accepted practices and procedures in the medical community in which defendants practiced;

o. failing to follow and abide by guidelines set forth by various governmental agencies; and

p. acting negligently per se.

63. As a direct and proximate result of the carelessness, negligence, gross negligence, recklessness and willful and wanton conduct of defendants, and each of them respectively, jointly and severally, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, Scheer was caused to sustain serious and excruciating personal injuries which ultimately led to his death.

64. He was caused to suffer agonizing aches, pains and mental anguish; he sustained loss of enjoyment of life and loss of life's pleasures.

65. As a result of his wrongful death, he has been prevented from performing all of his usual duties, occupations, recreational activities and avocation all to his and his beneficiaries' loss and detriment.

66. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the wrongful death of Scheer.

67. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries suffered, are suffering from an indefinite period of time in the future damages, injuries and losses, including, but not limited to, a loss of financial support, and the beneficiaries have been wrongfully deprived of the contributions they would have received from Scheer,

including monies which decedent would have provided for such items such as clothing, shelter, food, medical care and education.

68. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries would have been, continue to be and will be in the future wrongfully deprived of large and various sums of money which decedent would have contributed to their support.

69. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries incurred or have been caused to incur and paid large and various expenses including funeral, burial and estate administration.

70. Plaintiff makes claim on behalf of decedent's heirs-at-law and next-of-kin for the loss of love, affection, services, earnings, support and all other damages recoverable under the Wrongful Death Statute of the Commonwealth of Pennsylvania.

WHEREFORE, plaintiff Beverly Scheer, as Administrator and Personal Representative of the Estate of R. Scott Scheer, claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of Fifty-thousand Dollars (\$50,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages, dignity damages, interest and allowable costs of suit.

COUNT II - SURVIVAL ACTION

71. Plaintiff incorporates by reference the above paragraphs as if fully set forth at length herein.

72. As a direct and proximate result of the foregoing, R. Scott Scheer, has been, is being and will be in the future wrongfully deprived of earnings and the right to earn a living.

73. To address the foregoing, the Estate of R. Scott Scheer is entitled to recover in this action an amount equal to the gross amount decedent would have earned between the date of his death and the end of his life expectancy, subject to his cost of maintenance.

WHEREFORE, Beverly Scheer, as Administrator and Personal Representative of the Estate of R. Scott Scheer, claims of defendants, and each of them respectively, compensatory damages in excess of Fifty-thousand Dollars (\$50,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages, dignity damages, interest and allowable costs of suit.

COUNT III

LACK OF INFORMED CONSENT, BATTERY

74. Plaintiff incorporates by reference the above paragraphs as if fully set forth at length herein.

75. As set forth above, defendants, and each of them respectively, failed to inform Scheer, of the risks of all treatment, care, therapy and medications so as to afford Scheer the opportunity to make an informed decision as to the performance of said therapy and procedures.

76. As a result of the intentional tortious conduct of all the defendants, and each of them respectively, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, Scheer, was caused to suffer severe and agonizing personal injuries and pain and suffering which resulted in his untimely death.

77. As a result of the intentional tortious conduct of all the defendants, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, said decedent's heirs-at-law and next of kin have in the past been and will in the future continue to be deprived of the earnings, comfort, society and companionship of their said decedent, all to their great loss and detriment.

78. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries suffered, are suffering for an indefinite period of time in the future damages, injuries and losses, including but not limited to, a loss of financial support, and the beneficiaries

have been wrongfully deprived of the contributions they would have received from decedent, R. Scott Scheer, including monies which decedent would have provided for such items as clothing, shelter, food, medical care and education.

79. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries would have been, continue to be and will be in the future wrongfully deprived of large and various sums of money which decedent would have contributed to their support.

80. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries incurred or have been caused to incur and paid large and various expenses various funeral, burial and estate administration.

81. Plaintiff makes claim on behalf of decedent's heirs-at-law and next-of-kin for the loss of love, affection, services, earnings, support and all other damages recoverable under the Wrongful Death Statute of the Commonwealth of Pennsylvania.

82. Plaintiff makes claim on behalf of his decedent's heirs-at-law and next-of-kin for all damages recoverable under the Survival Statute of the Commonwealth of Pennsylvania.

WHEREFORE, Beverly Scheer, as Administrator and Personal Representative of the Estate of R. Scott Scheer, claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of Fifty-thousand Dollars (\$50,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages, dignity damages, interest and allowable costs of suit.

COUNT IV

COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

83. Plaintiff incorporates by reference the above paragraphs as if fully set forth at length herein.

84. Defendants made intentional misrepresentations and committed common law fraud in the allegations as set forth above.

85. The intentional misrepresentations set forth above were done to induce Scheer to participate in the ALLHAT trial.

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

87. Scheer justifiably relied upon the misrepresentations set forth above in making the decision as to whether to participate in the ALLHAT trial.

88. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, Scheer participated in the ALLHAT trial that ultimately resulted in his death.

89. As a direct and proximate result of the intentional misrepresentations of all the defendants, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, said decedent's heirs-at-law and next of kin have in the past been and will in the future continue to be deprived of the earnings, comfort, society and companionship of their said decedent, all to their great loss and detriment.

90. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries suffered, are suffering for an indefinite period of time in the future damages, injuries and losses, including but not limited to, a loss of financial support, and the beneficiaries have been wrongfully deprived of the contributions they would have received from Scheer, including monies which decedent would have provided for such items as clothing, shelter, food, medical care and education.

91. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries would have been, continue to be and will be in the future wrongfully deprived of large and various sums of money which decedent would have contributed to their support.

92. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries incurred or have been caused to incur and paid large and various expenses various funeral, burial and estate administration.

93. Plaintiff makes claim on behalf of decedent's heirs-at-law and next-of-kin for the loss of love, affection, services, earnings, support and all other damages recoverable under the Wrongful Death Statute of the Commonwealth of Pennsylvania.

94. Plaintiff makes claim on behalf of his decedent's heirs-at-law and next-of-kin for all damages recoverable under the Survival Statute of the Commonwealth of Pennsylvania.

WHEREFORE, Beverly Scheer, individually and as Administrator and Personal Representative of the Estate of R. Scott Scheer, claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of Fifty-thousand Dollars (\$50,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages, dignity damages, interest and allowable costs of suit.

COUNT V

NEGLIGENCE – MAIN LINE HOSPITALS INSTITUTIONAL REVIEW BOARD &

GEORGE A. REICHARD, Jr., Ph.D.

95. Plaintiff incorporates by reference the above paragraphs as if fully set forth at length herein.

96. The Main Line Hospitals Institutional Review Board (the “IRB”) and its Chairman George A. Reichard, Jr., Ph.D., who approved the experiment, had a duty to protect Scheer and other subjects from unethical research practices.

97. They were negligent in approving the design of the study, in approving the informed consent document, and in not appropriately monitoring the informed consent process and the conduct of the trial.

98. As a result of the negligent conduct of all the IRB and its members, and each of them respectively, Scheer was caused to suffer severe and agonizing personal injuries and pain and suffering which resulted in his untimely death.

99. As a result of the negligent conduct described above, said decedent's heirs-at-law and next of kin have in the past been and will in the future continue to be deprived of the earnings, comfort, society and companionship of their said decedent, all to their great loss and detriment.

100. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries suffered, are suffering for an indefinite period of time in the future damages, injuries and losses, including but not limited to, a loss of financial support, and the beneficiaries have been wrongfully deprived of the contributions they would have received from decedent, R. Scott Scheer, including monies which decedent would have provided for such items as clothing, shelter, food, medical care and education.

101. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries would have been, continue to be and will be in the future wrongfully deprived of large and various sums of money which decedent would have contributed to their support.

102. As a direct and proximate result of the foregoing, decedent's wrongful death, beneficiaries incurred or have been caused to incur and paid large and various expenses including funeral, burial and estate administration.

103. Plaintiff makes claim on behalf of decedent's heirs-at-law and next-of-kin for the loss of love, affection, services, earnings, support and all other damages recoverable under the Wrongful Death Statute of the Commonwealth of Pennsylvania.

104. Plaintiff makes claim on behalf of his decedent's heirs-at-law and next-of-kin for all damages recoverable under the Survival Statute of the Commonwealth of Pennsylvania.

WHEREFORE, Beverly Scheer, as Administrator and Personal Representative of the Estate of R. Scott Scheer, claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of Fifty-thousand Dollars (\$50,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages, dignity damages, interest and allowable costs of suit.

COUNT VI

BREACH OF FIDUCIARY DUTY

105. Plaintiff incorporates by reference the above paragraphs as if fully set forth at length herein.

106. Defendants owed a fiduciary duty to Scheer by virtue of the execution of the informed consent document and the establishment of the researcher-subject relationship.

107. This fiduciary duty carried with it, among other things, the obligation to provide Scheer with the information needed to make an informed decision of whether to participate in the experiment and to make sure such information was truthful and accurate.

108. Defendants breached that fiduciary duty as described above.

109. As a result of the intentional tortious conduct of all the defendants, and each of them respectively, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, Scheer

was caused to suffer severe and agonizing personal injuries and pain and suffering which resulted in his untimely death.

110. As a result of the intentional tortious conduct of all the defendants, by and through their separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, said decedent's heirs-at-law and next of kin have in the past been and will in the future continue to be deprived of the earnings, comfort, society and companionship of their said decedent, all to their great loss and detriment.

111. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries suffered, are suffering for an indefinite period of time in the future damages, injuries and losses, including but not limited to, a loss of financial support, and the beneficiaries have been wrongfully deprived of the contributions they would have received from Scheer, including monies which decedent would have provided for such items as clothing, shelter, food, medical care and education.

112. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries would have been, continue to be and will be in the future wrongfully deprived of large and various sums of money which decedent would have contributed to their support.

113. As a direct and proximate result of the foregoing, decedent's wrongful death beneficiaries incurred or have been caused to incur and paid large and various expenses various funeral, burial and estate administration.

114. Plaintiff makes claim on behalf of decedent's heirs-at-law and next-of-kin for the loss of love, affection, services, earnings, support and all other damages recoverable under the Wrongful Death Statute of the Commonwealth of Pennsylvania.

115. Plaintiff makes claim on behalf of his decedent's heirs-at-law and next-of-kin for all damages recoverable under the Survival Statute of the Commonwealth of Pennsylvania.

WHEREFORE, Beverly Scheer, as Administrator and Personal Representative of the Estate of R. Scott Scheer, claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of Fifty-thousand Dollars (\$50,000.00), delay damages pursuant to Pa. R.C.P. 238, punitive damages, dignity damages, interest and allowable costs of suit.

COUNT VII

LOSS OF CONSORTIUM

116. Plaintiff incorporates by reference the above paragraphs as if fully set forth at length herein.

117. As a result of the injuries sustained by Scheer, plaintiff has been deprived of the assistance, companionship, consortium and society of her husband, all to her loss and detriment.

WHEREFORE, Beverly Scheer claims of defendants, and each of them respectively, jointly and severally, compensatory damages in excess of Fifty-thousand Dollars (\$50,000.00), delay damages pursuant to Pa. R.C.P. 238, interest and allowable costs of suit.

**SHERMAN, SILVERSTEIN, KOHL,
ROSE & PODOLSKY**

BY: _____

**Alan C. Milstein
Derek T. Braslow
Attorneys for plaintiff**

DATE: July 8, 2003

JURY TRIAL DEMAND

Please take notice that the plaintiff demands a trial by jury as to all issue in the above matter.

**SHERMAN, SILVERSTEIN, KOHL,
ROSE & PODOLSKY**

BY:

**Alan C. Milstein
Derek T. Braslow
Attorneys for plaintiff**