DOLORES ADERMAN126 State StreetHarbor Beach, Michigan	**:**	**COURT OF COMMON PLEASPHILADELPHIA COUNT**
Plaintiffs,	**:**	**JUNE TERM, 2000**
vs	**:**	**No.: 3285**
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA3450 Hamilton WalkPhiladelphia, PA 19104	**:**	
and	**:**	
THE HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA 3400 Spruce Street Philadelphia, PA 19104	**:**	
and	**:**	
JAMES WILSON, M.D. 1350 N. Avignon DriveGladwyne, PA 19104.	**:**	
and	**:**	
STEVEN RAPER, M.D.127 Kynlyn Road Radnor, PA 19087	**:**	
and	**:**	
MARK BATSHAW, M.D.,Childrens National Medical Center 111 Michigan Avenue Washington, D.C.	**:**	

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Defendant.

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COMPLAINT B CIVIL ACTION

Dolores Aderman claims of defendants, both jointly and severally, a sum in excess of Fifty Thousand Dollars ($50,000.00) in compensatory and punitive damages, upon causes of action whereof the following are true statements:

1. In the spring of 1998, Plaintiff, Dolores Aderman, was recruited to participate in a clinical trial being conducted at the Institute for Human Gene Therapy (AIHGT@) located at the University of Pennsylvania.

2. At that time, Plaintiff was afflicted with and/or was a carrier of ornithine transcarbamylase deficiency (AOTC@), a rare metabolic disorder. 3. While at IHGT, Plaintiff was infused with trillions of particles of an adenovirus vector, which was developed at the University for the purpose of transferring OTC genes.

4. The adenovirus vector used by the defendants was known to be more toxic than other vectors used in gene transfer.

5. On September 17, 1999, another participant in the study, Jesse Gelsinger died as a direct result of the carelessness, negligence and

recklessness of defendants.

6. As a result of the carelessness, negligence and recklessness of the defendants, defendants' misrepresentations regarding the trial as set forth below and the resulting death of Jesse Gelsinger, Plaintiff has sustained severe emotional, psychological and physical injuries.

7. Defendant, the Trustees of the University of Pennsylvania (Athe University@) is an educational institution, incorporated in the Commonwealth of Pennsylvania, with its principal place of business located at 3450 Hamilton Walk, Philadelphia, PA 19104. IHGT is an institute within and under the control of the University, which conducts substantial, systematic, continuous and regular business in the County of Philadelphia, Commonwealth of Pennsylvania.

8. Defendant, The Hospital of the University of Pennsylvania, (AHUP@) is a duly licensed health care facility licensed by the Commonwealth of Pennsylvania with offices located at 3400 Spruce Street, Philadelphia, PA 19104.

9. Defendant, James Wilson, M.D., is a citizen and resident of the Commonwealth of Pennsylvania residing at 1350 N. Avignon Drive, Gladwyne, PA 19104.

10. At all times relevant hereto, Dr. Wilson was the founder of Genovo, a biotech company. At all times relevant hereto, Dr. Wilson controlled up to thirty percent (30%) of the Genovo stock.

11. Genovo agreed to provide the IHGT with over four million dollars a year for five years to conduct genetic research and experimentation.

12. In lieu of up-front payments to the University, Genovo transferred five percent (5%) equity ownership to the University.

13. In return for Genovo's sponsorship of genetic research and experimentation, the University agreed to grant Genovo licenses for the lung and liver applications for existing technologies developed by defendant, Dr. Wilson.

14. Genovo, retained an option to negotiate for licenses for any future developments by defendants, IHGT and/or Dr. Wilson.

15. The proposed licenses between the defendants included full patent reimbursement, milestone payments and royalties on product sales.

16. The shareholders of Genovo included numerous past and present University and/or IHGT employees.

17. In September of 2000, Targeted Genetics, Co. acquired Genovo.

18. Upon the acquisition of Genovo by Targeted Genetics, Defendant James Wilson received $13.5 million dollars worth of Targeted Genetics stock.

19. Dr. Wilson is a duly licensed practicing physician in the Commonwealth of Pennsylvania and, at all times mentioned herein and material hereto, was the director of the IHGT and an attending physician on the staff of Defendant, HUP. At all times mentioned herein and material hereto, Dr. Wilson was an agent, servant, representative and employee of the University and/or HUP.

20. At the time of the occurrence of the incidents described herein, Dr. Wilson was also acting as an agent, servant, workman, and employee of Genovo.

21. Defendant Steven Raper, M.D., is a duly licensed physician in the Commonwealth of Pennsylvania, residing at 127 Kynlyn Road, Radnor, PA 19087 and with offices located at 3450 Hamilton

Walk, Philadelphia, Pennsylvania and, at all times mentioned herein and material hereto, was an attending physician on the staff of HUP and the IHGT. At all times mentioned herein and material hereto, Dr. Raper was an agent, servant, representative and employee of the University, IHGT and HUP.

22. Defendant Mark L. Batshaw, M.D., is a duly licensed practicing physician in Washington, D.C., with offices located at Childrens National Medical Center, 111 Michigan Avenue, Washington, D.C. 20010, and, at all times mentioned herein and material hereto, was an attending physician on the staff of HUP and the IHGT. At all times mentioned herein and material hereto, Dr. Batshaw was an agent, servant, representative and employee of the University, Children's Hospital of Philadelphia, IHGT and HUP.

23. William N. Kelley, M.D. (ADr. Kelley@), is the former dean of the University of Pennsylvania Medical School and chief executive of its health system.

24. Dr. Kelley arrived at the University in 1989.

25. At the time of his arrival at the University, Dr. Kelley and two colleagues had already applied for a patent which Dr. Kelley claimed Ais a broad gene therapy patent which involves any DNA or piece thereof.@

26. This patent enabled Dr. Kelley to collect royalties should gene therapy research using the replication?defective adeno?viral (ARDAd@) vectors prove to be effective.

27. In 1992, Dr. Wilson founded Genovo, Inc., a company in the business of gene transfer research and development.

28. In the spring of 1993, Dr. Wilson was recruited by Dr. Kelley to come to the University and be the director of the IHGT.

29. Dr. Kelley approved Dr. Wilson's OTC gene transfer experiments involving a RDAd vector, a vector similar to the one patented by Dr. Kelley, Genovo and Dr. Wilson.

30. Genovo and Defendant, Dr. Wilson all stood to gain financially from the successful use of RDAd vectors.

31. Defendants, the University and/or IHGT, stood to gain financially through their equity stake in Genovo from the successful use of RDAd vectors.

32. The IHGT agreed to provide funding, in the amount of approximately $25,000.00 per year, for a bioethics faculty position.

33. In September of 1994, the stock of Genovo was distributed to the founders of Genovo.

34. These founders include Ms. Marian Grossman who became the Director of the Human Applications Laboratory of the IHGT; Mr. Dennis Berman; Dr. Barbara Handelin who was Genovo's Chief Scientific Officer and the wife of a University faculty member in Dr. Wilson's department; and Dr. Wilson.

35. Upon his arrival at the University, Dr. Wilson had numerous patents which, like the patent held by Dr. Kelley, involved the use of the RDAd vector for gene transfer.

36. In late 1994, the University began discussions with Dr. Wilson concerning his being employed by the University. At the same time the University began discussions with Dr. Wilson concerning an arrangement between the University and Genovo.

37. During this time, the University's Conflicts of Interest Standing Committee (ACISC@) held meetings during which the issue of what, if any, conflicts of interest would arise if an agreement was entered into between the University, Genovo and Dr. Wilson.

38. During the meeting of the CISC held on February 6, 1995, committee members asserted that a conflict of interest may exist regarding the relationship between the University, Dr. Wilson, and Genovo.

39. The CISC, an agent of the University, was expressly aware that a conflict of interest would exist if Dr. Wilson were permitted to conduct experiments at IHGT which, if successful, would directly benefit Dr. Wilson and Genovo financially.

40. Despite such express knowledge of the dangers such a conflict of interest would present, the University accepted the Genovo arrangement and allowed Dr. Wilson to conduct experiments at IHGT.

41. Earlier in her life Plaintiff, Dolores Aderman had been diagnosed with OTC.

42. Her first born child, Michael, died from OTC at the age of 3.

43. OTC is a rare metabolic disorder which affects the body's ability to breakdown ammonia, a normal byproduct of metabolism.

44. On April 27, 1998, Plaintiff was shown and discussed with Defendant, Steven Raper, various documents, including an informed consent document concerning the clinical trial she was about to become a part of.

45. Such documents and discussions were materially misleading and deceptive because, among other things:

a. the risks of the toxic effects of the injection of the adenovirus particles were understated;

b. no mention was made that monkeys injected with the virus had become ill and/or died;

c. no mention was made that patients who had previously participated in the trial suffered serious adverse effects; and,

d. the extent to which Dr. Wilson and the University had a conflict of interest was not adequately disclosed.

46. The effects of such misrepresentations and nondisclosure were that Plaintiff believed the risks of injection of the adenovirus vector were minimal and the potential benefits of Plaintiff's participation to the future treatment of OTC patients in the study were enormous.

47. In the spring of 1998, Plaintiff entered the gene transfer trial.

48. On September 17, 1999, Jesse Gelsinger was pronounced dead at 2:30 p.m. as a direct and proximate result of his participation in the OTC gene therapy trial. 49. The cause of Jesse Gelsinger's death was attributed to acute respiratory distress and multiple?organ failure, both of which were the direct result of injection of the adenovirus vector.

50. After Jesse Gelsinger's death and Plaintiff's completion of the trial, the FDA determined there were numerous violations of FDA guidelines by the defendants. Some of these violations were:

a. failing to tell the National Institute of Health Recombinant DNA Advisory Committee (Athe RAC@) of a change in the way the virus was to be delivered to patients;

b. changing the informed consent form from what had been approved by the FDA by removing information concerning the death or illness of several monkeys during a similar study;

c. failing to report to the FDA that patients prior to Jesse Gelsinger suffered significant liver toxicity which required that the study be put on hold;

d. failing to follow the study protocol which mandated that in each cohort at least two women be subject to injection before any male;

e. admitting Jesse Gelsinger in the trial when his blood ammonia level on the day before he received the gene transfer exceeded the limit set out in the FDA protocol; and,

f. allowing the vectors to sit and/or be stored on lab shelves for 25 months before being tested in animals, making them less potent then they could have been. Vectors administered to Jessie Gelsinger were only stored for two months. The 25 month storage in turn, may have resulted in an underestimation of the vectors potency in humans. Additionally, the animals who received the vector stored for 25 months would have been given a dose of vector from 52.2% to 65.3% below the vector dose specified in the FDA protocol.

FIRST CAUSE OF ACTION BREACH OF THE RIGHT TO BE TREATED WITH DIGNITY

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

52. Defendants' actions, as set forth above, were a willful and/or negligent breach of the right of plaintiff to be treated with essential human dignity, a fundamental right of all citizens of the United States.

53. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, Dolores Aderman, was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to her nerves and nervous system; she sustained other psychological things forming her usual duties,

occupations and avocations, all to her great detriment and loss.

54. As a direct and proximate result of defendants' actions, as set forth above, plaintiff has in the past been and may in the future continue to be compelled to expend monies and incur obligations for her medical care and treatment; she has also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which plaintiff may otherwise be entitled to recover.

55. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, Dolores Aderman, 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.

SECOND CAUSE OF ACTION 21 CFR '210, 211/21 CFR '601, 610/45 CFR '46

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

57. 21 CFR '210, 211 and 21 CFR '601, 610, part of the code of Federal Regulations, establish the law of the United States with respect to the manufacture and control of investigational biological drugs for clinical use.

58. 45 CFR '46, part of the Code of Federal Regulations, establishes the law of the United States with respect to the protection of human research subjects at institutions such as the

Defendant institution.

59. These latter regulations require:

> Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. . . . Risks to subjects are reasonable in relation to anticipated benefits. . . . Selection of subjects is equitable. . . . Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by '46.116. . . . Informed consent will be appropriately documented, in accordance with, and to the extent required by '46.117. . . . Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects. . . . Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. . . . Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

60. These regulations also require institutions such as Defendant, to appoint an IRB to oversee the Trial and to adhere to the opinions and directives of the IRB.

61. As set forth above, defendants have violated these regulations to the great damage and detriment of plaintiff.

62. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, Dolores Aderman, was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future

continue to be required to submit to medical examinations; she sustained other injuries to her nerves and nervous system; she sustained other psychological injuries, the full extent of which have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss.

63. As a direct and proximate result of defendants' actions, as set forth above, plaintiff has in the past been and may in the future continue to be compelled to expend monies and incur obligations for her medical care and treatment; she has also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which plaintiff may otherwise be entitled to recover.

64. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, Dolores Aderman, 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.

THIRD CAUSE OF ACTION THE BELMONT REPORT
Breach of the Assurance Agreement

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

66. The University, IHGT and HUP agreed that all human research at the University would be conducted in accordance with the Belmont Report.

67. This agreement is contained in a document known as the AMultiple Project Assurance Of Compliance With DHHS Regulations For Protection Of Human Research Subjects@ (AAssurance Agreement@).

68. This Assurance Agreement in essence is a contract between the The University, IHGT, HUP and the Department of Health and Human Services; plaintiff's was a third party beneficiaries to this agreement in that the purpose of the agreement was to protect all participants in clinical trials conducted at the University and/or HUP.

69. As set forth above, defendants breached this agreement by failing to follow the ethical principals in the Belmont Report and the requirements of 45 CFR'46.

70. As a result of this breach, plaintiff has suffered damages as set forth below.

71. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, Dolores Aderman, was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to her nerves and nervous system; she sustained other psychological injuries, the full extent of which have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and

treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss.

72. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, has in the past been and may in the future continue to be compelled to expend monies and incur obligations for her medical care and treatment; she has also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which plaintiff may otherwise be entitled to recover.

73. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, Dolores Aderman, 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.

FOURTH CAUSE OF ACTION INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

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

75. Defendants, and each of them respectively, failed to inform the

plaintiff of the risks of all treatment, care, therapy and procedures performed upon her so as to afford plaintiff the opportunity to make an informed decision as to the performance of said procedures.

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

a. understating the risks of the toxic effects of the injection of the adenovirus particles;

b. failing to inform plaintiff regarding the fact that monkeys injected with the virus had become ill and/or died;

c. failing to inform plaintiff that patients who had previously participated in the trial suffered serious adverse effects;

d. failing to adequately disclose the extent to which Dr. Wilson and the University had a conflict of interest;

e. failing to adequately disclose the financial interest that Dr. Wilson and the University had in relation to the study; and f. allowing the vectors to sit and/or be stored on lab shelves for 25 months before being tested in animals, making them less potent then they could have been. The 25 month storage in turn, may have resulted in an underestimation of the vectors potency in humans. Additionally, the animals who received the vector stored for 25 months would have been given a dose of vector from 52.2% to 65.3% below the vector dose specified in the FDA protocol.

77. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, Dolores Aderman, was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to her nerves and nervous system; she sustained other psychological injuries, the full extent of which

have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss.

78. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, has in the past been and may in the future continue to be compelled to expend monies and incur obligations for her medical care and treatment; she has also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which plaintiff may otherwise be entitled to recover.

79. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, Dolores Aderman, 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.

FIFTH CAUSE OF ACTION INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

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

81. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused Dolores Aderman severe emotional distress.

82. The conduct of defendants in making false statements to Dolores Aderman knowing she would rely on these statements in participate in the IHGT gene transfer trial, as well as defendant's negligence in causing the death of Jesse Gelsinger, has caused emotional harm to Dolores Aderman, and was extreme and outrageous.

83. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, Dolores Aderman, was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to her nerves and nervous system; she sustained other psychological injuries, the full extent of which have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss.

84. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, has in the past been and may in the future continue to be compelled to expend monies and incur obligations for her medical care and treatment; she has also incurred and may hereafter continue to incur other financial expenses or losses which do or may exceed amounts which plaintiff may otherwise be entitled to recover.

85. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania.

WHEREFORE, Plaintiff, Dolores Aderman 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.

SIXTH CAUSE OF ACTION COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

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

87. Defendants made the following intentional misrepresentations and committed common law fraud in:

a. intentionally misrepresenting the risks of the toxic effects of the injection of the adenovirus particles;

b. intentionally failing to inform Plaintiff, Dolores Aderman regarding the fact that monkeys injected with the virus had become ill and/or died;

c. intentionally failing to inform Plaintiff, Dolores Aderman that patients who had previously participated in the trial suffered serious adverse effects;

d. intentionally failing to adequately disclose the extent to which Dr. Wilson and the University had a conflict of interest; and

e. intentionally failing to adequately disclose the financial interest that Dr. Wilson and the University had in relation to the study.

88. The intentional misrepresentations set forth above were done to induce plaintiff to participate in the gene transfer trial.

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

90. Plaintiff justifiably relied upon the misrepresentations set forth above in making the decision as to whether to participate in the gene transfer trial.

91. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, Dolores Aderman, was caused to sustain serious, disabling and permanent personal and psychological injuries. She has in the past been required and may in the future continue to be required to submit to medical examinations; she sustained other injuries to her nerves and nervous system; she sustained other psychological injuries, the full extent of which have yet to be determined; she has in the past required and may in the future continue to require medicines, medical care and treatment; she has in the past and may in the future continue to be compelled to expend monies and incur obligations for such medical care and treatment; she has in the past suffered and may in the future continue to suffer agonizing aches, pains and mental anguish; she has in the past been and may in the future continue to be disabled from performing her usual duties, occupations and avocations, all to her great detriment and loss.

92. As a direct and proximate result of defendants' actions, as set forth above, plaintiff, has in the past been and may in the future continue to be compelled to expend monies and incur obligations for her medical care and treatment; she has also incurred and may hereafter continue to incur other financial expenses or losses which

do or may exceed amounts which plaintiff may otherwise be entitled to recover.

93. Plaintiff has sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental and psychological injuries, humiliation and embarrassment, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the Commonwealth of Pennsylvania. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff has suffered severe emotional, psychological and personal injuries.

WHEREFORE, Plaintiff, Dolores Aderman, 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, interest and allowable costs of suit.

SEVENTH CAUSE OF ACTION PUNITIVE DAMAGES

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

95. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff.

96. Defendants' intentional, wanton, willful and outrageous actions consisted of, but are not limited to:

a. intentionally failing to conform to FDA guidelines;

b. failing to tell the National Institute of Health Recombinant DNA

Advisory Committee (Athe RAC@) of a change in the way the virus was to be delivered to patients;

c. intentionally and recklessly changing the informed consent form from what had been approved by the FDA by removing information concerning the death or illness of several monkeys during a similar study;

d. intentionally and recklessly failing to report to the FDA that patients suffered significant liver toxicity which required that the study be put on hold;

e. intentionally and recklessly failing to follow the study protocol which mandated that in each cohort at least two women be subject to injection before any male;

f. intentionally and recklessly understating the risks of the toxic effects of the injection of the adenovirus particles;

g. intentionally and recklessly failing to inform plaintiff that monkeys injected with the virus had become ill and/or died;

h. intentionally and recklessly failing to inform plaintiff that patients who had previously participated in the trial suffered serious adverse effects;

i. intentionally and recklessly failing to adequately disclose the extent to which Dr. Wilson and the University had a conflict of interest; and

j. intentionally and recklessly failing to inform plaintiff of the significant financial interest defendants had in the regard to the outcome of the study.

97. Defendants' wanton, willful and outrageous conduct was the direct result of defendants decision to sacrifice patient safety in

exchange for the fame and glory which defendants anticipated obtaining if this study and follow up studies using the adenovirus vector were successful. 98. By reason of the wanton, willful and outrageous conduct of defendants, as aforesaid, plaintiff was caused to sustain severe emotional, psychological and personal injuries.

WHEREFORE, Dolores Aderman, claims o f defendants, and each of them respectively, jointly and severally, punitive 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.

Please take notice that the plaintiffs demand a trial by jury as to all issues in the above matter.

SHERMAN, SILVERSTEIN, KOHL, ROSE & PODOLSKY A Professional Corporation

Dated: _____

By: _____ Alan C Milstein 4300 Haddonfield Rd. Pennsauken, N.J. 08109 (856) 662-0700Attorneys for plaintiffs