THIS IS NOT AN ARBITRATION MATTER.
ASSESSMENT OF DAMAGES HEARING IS REQUIRED. JURY TRIAL OF TWELV (12) PERSONS DEMANDED.

SHERMAN, SILVERSTEIN, KOHL, ROSE & PODOLSKY

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ATTORNEYS FOR PLAINTIFFS

JOHN GELSINGER as ADMINISTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF JESSE GELSINGER AND PAUL GELSINGER, in his own right,	:	PHILADELPHIA COUNTY
	:	COURT OF COMMON PLEAS
	:	TRIAL DIVISION
	:	
	:	
	:	TERM, 2000
Plaintiffs	:	
	:	
	:	No.
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, JAMES WILSON, M.D.,	:	
	:	
	:	
GENOVO, INC., STEVEN RAPER, M.D. MARK BATSHAW, M.D., WILLIAM KELLEY, M.D.	:	
	:	
CHILDREN'S HOPSITAL OF	:	

PHILADELPHIA, :
CHILDREN'S NATIONAL MEDICAL
CENTER, AND
ARTHUR CAPLAN, Ph.D.

Defendants

COMPLAINT - CIVIL ACTION

John Gelsinger, as Administrator and Personal Representative of the Estate of Jesse Gelsinger, and Paul Gelsinger in his own right, claim 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. On September 17, 1999, Jesse Gelsinger, an 18 year old young man died while participating in a gene transfer experiment at the Institute for Human Gene Therapy ("IHGT") located at the University of Pennsylvania.

2. At the time of his death, Jesse suffered from a mild form of ornithine transcarbamylase deficiency ("OTC"), a rare metabolic disorder, which was controlled with a low-protein diet and drugs. Jesse volunteered to participate in the experiment, knowing it would not benefit his condition in the least, because he was led to believe his participation held little risk and would directly benefit yet to be born infants with OTC.

3. While at IHGT, Jesse Gelsinger 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. When Jesse Gelsinger received the vector, he suffered a chain reaction including jaundice, a blood-clotting disorder, kidney failure, lung failure and brain death.

6. On September 17, 1999, Jesse Gelsinger died as a direct result of the carelessness, negligence, recklessness and wanton and willful conduct of defendants as described in detail below.

7. Plaintiff, John Gelsinger, is an individual residing at 47 Tallowood Drive, Medford, New Jersey 08055.

8. Plaintiff, John Gelsinger, was duly appointed Personal Representative of the Estate of Jesse Gelsinger by Issuance of Letters dated March 22, 2000 by the Superior Court of Arizona, Pima County.

9. Plaintiff, Paul Gelsinger is a citizen and resident of the State of Arizona, residing at 6901 East Hawthorne Street, Tucson, Arizona 85710. Paul Gelsinger is the father of Jesse Gelsinger.

10. Defendant, the Trustees of the University of Pennsylvania ("the 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.

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

12. Defendant, Genovo, Inc., is a corporation organized and existing by and under the laws of the State of Delaware with its principal office and place of business located at 512 Elmwood Avenue, Elmwood Court Two, Sharon Hill, PA 19079. Genovo currently provides nearly a quarter of the budget for the IHGT, and conducts substantial, systematic, continuous and regular business in the County of Philadelphia, Commonwealth of Pennsylvania.

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

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

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

16. 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.

17. Defendant, Genovo, retained an option to negotiate for licenses for

any future developments by defendants, IHGT and/or Dr. Wilson.

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

19. The shareholders of Genovo include numerous past and present University and/or IHGT employees.

20. 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 the University of Pennsylvania Hospital. At all times mentioned herein and material hereto, Dr. Wilson was an agent, servant, representative and employee of the University.

21. 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.

22. 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 the University of Pennsylvania Hospital and the IHGT. At all times mentioned herein and material hereto, Dr. Raper was an agent, servant, representative and employee of both the University and the IHGT.

23. 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 the University of Pennsylvania Hospital 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, Children's National Medical Center and the IHGT.

24. Defendant, Children's Hospital of Philadelphia (CHOP), is a corporation and medical center, existing by and under the laws of the Commonwealth of Pennsylvania with its principal place of business at 34th Street and Civic Center Boulevard, Philadelphia, PA 19104-4399.

25. At all times mentioned herein and material hereto, defendant, CHOP, held itself and its agents, servants, workers, representatives,

physicians, nurses, staff, contractors, medical personnel and employees out to be skillful and qualified to administer medical care and treatment.

26. Defendant, Children's National Medical Center, is a corporation and medical center, existing by and under the law of the District of Columbia with its principal place of business located at 111 Michigan Avenue, Washington, D.C. 20010.

27. At all times mentioned herein and material hereto, defendant, Children's National Medical Center, held itself and its agents, servants, workers, representatives, physicians, nurses, staff, contractors, medical personnel and employees out to be skillful and qualified to administer medical care and treatment.

28. Defendant, William N. Kelley, M.D. ("Dr. Kelley"), is the former dean of the University of Pennsylvania Medical School and chief executive of its health system.

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

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

31. This patent enabled Dr. Kelley to collect royalties should gene therapy research using the replication-defective adeno-viral ("RDAd")vectors prove to be effective.

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

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

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

35. Defendants, Dr. Kelley, Genovo, and Dr. Wilson all stood to gain financially from the successful use of RDAd vectors.

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

37. Defendant, Arthur Caplan, Ph.D., is the director of the Bioethics Department of the University of Pennsylvania, with offices located at the University of Pennsylvania, 3401 Market Street, Suite 320, Philadelphia, PA 19104-3319.

38. Defendant, Arthur Caplan, was appointed as Trustee Professor of Bioethics in the Department of Molecular and Cellular Engineering, which defendant, Dr. Wilson, chaired.

39. Defendant, Arthur Caplan, was consulted to determine the ethical complications surrounding the OTC gene transfer experiment.

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

41. The gene therapy study was initially designed to enroll terminally ill infants as subjects for the experiment.

42. Defendant, Arthur Caplan, advised defendants, Drs. Wilson, Batshaw and Raper, that parents of terminally ill children were incapable of giving an informed consent and suggested that the gene transfer experiment be performed on otherwise healthy, adults with a mild, medically manageable, form of OTC.

43. Defendant, Arthur Caplan, was quoted subsequent to the death of Jesse Gelsinger as saying, "Not only is it sad that Jesse Gelsinger died, there was never a chance that anybody would benefit from these experiments. They are safety studies. They are not therapeutic in goal. If I gave it to you, we would try to see if you died, too, or if you did OK."

44. Defendant, Arthur Caplan, was also quoted in relation to gene therapy as follows, "If you cured anybody, you'd publish it in a religious journal. It would be a miracle. The researchers wouldn't say that. But I'm telling you. If you cured anybody from a phase one gene therapy trial, it would be a miracle. All you're doing is you're saying, I've got this vector, I want to see if it can deliver the gene where I want it to go without killing, or hurting or having side effects."

45. The Internal Review Board (IRB) of defendant, CHOP, reviewed and approved the protocol for the OTC gene transfer experiment.

46. Hematologists for defendant, CHOP, were consulted regarding the gene transfer experiment.

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

48. 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.

49. 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.

50. 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.

51. During this time, the University's Conflicts of Interest Standing Committee ("CISC") 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.

52. 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.

53. 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.

54. 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.

55. Jesse Gelsinger was first diagnosed with OTC at the age of two.

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

57. Over the next sixteen years, Jesse Gelsinger controlled the disease with a low-protein diet and medication.

58. In September 1998, Jesse was told by his treating physician of an OTC gene transfer trial which was being conducted at the IHGT.

59. On June 22, 1999, Jesse and Paul Gelsinger went to the IHGT where they met Dr. Raper who performed blood and liver-function tests to determine whether Jesse was eligible for the gene transfer trial. Jesse was to receive no financial compensation for participating in the trial.

60. Between June 22, 1999 and September 9, 1999, Jesse and Paul Gelsinger reviewed documents and had discussions with Drs. Raper and Batshaw which purportedly were to provide certain information necessary to make an informed decision as to whether Jesse was going to take part in and was an appropriate candidate for the gene transfer trial.

61. 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;

d. the representation was made that IHGT had achieved certain efficacy with respect to the treatment of OTC; and

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

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

63. On September 9, 1999, Jesse returned to Philadelphia to begin the gene transfer trial.

64. Jesse was scheduled to be the last of three patients in the sixth cohort in the trial.

65. On September 13, 1999, Jesse was taken to the interventional-

radiology suite where he was sedated and strapped to a table while a team of radiologists threaded two catheters into his groin.

66. At approximately 10:30 a.m., Dr. Raper drew 30 milliliters of the vector and injected it into Jesse.

67. The procedure was completed at approximately 12:30 p.m.

68. On the evening of September 13, 1999, Jesse was sick to his stomach and had a fever of 104.5 degrees.

69. The following morning Jesse seemed disoriented.

70. When Dr. Raper examined Jesse the morning of September 14, 1999, he noticed that Jesse's eyes were yellow.

71. Blood tests performed on September 14, 1999, indicated that Jesse's bilirubin was four times the normal level.

72. The symptoms that Jesse was experiencing were similar to those defendants had seen in the monkeys that had been given a similar vector.

73. By the afternoon of September 14, 1999, Jesse had slipped into a coma.

74. At 11:30 p.m. on September 14, 1999, Jesse's ammonia level was 393 micro moles per deciliter of blood. The normal level is 35 micro moles.

75. Thereafter, the doctors placed Jesse on dialysis.

76. Initially, Jesse's condition improved but soon began to deteriorate.

77. After consultation between Drs. Wilson, Raper and Batshaw, the doctors decided to perform extra corporeal membrane oxygenation.

78. On September 16, 1999, Jesse's kidneys stopped making urine and he began to suffer from multiple organ system failure.

79. On the evening of September 16, 1999, Jesse was bloated beyond recognition; his ears and eyes had swollen shut.

80. On the morning of September 17, 1999, tests indicated that Jesse was brain dead.

81. On September 17, 1999, the ECMO machine was shut off and

Jesse was pronounced dead at 2:30 p.m.

82. The cause of Jesse'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.

83. After Jesse's death, 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 ("the 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 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 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. The vectors administered to the plaintiff's decedent 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.

COUNT I - WRONGFUL DEATH

JOHN GELSINGER, AS ADMINISTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF JESSE GELSINGER v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, CHILDREN'S

HOSPITAL OF PHILADELPHIA, CHILDREN'S NATIONAL MEDICAL CENTER, JAMES WILSON, M.D., GENOVO, INC., STEVEN RAPER, M.D. MARK BATSHAW, M.D., WILLIAM N. KELLEY, M.D., AND ARTHUR CAPLAN, Ph.D.

84. Plaintiffs incorporate by reference paragraphs 1 through 83 as if fully set forth at length herein.

85. 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 Jesse Gelsinger, of properly and carefully examining him in order to determine his condition and eligibility for the gene transfer trial, of properly and carefully administering the gene transfer 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.

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

87. 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 Jesse Gelsinger's condition and eligibility for the gene transfer trial;

b. failing to properly diagnose Jessie Gelsinger's condition subsequent to the administration of the gene transfer;

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 monitor his ammonia levels both during and after the administration of the gene transfer;

g. failing to provide and afford proper and careful medical care and treatment;

h. 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;

i. failing to properly care for his condition under all of the circumstances;

j. caring for Jesse Gelsinger in a negligent and improper manner;

k. failing to properly monitor his condition both prior to and subsequent to the performance of the gene transfer procedure;

l. failing to use a proper, adequate and safe vector for gene transfer;

m. failing to inform Jesse Gelsinger of all the risks of performing the gene transfer procedure so as to afford him with the opportunity to make an informed decision as to the performance of said procedure;

n. failing to properly and timely observe, discover, diagnose, treat and care for his condition;

o. failing to conform to the standard of care and treatment prevailing in the medical community in which defendants practiced at the time in conducting gene transfer;

p. 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;

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

r. acting negligently per se.

88. 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, Jesse Gelsinger was caused to sustain serious and excruciating personal injuries which ultimately led to his death. Jesse Gelsinger died as a result of acute respiratory distress and multiple-organ

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

89. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the wrongful death of Jesse Gelsinger.

90. 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 Jesse Gelsinger, including monies which decedent would have provided for such items such 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 including 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.

WHEREFORE, John Gelsinger, as Administrator and Personal Representative of the Estate of Jesse Gelsinger, claim 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.

COUNT II - SURVIVAL ACTION

JOHN GELSINGER, AS ADMINISTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF JESSE GELSINGER v. THE

TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, CHILDREN'S HOSPITAL OF PHILADELPHIA, CHILDREN'S NATIONAL MEDICAL CENTER, JAMES WILSON, M.D., GENOVO, INC., STEVEN RAPER, M.D. MARK BATSHAW, M.D., WILLIAM N. KELLEY, M.D., AND ARTHUR CAPLAN, Ph.D.

94. Plaintiffs incorporate by reference paragraphs 1 through 93 as if fully set forth at length herein.

95. As a direct and proximate result of the foregoing, Jesse Gelsinger, has been, is being and will be in the future wrongfully deprived of earnings and the right to earn a living.

96. To address the foregoing, the Estate of Jesse Gelsinger, 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, John Gelsinger, as Administrator and Personal Representative of the Estate of Jesse Gelsinger, claim 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, interest and allowable costs of suit.

COUNT III -STRICT PRODUCTS LIABILITY

JOHN GELSINGER, AS ADMINISTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF JESSE GELSINGER v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, JAMES WILSON, M.D., GENOVO, INC.

97. Plaintiffs incorporate by reference paragraphs 1 through 96 as if fully set forth at length herein.

98. Defendants, Genovo, Inc. and James Wilson, M.D., designed, manufactured and supplied the adenovirus vector which ultimately caused the death of plaintiff's decedent, Jesse Gelsinger.

99. Defendant, IHGT, as a unit of the University, supplied the adenovirus vector which ultimately caused the death of plaintiff's decedent,

Jesse Gelsinger.

100. The United States Patent issued to Defendant, Wilson, for the adenovirus vector describes the vector as "The present invention provides a unique recombinant adenovirus capable of delivering transgenes to target cells, as well as the components for production of the unique virus and methods for the use of the virus to treat a variety of genetic disorders....This novel recombinant virus is produced by use of an adenovirus-based vector production system containing two components: 1) a shuttle vector that comprises adenovirus cis-elements necessary for replication and virion encapsidation and is deleted of all viral genes, which vector carries a reporter or therapeutic minigene and 2) a helper adenovirus which, alone or with a packaging of cell line, is capable of providing all of the viral gene products necessary for a productive viral infection when cotransfected with the shuttle vector...The methods of producing this viral vector from these components include both a novel means of packaging of an adenoviral/transgene containing vector into a virus, and a novel method for the subsequent separation of the helper virus from the newly formed recombinant virus."

101. IHGT, Dr. Wilson and Genovo breached their duties and obligations to plaintiffs by various sections of the Restatement of Torts, 2d, including Section 402(a) and are liable for causing injuries to Jesse Gelsinger for the following reasons:

a. designing, manufacturing, selling and/or distributing a product in a defective condition;

b. designing, manufacturing, selling and/or distributing a product which was unreasonably dangerous;

c. designing, manufacturing, selling and/or distributing a product which was not safe for normal use and consumption;

d. failing to have adequate warnings on the product;

e. failing to warn users of the dangers inherent in using this product;

f. designing, manufacturing, selling and/or distributing a product which could have been produced and manufactured more safely;

g. designing, manufacturing, selling and/or distributing a product wherein it was foreseeable that someone would be harmed by the product's use;

h. designing, manufacturing, selling and/or distributing a product which was not safe for its intended use;

i. designing, manufacturing, selling and/or distributing a product which was lacking of one or more elements necessary to make it safe for its intended use;

j. designing, manufacturing, selling and/or distributing a product which was defective and which could cause injury to the user;

k. failing to ensure that ultimate users were advised of the dangers of said product;

l. failing to exercise reasonable care in the design of this product;

m. failing to exercise reasonable care in the distribution of this product;

n. failing to adequately and properly test this product;

o. failing to use reasonable care under the circumstances;

p. delivering a product which was defective and could cause injury to the user;

q. producing a product which was defective and could cause injury to the user;

r. supplying a product which was defective and could cause injury to the user;

s. knowing of prior adverse reaction to the adenovirus and failing to inform the user of these adverse reactions;

t. failing to adequately and properly test the product after its design and manufacture;

u. failing to investigate and analyze prior adverse reactions information in order to warn and/or notify ultimate users of the product defects and dangers;

v. violating applicable sections of the Restatement of Torts, 2d;

w. engaging in other acts regarding the manufacturing, designing, testing, preparing, producing, and distributing this product as will be learned in discovery.

102. By conducting themselves as aforesaid, defendants increased the risk of harm, thereby causing the injuries and wrongful death of Jesse Gelsinger.

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

104. 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.

105. 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.

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

107. 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, John Gelsinger, as Administrator and Personal Representative of the Estate of Jesse Gelsinger, claim 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.

COUNT IV -

INTENTIONAL ASSAULT AND BATTERY, LACK OF INFORMED CONSENT

JOHN GELSINGER, AS ADMINISTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF JESSE GELSINGER v. THE

TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, CHILDREN'S HOSPITAL OF PENNSYLVANIA, JAMES WILSON, M.D., STEVEN RAPER, M.D. AND MARK BATSHAW, M.D.

108. Plaintiffs incorporate by reference paragraphs 1 through 107 as if fully set forth at length herein.

109. Defendants, and each of them respectively, failed to inform plaintiff's decedent, Jesse Gelsinger, of the risks of all treatment, care, therapy and procedures performed upon him so as to afford plaintiff's decedent the opportunity to make an informed decision as to the performance of said procedures.

110. 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's decedent regarding the fact that monkeys injected with the virus had become ill and/or died;

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

d. misrepresenting the fact that prior participants in the study had achieved certain efficacy with respect to the treatment of OTC;

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

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

g. 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 vectors administered to the plaintiff's decedent 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.

111. As a result of the intentional tortious conduct of all the defendants named herein, and each of them respectively, by and through their

separate and respective agents, servants, workmen, representatives, physicians, nurses, staff, contractors, medical personnel and employees, plaintiff's decedent, Jesse Gelsinger, was caused to suffer severe and agonizing personal injuries and pain and suffering which resulted in his untimely death on September 17, 1999.

112. As a result of the intentional tortious conduct of all defendants named herein, 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.

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

114. 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.

115. 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.

116. 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.

117. 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, John Gelsinger, as Administrator and Personal Representative of the Estate of Jesse Gelsinger, claim 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.

COUNT V - INTENTIONAL AND NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

JOHN GELSINGER, AS ADMINISTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF JESSE GELSINGER v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, CHILDREN'S HOSPITAL OF PHILADELPHIA, CHILDREN'S NATIONAL MEDICAL CENTER, JAMES WILSON, M.D., GENOVO, INC., STEVEN RAPER, M.D., MARK BATSHAW, M.D., WILLIAM N. KELLEY, M.D., AND ARTHUR CAPLAN, Ph.D.

118. Plaintiffs incorporate by reference paragraphs 1 through 117 inclusive, as if fully set forth at length herein.

119. Defendants engaged in the conduct described above and willfully, recklessly and/or negligently caused Paul Gelsinger severe emotional distress.

120. The conduct of defendants in making false statements to Paul Gelsinger, knowing he would rely on these statements in advising his son to participate in the IHGT gene transfer trial which ultimately and directly resulted in his son's death, has caused emotional harm to Paul Gelsinger, and was extreme and outrageous.

121. Paul Gelsinger has suffered severe emotional distress as a result of the conduct of the defendants.

122. Defendants' actions were willful and/or reckless thus entitling plaintiffs to punitive damages.

WHEREFORE, Paul Gelsinger 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.

COUNT VI - COMMON LAW FRAUD/INTENTIONAL MISREPRESENTATION

JOHN GELSINGER, AS ADMINISTRATOR AND PERSONAL

REPRESENTATIVE OF THE ESTATE OF JESSE GELSINGER AND PAUL GELSINGER v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, JAMES WILSON, M.D., GENOVO, INC., STEVEN RAPER, M.D. AND MARK BATSHAW, M.D.

123. Plaintiffs incorporate by reference paragraphs 1 through 122 as if fully set forth at length herein.

124. 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, Paul Gelsinger and plaintiff's decedent regarding the fact that monkeys injected with the virus had become ill and/or died;

c. intentionally failing to inform Plaintiff, Paul Gelsinger and plaintiff's decedent that patients who had previously participated in the trial suffered serious adverse effects;

d. intentionally misrepresenting the fact that prior participants in the study had achieved certain efficacy with respect to the treatment of OTC;

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

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

125. The intentional misrepresentations set forth above were done to induce plaintiff's decedent to participate in the gene transfer trial.

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

127. Plaintiff, Paul Gelsinger and plaintiff's decedent, Jesse Gelsinger, justifiably relied upon the misrepresentations set forth above in making the decision as to whether plaintiff's decedent would participate in the gene transfer trial.

128. As a direct and proximate result of defendants' intentional and material misrepresentations as set forth above, plaintiff's decedent, Jesse

Gelsinger, participated in the gene transfer trial which ultimately resulted in his death.

129. As a direct and proximate result of the intentional misrepresentations of all defendants named herein, 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.

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

131. 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.

132. 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.

133. 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.

134. 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, John Gelsinger, as Administrator and Personal Representative of the Estate of Jesse Gelsinger, and Paul Gelsinger, individually, claim 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.

COUNT VII - PUNITIVE DAMAGES

JOHN GELSINGER, AS ADMINISTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF JESSE GELSINGER v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, CHILDREN'S HOSPITAL OF PHILADELPHIA, CHILDREN'S NATIONAL MEDICAL CENTER, JAMES WILSON, M.D., GENOVO, INC., STEVEN RAPER, M.D., MARK BATSHAW, M.D., WILLIAM N. KELLEY, M.D., AND ARTHUR CAPLAN, Ph.D.

135. Plaintiffs incorporate by reference paragraphs 1 through 134 as if fully set forth at length herein.

136. 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's decedent.

137. 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 ("the 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 prior to Jesse 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 admitting plaintiff's decedent 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;

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

h. intentionally and recklessly failing to inform plaintiff's decedent regarding the fact that monkeys injected with the virus had become ill and/or died;

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

j. intentionally and recklessly misrepresenting the fact that prior participants in the study had achieved certain efficacy with respect to the treatment of OTC;

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

l. intentionally and recklessly failing to inform plaintiff's decedent of the significant financial interest defendants had in the regard to the outcome of the study.

138. 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.

139. By reason of the wanton, willful and outrageous conduct of defendants, as aforesaid, plaintiff's decedent, Jesse Gelsinger, was caused to sustain the catastrophic injuries which ultimately resulted in his death as described above.

WHEREFORE, John Gelsinger, as Administrator and Personal Representative of the Estate of Jesse Gelsinger, claim of 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.

COUNT VIII- FRAUD ON THE FOOD AND DRUG ADMINISTRATION

JOHN GELSINGER, AS ADMINISTRATOR AND PERSONAL REPRESENTATIVE OF THE ESTATE OF JESSE GELSINGER AND PAUL GELSINGER v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, JAMES WILSON, M.D., GENOVO, INC., STEVEN

RAPER, M.D. AND MARK BATSHAW, M.D.

140. Plaintiffs incorporate by reference paragraphs 1 through 139 as if fully set forth at length herein.

141. Defendants, Mark Batshaw, M.D., Steven Raper, M.D., James Wilson, M.D., IHGT, and Genovo intentionally and falsely made numerous fraudulent misrepresentations to the FDA concerning the protocol of the OTC gene transfer experiment.

142. Defendants, Mark Batshaw, M.D., Steven Raper, M.D., James Wilson, M.D., IHGT, and Genovo, failed to disclose that they allowed vectors to sit and/or be stored on lab shelves for 25 months before being tested on animals, making them less potent than they could have been. The vectors administered to the plaintiff's decedent were only stored for two months. The 25 months storage in turn, may have resulted in 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 65.6% below the dose specified in the FDA protocol.

143. Defendants, Mark Batshaw, M.D., Steven Raper, M.D., James Wilson, M.D., IHGT, and Genovo intended for the FDA to approve the gene transfer study based upon those fraudulent misrepresentations.

144. In reliance on those express fraudulent misrepresentations the FDA granted approval of the OTC gene transfer experiment.

145. Defendants altered the FDA approved consent form, deleting any reference to monkeys which became ill and died as a result of receiving a similar vector prior to the experiment.

146. Defendants represented that they would report any adverse or unexpected events associated with the administration of the gene transfer and/or participation in the study, and fraudulently failed to do so.

147. The FDA was without knowledge of the fraudulent nature of the above representations.

148. Were it not for the fraudulent misrepresentations the FDA would not have approved the study, the study would not have been performed, and the plaintiff's decedent would not have been subjected to the experiment which resulted in his death.

149. As a direct and proximate result of the wrongful conduct as alleged above plaintiff's decedent, Jesse Gelsinger, was caused to sustain the catastrophic injuries which resulted in his death.

WHEREFORE, John Gelsinger, as Administrator and Personal Representative of the Estate of Jesse Gelsinger, claim of 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.

SHERMAN, SILVERSTEIN, KOHL, ROSE & PODOLSKY

By:_____
ALAN C. MILSTEIN HARRIS L. POGUST

SALTZ, MONGELUZZI, BARRETT& BENDESKY, P.C.

By:_____

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