UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ROBERT SUTHERS and NIWANA MARTIN,	:	Docket No.: 05-CV-4158
Plaintiffs,	:	
v.	:	
AMGEN, INC., a Delaware Corporation,	:	
Defendant.	:	A Civil Action

COMPLAINT AND JURY TRIAL DEMAND

Robert Suthers ("Mr. Suthers") and Niwana Martin ("Ms. Martin") (collectively, "plaintiffs"), by and through their counsel, Alan C. Milstein of Sherman, Silverstein, Kohl, Rose & Podolsky, P.A., bring this action against Amgen, Inc., a Delaware Corporation ("Amgen"), to enforce their rights as human subjects in a clinical trial. In support of their action, they say, state, and aver as follows:

PARTIES

1. Mr. Suthers is an individual who resides on East Maple Road in Greenlawn, New York. He is a citizen of the State of New York.

2. Ms. Martin is an individual who resides on Cherry Run Road in Harpers Ferry, West Virginia. She is a citizen of the State of West Virginia.

3. Defendant Amgen is a Delaware corporation that has a principal place of business at One Amgen Center Drive, Thousand Oaks, CA 91320-1799. It is a citizen of the States of Delaware and California.

SUBJECT MATTER JURISDICTION

4. This Court has subject matter jurisdiction over this lawsuit pursuant to 28 U.S.C. § 1332(a), which provides that "[t]he district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between ... citizens of different States ... ."

PERSONAL JURISDICTION

5. This Court has personal jurisdiction over Amgen because it has minimum contacts with the State of New York and systematically and continuously transacts business in New York.

VENUE

6. Venue is proper in the Southern District of New York ("Southern District") pursuant to 28 U.S.C. § 1391(a)(2), which provides that in a federal suit founded upon diversity of citizenship, venue is proper in a district in which "a substantial part of the events or omissions giving rise to the claim occurred," because "a substantial part of the events or omissions giving rise to [this] claim occurred" in the Southern District.

7. Venue is also proper in the Southern District pursuant to 28 U.S.C. §§ 1391(a)(1) and 1391(c), which provide that in a federal suit founded upon diversity of citizenship, venue is proper in "a judicial district where any defendant resides" and that "a defendant that is a corporation [is] deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced," because Amgen is a corporation that is subject to personal jurisdiction in the Southern District of New York.

FACTS THAT ARE COMMON TO ALL COUNTS

8. Parkinson's disease ("Parkinson's") is a progressive neurodegenerative disorder characterized by the loss of dopaminergic neurons in the brain and resulting tremors, shaking, slow movement, and muscle stiffness and rigidity. See Certification of Michael Hutchinson, M.D., Ph.D. ("Hutchinson Cert."), attached as Exhibit "A," ¶ 3.

9. The existing therapies for Parkinson's all focus on replacing dopamine in the brains of Parkinson's sufferers, which has the effect of temporarily masking their symptoms. See Hutchinson Cert., ¶ 4.

10. These existing therapies are not curative and do not stop the death of the brain cells that make dopamine. See Hutchinson Cert., ¶ 5.

11. In an effort to create a curative treatment for Parkinson's, a Colorado biotechnology company named Synergen designed a protein called glial cell line-derived neurotropic factor, or GDNF ("GDNF"). See Hutchinson Cert., ¶ 6.

12. Synergen proceeded to test GDNF on monkeys with astounding results. See Hutchinson Cert., ¶ 7.

13. GDNF seemed to spur the growth of dopamine-producing cells that could influence the course of Parkinson's disease, not just temporarily mask its symptoms. See Hutchinson Cert., ¶ 8.

14. Amgen was so impressed with the drug that, in 1994, it bought Synergen for $240,000,000.00. See Hutchinson Cert., ¶ 9.

15. Amgen, however, much like Synergen, was confounded by the issue of how to effectively deliver it to the human brain. See Hutchinson Cert., ¶ 10.

16. Subsequently, Steven S. Gill ("Dr. Gill") of Frenchay Hospital in Bristol, England ("Frenchay Hospital") figured out a way to do so. See Hutchinson Cert., ¶ 11.

17. Dr. Gill designed a procedure whereby pumps are surgically implanted in a patient's abdomen and catheters are threaded through his or her chest, neck, and head, delivering GDNF directly to the brain. See Hutchinson Cert., ¶ 12.

18. In the first Phase I study conducted by Dr. Gill, all five patients tolerated the treatment and the drug without any serious adverse events, and they also showed dramatic improvement. See Hutchinson Cert., ¶ 13.

19. In a second Phase I trial conducted by John Slevin, M.D. and Byron Young, M.D. at the University of Kentucky Medical Center ("University of Kentucky"), all ten patients in the trial showed benefit at six months, demonstrating that the drug and the treatment were safe. See Hutchinson Cert., ¶ 14.

20. In 2003, Amgen sponsored a placebo-controlled Phase II trial involving thirty-four patients at multiple sites, including New York University Downtown Hospital ("NYU Hospital"), University of Chicago Hospital ("University of Chicago"), University of Kentucky, and Frenchay Hospital. See Hutchinson Cert., ¶ 15.

21. Amgen designated Michael Hutchinson, M.D. ("Dr. Hutchinson") as the Principal Investigator in the trial at the NYU Hospital location. See Hutchinson Cert., ¶ 16.

22. Dr. Hutchinson is a renowned neurologist who, besides serving as Associate Professor of Clinical Neurology at NYU School of Medicine, has had numerous peer-reviewed publications and invited lectures on Parkinson's Disease and neuroimaging. See Hutchinson Cert., ¶ 2.

23. The Protocol for the trial was submitted to, and approved by, the Institutional Review Board at NYU Hospital.

24. The Protocol provided that the trial was to begin with each of the subjects having pumps inserted in their abdomen and holes drilled in their skull. There would then be a six-month placebo phase during which time half of the research participants would receive no treatment whatsoever, while the other half received GDNF. See Hutchinson Cert., ¶ 17.

25. The Protocol further provided that at the conclusion of the placebo phase, those subjects would be, in the words of the protocol and the informed consent document, guaranteed that they would receive GDNF indefinitely, so long as it was safe and effective. See Hutchinson Cert., ¶ 18; cf. Certification of Robert Suthers ("Suthers Cert."), attached as Exhibit "B," ¶ 17 (stating that "I expected to continue receiving doses of the drug indefinitely"); Certification of Niwana Martin ("Martin Cert."), attached as Exhibit "C," ¶ 16 (stating that "I expected to continue receiving doses of the drug indefinitely").

26. Mr. Suthers and Ms. Martin participated in the trial at the NYU Hospital location. See Hutchinson Cert., ¶ 19; see also Suthers Cert., ¶ 8; Martin Cert., ¶ 8.

27. Prior to their doing so, Dr. Hutchinson and the plaintiffs engaged in the informed consent process consistent with the federal regulations popularly known as the Common Rule, 45 C.F.R. § 46.101, et seq. See Hutchinson Cert., ¶ 20.

28. Thereafter, each of the plaintiffs signed the informed consent document, evidencing their agreement to participate in the research. See Hutchinson Cert., ¶ 21; see also Suthers Cert., ¶ 10; Martin Cert., ¶ 10.

29. The plaintiffs agreed to take the substantial risks of such participation because they knew of the devastating progressive nature of their disease and because they knew that they

would receive in return not only the potential benefit of a cure but knowledge that they were contributing to the greater good and the advancement of medicine. See Suthers Cert., ¶ 11; see also Martin Cert., ¶ 11.

30. Subsequently, both of the plaintiffs had the pumps surgically implanted in their abdomen, had catheters threaded under their skin from their abdomen to their brains, and had holes drilled in their skulls. See Suthers Cert., ¶ 12 see also Martin Cert., ¶ 12.

31. Each of these procedures was time-consuming, painful, and emotionally trying for the patients, their caregivers, and their loved ones. See Suthers Cert., ¶ 14; see also Martin Cert., ¶ 13.

32. In Mr. Suthers' case, he suffered a stroke that caused him damage and pain, and he had to undergo a second brain surgery to correctly place a catheter that had come loose. See Suthers Cert., ¶ 13.

33. Both of the plaintiffs were randomized into the placebo arm of the trial, meaning that they had pumps implanted in their abdomens and holes drilled into their skulls and received saline solution, rather than GDNF, for six months. See Suthers Cert., ¶ 15; see also Martin Cert., ¶ 14.

34. Neither individual was aware that saline solution, not GDNF, was being pumped into their brains during these six months, and neither plaintiff experienced any benefit during this time. See Suthers Cert., ¶ 15; see also Martin Cert., ¶ 14.

35. Thus, the plaintiffs experienced no placebo effect.

36. After six months, pursuant to the Protocol, both plaintiffs crossed over to the GDNF arm of the trial. See Suthers Cert., ¶ 16; see also Martin Cert., ¶ 15.

37. Both of the plaintiffs then experienced marked improvement. See Suthers Cert., ¶¶ 18-21; see also Martin Cert., ¶ 19.

38. Indeed, for the first time in years, they had hope for an end to the misery that is Parkinson's disease.

39. Mr. Suthers, who had received the placebo beginning on October 30, 2003 and received GDNF beginning on March 30, 2004, had significantly more "on" time, and felt physically, cognitively, and emotionally better once he was on GDNF. See Suthers Cert., ¶¶ 18-21; see also Hutchinson Cert., ¶¶ 27-29.

40. In fact, he was able to walk up to two miles a day during this period of time. Suthers Cert., ¶ 19; see also Hutchinson Cert., ¶¶ 27-29.

41. Ms. Martin, who had received the placebo beginning in October 2003 and received GDNF beginning on April 4, 2004, was able to walk and run, lost her facial mask, had an improved sense of smell, and had significantly more "on" time once she was on GDNF. See Martin Cert., ¶ 19; see also Hutchinson Cert., ¶¶ 27-29.

42. The Principal Investigators, the doctors who performed these procedures on the plaintiffs and who treated them and knew them best, believed that GDNF was safe and of benefit to the plaintiffs. See Hutchinson Cert., ¶ 30; see also Certification of Richard Penn, M.D. ("Penn Cert."), attached as Exhibit "D," ¶ 26; see generally Affidavit of Don M. Gash, Ph.D., John Slevin, M.D., Byron Young, M.D., and Greg Gerhardt, Ph.D. ("Gash Aff."), attached as Exhibit "E."

43. Because of the time spent developing the delivery method for GDNF, the patent for GDNF would expire shortly after the drug was ultimately approved by the Food and Drug Administration ("FDA").

44. In addition, GDNF had a short shelf life, requiring constant production of new protein.

45. Additionally, as set forth above, the delivery method for GDNF posed a hardship and an inconvenience to users, so only those facing serious Parkinson's effects would choose to use GDNF.

46. All of this presented a drug with questionable financial potential for Amgen.

47. In August 2004, Amgen received results from certain primate studies on GDNF in which four out of seventy monkeys that were given GDNF suffered cerebellar toxicity. See Hutchinson Cert., ¶ 31.

48. The Principal Investigators, who saw no such adverse effects in humans, had noted that the monkeys had been receiving doses outside the clinically relevant dose range, at least ten times higher than anything that had been, or would ever be, given to a human being, and that the cause of cerebellum damage in the four monkeys was abrupt withdrawal of GDNF. See Hutchinson Cert., ¶ 31.

49. After it received the primate studies, without consulting the Principal Investigators or the IRB's at the institutions where the trials were being held, and without considering the subjects who had exposed themselves to serious risk and discomfort, Amgen announced it was unilaterally terminating the clinical trial. See Hutchinson Cert., ¶ 33.

50. The Principal Investigators, along with representatives from Amgen, held a meeting with representatives of the FDA to seek approval for the "compassionate use" of GDNF, which would allow the subjects continued use of GDNF even if the safety data from the animal studies proved to be correct.

51. The FDA said that it would not stand in the way of "compassionate use."

52. Notwithstanding this, Amgen announced it would no longer provide GDNF to the Principal Investigators and to the subjects so desperately dependent on the drug. See Hutchinson Cert., ¶ 33; see also Penn Cert., ¶¶ 29-31.

53. Amgen represented that any positive effects experienced by the subjects were a placebo effect and that GDNF simply did not work. See Hutchinson Cert., ¶ 33; see also Penn Cert., ¶¶ 29-31.

54. The Principal Investigators disagree and believe GDNF is both safe and effective. See Hutchinson Cert., ¶¶ 44-45; see also Penn Cert., ¶¶ 38-39.

55. Together, the doctors wrote that "GDNF has the potential to revolutionize treatment of Parkinson's." See Hutchinson Cert., ¶ 37.

56. Together, the doctors wrote that "GDNF can be safely delivered within the clinically effective dose range." See Hutchinson Cert., ¶ 38.

57. Together the doctors wrote that "[w]e strongly support making the drug available to the patients." See Hutchinson Cert., ¶ 39.

58. Dr. Gash as well as the other doctors have observed that if the patients had experienced a placebo effect, the positive effects would have been observed for only a few weeks, and then would have subsided. By contrast, the positive effects of the drug lasted as long as three years in the Phase I patients who had the opportunity to receive the treatment for that period of time. See Hutchinson Cert., ¶ 40; see generally Gash Aff.

59. Since GDNF was withdrawn, Mr. Suthers has been confused easily, has had serious language difficulties, has had serious walking difficulty, can no longer bathe himself, has suffered from increased tremors, and can only walk one-quarter of a mile per day, as opposed to

two miles per day while he was on GDNF. See Suthers Cert., ¶ 23; see also Hutchinson Cert., ¶ 41.

60. The devolvement of Mr. Suthers' condition was recently demonstrated to viewers of the television program "Good Morning America."

61. Similarly, all of the improvements that Ms. Martin showed during the period of time that she was on GDNF are gone. See Martin Cert., ¶ 21; see also Hutchinson Cert., ¶ 42.

62. As for the patients enrolled in the trial at the University of Kentucky location, Drs. Gash, Slevin, Young, and Gerhardt have confirmed that

> [i]n the six months following withdrawal of GDNF, the Parkinson's disease features in the ten patients in the Kentucky study have worsened. While the patients had experienced significant functional improvements while receiving GDNF, their disease is now progressing. They require significantly higher doses of conventional anti-parkinsonian medication, which produce unwanted side effects such as dyskinesia (shaking), dystonia (muscle cramps) and cognitive disturbances (hallucinations and dementia).

See Gash Aff., ¶ 6e.

63. Edward L. Abney, one such patient, has stated that, while he had significantly more "on" time, and experienced numerous improvements, while he was being treated with GDNF, since GDNF was withdrawn from his system, he has experienced irregular "on" times, including times of no "on" time, rigidity, excess saliva, slurred speech, and cramps. See Certification of Edward L. Abney, attached as Exhibit "F," ¶¶ 15-20.

64. Delbert Jackson, a patient also being treated there, has stated that, while he had "significantly more 'on time with less medication and more relief," "a better general overall feeling," and an increased sense of "smell, taste, and hearing" while he was on GDNF, he has "gradually fallen back into the days of old suffering," with a "loss of ability to function ... under

normal conditions ... ," since GDNF left his system. See Certification of Delbert Jackson, attached as Exhibit "G," ¶¶ 15-20.

65. Roger Thacker, another patient being treated there ("Mr. Thacker"), has stated that, while he experienced increased "[o]n times," more productive "[o]ff times," increased energy and appetite levels," among many other positives, while he was on GDNF, he has "drastically deteriorated" since the drug was pulled, noting that "[m]ost of the symptoms I experienced ... before GDNF have manifested one more. Speech, sleep, balance, pain, ability to function independently, ability to socialize and to work my farm have all been adversely affected." See Certification of Roger Thacker ("Thacker Cert."), attached as Exhibit "H," ¶¶ 15-20.

66. Steven Kaufman, a patient being treated at the University of Chicago location, has stated that, while he "had significantly more 'on' time," "felt mentally and physically better within 1 month of receiving the GDNF," and was in fact "able to remodel [his] kitchen and build a deck" during that time, since GDNF was withdrawn from his system, he has experienced "increased tremors, leg and back pain, and lower self-esteem." See Certification of Steve Kaufman, attached as Exhibit "I," ¶¶ 15-20.

67. Based on the observations of their physicians, and of their own sense of the fact that they were improving while they were on the drug, the plaintiffs are willing to accept any risk of continuing treatment with GDNF.

68. The plaintiffs want the drug so they can enjoy their lives and love their families.

69. The decision by Amgen to terminate the trial was unreasonable and contrary to its fiduciary, contractual, and ethical obligations to the plaintiffs.

70. This decision will cause the plaintiffs immediate irreparable harm.

71. As to such harm, Dr. Hutchinson has concluded:

> The failure to provide the drug is causing and will continue to cause the plaintiffs immediate irreparable harm and damage because there is no other drug currently being tested in the United States that could potentially serve as a cure for Parkinson's, and because, in the absence of their taking the drug, the plaintiffs' Parkinson's disease will, at best, stay the same and, at worst, continue to progressively worsen. ... Indeed, it is my opinion, to a reasonable degree of medical certainty, as principal investigator at the New York location of the trial on the efficacy of GDNF, that the drug is not toxic, and likely has great potential.

See Hutchinson Cert., ¶¶ 44-45.

72. Dr. Penn has reached a similar conclusion:

> The failure to provide the drug is causing and will continue to cause the plaintiffs harm and damage because there is no other drug currently being tested in the United States that could potentially serve as a cure for Parkinson's, and because, in the absence of taking the drug, the plaintiffs' Parkinson's disease will, at best, stay the same and, at worst, continue to rapidly deteriorate. ... Indeed, it is my opinion, to a reasonable degree of medical certainty, as co-principal investigator at the University of Chicago location of the trial on the efficacy of GDNF, that the drug has been not only safe and effective for the trial patients, but also shows enormous potential for the treatment of Parkinson's Disease.

See Penn Cert., ¶¶ 38-39.

73. Drs. Gash, Slevin, Young, and Gerhardt have reached the same conclusion, opining that GDNF "is the bird in the hand. This is of utmost importance for today's advanced Parkinson's patients and their families as other methods for delivering the drug are five to ten years or more away. By the time these methods are available, it will be too late for many. They will be either dead or totally debilitated!" See Gash Aff., ¶ 6b.

74. Still more powerful are the words of Mr. Thacker:

> GDNF works! The formula and method of administering GDNF into my brain has been totally successful. I have not experienced one side effect or negative reaction to this drug. It gave me back

> my life. GDNF is a means of hope and help for the million people in this country alone, who suffer from this terrible disease. It could be the miracle needed for those who will one day be diagnosed with Parkinson's Disease. How can we be denied, by a drug company who claims its purpose is to develop drugs to relieve human suffering, of a drug that does exactly that?

See Thacker Cert., ¶ 18.

CAUSES OF ACTION

COUNT ONE - PROMISSORY ESTOPPEL

75. The foregoing paragraphs are incorporated herein as if they were set forth fully at length.

76. Amgen, through its agents, the Principal Investigators, promised the plaintiffs that if the plaintiffs agreed to participate in a clinical trial to test the efficacy of GDNF, and if GDNF was shown to be safe and effective, the plaintiffs would have continued access to the drug for as long as it was helping them.

77. Amgen also represented to the plaintiffs, through the structure of the research enterprise that it had set up for the clinical trial, that the plaintiffs could rely on the Principal Investigators to decide what was in their best therapeutic interest so as to protect them as human subjects and as seriously ill patients.

78. The plaintiffs reasonably relied on these representations after meeting with Dr. Hutchinson and seeing how professional, knowledgeable, and compassionate he was.

79. The plaintiffs detrimentally relied on these promises in the most extreme sense because the plaintiffs then had holes drilled in their skulls and pumps inserted in their abdomens.

80. Amgen breached its promises by terminating plaintiffs' access to GDNF and by ignoring the opinion and conclusion of Dr. Hutchinson and the other Principal Investigators that the plaintiffs should be allowed to continue receiving GDNF.

81. As a result of Amgen's failure to honor its promises, the plaintiffs have sustained and will continue to sustain serious harm and damage.

WHEREFORE, the plaintiffs pray for temporary, preliminary, and permanent injunctive relief, including an injunction ordering Amgen to provide GDNF to the Principal Investigators so that the plaintiffs may continue their participation in the trial, money damages in an amount exceeding $75,000.00, attorney's fees, costs of suit, and such other relief as this Court deems to be just and proper in the circumstances that are presented.

COUNT TWO - BREACH OF FIDUCIARY DUTY

82. The foregoing paragraphs are incorporated herein as if they were set forth fully at length.

83. Once the plaintiffs agreed to participate as subjects in the clinical trial Amgen was conducting, Amgen owed a fiduciary duty to them

84. This fiduciary duty included the duty to act in the best interests of the plaintiffs in conducting the clinical trial.

85. Amgen breached this duty by its actions as set forth above.

86. As a result of Amgen's breach, the plaintiffs have suffered and will continue to suffer irreparable harm that is not compensable by money damages as well as pain and suffering that is compensable by money damages exceeding $75,000.00.

WHEREFORE, the plaintiffs pray for temporary, preliminary, and permanent injunctive relief, including an injunction ordering Amgen to provide GDNF to the Principal Investigators so that the plaintiffs may continue their participation in the trial, money damages in an amount exceeding $75,000.00, attorney's fees, costs of suit, and such other relief as this Court deems to be just and proper in the circumstances that are presented.

COUNT THREE - BREACH OF CONTRACT

87. The foregoing paragraphs are incorporated herein as if they were set forth fully at length.

88. The informed consent document is attached as Exhibit "J."

89. This informed consent document was created by Amgen and signed by the plaintiffs, creating a valid, binding contract between Amgen and the plaintiffs.

90. This contract provided that the plaintiffs were to allow the Principal Investigators to drill holes in their brains and insert catheters, and provided that, at a bare minimum, the plaintiffs could receive GDNF indefinitely.

91. Amgen breached this contract by terminating the clinical trial for no sound scientific or ethical reason once it was underway, and once the plaintiffs had undergone the surgical procedures necessary for delivery of the GDNF.

92. As a result of Amgen's breach, the plaintiffs have suffered and will continue to suffer irreparable harm that is not compensable by money damages as well as pain and suffering that is compensable by money damages exceeding $75,000.00.

WHEREFORE, the plaintiffs pray for temporary, preliminary, and permanent injunctive relief, including an injunction ordering Amgen to provide GDNF to the Principal Investigators so that the plaintiffs may continue their participation in the trial, money damages in an amount exceeding $75,000.00, attorney's fees, costs of suit, and such other relief as this Court deems to be just and proper in the circumstances that are presented.

COUNT FOUR - BREACH OF THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

93. The foregoing paragraphs are incorporated herein as if they were set forth fully at length.

94. The informed consent document created by Amgen and signed by the plaintiffs created a valid, binding contract between Amgen and the plaintiffs.

95. In addition to their express terms, all contracts contain a covenant of good faith and fair dealing. See, e.g., Kirke La Shelle Co. v. Armstrong Co., 263 N.Y. 79, 87 (1933); Kendall v. Ernest Pestana, Inc. 40 Cal.3d 488, 490 (1985).

96. The plaintiffs discharged each and every obligation imposed upon them by the informed consent document.

97. Amgen breached this contract by terminating the clinical trial for no sound scientific or ethical reason once it was underway, and once the plaintiffs had undergone the surgical procedures necessary for delivery of the GDNF, thereby depriving the plaintiffs of the fruits of the contract in bad faith.

98. As a result of Amgen's breach, the plaintiffs have suffered and will continue to suffer irreparable harm that is not compensable by money damages as well as pain and suffering that is compensable by money damages exceeding $75,000.00.

WHEREFORE, the plaintiffs pray for temporary, preliminary, and permanent injunctive relief, including an injunction ordering Amgen to provide GDNF to the Principal Investigators so that the plaintiffs may continue their participation in the trial, money damages in an amount exceeding $75,000.00, attorney's fees, costs of suit, and such other relief as this Court deems to be just and proper in the circumstances that are presented.

COUNT FIVE - VIOLATIONS OF GENERAL BUSINESS LAW § 349

99. The foregoing paragraphs are incorporated herein as if they were set forth fully at length.

100. In requiring the plaintiffs to have holes drilled in their heads and pumps and catheters inserted in their stomachs in order to receive GDNF and then withdrawing GDNF under the circumstances presented, Amgen engaged in a misleading practice in violation of General Business Law § 349.

101. As a result of this practice, the plaintiffs have suffered and will continue to suffer irreparable harm that is not compensable by money damages as well as pain and suffering that is compensable by money damages exceeding $75,000.00.

WHEREFORE, the plaintiffs pray for temporary, preliminary, and permanent injunctive relief, including an injunction ordering Amgen to provide GDNF to the Principal Investigators so that the plaintiffs may continue their participation in the trial, money damages in an amount exceeding $75,000.00, attorney's fees, costs of suit, and such other relief as this Court deems to be just and proper in the circumstances that are presented.

COUNT SIX - NEGLIGENCE

102. The foregoing paragraphs are incorporated herein as if they were set forth fully at length.

103. Amgen had the duty to exercise reasonable care toward the plaintiffs.

104. Amgen breached this duty by its actions as set forth above.

105. As a result of Amgen's breach, the plaintiffs have suffered and will continue to suffer irreparable harm that is not compensable by money damages as well as pain and suffering that is compensable by money damages exceeding $75,000.00.

WHEREFORE, the plaintiffs pray for temporary, preliminary, and permanent injunctive relief, including an injunction ordering Amgen to provide GDNF to the Principal Investigators so that the plaintiffs may continue their participation in the trial, money damages in an amount

exceeding $75,000.00, attorney's fees, costs of suit, and such other relief as this Court deems to be just and proper in the circumstances that are presented.

JURY TRIAL DEMAND

The plaintiffs demand a trial by jury as to all counts so triable.

Dated: Monday, April 25, 2005

/s/Alan C. Milstein

Alan C. Milstein - ACM2759
Michael Dube - Admission Pending
Sherman, Silverstein, Kohl,
Rose & Podolsky, P.A.
Fairway Corporate Center
4300 Haddonfield Road, Suite 311
Pennsauken, NJ 08109
Telephone: 856-662-0700
Facsimile: 856-488-4744
E-Mail: AMilstein@sskrplaw.com,
MDube@sskrplaw.com
Attorneys for the Plaintiffs