UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF KENTUCKY

EDWARD L. ABNEY, BARBARA ALLEN, JAMES DAY, ROBERT GREEN, DELBERT JACKSON, JAMES PUGH, ROGER THACKER, and DANIEL HUNTER WEBSTER,	:	Docket No.:
Plaintiffs,	:	
v.	:	
AMGEN, INC., a Delaware Corporation,	:	
Defendant.	:	A Civil Action

COMPLAINT AND JURY TRIAL DEMAND

Edward Abney ("Mr. Abney"), Barbara Allen ("Ms. Allen"), James Day ("Mr. Day"), Robert Green ("Mr. Green"), Delbert Jackson ("Mr. Jackson"), James Pugh ("Mr. Pugh"), Roger Thacker ("Mr. Thacker"), and Daniel Webster ("Mr. Webster") (collectively, "Kentucky patients" or "plaintiffs"), by and through their counsel, Alan C. Milstein of Sherman, Silverstein, Kohl, Rose & Podolsky, P.A. in Pennsauken, New Jersey and Debora Doss of the Law Offices of Debora Doss in Lexington, Kentucky, 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 each say, state, and aver as follows:

PARTIES

1. Mr. Abney is an individual who resides in Berea, Kentucky. He is a citizen of the State of Kentucky.

2. Ms. Allen is an individual who resides in Salyersville, Kentucky. She is a citizen of the State of Kentucky.

3. Mr. Day is an individual who resides in Nicholasville, Kentucky. He is a citizen of the State of Kentucky.

4. Mr. Green is an individual who resides in Wilmore, Kentucky. He is a citizen of the State of Kentucky.

5. Mr. Jackson is an individual who resides in Mize, Kentucky. He is a citizen of the State of Kentucky.

6. Mr. Pugh is an individual who resides in Owensboro, Kentucky. He is a citizen of the State of Kentucky.

7. Mr. Thacker is an individual who resides in Versailles, Kentucky. He is a citizen of the State of Kentucky.

8. Mr. Webster is an individual who resides in Irvine, Kentucky. He is a citizen of the State of Kentucky.

9. 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

10. 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

11. This Court has personal jurisdiction over Amgen because it has minimum contacts with the State of Kentucky and systematically and continuously transacts business here.

VENUE

12. Venue is proper in the Eastern District of Kentucky ("Eastern 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 Eastern District.

13. Venue is also proper in the Eastern 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 Eastern District.

FACTS THAT ARE COMMON TO ALL COUNTS

14. This case is extraordinary. It presents the Court with the critical issue of what rights human subjects have in the research enterprise. Are they simply guinea pigs, nothing but a means to a drug company's ends? Or, once they have been recruited as subjects, once they have agreed to be subjected to considerable risk and personal sacrifice, do they have the right to receive what they bargained for – the benefits of a life-saving therapy?

15. 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; see generally Certification of Michael Hutchinson, M.D. ("Hutchinson Cert. 2"), attached as Exhibit "B."[1]

16. 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.

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

18. 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.

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

20. 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.

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

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

23. 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.

[1] The majority of the Certifications that are attached to this Complaint were prepared for a lawsuit related to this one that was filed in the United States District Court for the Southern District of New York on or around April 26, 2005.

24. 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.

25. 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.

26. In a second Phase I trial conducted by John Slevin, M.D. ("Dr. Slevin") and Byron Young, M.D. ("Dr. Young") 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.

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

28. Amgen designated Drs. Slevin and Young as the Principal Investigators in the trial at the University of Kentucky location, with Don M. Gash, Ph.D. ("Dr. Gash") and Greg Gerhardt, Ph.D. ("Dr. Gerhardt") (collectively, "Kentucky doctors") working alongside them. 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 "C"; see also Certification of Don M. Gash, Ph.D., John T. Slevin, M.D., and Greg Gerhardt, Ph.D., attached as Exhibit "D" ("Gash Cert."); University of Kentucky Medical Center Consent to Participate in a Research Study ("Informed Consent Document"), attached as Exhibit "E."

29. The Kentucky doctors are preeminent leaders in their fields; by way of example, Dr. Gash is a pioneer in neural regeneration, Dr. Slevin is a leader in the field of translational research, and Dr. Gerhardt has received numerous awards in anatomy and neurobiology and has published over two hundred original papers and book chapters in those areas. See Gash Cert., ¶¶ 2-4.

30. The Protocol for the trial was submitted to, and approved by, the Institutional Review Board at the University of Kentucky. See generally Informed Consent Document.

31. 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. See generally Informed Consent Document.

32. In Amgen's words to the plaintiffs,

> [y]ou will be asleep (general anesthesia) during all or part of the surgery. Dr. Byron Young or a member of his team will make an incision about one to two inches long in your scalp, and make a hole 1/2" to 3/4" wide in your skull that will allow placement of the … catheter. The catheter will be placed through the brain tissue to the putamen, and will be fastened securely into place with screws and/or stitches. The skin will be stapled closed, and the frame will be removed. The … pump will then be placed inside an incision in your abdomen. The doctor will then create a tunnel under the skin from the abdomen to the head and connecting tubing will be pulled through this tunnel and connected to the pump and the IPA catheter. You may have an incision in the side of your neck as part of the tunneling process. You will then be awakened and taken to the recovery room.
>
> [See Informed Consent Document, page 6.]

33. The Protocol also provided for the following treatment periods:

> 1. The Screening Period: Week –8 (eight weeks before the surgery during which the pump and the catheter will be placed) through Week 0 (the time of surgery). The length of this period may be shortened, depending on what medications you are taking.

> 2. The Treatment Period: Week 0 through Week 28 (28 weeks after surgery). During the first 4 weeks the pump will contain the vehicle (the liquid that the drug will be dissolved in). Then over the next 24-25 weeks you'll receive the study drug.
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> 3. The Follow-Up Period: Week 28 through week 33. At week 28, the study drug will be removed and the pump will be filled with vehicle. You'll be asked to come in for a visit approximately 5 weeks after this is done.
>
> **4. Extended Treatment Period: Starting at week 28 you may elect to continue treatment for up to an additional 24 months. If you elect to continue treatment the procedures listed for week 33 will be done approximately 1 month after the conclusion of the extended treatment period.**
>
> [See Informed Consent Document, page 2 (emphasis in original).]

34. The plaintiffs participated in the trial at the University of Kentucky location. See, e.g., Certification of Edward L. Abney ("Abney Cert."), attached as Exhibit "F"; Certification of James Day ("Day Cert."), attached as Exhibit "G"; Certification of Delbert Jackson ("Jackson Cert."), attached as Exhibit "H"; Certification of Roger Thacker ("Thacker Cert."), attached as Exhibit "I"; Certification of Daniel Hunter Webster (Webster Cert."), attached as Exhibit "J"; Supplemental Certification of Edward Abney, Barbara Allen, James Day, Robert Green, Delbert Jackson, James Pugh, Roger Thacker, and Daniel Webster ("Supplemental Cert."), attached as Exhibit "K" (collectively, "Kentucky Patients Certs").

35. Prior to their doing so, Drs. Slevin and Young 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 generally Gash Aff.; see also Informed Consent Document.

36. During this process, the Kentucky doctors promised the plaintiffs "that [they] would continue to receive GDNF as long as it was safe and effective and in [their] best therapeutic interest." See Supplemental Cert., ¶ 1.

37. Indeed, the plaintiffs, in their words, "expected to continue receiving doses of the drug indefinitely." See generally Kentucky Patients Certs.

38. Thereafter, evidencing the informed consent process, each of the plaintiffs signed a copy of the Informed Consent Document, evidencing their agreement to participate in the research. See generally Kentucky Patient Certs.

39. Consistent with the Kentucky doctors' representations to the plaintiffs, the Informed Consent Document provided that "[t]he sponsor of this study is Amgen, Inc." and further provided that "[t]he people in charge of this study are Dr. John Slevin, MD, of Neurology, and Dr. Byron Young, MD, of Neurosurgery." See Informed Consent Document, page 1.

40. The Informed Consent Document further provided that "[t]he individuals conducting the study may need to withdraw you from the study. This may occur if they find that your being in the study is more risk than benefit to you, if you are not able to follow the directions they give you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons." See Informed Consent Document, page 15.

41. The Informed Consent Document did not provide any guidance as to what the verbiage "the agency funding the study" means; it is clear, however, that it does not mean Amgen, as the Informed Consent Document instead provided that Amgen was the "sponsor" of the study. See Informed Consent Document, page 1.

42. The plaintiffs agreed to take the substantial risks of participation in the trial 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 generally Kentucky Patients Certs.

43. Subsequently, consistent with the Protocol, the plaintiffs had the pumps surgically implanted in their abdomens had catheters threaded under their skin from their abdomens to their brains, and had holes drilled in their skulls. See generally Kentucky Patients Certs.

44. Each of these procedures was time-consuming, painful, and emotionally trying for the plaintiffs, their caregivers, and their loved ones. See generally Kentucky Patients Certs.

45. The plaintiffs whose certifications are attached were randomized into the GDNF arm of the trial. See generally Kentucky Patients Certs.

46. The plaintiffs then experienced marked improvement. See generally Kentucky Patients Certs.

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

48. Mr. Abney, who had surgery on November 24, 2003 and received GDNF beginning on December 23, 2003, had significantly more "on" time, and felt physically, cognitively, and emotionally better once he was on GDNF. See Abney Cert., ¶¶ 15-19.

49. Mr. Day, who had surgery on August 25, 2003 and received GDNF beginning on September 23, 2003, "had significantly less dyskinesia (uncontrollable movements of [her] limbs), and stopped freezing and being paralyzed for long periods of time. [She] had more 'on' time and less 'off' time. [She] could walk better and longer than [she] could prior to the surgery, and [she] stopped falling down" once she was on GDNF. See Day Cert., ¶¶ 13-17.

50. Mr. Jackson, who had surgery on April 2, 2003, and received GDNF beginning in the last week of April 2003, had "significantly more on time with less medication and more relief

... , a better general overall feelings, ... gained smell, taste, and hearing ... tremendously, [and had the] most energy [he] ever had in [his] life" once he was on GDNF. See Jackson Cert., ¶¶ 11-17.

51. Mr. Thacker, who had surgery on June 11, 2003, and received GDNF beginning on July 9, 2003, had significantly more "on" time, less troublesome "off" time, was able to sleep in a relaxed posture, lost his facial mask, was able to attend to all of his private functions and grooming, and gained the ability to walk in a normal manner once he was on GDNF. See Thacker Cert., ¶¶ 11-18.

52. Mr. Webster, who had surgery on September 18, 2002, and who received GDNF beginning on October 16, 2002, "had significantly more 'on' time, and felt physically, cognitively and emotionally better once [he] was on GDNF." See Webster Cert., ¶¶ 11-18.

53. In his words, the improvement represented "the difference between night and day." See Webster Cert., ¶ 18.

54. The Kentucky patients' improvement was consistent with the improvement of the patients who had enrolled in the trial at the other locations. See generally Certification of Robert Suthers, attached as Exhibit "L" (New York University location); Certification of Niwana Martin, attached as Exhibit "M" (New York University location); Certification of Raymond Hudson, attached as Exhibit "N" (New York University location); Certification of Oliver David Plunkett, attached as Exhibit "O" (Frenchay Hospital location); Certification of Thelma Martin, attached as Exhibit "P"; Certification of Diana Byrne, attached as Exhibit "Q" (Frenchay Hospital location); Certification of Neil Shadwick, attached as Exhibit "R" (Frenchay Hospital location); Certification of Steven Kaufman, attached as Exhibit "S" (University of Chicago location).

55. 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 generally Gash Aff.; Gash Cert.; Hutchinson Cert., ¶ 30; Certification of Richard Penn, M.D. ("Penn Cert."), attached as Exhibit "T," ¶ 26.

56. 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").

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

58. 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.

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

60. 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.

61. 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.

62. 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.

63. 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.

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

65. 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.

66. Amgen represented that any positive effects experienced by the subjects were a placebo effect.

67. As Dr. Hutchinson explains, however,

> [t]here is nothing in the history of medicine where a placebo effect of this magnitude has been witnessed. Nothing, whether surgical or non-surgical, resembles this. To be precise, the fact that fifteen out of fifteen patients have become progressively better, year by year, in a disease where progressive worsening is inevitable, is unheard of in regard to a "placebo effect." Furthermore, there was no statistical evidence from the [double-blind trial] of a significant placebo effect. ... Fifteen our of fifteen patients becoming objectively better over months and years, in a condition where worsening is otherwise inevitable, is not a placebo effect.
>
> * * * *
>
> The FDA made a through review of the existing data. They noted that there was signal in both the phase I and phase II studies suggesting that GDNF is efficacious, and they were well aware that efficacy is difficult to prove in small phase II studies. They concluded that it was reasonable for Amgen to refill the pumps with GDNF, and gave Amgen the green light to do so ... .
>
> [See Hutchinson Cert. 2, ¶¶ 22, 24, 71.]

68. The Kentucky doctors confirm this, opining "that there is significant evidence for the ... efficacy of ... GDNF. Our preclinical research posits that the efficacy of intraputamenal GDNF therapy is directly related to dose and tissue distribution. These parameters were sufficiently optimized in the two Phase 1 trials where 15 out of 15 treated patients showed significant clinical improvements." See Gash Cert., ¶ 10.

69. Amgen also represented that GDNF put patients at risk for the development of neutralizing antibodies and cerebellar lesions.

70. As the Kentucky doctors explain, the development of neutralizing antibodies is completely normal and of no clinical significance:

> Contrary to the statements provided by some other individuals, the situation of neutralizing GDNF antibodies is similar to that of neutralizing antibodies to beta interferon. Up to 45% of the patients treated with beta interferon develop antibodies, without clinical manifestations. One reason is that other related proteins in the body can substitute for beta interferon. GDNF also has closely related proteins that can substitute for it. An example is neurturin, which is found in overlapping brain areas with GDNF. Other proteins related to GDNF are found outside of the brain in the body. It should be stated again that clinical manifestations to GDNF antibodies have not been documented in patients receiving GDNF therapy. The muscle weakness in one patient receiving GDNF has since been reported as being due to other causes.
>
> [See Gash Cert., ¶ 8.]

71. And, as Dr. Hutchinson explains,

> [r]egarding the antibody issue, "neutralizing antibodies" are almost invariably seen when proteins are injected into the body. This is true of Amgen's leading drug, Epogen. This is true of the interferons used to treat multiple sclerosis, where up to 50% of patients develop them. Despite the pejorative appellation, neutralizing antibodies simply reduce the effectiveness of a drug and very rarely cause life-threatening complications. They are to be expected.
>
> It can now be said that about 10% of patients treated with GDNF will develop neutralizing antibodies. Two out of fifteen patients in

> Bristol and Kentucky have them, and have presumably had them for years (since they take only about 3 months to develop), yet have suffered no ill effects.
>
> [See Hutchinson Cert. 2, ¶¶ 58-59.]

72. Similarly, as explained by Dr. Hutchinson, the cerebellular lesions are not the byproduct of taking GDNF in the normal course:

> While on vacation in England, on September 1, 2004, I received a telephone call from Mr. Dan Lee at Amgen. He told me that the study was to be stopped because of damage seen in the cerebellum in three of the monkeys. ...
>
> Upon my return to New York, on or about September 8th 2004, I reviewed the pathology slides that had been emailed to us. My first reaction was astonishment. There was indeed some loss of Purkinje cells, but no evidence of inflammation, arguing against hypoxic-ischemic change or direct toxicity.
>
> Then I noticed that the three affected monkeys were all in the high-dose recovery group. The animal experiment was as follows: 15 animals received high doses of GDNF. All fifteen animals had their pumps abruptly switched off at six months. Ten were sacrificed immediately and their brains examined for signs of toxicity. None were found. The five remaining monkeys had their pumps switched off but were kept alive for an additional three months (the "recovery phase") before being sacrificed. Lesions were seen in the cerebellum in 3/5 of these monkeys.
>
> If Amgen's hypothesis were correct, i.e., that the lesions were due to the direct toxicity of GDNF, then all monkeys would be equally at risk, since they had all been exposed for six months. The math is simple. Assuming Amgen's hypothesis of direct GDNF toxicity is correct, the probability that lesions would only be seen in the five recovery animals can be calculated exactly. It is 2.2%. Therefore Amgen's hypothesis is rejected with 97.8% confidence, i.e. beyond any reasonable scientific doubt.
>
> [See Hutchinson Cert. 2, ¶¶ 58-59.]

73. And as explained by the Kentucky doctors,

> [i]f the cerebellar lesions are not an artifact resulting from the procedural problems (and the lesions seen in the study have not been replicated), a complete and independent assessment of the

> factors underlying the development of cerebellar lesions in the four monkeys cannot be made until all the data are made public. In our opinion, GDNF withdrawal is the other leading candidate as the mechanism of action producing the lesions and is consistent with confidential information which Amgen has not released. ... Contrary to the statements provided by some other individuals, the cerebellum can be closely monitored for tissue loss by MRI. Techniques are available and used for the patients in the Kentucky study to detect the loss of as little as 0.5% of cerebellar tissue. It is generally considered that tissue loss/injury compromising more than 25% of the cerebellum is required before clinical symptoms emerge. It should be stated again that cerebellar lesions from GDNF therapy have not been found in patients.
>
> [See Gash Cert., ¶¶ 5-6.]

74. The Principal Investigators disagree with Amgen's decision and believe GDNF is both safe and effective. See Gash Aff.; see also Gash Cert.; Hutchinson Cert., ¶¶ 44-45; Penn Cert., ¶¶ 38-39.

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

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

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

78. Since GDNF was withdrawn from the Kentucky patients' systems, all of the benefits of the drug to them have disappeared. See generally Kentucky Patient Certs.

79. For example, Mr. Abney has averred that "[s]ince GDNF was withdrawn from my system, I have experienced irregular "on" times, including times or no on time, rigidity, excess saliva, slurred speech (worse), [and] cramps." See Abney Cert., ¶ 20.

80. Ms. Day has averred that

> [s]ince GDNF was withdrawn from my system, I now fall 2-3 times per day; subsequently, I have 2 cracked ribs, and now need live-in assistance 24 hours a day; I did not need live-in help prior to the surgery. All of my PD symptoms that had disappeared while on GDNF have slowly returned. I am no longer able to work as far or as well as I could on GDNF; I can barely walk at all. In fact, I cannot even leave the house alone. I am no longer able to drive. My speech is once again very difficult to understand adding to the loneliness that goes with Parkinson's Disease.
>
> [See Day Cert., ¶ 20.]

81. Mr. Jackson 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 Jackson Cert., ¶¶ 15-20.

82. 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 Thacker Cert., ¶¶ 15-20.

83. The devolvement of the Kentucky patients' condition was recently demonstrated to viewers of the television program "Good Morning America."

84. 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.]

85. 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.

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

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

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

89. 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.]

90. 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.]

91. 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.

92. 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?
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> [See Thacker Cert., ¶ 18.]

93. According to the Executive Director of the Parkinson's Pipeline Project,

> The Parkinson Pipeline Project ... unanimously supports the [plaintiffs'] request for reinstatement of their GDNF treatments. ... By halting the GDNF trials, Amgen is denying the Parkinson's community potentially valuable information on GDNF therapy.
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> * * * *
>
> New treatments average nearly 15 years to move from scientific discovery to the drugstore. People with Parkinson's do not have years to wait for a cure or better therapy; for us, time is simply not neutral. ...
>
> * * *
>
> What Amgen sees as the "failure" of its phase II, placebo control study to reach primary endpoints is not considered conclusive by

> many of the study doctors. They point to important differences between this study and the successful Phase I studies in the methods for applying the medication to the affected parts of the mid-brain and the doses administered (1/3), as well as flaws in the measurement and analysis methods. ...
>
> Since Amgen ceased their treatments, many trial participants have been forced back into the prison of advanced Parkinson's disease, for which there are currently no other treatment options, since Parkinson's medications no longer work for them. ...
>
> * * * *
>
> Reinstatement of GDNF treatment is important not only to today's patients but to our prospects of being able to recruit sufficient numbers of people for future trials. If pharmaceutical companies do not treat human research participants with respect, if they ignore patients' viewpoints of the trial process and the evaluation of treatments, and cause participants unnecessary suffering, patients will become less inclined to volunteer for future clinical trials. All of us – people with Parkinson's, researchers and the pharmaceutical companies, such as Amgen – will lose.
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> [See generally Certification of Perry Cohen, Ph.D., attached as Exhibit "U."]

COUNTS AND CAUSES OF ACTION

COUNT ONE - PROMISSORY ESTOPPEL

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

95. 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.

96. 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.

97. The plaintiffs reasonably relied on these representations after meeting with the Kentucky doctors and seeing how professional, knowledgeable, and compassionate they were.

98. 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.

99. Amgen breached its promises by terminating plaintiffs' access to GDNF and by ignoring the opinion and conclusion of the doctors that the plaintiffs should be allowed to continue receiving GDNF.

100. 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

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

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

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

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.

COUNT THREE - BREACH OF CONTRACT

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

107. This Informed Consent Document was created by Amgen and signed by the plaintiffs, creating a valid, binding contract between Amgen and the plaintiffs.

108. This document 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.

109. 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.

110. 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

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

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

113. In addition to their express terms, all contracts contain a covenant of good faith and fair dealing.

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

115. 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.

116. 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 KENTUCKY STATUTE 367.170

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

118. 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 Kentucky Statute 367.170, which provides as follows:

> Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.
>
> For purposes of this section, unfair shall be construed to mean unconscionable.

119. 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

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

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

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

123. 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: Friday, June 17, 2005

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