

EXHIBIT "A"

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ROBERT SUTHERS and NIWANA
MARTIN,

Plaintiffs,

v.

AMGEN, INC., a Delaware Corporation,

Defendant.

**CERTIFICATION OF
MICHAEL HUTCHINSON, M.D., Ph.D.**

I, Michael Hutchinson, of full age and sound mind, hereby certify as follows:

1. I am the principal investigator at the New York University Hospital ("NYU Hospital") location of the clinical trial that forms the subject of this lawsuit.

2. I am a Board Certified neurologist, currently Associate Professor of Clinical Neurology at NYU School of Medicine. I was trained in Neurology at the University of Washington, Seattle. I had fellowship training in Neuroimaging at the University of California Los Angeles, and have served as Honourary Visiting Research Fellow at the Institute of Neurology, Queen Square, London. I have had numerous peer-reviewed publications and invited lectures on Parkinson's Disease, on neuroimaging, as well as on fundamental aspects of Magnetic Resonance Imaging (MRI).

3. 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.

4. The existing therapies for Parkinson's all focus on increasing dopamine in the brains of Parkinson's sufferers, which has the effect of temporarily masking their symptoms.

5. These existing therapies are not curative and do not stop the death of the brain cells that make dopamine.

6. 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 neurotrophic factor, or GDNF ("GDNF").

7. Synergen proceeded to test GDNF on monkeys with impressive results.

8. 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.

9. Amgen was so impressed with the drug that, in 1994, it bought Synergen.

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

11. Subsequently, Steven S. Gill ("Mr. Gill"), a neurosurgeon at Frenchay Hospital in Bristol, England ("Frenchay Hospital") conceived of a way to do so.

12. Mr. Gill was the first to surgically implant in a patient's abdomen catheters that were threaded through his or her chest, neck, and head, delivering GDNF directly to the brain.

13. In the first Phase I study of Mr. Gill's procedure, which was conducted by Mr. Gill himself, all five patients tolerated the treatment and the drug without any serious adverse events, and they also showed dramatic improvement.

14. 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.

15. In 2003, Amgen sponsored a placebo-controlled Phase II trial involving thirty-four patients at multiple sites, including NYU Hospital, University of Chicago Hospital, University of Kentucky, and Frenchay Hospital.

16. As previously stated, the trial at the New York University location was supervised by me.

17. 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.

18. At the conclusion of the placebo phase, those subjects would be, in the words of the protocol and the informed consent document, guaranteed they would receive GDNF indefinitely.

19. Plaintiffs Mr. Suthers and Ms. Martin participated in the trial at the New York University location.

20. Prior to their doing so, the plaintiffs and I 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.

21. Thereafter, each of the plaintiffs signed the informed consent document, evidencing their agreement to participate in the research.

22. 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.

23. Each of these procedures was time-consuming, painful, and emotionally trying for the patients, their caregivers, and their loved ones.

24. In Mr. Suthers' case, he had to undergo a second brain surgery to correctly place a catheter that had come loose.

25. Both of the plaintiffs experienced significant improvement after receiving GDNF.

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

27. 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.

28. In fact, he was able to walk up to two miles a day during this period of time.

29. 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.

30. I, along with other principal investigators, believed, and still believe, that GDNF was safe and of benefit to the plaintiffs.

31. 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.

32. The principal investigators who saw no such adverse effects in humans noted that the monkeys had been receiving doses outside the clinically relevant dose range, namely 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.

33. Nevertheless, without consulting us, and without considering the subjects who had exposed themselves to serious risk and discomfort, Amgen announced it was terminating the clinical trial.

34. This decision was made within less than one day.

35. In September 2004, Amgen directed us to shut the study down, and I was unable to give the plaintiffs the drug.

36. The principal investigators disagree with Amgen's decision and believe GDNF is both safe and effective.

37. Together, the doctors wrote: "GDNF has the potential to revolutionize treatment of Parkinson's."

38. Together, the doctors wrote: "GDNF can be safely delivered within the clinically effective dose range."

39. Together the doctors wrote: "We strongly support making the drug available to the patients."

40. Dr. Gash, as well as the other doctors, has 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.

41. 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.

42. Similarly, all of the improvements that Ms. Martin showed during the period of time that she was on GDNF are gone.

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

44. 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.

45. 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.

Dated: 4/20/05



Michael Hutchinson, M.D., Ph.D.

Subscribed & sworn to

before me this 20th day of April 2005



CAROLINE ALBERTI
Notary Public, State of New York
No. 01AL4852441
Qualified in Bronx County
Commission Expires Feb 10, 200 6