

# EXHIBIT “D”

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

**ROBERT SUTHERS,**  
**NIWANA MARTIN**

Plaintiffs,

v.

AMGEN, INC., a Delaware Corporation,

Defendant.

**CERTIFICATION OF  
RICHARD PENN, M.D.**

I, Richard Penn, M.D., of full age and sound mind, hereby certify as follows:

1. I am the co-principal investigator at the University of Chicago location of the clinical trial that forms the subject of this lawsuit.

2. I have been a neurosurgeon since 1973, when I graduated from the Columbia University College of Physicians & Surgeons, and have been a Professor of Neurosurgery since 1984. In 1976, I was Board Certified by the American Board of Neurological Surgery. I have received numerous federal and private funding awards since the early 1970's including a Center for Excellence Grant at the University of Chicago from Medtronic, Inc. to investigate movement disorders, hydrocephalus and epilepsy, as well as a grant to study Intraparenchymal GDNF for Parkinson's disease from Amgen, Inc. that is still ongoing. In addition, I have published over 127 research articles in peer-reviewed medical journals and co authored 3 books.

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 replacing 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 positive 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 bought Synergen, the company that originally produced GDNF in 1994.

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

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

12. 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.

13. In the first Phase I study of Dr. Gill's procedure, which was conducted by Dr. 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 Medical Center, University of Chicago Medical Center, University of Kentucky Medical Center, and Frenchay Hospital.

16. For the trial at the University of Chicago location I was the neurosurgeon caring for the patients at this location.

17. The trial was to begin with each of the subjects having pumps inserted in their abdomen and holes drilled in their skull. Thereafter, there was to be a six-month placebo phase during which time half of the study subjects would receive no active treatment, while the other half received GDNF.

18. At the conclusion of the placebo phase, those subjects who did not receive GDNF would be, in the words of the protocol and the informed consent document, guaranteed they would receive a trial GDNF.

19. Prior to doing so, the study subjects 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.

20. Thereafter, the subjects signed the informed consent document, evidencing their agreement to participate in the research.

21. Subsequently, the subjects had the infusion system surgically implanted in their abdomens, had catheters threaded under the skin from the abdomen to the brain, and had holes drilled in the skull.

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

23. The study subjects at the Chicago location experienced significant improvement after receiving GDNF.

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

25. Study subjects had significantly more "on" time, and felt physically, cognitively, and emotionally better once they were on GDNF.

26. I, along with the other principal investigator at Chicago, believed, and still believe, that GDNF is safe and of benefit to the patients, based on our experience.

27. 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.

28. The principal investigators saw no such adverse effects in any of the study subjects and 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 ever would be, given to a human being.

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

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

31. In September 2004, Amgen directed us to shut the study down, and I was unable to give the study participants any more GDNF.

32. I disagree with Amgen's decision and believe GDNF is likely to be safe and effective.

33. Together, a number of doctors including myself wrote: "GDNF has the potential to revolutionize treatment of Parkinson's."

34. and "GDNF can be safely delivered within the clinically effective dose range."

35. and "We strongly support making the drug available to the patients."


36. Dr. Gash of the University of Kentucky, as well as other doctors, have observed that if the study subjects 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 GDNF lasted as long as three years in the Phase I patients who had the opportunity to receive the treatment for that period of time.

37. The decision by Amgen to terminate the trial was premature and not justified based on the safety data.

38. 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.

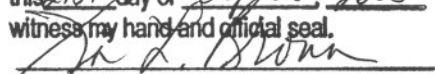
39. Indeed, it is my opinion, to a reasonable degree of medical certainty, as co-principal investigator at the University of Chicago location of the trial on the efficacy of GDNF, that the drug has been not only safe and effective for the trial patients, but also shows enormous potential for the treatment of Parkinson's Disease.

Dated: 4/21/05

  
Richard Penn, M.D.

State of Illinois  
County of Cook

Sworn to and subscribed to before me  
this 21st day of April, 2005  
witness my hand and official seal.

  
Velma L. Brown, Notary  
My commission expires May 18, 2006

