

EXHIBIT "C"

**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
PERRY COHEN, Ph.D.

I, Perry Cohen of full age and sound mind, hereby certify as follows:

1. I am the Executive Director of the Parkinson's Pipeline Project.
2. The Parkinson Pipeline Project, a grassroots organization of people with Parkinson's disease, unanimously supports the claimants' request for reinstatement of their GDNF treatments. The Project's goal is to involve patients in speeding up and enhancing the process of developing and delivering to market safer, more effective treatments for PD. We believe it is in the best interests of the PD community as a whole that Amgen Inc. reinstates GDNF treatment for those participants who request it. **By halting the GDNF trials, Amgen is denying the Parkinson's community potentially valuable information on GDNF therapy.**
3. One of the Pipeline Project's activities is tracking and collecting information on pre-clinical PD treatments in the pipeline and in clinical trials. We have followed the Phase I and II GDNF clinical trials both in the United States and in the United Kingdom, and are convinced GDNF could be one of the most promising treatments currently in development, due to its potential to slow and reverse the degenerative effects of Parkinson's disease.
4. 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. Every day we become more disabled, endure repeated falls, and lose the pleasures of work and family. This is why there is so much anguish in the patient community concerning Amgen, Incorporated's decision to halt clinical trials of GDNF. As Parkinson's patients we understand very intimately the pain and suffering of the trial participants whose treatments were abruptly halted. As informed lay people, we also understand that medical progress builds on the knowledge obtained in earlier research studies.

5. Participation in medical research requires an informed calculation of the benefits and risks involved. The decision to volunteer for Amgen's GDNF trials required great courage on the patients' part. They accepted the risk of having a "pump" surgically implanted into their abdomens and catheters inserted into their brains to administer this nerve growth factor, in hopes of turning back the clock on their Parkinson's disease and being able to return to a normal life. Indeed for many of them, GDNF worked dramatically. Participants reported "miracles" of being able to drive again, to feed themselves, and to hold a grandchild. GDNF worked.

6. Medical journal articles on the phase I trials reported similar results among the trial participants at Frenchay Hospital, in Bristol, United Kingdom (1,2), and at the University of Kentucky Udall Parkinson's Center of Excellence (3) for up to two years, with no serious side effects. These included improvements in Parkinson's symptoms as measured by *Unified Parkinson's Disease Rating Scales*; improvements of activities of daily living scores; and reduction of medication-induced dyskinesias. PET scans "showed an increase of dopamine storage suggesting a direct effect of GDNF on dopamine function."

7. What Amgen sees as the "failure" of its phase II, placebo controlled 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. After further investigation of the data in light of the methodological flaws of the Amgen study, these trial doctors identified data that suggested benefit from the treatment. **Although not conclusive proof of efficacy, the data are sufficient to warrant further study of this treatment under FDA guidelines, for this phase of development.**

8. 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.** Amgen has suggested Deep Brain Stimulation as an alternative treatment. However, there are strict guidelines for this surgery and not all patients are eligible. It also would involve more potentially dangerous brain surgery. DBS results have been mixed - very much depending on the accessibility of experienced medical personnel to perform the surgery and periodic adjustments to the stimulator. It is not a viable option for patients such as Mr. Suthers.

9. Although animal research using other delivery methods of GDNF is expected to continue, such as gene therapy and stem cells, these methods will not be available for human use for a number of years. The pump method of delivery is available right now. Many of the trial participants benefited from it, and we believe it was insensitive and unethical of Amgen to deny them further treatments.

10. The fact remains that all Parkinson's patients would benefit if these GDNF treatments were continued. This would allow for further collection of data and would

enable scientists and regulatory authorities to monitor the long-term safety and efficacy of GDNF. Observation of increased fluorodopa uptake in PET scans could also be followed over time to determine if this will eventually translate into clinical improvement.

11. Our view and that of many informed scientists and patients is that GDNF is one of the most promising treatments on the horizon. Delivery of this medication through the pump is the closest we have come to the end of the long pipeline of development and evaluation of a breakthrough therapy of this magnitude.

12. Amgen cited safety issues of neutralizing antibodies (found in some of the human participants) and of cerebellar degeneration in some of the primate subjects that received much higher doses of GDNF. Some of the study doctors believed that Amgen overstated these safety concerns, but they do need to be investigated and better understood, for future human trials. These study doctors requested a meeting with the FDA, which must concur with any decision to use an experimental treatment on humans. **Although Amgen failed to reference this meeting in their press releases, company officials have acknowledged unequivocally in presentations to PD advocacy and research organizations that FDA officials concluded that (1) new patients should not be exposed to this treatment until the safety issues were further studied and (2) patients that had already been exposed to the treatment and taken the main risk of brain surgery could be permitted to continue the treatment.** The trial participants were willing to accept these risks, and release Amgen of any legal responsibility if their treatment was reinstated. Amgen refused.

13. 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. And all of us -- people with Parkinson's, researchers and the pharmaceutical companies, such as Amgen - will lose.

May 20, 2005
Date

Perry D. Cohen
Perry D. Cohen, PhD.
Project Director
Parkinson Pipeline Project

References:

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2. Patel NK; Bunnage M; Plaha P; Svendsen CN; Heywood P; Gill SS . “ Intraputaminal infusion of glial cell line-derived neurotrophic factor in PD: A two-year outcome study.”

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3. John Slevin, Greg A. Gerhardt, Charles D. Smith, Don Gash, Richard Kryscio, and Byron Young. “ Improvement of bilateral motor functions in patients with Parkinson disease through the unilateral intraputaminal infusion of glial cell line-derived neurotrophic factor.” *Journal of Neurosurgery*, 102:216-222, 2005.