## EXHIBIT "E"

## IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

ROBERT SUTHERS and

NIWANA MARTIN,

Plaintiffs,

vs.

AMGEN, INC.

One Amgen Center Drive

Thousand Oaks, CA

Defendant.

## Affidavit of Don M. Gash, PhD, John Slevin MD, Byron Young, MD and Greg Gerhardt, PhD.

Don M. Gash, PhD, John Slevin, MD, Byron Young, MD and Greg Gerhardt, PhD., are hereby duly sworn according to law depose and say:

- 1. On September 1, 2004, Amgen decided to discontinue three small ongoing clinical trials testing the continuous infusion of a human protein (glial cell line-derived neurotrophic factor, GDNF) into the brain for the treatment of advanced Parkinson's disease in about 50 patients.
- 2. The decision was made because of concerns that had arisen about the safety and efficacy of the drug.
- 3. Many of the patients receiving GDNF felt that the drug was a "godsend," providing relief from the pain and suffering while promoting significant improvements in their parkinsonian condition.

- 4. Many of them have adamantly expressed their desire to begin receiving the drug again.
- 5. Many of the investigators conducting the trials also feel that the drug has great promise.
- 6. The research team conducting the Kentucky Phase 1 Clinical Trail affirm that in their best professional judgment the following are true:
  - a. GDNF has the potential to revolutionize the treatment of Parkinson's disease. In contrast to other available therapies including Deep Brain Stimulation (DBS), GDNF promises to significantly slow disease progression and promote restoration of function in moderate to advanced Parkinson's disease patients.
  - b. Direct infusion of GDNF into the brain is a technology that can be used today to treat hundreds of thousands of advanced Parkinson's disease patients. It 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!
  - c. Efficacy of GDNF is directly related to dose and tissue distribution. Infusion procedures using Convection Enhanced Delivery to increase GDNF penetration into surrounding brain tissue is crucial for the direct infusion approach to work properly. The methods used in the two Phase 1 studies achieved this goal, with 15 out of 15 advanced Parkinson's disease patients showing significant functional improvements. Dose and delivery procedures need to be optimized for the Phase 2 patients.
  - d. GDNF can be safely delivered within the clinically effective dose range. Despite the fact that GDNF was safe and well tolerated in the Phase 1 and 2 trials, two safety issues have arisen. Cerebellar toxicity was seen with very high doses of GDNF in rhesus monkeys and GDNF antibodies have been expressed in some patients. While

they remain a concern, it is important to place them in perspective. First and foremost, to date none of the patients have shown evidence of cerebellar toxicity or autoimmune symptomatology. Cerebellar toxicity in rhesus monkeys occurred outside of the clinically relevant dose range. Antibody expression frequently occurs with other proteins used to treat diseases of the brain, such as β-interferon therapy for multiple sclerosis, without producing recognizable clinical autoimmune disease and without precluding clinical treatment. While both safety issues dictate that the patients receiving GDNF be closely monitored, further testing is needed to determine their relevance, if any, in clinical treatment.

In 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 antiparkinsonian medication, which produce unwanted sideeffects such as dyskinesia (shaking), dystonia (muscle cramps) and cognitive disturbances (hallucinations and dementia).

SWORN TO AND SUBSCRIBED BEFORE ME THIS 20Th DAY , 2005.

ohn Slevin MD.

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Commission expires

Byron Young, MD

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