UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, a : Maryland corporation, BAXTER : HEALTHCARE CORPORATION, a Delaware: corporation, and BECTON DICKINSON :

AND COMPANY, a New Jersey corporation,:

Case No. 94-105 RRM

Plaintiffs,

CELLPRO, INC., a Delaware corporation,

Defendant.

DECLARATION OF DR. GARY SCHILLER

DECLARATION OF DR: GARY SCHILLER

- I, Gary Schiller, M.D., declare as follows:
- 1. I am an Assistant Professor of Medicine in the Division of Hematology & Oncology of the Department of Medicine at the University of California, Los Angeles. A copy of my Curriculum Vitae is attached as Exhibit A.
- 2. I am well familiar with the operation and capabilities of CellPro's CEPRATE® SC stem cell concentrator, based on having regularly worked with the device in the course of CellPro-sponsored clinical trials and studies that I conducted over the last five years. I have performed numerous transplants using the CellPro device including six (6) allogeneic transplants and approximately seventy five (75) autologous transplants.
- 3. Based on my experience, I consider the CellPro device to offer improvements over the traditional Buffy Coat Progenitor Cell Transplant ("PCT") technique in that stem cells processed by the CellPro device have, in my experience, reduced risks of infusion-related toxicity and associated adverse effects such as nausea, vomiting and lung complications. Processing with the CEPRATE® system reduces the presence of residual tumor in graft which may be associated with a lower likelihood of relapse. Further, processing with the CEPRATE® system results in improvement over the traditional techniques in terms of storage because of the progenitor cell concentration with the CellPro device.
- 4. I have experience with the CellPro device based on several considerations: (a) its high-efficiency of T-cell purging which is an important consideration in allogeneic transplants; (b) the stem cell product produced by the CellPro device

achieved reproducible hematopoietic recovery (that is, one can predict when hematopoietic recovery occurs after a transplant using the CellPro device); (c) the CellPro device produces a stem cell product that is safe and effective; and d) the CellPro device is reliable, user-friendly and easy to use.

- 5. In my clinical research when I perform studies, my hope is that any therapeutic advance that I may discover will be widely used, and I believe the fact that a particular course of therapy is built on an FDA-approved device (such as CellPro's device) improves the odds that the new therapy will be widely practiced.
- 6. Further, in my experience, it is easier to get an experimental protocol approved by the FDA and/or obtain institutional clearance from the hospital or the university approval committee, if at least the stem-cell-enrichment and transplant step is performed with an FDA-approved device such as CellPro's CEPRATE® SC device.
- 7. In addition, as a practical matter, the fact that a device is approved by the FDA is reassuring to the patient who may be considering to undergo a particular investigation procedure with that device, and helps the patient make an informed decision to undergo an experimental treatment.
- 8. In my opinion, the availability of the CellPro device has opened up new fields of investigation such as transplant of mismatched related bone marrow.
- 9. I consider the availability of, and access to, the CellPro's CEPRATE® SC device a compelling public interest. In fact, for patients afflicted with lymphoma, multiple myeloma, low grade lymphoma or breast cancer (where purging of tumor cells is potentially valuable), who are otherwise ineligible for treatment with an investigational

device, the CellPro device offers the only available processing system.

I further declare under penalty of perjury that the foregoing is true and correct.

Executed at Los Angeles, California, this ____3 day of April, 1997.

Gary Schiller, M.D.

Gary John Schiller, M.D.

CURRICULUM VITAE

PERSONAL HISTORY:

Business Address:

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Date and Place of Birth: March 20, 1959

Los Angeles, California

Citizenship: USA

Marital Status: Single

Social Security No.: 546-80-5317

EDUCATION:

1976-1980: University of Southern California

Department of Biological Sciences

Degree: Bachelor of Science, Summa Cum Laude, 1980

1980-1984: University of Southern California School of Medicine

Los Angeles, California Degree: M.D., 1984

1984-1987: Internship and Residency, Department of Medicine

University of California, Los Angeles, School of Medicine

1988-1989: Chief Resident, Department of Medicine

University of California, Los Angeles, School of Medicine

1987-1990: Fellowship, Division of Hematology/Oncology

University of California, Los Angeles, School of Medicine

MEDICAL LICENSE:

California License #G56172

BOARD CERTIFICATION:

Board Certified Internal Medicine, 1987, Certificate #114088 Board Certified Oncology, November 1989 Board Certified Hematology, November 1990