IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, BAXTER HEALTHCARE CORPORATION, BECTON DICKINSON AND COMPANY,	§	
Plaintiffs,	§	
v.	§	Civil Action No. 94-105-RRM
CELLPRO,	§	
Defendant.	§	

DECLARATION OF DR. SCOTT D. ROWLEY

William J. Marsden, Jr. (#2247)
Joanne Ceballos (#2854)
Michael S. McGinniss (#3203)
POTTER ANDERSON & CORROON
350 Delaware Trust Building
Post Office Box 951
Wilmington, Delaware 19899-0951
(302) 984-6000

Attorneys for Plaintiffs

OF COUNSEL:

Donald R. Ware
Foley Hoag & Eliot
One Post Office Square
Boston, Massachusetts 02109

Steven J. Lee
Kenyon & Kenyon
One Broadway
New York, New York 10004

Michael Sennett
Bell Boyd & Lloyd
Three First National Plaza
70 West Madison Street
Chicago, Illinois 60602

Dated: May 28, 1997
PA&C/261077

DECLARATION OF DR. SCOTT D. ROWLEY

I, Scott D. Rowley, M.D., hereby declare:

1. I am an attending physician in the Clinical Transplant Program at the Fred Hutchinson Cancer Research Center ("FHCRC") in Seattle, Washington, and Director of the Clinical Cryobiology Laboratory, the Apheresis Unit, and the Bone Marrow Harvest Team at FHCRC. In addition, I am Associate Professor of Medicine at the University of Washington School of Medicine. I am a co-author of 73 published scientific papers in peer-reviewed journals and a dozen book chapters in the fields of oncology, hematopoietic stem cell transplantation, and related subjects. I have editorial responsibilities for two refereed journals, Journal of Hematotherapy and Journal of Cancer Therapy and Control. I am also the President-Elect of the International Society of Hematotherapy and Graft Engineering ("ISHAGE"), a professional organization dedicated to the science and medicine of cell processing for hematopoietic cell therapy. A copy of my Curriculum Vitae is attached hereto as Exhibit A.

2. FHCRC is one of the world's leading centers for hematopoietic stem cell transplantation. In the past five years, we performed, on average, more than 400 transplants per year for adult and pediatric patients suffering from malignancies and other diseases of the blood and immune systems. In the course of my career I have been involved in several thousand transplantation procedures.

3. In my capacity as director of clinical cryobiology at FHCRC, I have responsibility for collection, processing, cryopreservation, and reinfusion of all bone marrow and peripheral blood components used in all clinical transplants at FHCRC and in most transplants at collaborating institutions in the Puget Sound area. These responsibilities encompass all stem cell selection and tumor and T-cell purging procedures done at FHCRC using both CellPro's

Ceprate® SC system and Baxter's Isolex® 300 system. The recently publicized stem cell selection and tumor cell purging process performed for CellPro's president, Rick Murdock, was done at FHCRC under my supervision. The statements made in this declaration are made on my own personal knowledge and are based on my experience and my review of data kept at FHCRC in the ordinary course of business.

4. I am personally familiar with the capabilities of Baxter's Isolex® 300 Stem Cell Selection System and CellPro's Ceprate® SC Stem Cell Concentrator system, both of which are currently being used under my supervision at FHCRC. Beginning in late 1994 and continuing to date, we have used Baxter's system in transplant procedures for a total of 47 patients (19 autologous and 28 allogeneic). In that same period, we have used CellPro's system in transplant procedures for a total of 27 patients (7 autologous and 20 allogeneic).

5. I recently completed an FDA-approved clinical trial using Baxter's Isolex® 300 system for the processing of peripheral blood stem cells for autologous transplantation in patients with B-lymphoid malignancies, including non-Hodgkin's lymphoma, multiple myeloma, and chronic lymphocytic leukemia. I was Principal Investigator in the trial, in which a total of 19 patients were transplanted between 1995 and 1996. Following high dose chemotherapy, the patients were reinfused with stem cells harvested from their peripheral blood and purified using the Baxter Isolex® 300 system. Initially, we used the Baxter Isolex® 300 SA device, and beginning in 1996 we used the newer model, called the Isolex® 300I, which automates the process and shortens the processing time. The Baxter system uses a monoclonal antibody specific for the CD34 antigen and an immunomagnetic separation technique to select CD34 positive cells. In this technique, the CD34+ cells initially attach to paramagnetic microspheres. The cells are

passed over a magnet to collect the CD34+ cells and are then released from the microspheres using either enzymatic treatment with chymopapain or competitive binding with a synthetic peptide. For patients treated using the Isolex® 300 SA, in some cases we used the chymopapain release and in others we used the peptide release. In all cases in which the Isolex® 300i was used, the release of cells was accomplished using the synthetic peptide.

6. The results of this trial were highly successful. Reinfusion of peripheral blood stem cells processed using the Baxter devices resulted in rapid and sustained engraftment: the median time to achieve platelet transfusion independence was just 9 days, and the median time to peripheral blood neutrophil count of over 500/uL was just 11 days. The Baxter devices produced high CD34+ purity, averaging 90.8% and ranging as high as 98.7%. The data showed that transplanting highly purified stem cells obtained by use of the Baxter system results in rapid engraftment when either the Isolex® 300 SA or the Isolex® 300i is used, and that the same clinical results are achieved irrespective of whether we used the chymopapain release or the peptide release. The advantage of using highly purified CD34 positive cells in transplantation is that the high purity translates into significant depletion of unwanted CD34 negative cells, such as tumor cells. In our study using the Baxter devices, the CD34 positive purities in the cell compositions translated into depletion of 99.96% of CD34 negative cells (range 99.61-99.99%). In my opinion, these results confirm the safety and efficacy of the Baxter system for autologous stem cell transplants.

7. I am co-investigator in another ongoing clinical trial at FHCRC that uses the Baxter Isolex® 300i in allogeneic (donor) transplantation of peripheral blood stem cells in older patients suffering from advanced hematologic malignancies, including acute myeloid

leukemia, acute lymphocytic leukemia, non-Hodgkin's lymphoma, chronic myeloid leukemia, and multiple myeloma. Twenty-eight patients have been treated thus far under the protocol. Median CD34+ purity was 92% using the Baxter system. The patients experienced rapid engraftment. This study has shown that CD34 enrichment using the Baxter system removes up to 4 logs (99.99%) of T cells and reduces acute graft versus host disease (GVHD).

8. Coincidentally, another investigator at FHCRC is conducting a separate allogeneic trial using CellPro's Ceprate® SC device for processing of peripheral blood stem cells, following the same protocol as the Baxter allogeneic trial except for the device used to process the cells. To date, data from the two trials has shown that the Baxter device provides superior depletion of unwanted lymphocytes in the selected cell population.

9. Overall, our data have shown that the Baxter and CellPro systems provide equivalent yield of CD34+ cells (i.e, number of CD34+ cells in selected population as compared to number of CD34+ cells in original, unprocessed population), but that the Baxter system provides consistently superior CD34 positive purity (and, correspondingly, superior depletion of unwanted CD34 negative cells, including tumor cells).

10. To illustrate the latter conclusion, another investigator at FHCRC has been conducting an autologous peripheral blood stem cell transplant trial for patients suffering from chronic lymphocytic leukemia. The original protocol for that trial specifies use of CellPro's Ceprate® SC device. However, because of the concentration of tumor cells that remained in the cell suspensions that were harvested from patients in the trial and processed using the CellPro device, the investigator is planning to amend the protocol in order to use the Baxter device instead of the CellPro device.

11. Based upon the data generated at FHCRC and my own personal experiences with the CellPro and Baxter systems, it is my opinion that the Baxter system achieves superior results for both autologous and allogeneic stem cell transplants. I have discussed the merits of both systems with the technicians in my laboratory at FHCRC who operate them for clinical procedures and they likewise have stated their preference for the Baxter system because of the better results that it provides. In addition, it is my opinion, based upon the data I have reviewed at FHCRC and my knowledge of the CellPro system, that the CellPro system, as it exists today, is substantially less effective than the Baxter system for depleting tumor cells.

12. As mentioned above, I was responsible for the collection and processing of peripheral blood used in Rick Murdock's transplant procedure in 1996. We used the Ceprate® SC system in that procedure, in accordance with a protocol specified by CellPro and approved by Mr. Murdock's attending physician. The procedure involved two steps: a tumor purging step using monoclonal antibodies specific for the CD19 and CD20 antigens expressed on B cells; and a stem cell selection step using a monoclonal antibody (12.8) specific for the CD34 antigen expressed on stem cells. Based upon my experience with the Baxter Isolex® 300 system and the data generated from the use of that system in clinical trials at FHCRC, it is my opinion that the same combination of steps used in treating Mr. Murdock could be performed with equal or better results using the Baxter system.

13. In fact, at FHCRC we are planning to initiate a new clinical trial that will use the combination of CD34+ selection and CD19/CD20 tumor cell purging for treatment of B cell malignancies. I am the principal investigator for this trial, and I will specify use of the Baxter system in the protocol.

14. It is my understanding that CellPro's Ceprate® SC system received FDA approval in December for use in processing autologous bone marrow. This is a procedure that is almost never performed anymore, either at FHCRC or at other U.S. transplant centers. By way of example, in 1996, at FHCRC we transplanted 119 patients with autologous peripheral blood stem cells. By contrast, we only transplanted 5 patients with autologous bone marrow. It is extremely unlikely that FHCRC will utilize the CellPro system in the future for the indication for which it was approved by the FDA.

15. Since CellPro received FDA approval last December, FHCRC has purchased Ceprate® disposables for use in transplantation for only one patient.

16. It is my opinion that if for any reason CellPro's Ceprate® SC system became unavailable in the future, FHCRC could meet its stem cell processing needs using Baxter's Isolex® 300 system, either through FDA-authorized clinical trials or, following FDA approval of the Baxter system, by purchase from Baxter.

17. I have not been compensated by Baxter in connection with the preparation of this declaration. In 1993, I was asked by Baxter's Immunotherapy Division to serve on its Scientific Advisory Board, and I have received a standard fee from Baxter for serving on that Board. I own no stock in Baxter, and I have no financial interest in the outcome of the dispute between Johns Hopkins, Baxter and Becton Dickinson on the one hand and CellPro on the other. My laboratory has received financial support from both Baxter and CellPro in connection with clinical trials conducted at FHCRC. I understand that my employer, FHCRC receives royalty payments from CellPro based upon CellPro's sales of its Ceprate® SC system and disposable supplies.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 19th day of May, 1997.

Scott D. Rowley, M.D.

** TOTAL PAGE.08 **

CURRICULUM VITAE

Scott Douglas Rowley, M.D.

Social Security No. 022-38-9413

Current Appointments

Research Center: Associate Member
Fred Hutchinson Cancer Research Center

University: Associate Professor of Medicine
University of Washington

Hospital: Active Staff, Medicine
Swedish Hospital
Seattle, Washington

Addresses

Office: Fred Hutchinson Cancer Research Center
1124 Columbia Street
Seattle, Washington 98104

Tel. (206) 667-5914
Fax. (206) 667-6547

Home: 8001 SE 37th Place
Mercer Island, Washington 98040
Tel. (206) 232-3287

Personal and Family

Date of Birth: July 1, 1952

Place of Birth: Ft. Campbell, Kentucky

Marital Status: Married

Wife's Name: Phyllis Liberman

Year of Marriage: 1979

Children: Rebecca Hannah Year: 1983
Sarah Julia 1986

CURRICULUM VITAE

Scott Douglas Rowley, M.D.

Education

1970-74	B.A (Cum Laude) Williams College Williamstown, Massachusetts
1974-78	M.D., University of Massachusetts Medical School Worcester, Massachusetts

Postgraduate Training

1978-79	Intern, Department of Medicine Rhode Island Hospital Providence, Rhode Island
1979-80	Junior Assistant Resident Department of Medicine Rhode Island Hospital Providence, Rhode Island
1979-81	Teaching Fellow, Brown University School of Medicine, Providence, Rhode Island
1980-81	Senior Assistant Resident Department of Medicine Rhode Island Hospital Providence, Rhode Island
1981-83	Assistant in Oncology The Johns Hopkins University School of Medicine, Baltimore, Maryland
1981-83	Assistant in Medicine The Johns Hopkins University School of Medicine, Baltimore, Maryland
1981-83	Associate Staff, Oncology Center The Johns Hopkins Hospital, Baltimore, Maryland
1981-83	Associate Staff, Medicine The Johns Hopkins Hospital, Baltimore, Maryland
1983-84	Senior Clinical Fellow in Oncology The Johns Hopkins University School of Medicine, Baltimore, Maryland
1983-84	Senior Clinical Fellow in Hematology The Johns Hopkins University School of Medicine, Baltimore, Maryland

CURRICULUM VITAE

Scott Douglas Rowley, M.D.

Faculty Positions Held

1984-86	Instructor in Oncology The Johns Hopkins University School of Medicine, Baltimore, Maryland
1984-1991	Assistant Director, Hemapheresis Treatment Center, The Johns Hopkins Hospital, Baltimore, Maryland
1984-1991	Member, Full-Time Active Staff, The Johns Hopkins Hospital, Baltimore, Maryland
1986-1991	Assistant Professor of Oncology The Johns Hopkins University School of Medicine, Baltimore, Maryland
1991-	Associate Member, Fred Hutchinson Cancer Research Center Seattle, WA
1994-	Associate Professor of Medicine University of Washington School of Medicine Seattle, WA

Honors

1974	Cum Laude, Williams College
1988	Fellow, American College of Physicians

Board Certifications

1981	Diplomate, American Board of Internal Medicine
1983	Diplomate, Medical Oncology, American Board of Internal Medicine
1984	Diplomate, Hematology, American Board of Internal Medicine

Current Licenses

1980	License to Practice Medicine Commonwealth of Massachusetts
1981	License to Practice Medicine State of Maryland
1991	License to Practice Medicine State of Washington

CURRICULUM VITAE

Scott Douglas Rowley, M.D.

Membership in Professional Organizations

1979	American College of Physicians
1984	American Society of Clinical Oncology
1985	American Society of Hematology
1987	American Association of Blood Banks
1993	International Society of Hematology and Graft Engineering
1995	American Society of Blood and Marrow Transplantation
1996	Foundation for Accreditation of Hematopoietic Cell Transplantation

Offices Held

1993-1997	Vice President, International Society of Hematotherapy and Graft Engineering
1993-	Chairman, Legal and Regulatory Affairs Committee, International Society of Hematotherapy and Graft Engineering
1993-1994	Chairman, Ad Hoc Cellular Therapies Committee, American Association of Blood Banks
1994-	Member, Cellular Therapies Committee, American Association of Blood Banks
1995-	Board of Trustees, American Society of Blood and Marrow Transplantation
1996-	Board of Trustees, Foundation for Accreditation of Hematopoietic Cell Transplantation

Editorial Responsibilities

1992-	Journal of Hematotherapy
1992-	Cancer Therapy and Control

Local Responsibilities

1991-	Clinical Laboratories Directors Committee, Fred Hutchinson Cancer Research Center
1992-	Clinical Directors Committee, Fred Hutchinson Cancer Research Center

CURRICULUM VITAE

Scott Douglas Rowley, M.D.

Local Responsibilities (con't)

1994-	Transfusion Committee, FHCRC
1995-	Laboratory Committee, Swedish Hospital

Scott Douglas Rowley, M.D.

A. Manuscripts in Refereed Journals

1. Rowley, S.D., Brown, N.C.: Bacillus subtilis DNA polymerase III is required for the replication of DNA of bacteriophages SPP-1 and 0105. J. Virol. 21: 493-496, 1977.

2. Rowley, S., Colvin, O.M., Stuart, R.K.: Human multilineage progenitor cell sensitivity to 4-hydroperoxycyclophosphamide. Exp. Hematol. 13: 295-298, 1985.

3. Sieber, F., Rao, S., Rowley, S., Sieber-Blum, M.: Dye-mediated photolysis of human neuroblastoma cells: implications for autologous bone marrow transplantation. Blood 68: 32-36, 1986.

4. Strauss, L.C., Rowley, S.D., LaRussa, V.F., Sharkis, S.J., Stuart, R.K., Civin, C.I.: Antigenic analysis of hematopoiesis. V. Characterization of My-10 antigen expression by normal lymphohematopoietic progenitor cells. Exp. Hematol. 14: 878-886, 1986.

5. Yeager, A.M., Kaizer, H., Santos, G.W., Saral, R., Colvin, O.M., Stuart, R.K., Braine, H.G., Burke, P.J., Ambinder, R.F., Burns, W.H., Fuller, D.J., Davis, J.M., Karp, J.E., May, W.S., Rowley, S.D., Sensenbrenner, L.L., Vogelsang, G.B., Wingard, J.R.: Autologous bone marrow transplantation in patients with acute nonlymphocytic leukemia, using ex vivo marrow treatment with 4-hydroperoxycyclophosphamide. N. Engl. J. Med. 316: 141-147, 1986.

6. Rowley, S.D., Sharkis, S.J., Hattenburg, C., Sensenbrenner, L.L.: Culture from human bone marrow of blast progenitor cells with an extensive proliferative capacity. Blood 68: 804-808, 1987.

7. Sieber, F., Stuart, R.K., Rowley, S.D., Sharkis, S.J., Sensenbrenner, L.L.: Dye-medicated photolysis of normal and neoplastic hematopoietic cells. Leuk. Res. 11: 43-49, 1987.

8. Rowley, S.D., Zuehlsdorf, M., Braine, H.G., Colvin, O.M., Davis, J., Jones, R.J., Saral, R., Sensenbrenner, L.L., Yeager, A., Santos, G.W.: CFU-GM content of bone marrow graft correlates with time to hematologic reconstitution following autologous bone marrow transplantation with 4-hydroperoxycyclophosphamide purged bone marrow. Blood 70: 271-275, 1987.

9. Braine, H.G., Santos, G.W., Kaizer, H., Yeager, A.M., Mann, R.B., Burns, W.H., Civin, C.I., Fuller, D.J., Rowley, S.D., Saral, R., Sensenbrenner, L.L., Stuart, R.K., Wingard, J.R., Munoz, L.L.: Treatment of poor prognosis non-Hodgkin's lymphoma using cyclophosphamide and total body irradiation regimens with autologous bone marrow rescue. Bone Marrow Transplantation 2: 7-14, 1987.

10. Rowley, S.D., Davis, J.M., Dick, J., Braine, H.G., Charache, P., Saral, R., Sensenbrenner, L.L., Santos, G.W.: Bacterial contamination of bone marrow grafts intended for autologous and allogeneic bone marrow transplantation: Incidence and clinical significance. Transfusion 28: 109-112, 1988.

11. Jones, R.J., Sharkis, S.J., Celano, P., Colvin, O.M., Rowley, S.D., Sensenbrenner, L.L.: Progenitor cell assays predict hematopoietic reconstitution after syngeneic transplantation in mice. Blood 70: 1186-1192, 1987.

12. Jones, R.J., Zuehlsdorf, M., Rowley, S.D., Hilton, J., Santos, G.W., Sensenbrenner, L.L., Colvin, O.M.: Variability in 4-hydroperoxycyclophosphamide activity during clinical purging for autologous bone marrow transplantation. Blood 70: 1490-1494, 1987.

13. Donnenberg, A.D., Hess, A.D., Duff, S.C., Bright, E.C., Noga, S.J., Rowley, S.D., Saral, R., Santos, G.W.: Regeneration of genetically restricted immune functions after human bone marrow transplantation: influence of four different strategies for graft-v-host disease prophylaxis. Transplant. Proc. 19: 144-152, 1987.

14. Wagner, J.E., Donnenberg, A.D., Noga, S.J., Cremo, C.A., Gao, I.K., Yin, H.J., Vogelsang, G.B., Rowley, S.D., Saral, R., Santos, G.W.: Lymphocyte depletion of donor bone marrow by counterflow centrifugal elutriation: Results of a phase I clinical trial. Blood 72: 1168-1176, 1988.

Scott Douglas Rowley, M.D.

A. Manuscripts in Refereed Journals

15. Rowley, S.D., Jones, R.J., Piantadosi, S., Braine, H.G., Colvin, O.M., Davis, J., Saral, R., Sharkis, S., Wingard, J., Yeager, A.M., Santos, G.W.: Efficacy of ex vivo purging for autologous bone marrow transplantation in treatment of acute nonlymphoblastic leukemia. Blood 74: 501-506, 1989.

16. Rowley, S.D., Piantadosi, S., Santos, G.W.: Correlation of hematologic recovery with CFU-GM content of autologous bone marrow grafts treated with 4-hydroperoxycyclophosphamide. Culture after cryopreservation. Bone Marrow Transplantation 4: 563-568, 1989.

17. Geller, R.B., Saral, R., Piantadosi, S., Zahurak, M., Vogelsang, G.B., Wingard, J.R., Ambinder, R.F., Beschorner, W.B., Braine, H.G., Burns, W.H., Hess, A.D., Jones, R.J., May, W.S., Rowley, S.D., Wagner, J.E., Yeager, A.M., Santos, G.W.: Allogeneic bone marrow transplantation after high-dose busulfan and cyclophosphamide in patients with acute nonlymphocytic leukemia. Blood 73: 2209-2218, 1989.

18. Davis, J.M., Rowley, S.D., Braine, H.G., Piantadosi, S., Santos, G.W.: Clinical toxicity of cryopreserved bone marrow graft infusion. Blood 75: 781-786, 1990.

19. Jones, R.J., Piantadosi, S., Mann, R.B., Ambinder, R.F., Seifter, E.J., Vriesendorp, H.M., Abeloff, M.D., Burns, W.H., May, W.S., Rowley, S.D., Vogelsang, G.B., Wagner, J.E., Wiley, J.M., Wingard, J.R., Yeager, A.M., Saral, R., Santos, G.W.: High-dose cytotoxic therapy and bone marrow transplantation for relapsed Hodgkin's disease. J. Clin. Oncol. 8: 527-537, 1990.

20. Jones, R.J., Miller, C.B., Zehnbauer, B.A., Rowley, S.D., Santos, G.W.: In vitro evaluation of combination drug purging for autologous bone marrow transplantation. Bone Marrow Transplantation 5: 301-307, 1990.

21. Wagner, J.E., Santos, G.W., Noga, S.J., Rowley, S.D., Davis, J., Vogelsang, G.B., Farmer, E.R., Zehnbauer, B.A., Saral, R., Donnenberg, A.D.: Bone marrow graft engineering by counterflow centrifugal elutriation: Results of a phase I-II clinical trial. Blood 75: 1370-1377, 1990.

22. Rowley, S.D., Davis, J.M.: Standards for bone marrow processing laboratories. Transfusion 30: 571-572, 1990.

23. Rowley, S.D., Davis, J.M., Piantadosi, S., Jones, R.J., Yeager, A.M., Santos, G.W.: Density-gradient separation of autologous bone marrow grafts before ex vivo purging with 4-hydroperoxycyclophosphamide. Bone Marrow Transplantation 6: 321-327, 1990.

24. Miller, C.B., Zehnbauer, B.A., Piantadosi, S., Rowley, S.D., Jones, R.J.: Correlation of occult clonogenic leukemia drug sensitivity with relapse after autologous bone marrow transplantation. Blood 78: 1125-1131, 1991.

25. Rowley, S.D., Piantadosi, S., Marcellus, D.C., Jones, R.J., Davidson, N.E., Davis, J.M., Kennedy, J., Wiley, J.M., Wingard, J., Yeager, A.M., Santos, G.W.: Analysis of factors predicting speed of hematologic recovery after transplantation with 4-hydroperoxycyclophosphamide-purged autologous bone marrow grafts. Bone Marrow Transplantation 7: 183-191, 1991.

26. Rowley, S.D., Miller, C.B., Piantadosi, S., Davis, J.M., Santos, G.W., Jones, R.J.: Phase I study of combination drug purging for autologous bone marrow transplantation. J. Clin. Oncol. 9: 2210-2218, 1991.

27. Strauss, L.C., Trischmann, T.M., Rowley, S.D., Wiley, J.M., Civin, C.I.: Selection of normal human hematopoietic stem cells for bone marrow transplantation using immunomagnetic microspheres and CD34 antibody. Am. J. Ped. Hematol. Oncol. 13: 217-221, 1991.

28. Rowley, S.D., Byrne, D.V.: Low-temperature storage of bone marrow in nitrogen vapor-phase refrigerators: decreased temperature gradients with an aluminum racking system. Transfusion 32: 750-754, 1992.

Scott Douglas Rowley, M.D.

A. Manuscripts in Refereed Journals

29. Yeager, A.M., Rowley, S.D., Kaizer, H., Santos, G.W.: Ex vivo chemopurging of autologous bone marrow with 4-hydroperoxycyclophosphamide to eliminate occult leukemic cells. Laboratory and Clinical Observations. Am. J. Ped. Hematol. Oncol. 12: 245-256, 1990.

30. Kennedy, M.J., Beveridge, R.A., Rowley, S.D., Gordon, G.B., Abeloss, M.D., Davidson, N.E.: High-dose chemotherapy with reinfusion of purged autologous bone marrow following dose-intense induction as initial therapy for metastatic breast cancer. J. Natl. Cancer Inst. 83: 920-926, 1991.

31. Wagner, J.E., Zahurak, M., Piantadosi, S., Geller, R.B., Vogelsang, G.B., Wingard, J.R., Saral, R., Griffin, C., Shah, N., Zehnbauer, B.A., Ambinder, R., Burns, W., Jones, R., May, W.S., Rowley, S., Yeager, A., Santos, G.W.: Bone marrow transplantation of chronic myelogenous leukemia in chronic phase: Evaluation of risks and benefits. J. Clin. Oncol. 10: 779-789, 1992.

32. Wingard, J.R., Piantadosi, S., Santos, G.W., Saral, R., Briesendorp, H.M., Yeager, A.M., Burns, W.H., Ambinder, R.F., Braine, H.G., Elfenbein, G., Jones, R.J., Kaizer, H., May, W.S., Rowley, S.D., Sensenbrenner, L.L., Stuart, R.K., Tutschka, P.J., Vogelsang, G.B., Wagner, J.E., Beschorner, W.E., Brookmeyer, R., Farmer, E.R.: Allogeneic bone marrow transplantation for patients with high-risk acute lymphoblastic leukemia. J. Clin. Oncol. 8: 820-830, 1990.

33. Schiffman, K., Clift, R., Appelbaum, F.R., Sanders, J., Bensinger, W., Petersen, F.B., Rowley, S., Hill, R., Martin, P., Storb, R., Welden, P., Thomas, E.D., Hansen, J.A., Buckner, C.D.: Consequences of cryopreserving first remission autologous marrow for use after relapse in patients with acute myeloid leukemia. Bone Marrow Transplantation 11: 227-232, 1993.

34. Rowley, S.D.: Techniques of bone marrow and stem cell cryopreservation and storage. Marrow Transplantation: Practical and Technical Aspects of Stem Cell Reconstitution, Sacher, R.A. and AuBuchon, J.P. (eds.): American Association of Blood Banks, Bethesda. 5:105-127, 1992.

35. Rowley, S.D.: Hematopoietic stem cell cryopreservation: A review of current techniques. J. Hematotherapy 1: 233-250, 1992.

36. Bensinger, W., Singer, J., Appelbaum, F., Lilleby, K., Longin, K., Rowley, S., Clarke, E., Clift, R., Hansen, J., Shields, T., Storb, R., Weaver, C., Welden, P., Buckner, C.D.: Autologous transplantation with peripheral blood mononuclear cells collected after administration of recombinant granulocyte stimulating factor. Blood 81: 3158-3163, 1993.

37. Rowley, S.D., Brashem-Stein, C., Andrews, R., Bernstein, I.: Hematopoietic precursors resistant to treatment with 4-Hydroperoxycyclophosphamide: Requirement for an interaction with marrow stroma in addition to hematopoietic growth factors for maximal generation of colony-forming activity. Blood 82: 60-65, 1993.

38. Petersen, F.B., Lynch, M.H.E., Clift, R.A., Appelbaum, F.R., Sanders, J.E., Bensinger, W.I., Benyunes, M.C., Doney, K., Fefer, A., Martin, P., Storb, R., Rowley, S., Sullivan, K.M., Witherspoon, R., Welden, P., Thomas, E.D., Fisher, L., Hansen, J.A., Buckner, C.D.: Autologous marrow transplantation for patients with acute myeloid leukemia in untreated first relapse or in second complete remission. J. Clin. Oncol. 11: 1353-1360, 1993.

39. Weaver, C.H., Appelbaum, F.R., Petersen, F.B., Clift, R., Singer, J., Press, O., Bensinger, W., Bianco, J., Martin, P., Anasetti, C., Badger, C., Deeg, J., Doney, K., Hansen, J.A., Petersdorf, E., Rowley, S., Storb, R., Sullivan, K., Witherspoon, R., Welden, P., Buckner, C.D.: High-dose cyclophosphamide, carmustine and etoposide followed by autologous bone marrow transplantation in patients with lymphoid malignancies who have received dose-limiting radiation therapy. J. Clin. Oncol. 11: 1329-1335, 1993.

Scott Douglas Rowley, M.D.

A. Manuscripts in Refereed Journals

40. Stroncek, D.F., Holland, P.V., Barton, G., Bixby, T., Simmons, R.G., Antin, J.H., Anderson, K.C., Ash, R.C., Bolwell, B.J., Hansen, J.A., Heal, J.M., Henslee-Downey, P.J., Jaffé, E.R., Klein, H.G., Lau, P.M., Perkins, H.A., Popovsky, M.A., Price, T.H., Rowley, S.D., Stehling, L.C., Weiden, P.L., Wissel, M.E., McCullough, J.: Experiences of the first 493 unrelated marrow donors in the National Marrow Donor Program. Blood 81: 1940-1946, 1993.

41. Shah, N., Wingard, J., Plantadosi, S., Rowley, S.D., Santos, G.W., Griffin, C.: Chromosome abnormalities in patients treated with 4-hydroperoxycyclophosphamide (4-HC)-purged autologous bone marrow transplantation. Cancer Genet. Cytogenet. 66: 135-140, 1993.

42. Rowley, S.D., Anderson, G.L.: Effect of dimethylsulfoxide exposure without cryopreservation on hematopoietic progenitor cells. Bone Marrow Transplantation 11: 389-393, 1993.

43. Graham, M.L., Yeager, A.M., Leventhal, B.G., Wiley, J.M., Civin, C.I., Strauss, L.C., Hurwitz, C.A., Dubowy, R.L., Wharam, M.D., Colombani, P., Rowley, S.D., Braine, H.G., Santos, G.W.: Treatment of recurrent and refractory pediatric solid tumors with high-dose busulfan and cyclophosphamide followed by autologous bone marrow rescue. J. Clin. Oncol. 10: 1857-1864, 1992.

44. Weaver, C.H., Buckner, C.D., Longin, K., Appelbaum, F.R., Rowley, S., Lilleby, K., Miser, J., Storb, R., Hansen, J.A., Bensinger, W.: Syngeneic transplantation with peripheral blood mononuclear cells collected after the administration of recombinant human granulocyte colony-stimulating factor. Blood 82: 1981-1984, 1993.

45. Rowley, S.D.: Hematopoietic stem cell processing and cryopreservation. J. Clin. Apher. 7: 132-134, 1992.

46. Rowley, S.D., Bensinger, W.I., Gooley, T.A., Buckner, C.D.: Effect of cell concentration on bone marrow and peripheral blood stem cell cryopreservation. Blood 83: 2731-2736, 1994.

47. Bernstein, I.D., Andrews, R.G., Rowley, S.: Isolation of human hematopoietic stem cells. Blood Cells 20: 15-24, 1994.

48. Bensinger, W.I., Longin, K., Appelbaum, F., Rowley, S., Weaver, C., Lilleby, K., Gooley, T., Lynch, M., Higano, T., Klamet, J., Chauncey, T., Storb, R., Buckner, C.D.: Peripheral blood stem cells (PBSCs) collected after recombinant granulocyte colony stimulating factor (rhG-CSF): an analysis of factors correlating with the tempo of engraftment after transplantation. Br. J. Haematol. 87: 825-831, 1994.

49. Andrews, R.G., Briddell, R.A., Knitter, G.H., Rowley, S.D., Appelbaum, F.R., McNiece, I.K.: Rapid engraftment by peripheral blood progenitor cells mobilized by recombinant human stem cell factor and recombinant human granulocyte colony-stimulating factor in nonhuman primates. Blood 85: 15-20, 1995.

50. Weaver, C.H., Petersen, F.B., Appelbaum, F.R., Bensinger, W.I., Press, O., Martin, P., Sandmaier, B., Deeg, H.J., Hansen, J.A., Brunvand, M., Rowley, S., Banyunes, K., Chauncey, T., Fefer, A., Hackman, R., Gooley, T., Schiffman, K., Storb, R., Sullivan, K.M., Weiden, P., Witherspoon, R., Buckner, C.D.: High-dose fractionated total-body irradiation, etoposide, and cyclophosphamide followed by autologous stem-cell support in patients with malignant lymphoma. J. Clin. Oncol. 12: 2559-2566, 1994.

51. Bensinger, W.I., Weaver, C.H., Appelbaum, F.R., Rowley, S., Demirer, T., Sanders, J., Storb, R., Buckner, C.D.: Transplantation of allogeneic peripheral blood stem cells mobilized by recombinant human granulocyte colony-stimulating factor. Blood 85: 1655-1658, 1995.

Scott Douglas Rowley, M.D.

A. Manuscripts in Refereed Journals

52. Demirer, T., Buckner, C.D., Appelbaum, F.R., Petersen, F.B., Rowley, S., Weaver, C.H., Lilleby, K., Sanders, J., Chauncey, T., Storb, R., Schiffman, K., Benyunes, M.C., Fefer, A., Montgomery, P., Bensinger, W.I.: Rapid engraftment after autologous transplantation utilizing marrow and recombinant granulocyte-colony stimulating factor-mobilized peripheral blood stem cells in patients with acute myelogenous leukemia. Bone Marrow Transplantation 15: 915-922, 1995.

53. Weaver, C.H., Bensinger, W.I., Appelbaum, F.R., Lilleby, K., Sandmaier, B., Brunvand, M., Rowley, S., Petersdorf, S., Rivkin, S., Gooley, T., Weiden, P., Zuckerman, N., Montgomery, P., Trueblood, K., Klamet, J., Buckner, C.D.: Phase I study of high-dose busulfan, melphalan and thiotepa with autologous stem cell support in patients with refractory malignancies. Bone Marrow Transplantation 14: 813-819, 1994.

54. Demirer, T., Gooley, T., Buckner, C.D., Petersen, F.B., Lilleby, K., Rowley, S., Sanders, J., Storb, R., Appelbaum, F.R., Bensinger, W.I.: Influence of total nucleated cell dose from marrow harvests on outcome in patients with acute myelogenous leukemia undergoing autologous transplantation. Bone Marrow Transplantation 15: 907-913, 1995.

55. Demirer, T., Rowley, S., Buckner, C.D., Appelbaum, F.R., Lilleby, K., Storb, R., Schiffman, K., Bensinger, W.I.: Peripheral-blood stem-cell collections after paclitaxel, cyclophosphamide, and recombinant human granulocyte colony-stimulating factor in patients with breast and ovarian cancer. J. Clin. Oncol. 13: 1714-1719, 1995.

56. Langenmayer, I., Weaver, C., Buckner, C.D., Lilleby, K., Appelbaum, F.R., Longin, K., Rowley, S., Storb, R., Singer, J., Bensinger, W.I.: Engraftment of patients with lymphoid malignancies transplanted with autologous bone marrow, peripheral blood stem cells or both. Bone Marrow Transplantation 15: 241-246, 1995.

57. Bensinger, W.I., Clift, R.A., Anasetti, C., Appelbaum, F.R., Demirer, T., Rowley, S., Sandmaier, B.M., Torok-Storb, B., Storb, R., Buckner, C.D.: Transplantation of allogeneic peripheral blood stem cells mobilized by recombinant human granulocyte colony-stimulating factor. Stem Cells 14: 90-105, 1996.

58. Bensinger, W., Appelbaum, F., Rowley, S., Storb, R., Sanders, J., Lilleby, K., Gooley, T., Demirer, T., Schiffman, K., Weaver, C., Clift, R., Chauncey, T., Klamet, J., Montgomery, P., Petersdorf, S., Weiden, P., Witherspoon, R., Buckner, C.D.: Factors that influence collection and engraftment of autologous peripheral-blood stem cells. J. Clin. Oncol. 13: 2547-2555, 1995.

59. Bensinger, W.I., Demirer, T., Rowley, S., Buckner, C.D.: Factors predictive of rapid engraftment after peripheral blood stem cell infusions. Bone Marrow Transplantation 15: S83-S85, 1995.

60. Rowley, S.D.: Standards for bone marrow processing. Bone Marrow Transplantation 15: S40-S44, 1995.

61. Gee, A., Rowley, S., Collins, N.H.: Bone marrow processing - facing the spectre in your laboratory: product evaluation and process regulation. Bone Marrow Transplantation 15: S45-S53, 1995.

62. Attarian, H., Feng, Z., Buckner, C.D., MacLeod, B., Rowley, S.D.: Long-term cryopreservation of bone marrow for autologous transplantation. Bone Marrow Transplantation 17: 425-430, 1996.

63. Rowley, S.: Recombinant human deoxyribonuclease for hematopoietic stem cell processing. J. Hematotherapy 4: 99-104, 1995.

64. Bensinger, W.I., Buckner, C.D., Shannon-Dorcy, K., Rowley, S., Appelbaum, F.R., Benyunes, M., Clift, R., Martin, P., Demirer, T., Storb, R., Lee, M., Schiller, G.: Transplantation of allogeneic CD34+ peripheral blood stem cells in patients with advanced hematologic malignancy. Blood 88: 4132-4138, 1996.

Scott Douglas Rowley M.D.

A. Manuscripts in Refereed Journals

65. Bensinger, W.I., Clift, R., Martin, P., Appelbaum, F.R., Demirer, T., Gooley, T., Lilleby, K., Rowley, S., Sanders, J., Storb, R., Buckner, C.D.: Allogeneic peripheral blood stem cell transplantation in patients with advanced hematologic malignancies: A retrospective comparison with marrow transplantation. Blood 88: 2794-2800, 1996.

66. Demirer, T., Buckner, C.D., Appelbaum, F.R., Clift, R., Storb, R., Myerson, D., Lilleby, K., Rowley, S., Bensinger, W.I.: High-dose busulfan and cyclophosphamide followed by autologous transplantation in patients with advanced breast cancer. Bone Marrow Transplantation 17: 769-774, 1996.

67. Attarian, H., Bensinger, W.I., Buckner, C.D., McDonald, D.L., Rowley, S.D.: Microbial contamination of peripheral blood stem cell collections. Bone Marrow Transplantation 17: 699-702, 1996.

68. Schiffman, K.S., Bensinger, W.I., Appelbaum, F.R., Rowley, S., Lilleby, K., Clift, R.A., Weaver, C.H., Demirer, T., Sanders, J.E., Petersdorf, S., Gooley, T., Weiden, P., Zuckerman, N., Montgomery, P., Maziarz, R., Klamet, J.P., Rivkin, S., Trueblood, K., Storb, R., Holmberg, L., Buckner, C.D.: Phase II study of high-dose busulfan, melphalan and thiotepa with autologous peripheral blood stem cell support in patients with malignant disease. Bone Marrow Transplantation 17: 943-950, 1996.

69. Demirer, T., Buckner, C.D., Gooley, T., Appelbaum, F.R., Rowley, S., Chauncey, T., Lilleby, K., Storb, R., Bensinger, W.I.: Factors influencing collection of peripheral blood stem cells in patients with multiple myeloma. Bone Marrow Transplantation 17: 937-941, 1996.

70. Demirer, T., Petersen, F.B., Bensinger, W.I., Appelbaum, F.R., Fefer, A., Rowley, S., Sanders, J., Chauncey, T., Storb, R., Lilleby, K., Buckner, C.D.: Autologous transplantation with peripheral blood stem cells collected after granulocyte-colony stimulating factor in patients with acute myelogenous leukemia. Bone Marrow Transplantation 18: 29-34, 1996.

71. Bensinger, W.I., Rowley, S.D., Demirer, T., Lilleby, K., Schiffman, K., Clift, R.A., Appelbaum, F.R., Fefer, A., Barnett, T., Storb, R., Chauncey, T., Maziarz, R.T., Klamet, J., McSweeney, P., Holmberg, L., Maloney, D.G., Weaver, C.H., Buckner, C.D.: High-dose therapy followed by autologous hematopoietic stem-cell infusion for patients with multiple myeloma. J. Clin. Oncol. 14: 1447-1456, 1996.

72. Brunvand, M.W., Bensinger, W.I., Soll, E., Weaver, C.H., Rowley, S.D., Appelbaum, F.R., Lilleby, K., Clift, R.A., Gooley, T.A., Press, O.W., Fefer, A., Storb, R., Sanders, J.E., Martin, P.L., Chauncey, T., Maziarz, R.T., Zuckerman, N., Montgomery, P., Dorn, R., Weiden, P.L., Demirer, T., Holmberg, L.A., Schiffman, K., McSweeney, P.A., Maloney, D.G., Buckner, C.D.: High-dose fractionated total-body irradiation, etoposide and cyclophosphamide for treatment of malignant lymphoma: comparison of autologous bone marrow and peripheral blood stem cells. Bone Marrow Transplantation 18: 131-141, 1996.

73. Demirer, T., Buckner, C.D., Storer, B., Lilleby, K., Rowley, S., Clift, R., Appelbaum, F.R., Storb, R., Bensinger, W.I.: Effect of different chemotherapy regimens on peripheral-blood stem-cell collections in patients with breast cancer receiving granulocyte colony-stimulating factor. J. Clin. Oncol. 15: 684-690, 1997.

Scott Douglas Rowley, M.D.

B. Book Chapters

1. Santos, G.W., Saral, R., Burns, W.H., Braine, H.G., Sensenbrenner, L.L., Wingard, J.R., Yeager, A.M., Ambinder, R.F., Rowley, S.D., May, S., Vogelsang, G.B.: Bone marrow transplantation with HLA identical donors in the acute leukemias - Baltimore experience. Minimal Residual Disease in Acute Leukemia, Lowenberg, B. and Hagenbeek, A. (eds.): Martinus Nijhoff, Boston, Mass., 1986.

2. Davis, J., Rowley, S., Dick, J., Braine, H., Charache, P., Saral, R., Sensenbrenner, L., Santos, G.: Bacterial contamination of bone marrow grafts: incidence and clinical significance. Bone Marrow Transplantation, Gee, A.P. and Gross, S. (eds.): Macmillan Press, Ltd. 125, 1987.

3. Yeager, A.M., Rowley, S.D., Kaizer, H., Colvin, O.M., Braine, H.G., Saral, R., Santos, G.W.: Autologous bone marrow transplantation in acute nonlymphocytic leukemia: Studies of ex vivo chemopurging with 4-hydroperoxycyclophosphamide. Bone Marrow Transplantation: Current Concepts, Gale, R.P. and Champlin, R. (eds.): Alan R. Liss, New York, N.Y., 1988.

4. Davis, J., Rowley, S., Santos, G.: Toxicity of autologous bone marrow graft infusion. Progress in Clinical and Biological Research: Bone Marrow Purging and Processing, Gross, S., Gee, A.P., and Worthington-White, D. (eds.): Wiley-Liss, New York, 1990.

5. Noga, S., Wagner, J., Rowley, S., Davis, J., Vogelsang, G., Hess, A., Saral, R., Santos, G.: Using elutriation to engineer bone marrow allograft. Progress in Clinical and Biological Research: Bone Marrow Purging and Processing, Gross, S., Gee, A.P., and Worthington-White, D. (eds.): Wiley-Liss, New York, 1990.

6. Rowley, S., Davis, J., Braine, H., Jones, R., Yeager, A., Saral, R., Santos, G.: Density-gradient separation for 4-hydroperoxycyclophosphamide (4-HC) purging of autologous bone marrow grafts. Progress in Clinical and Biological Research: Bone Marrow Purging and Processing, Gross, S., Gee, A.P., and Worthington-White, D. (eds.): Wiley-Liss, New York, 1990.

7. Rowley, S.D., Davis, J.M.: The use of 4HC in autologous purging. Bone Marrow Processing and Purging, A Practical Guide, Gee, A. (ed.): CRC Press, Boca Raton, 247-262, 1991.

8. Rowley, S.D., Davis, J.: Purging techniques in autologous transplantation. Bone Marrow and Stem Cell Processing, Araman, E., Deeg, H.J., and Sacher, R. (eds.): FA Davis, Philadelphia, PA, 218-291, 1992.

9. Rowley, S.D.: Pharmacological purging of malignant cells. Bone Marrow Transplantation, Forman, S.J., Blume, K.G., and Thomas, E.D. (eds.): Blackwell Scientific Publications, Boston, MA, 14:164-178, 1994.

10. Bernstein, I.D., Andrews, R.G., Rowley, S.: Isolation of human hematopoietic stem cells. Marrow and stem cell processing for transplantation, Lasky, L. and Warkentin, P. (eds.): Am.Assoc.Blood Banks, Bethesda, MD, 209-220, 1994.

11. Rowley, S.D.: Bone marrow stem cells. Scientific Basis of Transfusion Medicine, Anderson, K.C. and Ness, P.M. (eds.): W.B. Saunders, Orlando, FL, 1994.

12. Rowley, S.D.: Standards for hematopoietic progenitor cell processing. Hematopoeitic Progenitor Cells: Processing, Standards and Practice, Brecher, M.E., Lasky, L.C., Sacher, R.A., and Iasitt, L.A. (eds.): Amer Assoc of Blood Banks, Bethesda, 8:183-199, 1995.

Scott Douglas Rowley, M.D.

C. Other Publications

1. Rowley, S.D.: Bone marrow purging, 4-hydroperoxycyclophosphamide, and the FDA (editorial). J. Hematotherapy 2: 289-292, 1993.

2. Rowley, S.D.: Bone marrow transplantation: current controversies (book review). J. Natl. Cancer Inst. 81: 810, 1989.

FRED
HUTCHINSON
CANCER
RESEARCH
CENTER

Robert W. Day, M.D., Ph.D.
President and Director

May 27, 1997

VIA: FEDERAL EXPRESS

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building, Room 615S
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala,

I understand that you have received a declaration from Dr. Scott D. Rowley which was filed by Becton Dickinson and Co./Baxter Health Care in opposition to CellPro's request that the Department of Health and Human Services execute its "march-in" rights to the Civin patents.

Although Dr. Rowley is a faculty member at Fred Hutchinson Cancer Research Center, the views expressed in his declaration are his own and do not represent the views of Fred Hutchinson Cancer Research Center. Fred Hutchinson Cancer Research Center remains firmly committed to the views expressed to you in the letter from me and Dr. Hartwell dated April 25, 1997. For the reasons stated in that letter, Fred Hutchinson Cancer Research Center continues to urge the Department of Health and Human Services to ensure that a commercially reasonable license under the Civin patents is offered to CellPro.

Very truly yours,

Fred Hutchinson Cancer Research Center

Robert W. Day

Robert W. Day, M.D.

cc: Robert Lanman, Esq.
Dr. Harold Varmus

1124 Columbia Street, LY-301 Seattle, Washington 98104 206-667-4302 (FAX) 206-667-5268

From: Amy Ross
To: MURDORD
Date: 5/27/97 1:59pm
Subject: Scott Rowley

Dear Rick:

It is with concern that I read Dr. Scott Rowley's recent declaration regarding his assessment of the CellPro CEPRATE SC and Baxter Isolex SA and 300i CD34+ cell selection systems. Recently (May 1 - 4, 1997) Dr. Rowley and I were invited speakers at the Peripheral Blood Stem Cells '97 Workshop in Tempe, AZ. The workshop, which is designed to provide stem cell researchers and technologists with state-of-the-art training data, was co-sponsored by ISHAGE, Johns Hopkins University, and the University of South Carolina. During an "Ask the Experts" workshop, Mr. Ricardo Sumugod, a stem cell processing technologist at the Canadian Red Cross, Winnipeg, Manitoba, Canada, asked the panel (comprised of Dr. Rowley, Dr. Stephen Noga, Dr. Adrian Gee, and myself) if anyone could provide a comparison of the CEPRATE and Isolex systems. Dr. Rowley responded that purity and yields varied due to a variety of factors, some patient-related and some technology-related. He did state that the new Isolex 300i showed somewhat better purities than the CEPRATE and the Isolex SA. However, he also stated that, from an ease-of-use point of view, his laboratory staff liked the CEPRATE system, as it was more user-friendly. These comments are contrary to those stated by Dr. Rowley in his signed declaration of May 19, 1997. I just wanted to make you aware of these apparently conflicting statements.

Amy Ross
Division of Diagnostic Applications

CC: JACOBC, REITEJM, TARNOJS, CULVELG

FRED HUTCHINSON CANCER RESEARCH CENTER

April 25, 1997

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building, Room 615S
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala,

We are writing to you in support of CellPro's request that the Department of Health and Human Services exercise its "march-in" rights under the Bayh-Dole Act to the Civin patents (U.S. Patent No. 4,965,204, U.S. Patent No. 4,965,680, U.S. Patent No. 5,035,994, and U.S. Patent No. 5,130,144), which are owned by Johns Hopkins University and were developed through government-funded research. We believe that this action is necessary under the circumstances to ensure the availability to the public of a potentially life-saving product for patients with breast cancer, lymphoma, and related cancers.

CellPro was founded in 1989 by Dr. Ronald Berenson, a clinical investigator at Fred Hutchinson Cancer Research Center ("Hutchinson Center") who developed a unique method of isolating and separating stem cells that used an antibody directed to a CD34 antigen. Subsequently, CellPro licensed the Hutchinson Center's rights to the core technology, which was the subject of a pending patent application, and an unpatented anti-CD34 monoclonal antibody designated 12.8. Like the Johns Hopkins technology, both the core technology and the 12.8 antibody were developed with federal grant funding. CellPro has diligently developed this technology into a useful and life saving product. CellPro's Ceparate SC Product, which was approved by the FDA in December of 1996.

As you know, CellPro is involved in a commercial dispute with Becton Dickinson & Company/Baxter HealthCare, the licensees of the Johns Hopkins technology, involving the right to practice the Hutchinson Center and Johns Hopkins technologies. Whatever the merits of the parties respective legal positions in this dispute, none of the parties should be allowed to use patent rights developed with federal funds to prevent a useful and potentially life-saving product from being made available to the public.

1124 Columbia Street Seattle, Washington 98104-2092 206-667-5000

Private ownership of the patent rights at issue was made possible by the Bayh-Dole Act. The purpose of that Act was to promote the commercialization and public availability of inventions made in the United States by United States industry and labor. As a licensor of many inventions based on government funded research, we share the view of many in the research and biotechnology community that the non-judicious use of "march-in" rights of the government could have a chilling effect on commercialization of government funded technology. However, the special rights granted by the Bayh-Dole Act were not intended to be used by commercial entities that benefit from the Act's provision to prevent the public which funded those very rights from having access to useful products. The situation is even more egregious in cases such as this, in which the product involved is not only useful, but potentially life-saving. At a minimum, we believe it is incumbent upon DHHS and NIH to ensure that a commercially reasonably license under the Johns Hopkins patents is offered to CellPro.

Thank you for your consideration of this letter.

Very truly yours,

Fred Hutchinson Cancer Research Center

Robert W. Day, M.D.
President and Director

Leland H. Hartwell, Ph.D.
President and Director Elect