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**UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF DELAWARE**

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| 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, | : | |
| v. | : | |
| CELLPRO, INC., a Delaware corporation, | : | |
| Defendant. | : | |

**DECLARATION OF ANDREW M. YEAGER, M.D.**

**DECLARATION OF ANDREW M. YEAGER, M.D.**

I, Andrew M. Yeager, M.D., do hereby declare:

1. I am Professor and Director, Bone Marrow Transplant/Leukemia Program, Department of Medicine, and Director, Division of Pediatric Hematology/Oncology and Bone Marrow Transplant, of the Emory University School of Medicine in Atlanta, Georgia. A copy of my curriculum vitae is attached hereto as **EXHIBIT A**.

2. I have been using CellPro's CEPRATE® SC stem cell concentrator since 1992, and have been using the device in support of clinical trials since 1994. I have personally performed approximately two dozen stem cell transplants using the CellPro device.

3. I am presently involved in a clinical trial which uses CellPro's CEPRATE® SC stem cell concentrator to prepare transplant suspensions from bone marrow and from mobilized peripheral blood apheresis products from half-matched (haploidentical) parent donors for the treatment of children with high-risk leukemia. The 16 children so far treated in the course of this trial have ranged in age from one year to 16 years, the average age being about 8 years. Each was an end-stage leukemia patient who was judged not to be a candidate for any conventional

therapy and whose prognosis (without transplant) was terminal, with a life expectancy in the range of only a few months. The patients who have been and will be involved in this clinical trial are all patients who lack suitable matched related or unrelated bone marrow donors. Historically, when patients in this situation were treated with unseparated bone marrow from partially- or half-matched relatives, death invariably resulted, either from graft failure or from Graft-Versus-Host Disease ("GVHD") or its complications.

4. The basic concept under study in this trial is to expand the bone marrow or stem cell donor pool (that is, expand the universe of persons who are adequate donors) by using the CellPro CEPRATE® SC stem cell concentrator to prepare suspensions that are enriched for stem and progenitor cells but sufficiently depleted of T-lymphocytes to avoid mortality and reduce morbidity from GVHD.

5. Of the 16 children so far treated in this study, four are still alive and well, without leukemia or GVHD. Three of these are more than two years post-transplant and the other is nearly one year post-transplant. Before the availability of the CellPro device, there simply was no clinically practical technology that would have enabled us to cross the HLA

(histocompatibility) barrier; haploidentical transplant would not have been an option; and all of these children would have died of leukemia within a few months after diagnosis of recurrence. The 25 percent survival (4 of 16 patients) in this trial is similar to what would be expected after BMT from unrelated donors in these high-risk patients.

6. This past winter we initiated another clinical trial involving CellPro's second-generation ("TCD") immunoselection column. This column accomplishes a stem-and progenitor-cell enrichment step using the 12.8 antibody and follows this with a further T-cell depletion step using a CD 2 antibody. Again, the donors are haploidentical parents and the patients are children with end-stage leukemia for whom there are no conventional treatment options available. The aim of the study is to determine whether the further T-cell depletion possible with the CellPro TCD column will result in even further reduction of morbidity from GVHD, without compromise to the speed and reliability of engraftment and without loss of the beneficial "graft-versus-leukemia effect." If for any reason the CellPro TCD device were to become unavailable, this study would need to be shut down. If that were to happen, children would die.

7. In addition to the studies just described, we also have an IDE application (BB-IDE #6918)_which cleared the FDA in January 1997 and which aims at the treatment of children with immunodeficiency diseases and genetic storage diseases (such as sickle-cell anemia and Thalassemia) by transplanting the patients with $CD34^+$ cell suspensions prepared using the CellPro CEPRATE® SC device from GCSF-mobilized peripheral blood cells of haploidentical parents. These investigator-initiated trials will be sponsored in part by a grant from the NIH Comprehensive Sickle Cell Center (NIH Grant No. P60 HL48482, entitled "Georgia NIH Comprehensive Sickle Cell Center").

8. There are a number of reasons why I chose the CellPro CEPRATE® SC stem cell concentrator for use in clinical studies and trials. I regard the CellPro device as a very well-engineered device which is manufactured to high quality-control standards and which performs well in terms of yield, purity, reproducibility of results, and reliability of operation. The device also ranks well, in my estimation, in terms of "user friendliness," which facilitates staff training. In addition, I would rate the quality of technical support from CellPro as superb. In my experience, the company's technical personnel have

not only been very knowledgeable but also highly accessible to us.

9. It is my belief that if the CellPro immunoseparation columns involved in our trials and studies were to become unavailable, patients would die. Even if there are applications for which an alternate immunoselection device might be adequate, a switchover to such a device could not be accomplished without substantial delay. I would estimate that months of legal, regulatory and institutional work would need to be done to get a new device on track, and this delay would be fatal to the children involved in our haploidentical parent-to-child leukemia transplant studies, who are not candidates for non-immunoselected stem cell transplant and whose life expectancies (if untreated) are too short for any significant delay to be tolerable in their cases. In addition, our staff has made a large investment of time and effort to become experienced in the use of the CellPro device, and we have ongoing clinical trials that rely on it. To change over to a different immunoselection device (assuming that there is a practical alternative) would entail not only delay but also waste of effort and research funds.

10. It is not clear that switching from one device to another in mid-trial would even be permitted by the FDA. Even if the FDA did not require that we discard data gathered using the CellPro device and begin anew, it would still be undesirable, from the standpoint of sound scientific methodology, to make a substitution of such an important piece of equipment in the midst of a trial.

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

Executed at Atlanta, Georgia, this SECOND day of April 1997.

Andrew M. Yeager

Andrew M. Yeager, M.D.

(updated 31 March 1997)

**CURRICULUM VITAE**

**Name** Andrew Michael Yeager

**Appointments**

University:

Professor of Pediatrics
Emory University School of Medicine

Professor of Anatomy and Cell Biology
Emory University School of Medicine

Professor in the Winship Cancer Center
Emory University School of Medicine

Professor of Medicine
Emory University School of Medicine

Professor of Neurology
Emory University School of Medicine

Director, Division of Hematology/Oncology and Bone Marrow Transplantation
Department of Pediatrics
Emory University School of Medicine

Director, Bone Marrow Transplantation/Leukemia Program
Department of Medicine
Emory University School of Medicine

Hospital:

Director, Bone Marrow Transplant and Leukemia Services
Emory University Hospital

Physician, Hematology/Oncology and Bone Marrow Transplantation Service
Egleston Children's Hospital at Emory University

Active Medical Staff, Emory University Hospital

Active Medical Staff, Egleston Children's Hospital at Emory University

Active Medical Staff, Grady Health System