IN THE 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,	)	
Plaintiffs,	)	Civil Action No. 94-105-RRM
v.	)	
CELLPRO, a Delaware corporation,	)	
Defendant.	)	

DECLARATION OF DR. BONNIE J. MILLS

Submitted by:

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Dated: April 28, 1997

DECLARATION OF DR. BONNIE J. MILLS

I, Bonnie J. Mills, Ph.D., hereby declare:

1. I am the Assistant Director of Clinical Research in Baxter's Immunotherapy Division. I have personal knowledge concerning the preparation of the clinical protocols that support Baxter's premarket approval application ("PMA") to the FDA for approval to begin commercial sales of the Isolex® 300 Stem Cell Separation System. In addition, I was personally involved in the preparation of the PMA submission, which was filed with the FDA on February 24, 1997.

2. Baxter's PMA submission is directed to use of the Isolex® 300 System in autologous transplant patients. It is supported by data from from a pivotal, controlled randomized clinical trial. This study was designed to evaluate engraftment in breast cancer patients following transplant of isolated CD34+ cells or unselected peripheral blood stem cells ("PBSC") for hematologic support after myeloablative therapy. The submission also presents data in support of the autologous transplant indication from uncontrolled nonrandomized studies, including two other PBSC transplant studies. These studies were conducted under FDA-approved Baxter-sponsored investigational device exemptions ("IDEs"). The FDA has also received data in support of autologous transplantation using the Isolex® 300 System from a bone marrow transplant clinical trial conducted under an FDA approved, investigator-sponsored study.

3. Baxter has also sponsored IDE studies of the Isolex® 300 System for other indications, including allogeneic bone marrow and stem cell transplants. In 1996, the FDA approved a pivotal, controlled randomized study of the system for allogeneic transplants.

4. In 1996, Baxter introduced an enhanced version of the Isolex® 300

System, called the "300i", which automates most of the cell processing to make the system faster and easier to use. All of the Baxter-sponsored-IDE sites in the United States have now substituted the 300i for the earlier model (sometimes referred to as the "300 SA."), retaining the 300 SA version as a back-up. To permit substitution of the 300i, Baxter amended the applicable IDEs. This amendment did not raise any new issues of safety or efficacy, and the amendment was made without objection from the FDA. Baxter expects to amend or supplement the PMA to cover the 300i, or else to file a separate PMA for the 300i later this year.

5. Contrary to CellPro's assertions, the timing of Baxter's filing of its PMA was unrelated to the pendency of the CellPro trial. The filing of the PMA grew out of discussions at a meeting with the FDA in May 1996, after which Baxter made the decision to go forward with a PMA, which it hoped to file by the end of 1996. During the fall of 1996, Baxter engaged in an interactive process with the FDA to assure the FDA's acceptance of Baxter's proposed statistical analysis of randomized clinical data before undertaking that analysis. These discussions addressed the primary endpoint criterion for clinical evaluation and the statistical methods and model to be used to demonstrate achievement of the endpoint. The discussions also covered methods of monitoring and data collection to assure validity of the data. During these conferences, the statistical model was discussed in detail, and the clinical data that served as the basis of the model was shared with the FDA staff. Baxter waited to perform the actual data analysis until it was confident its proposed methodology was acceptable to the FDA.

6. In November, the FDA accepted in principle Baxter's statistical model

and its plan to rely upon statistical analysis of data from the randomized breast cancer study as the basis for PMA approval. Baxter proceeded with the data analysis, and filed the PMA as soon possible after the analysis was finished and its assembly of supporting information for the PMA was complete. The PMA submitted by Baxter on February 24, 1997 consists of 56 volumes of supporting text and data, totaling just under 20,000 pages of information. It most certainly was not prepared hastily for an "eve of trial" submission, as I understand CellPro alleges.

7. Baxter's approach, involving extensive advance discussions with the FDA concerning Baxter's clinical data and its proposed statistical model for data analysis paid off earlier this month. By letter dated April 9, 1997, the FDA formally accepted Baxter's PMA submission as sufficient to permit substantive review as is, with February 24 as the filing date. As we understand it, the PMA will go through a review cycle of approximately six months. Consistent with this understanding, the FDA has advised Baxter that it will conduct a mid-cycle review meeting concerning Baxter's PMA in May. We believe, based upon our informal discussions with FDA staff, that the PMA is on track for approval by the end of 1997.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 28th day of April, 1997

Bonnie J. Mills

Bonnie J. Mills, Ph.D.

CERTIFICATE OF SERVICE

I, Joanne Ceballos, hereby certify that on this 28th day of April, 1997, copies of the within document were caused to be served on the attorneys of record at the following addresses as indicated:

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