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August 23, 2004

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: [Docket No. 2004D-0-193]

Dear Madams and Sirs,

I am writing this letter strongly supporting the comments submitted by The American Association of Tissue Banks to the Draft "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps)". As a member of the Reproductive Council of the AATB, I was involved in drafting the comments submitted to the FDA from the AATB. Great thought and care went into drafting these comments and I feel that they are reasonable and deserve fair consideration by the FDA.

As a member of AATB, I have supported FDA regulation of reproductive cells and tissues. I feel that the comments submitted to FDA by the AATB raise important issues that will impact the safety and availability of tissue to the public. Thank you in advance for your review of our comments.

Sincerely,

A handwritten signature in black ink that reads "Russell Bierbaum". The signature is written in a cursive style with a large initial 'R'.

Russell Bierbaum
President

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Protection for the future through cryopreservation