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8/20/04

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

RE: *Docket No. 2004D-0193: Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*

To whom it may concern:

We would like to submit comments on behalf of The Sperm Bank of California (TSBC) regarding the Food and Drug Administration's draft Guidance for Industry "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)." Since 1982 our sperm bank has been a leader in creating high standards for the sperm banking industry. We have worked closely with the Department of Health Services in California in creating mandated standards for the banking of reproductive tissue. We have never had an incidence of disease transmission in 22 years. With this history in mind, TSBC strongly urges the FDA to make the following changes to the donor screening section (III.E.1.) in the draft guidance document:

We are deeply concerned with the safety of the sperm samples we provide our recipients and we support the inclusion of low-risk men who have sex with men as anonymous sperm donors. Unlike most other human tissues, sperm can be frozen and quarantined for a length of time well beyond the seroconversion window period, after which the donor can be retested for HIV and other STDs prior to the release of any tissue. This HIV testing and 6 month quarantine system is extremely reliable and accurate, allowing a measure of safety beyond that possible in testing most tissue donors.

We question the scientific rationale for declaring as ineligible all men who have had sex with men in the past five years. Five years is both significantly beyond the window period for HIV (now recognized to be less than six months) and five times longer than most other exclusions in the guidance document. Additionally, excluding all men who have had sex with men, regardless of individual risk behavior, is a population-based approach to screening that will rule out many low-

risk, healthy, HIV-negative men. Evaluating each individual's behavior, rather than whether they belong to a specific subpopulation, seems to us to be a more appropriate way to identify those at increased risk. One example of guidelines based on individual behavior are those developed by the HIV Medicine Association of the Infectious Diseases Society of America. The Association recommends that the FDA should prohibit blood donation by any individual who:

(1) has tested positive for HIV;
(2) has used illicit drugs within the previous 12 months;
(3) has had a needle stick exposure to someone else's blood within the previous 12 months; or
(4) in the previous 12 months, has had unprotected oral, vaginal, or anal sexual intercourse with:
    - An individual with HIV,
    - An individual known to use illicit drugs, or
    - An individual of unknown HIV status outside of a monogamous relationship

While these guidelines were developed for screening blood donors, we believe a similar approach would be effective in screening sperm donors. We urge you to consider recommending a screening protocol like this one that screens potential donors on the basis of individual risk.

We share the FDA's goal of protecting the health of cell and tissue recipients and we commend you for acknowledging that the guidance document represents only one of many possible legitimate approaches to donor screening. Even if the proposed guidance is not changed, we expect the FDA will recognize that a tissue bank may follow alternative donor screening as approved by the bank's medical director, and used in combination with the required testing, to satisfy the requirements of the new donor screening regulations.

Thank you for your consideration of the above-mentioned items. Please feel free to call on us for any assistance we may provide as you consider suggested revisions.

Sincerely,

Lorraine Bonner, MD
Medical Director
The Sperm Bank of California

Alice Ruby, MPH, MPPM
Executive Director
The Sperm Bank of California

Attachment: References

References:

RE: HIV and Hepatitis B window period for seroconversion:

L. R. Petersen et al., Duration of Time from Onset of Human Immunodeficiency Virus Type 1 Infectiousness to Development of Detectable Antibody, *Transfusion* 1994; 34: 283.

C. A. Ciesielski et al., Duration of Time Between Exposure and Seroconversion in Healthcare Workers with Occupationally Acquired Infection with Human Immunodeficiency Virus, *American Journal of Medicine* 1997; 102(5B):115.

S. Lindbäck et al., Diagnosis of Primary HIV-1 Infection and Duration of Follow-up After HIV Exposure, *AIDS* 2000; 14: 2337.

Centers for Disease Control and Prevention, Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients, *Morbidity and Mortality Weekly Report* 2001; 50 (No. RR-5): 2-9, 11-12.

RE: Rarity of testing error

M.P. Busch et al., False-Negative Testing Errors in Routine Viral Marker Screening of Blood Donors, *Transfusion* 2000, 40:585-589.

M.J. Roy et al., *Absence of True Seroreversion of HIV-1 in Seroreactive Individuals,* JAMA 1993; 269(22): 2876-2879.

Human Cells, Tissues and Cellular and Tissue-Based Products: Risk Factors for Semen Donation, BPAC Meeting, Hilton Silver Spring Hotel, December 14, 2001, testimony of George Schreiber ("Testing error is very small, and with the quarantine, . . . it's reduced almost to zero.").