

BLOOD PRODUCTS ADVISORY COMMITTEE MEETING

TOPIC III. Human Cells, Tissue and Cellular and Tissue-Based Products: Risk Factors for Semen Donation

**December 14, 2001
Gaithersburg Hilton, 620 Perry Parkway
Gaithersburg, MD 20877**

SUMMARY OF ISSUE:

- FDA is in the process of completing rulemaking and drafting guidance aimed at preventing the spread of communicable disease by human cells, tissues, and cellular and tissue-based products. These rules and guidance will apply to semen banking.
- FDA published a proposed rule, entitled "Suitability Determination for Donors of Human Cellular and Tissue-Based Products" on Sept. 30, 1999 (64 FR 52696). The comment period closed on July 17, 2000. This proposed rule would apply to donors of semen.
- FDA has proposed that establishments be required to screen and test semen donors who are not intimate sexual partners of the recipients. Screening entails asking potential donors specific questions to reveal risk factors for and clinical evidence of infection due to relevant communicable disease agents or diseases. Although the proposed rule did not specify risk factors, commenters anticipated that one of the risk behaviors that the agency would identify for male donors was having had sex with another man within the previous five years.
- The proposed rule would require testing for HIV-1 and 2, HBV, HCV, syphilis, HTLV-I and II, CMV, Chlamydia trachomatis and Neisseria gonorrhoea. FDA also proposed to require that donations of reproductive cells and tissue that can be reliably stored be cryopreserved in quarantine for 6 months, at which time the donor would be re-tested. This is consistent with CDC guidelines (Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs, May 20, 1994), and industry's voluntary standards (American Society for Reproductive Medicine Guidelines for Gamete and Embryo Donation, October 1998).
- Under the proposed rule, semen donations of anonymous donors (donors unknown to the recipient) would be released only if the screening and testing results were all negative (i.e., the donor had not engaged in risk behaviors, and blood tests taken before and after the quarantine period did not show the presence of the infectious agents). For directed donors, positive results would not preclude donation, provided that the risks were explained to the recipient and she gave informed consent.

- The agency has received many comments criticizing its proposed requirement for six month cryopreservation and quarantine of semen from directed donors (a donor who is known and requested by the female recipient, but is not her sexually intimate partner), and its proposed recommendation that men who have had sex with other men within the previous five years not be accepted as anonymous semen donors.
- The September BPAC meeting will include presentations of scientific data and information relating to these issues. FDA believes that a scientifically rigorous review in a public forum will allow it to better evaluate and respond to these comments. Speakers will present data on incidence and prevalence of HIV, HBV, and HCV in certain risk groups as compared to the general population, current practices in semen banking, risks of and actual transmissions of sexually transmitted diseases by artificial insemination, HHV-8 as an emerging pathogen, window period risk, semen cryopreservation techniques, and comparison of pregnancy rates using fresh vs. cryopreserved semen for artificial insemination.
- Several individuals who submitted comments to FDA will present data and information during the open public hearing. Following a public discussion, FDA will ask the committee members the following questions:
 1. Is safety increased when cryopreserved semen is quarantined and the donor is re-tested after at least six months?
 2. As compared with the use of fresh semen, does use of cryopreserved semen for artificial insemination reduce pregnancy rates? If so,
 - 2a. What is the estimated reduction in pregnancy rates?
 - 2b. Are there procedures for cryopreservation and/or for insemination that can improve the pregnancy rates using cryopreserved semen? If so,
 - 2c. What are the benefits and risks of these procedures?
 3. Are there existing data that identify subsets of men who have had sex with other men, in which the incidence and prevalence rates for HIV, HBV, and HCV of the subsets are similar to the population at large? If so,
 - 3a. Are there questions that could be asked to potential donors that would accurately identify members of these subsets to the exclusion of all others?