



AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

Formerly *The American Fertility Society*

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April 28, 2005

Jesse L. Goodman MD, MPH
Director
Center for Biologics Evaluation and Research
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Pending Implementation of Donor Testing Requirements for Reproductive Tissue

Dear Dr. Goodman:

Thank you for taking time to meet with representatives of the American Society for Reproductive Medicine ("ASRM") and the Society for Assisted Reproductive Technology ("SART") on April 25, 2005, to discuss the upcoming implementation of FDA's Eligibility Determination of Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 21 CFR 1271.45, *et seq.* ASRM and SART seek a stay of the 7 day testing rule for the reasons set out in our April 19, 2005 letter to you and the reasons we discussed on April 25. We believe the meeting was very productive and thank you for your continued willingness to examine the difficult issues concerning application of the communicable disease provisions of the Public Health Service Act to reproductive tissues.

This letter briefly supplements our April 25 conversation and provides support for the issues we discussed. As you know, ASRM and SART remain concerned about the potential impact of the 7 day donor testing rule on egg and oocyte donation. We agree that all donors should undergo standardized infectious disease screening and a thorough risk assessment. But, the 7 day rule will require repeat testing that could substantially reduce the availability of donated embryos and oocytes. As we discussed, this is the case for a variety of reasons including false positive test results, laboratory error, and broken or lost samples. All of these

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require re-testing which would likely occur outside the 7 day window – thus eliminating the option of using the tissue at issue.

Additionally, we discussed the fact that ASRM and SART have developed voluntary guidelines that ensure appropriate donor screening while minimizing the testing burden for oocyte and embryo donors. Although we will likely revise the guidelines based on FDA's final regulation, we briefly summarize them here for your information.

ASRM Guidelines for Gamete and Embryo Donation outline recommended testing and screening for donors in the United States. They do not address the timing of testing because there is little risk of transmission of infectious diseases through reproductive tissue. In addition to physical and psychological examination, ASRM recommends oocyte donors be screened for syphilis, hepatitis B, hepatitis C, gonorrhea, Chlamydia, cytomegalovirus, and human immunodeficiency virus 1 (HIV-1) and 2 (HIV-2). ASRM, *Guidelines for oocyte donation* (June 2002) at III.D, VII.B. In addition, a personal and sexual history should be obtained to exclude as donors individuals who may be at a high risk of sexually transmitted infections. *Id.* at VII.A.

Embryo donors whose embryos are the product of their own biological gametes must provide a medical and genetic history, including information on risk factors for HIV and transmissible spongiform encephalopathy (TSE). ASRM, *Guidelines for cryopreserved embryo donation* (June 2002) at II.A. Embryo donors should be screened for HIV-1, hepatitis B, hepatitis C, and syphilis at the time of IVF treatment and retested for HIV-1 after 6 months.¹ *Id.* at II.E. Embryos will not be transferred if a donor fails to undergo appropriate infectious disease testing. *Id.*

We also discussed the percentage of in vitro fertilization (IVF) couples who later donate embryos for use by others. According to research conducted by SART and the RAND's Health & Law Initiative, there are approximately 400,000 embryos that have been frozen and stored since the late 1970s. Hoffman, DI, et al, *Cryopreserved Embryos in the United States and Their Availability for Research*, *Fertility and Sterility* 79 (5): 1063-69. Of these, 2.3 percent are available for donation to another patient. *Id.* 88.2 percent are being held for the donor's "family building" and 2.8 percent are made available for research. *Id.* As we discussed in our April 19, 2005 letter

¹ In the case of the death of one of the partners, embryos may be transferred to recipients without postquarantine donor testing so long as the donor underwent infectious disease testing as part of the initial in vitro fertilization evaluation. This exception does not apply when the donor's death may be attributable to HIV, hepatitis, a sexually transmitted disease, or TSE.

to you and during our meeting, under FDA's regulation the vast majority of these embryos will not be available for donation under the 7 day testing rule.

Although the number of donated embryos may seem small, this option is particularly important to couples who have ethical concerns about embryo destruction. The availability of donated embryos is also an attractive "family building" strategy for couples who cannot afford extensive IVF treatment. Consequently, we believe that embryo donation should continue to be available to those seeking assisted reproductive services. Without this option, which we fear the 7 day rule will reduce dramatically, couples could face substantial ethical and financial choices with potential moral and political ramifications. Fortunately, regulatory alternatives exist that should meet the agency's concerns about the potential transmission of communicable diseases.

Thank you, again, for taking the time to discuss these issues with us on April 25, 2005. Please don't hesitate to contact anyone at ASRM or SART should you need additional information or assistance.

Sincerely,



Eric S. Surrey, MD
President, SART



Sean Tipton, MA
Director of Public Affairs, ASRM

cc: Diane Maloney, CBER, Associate Director for Policy
Catherine Cook, Esq., Office of the Chief Counsel