

**Atlanta Center for Reproductive Medicine, LLC**  
*Reproductive Endocrinology ♦ Gynecology ♦ Infertility*

*Lisa A. Hasty, M.D., F.A.C.O.G.*  
*André L. C. Denis, M.D., F.A.C.O.G.*

*Chad A. Johnson, PhD, HCLD*  
*Director-IVF and Reproductive*  
*Studies Laboratories*

*Steven C. Gerson, C.P.A.*  
*Chief Financial Officer*

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5360 Fishers Lane Room 1061  
Rockville, Maryland 20852

To Whom it May Concern:

I am writing to respond to the proposed rules regarding "Suitability Determination for donors of Human Cellular and Tissue-based Products". According to the proposed rules, medical practices performing IVF and offering anonymous donor oocytes would be required to first produce embryos, then quarantine the embryos for 6 months until the oocyte donor could be retested. This rule would place an unacceptable burden on both the patient and the medical practice for the following reasons:

1. There is no evidence that oocytes, embryos or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the proposal. HIV and other infectious agents are not passed by IVF-ET. To date, HIV has never been contracted from IVF as far as anyone knows.
2. Quarantining embryos will significantly increase costs and increase the number of attempts needed to achieve pregnancy. This could cost some patients additional thousands of dollars.
3. It is well documented that frozen embryo pregnancy rates are lower than with fresh transfer, in some programs by as much as 50%. This decrease in pregnancy rate would and should be unacceptable to patients.
4. With approximately 10-20% of embryos not surviving the freezing/thawing process, thousands of embryos (potential babies to infertile patients) will not be available to patients.

*Towne Lake Overlook, 100 Stone Forest Drive, Suite 300, Woodstock, Georgia 30189*  
*Telephone 770-928-2276 Fax 770-592-2092*  
*E-Mail Info@ACRM.com*

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Given the above facts, most specifically that IVF has not been shown to be a vector for disease transmission, the rule to mandate quarantine of donor oocyte-produced embryos is flawed and should not be adopted. When considering such regulation, it would be prudent to work with the organization which will be most affected by these actions, namely, ASRM (professional organization) and an advocacy group for patients (such as Resolve).

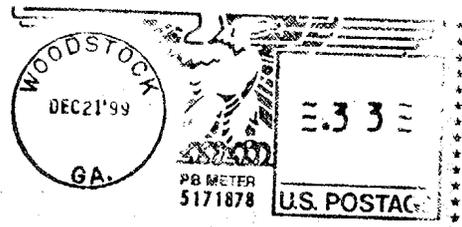
While the bulk of the regulations are welcome and necessary, this one is not.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chad A. Johnson', with a long horizontal flourish extending to the right.

Chad A. Johnson, PhD, HCLD  
Director of Reproductive Laboratory Services

Atlanta Center for  
Reproductive Medicine  
100 Stone Forest Dr., Ste 300  
Woodstock, GA 30189



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