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December 22, 1999

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

Dear Sir or Madam:

As an infertility specialist who has dealt with thousands of infertile patients, I read the proposed guidelines for donor egg IVF cycles with dismay. This is a poorly considered recommendation which has significant negative impact on clinical practice. There is no evidence that oocytes, embryos, or isolated sperm cells used with assisted reproductive techniques are vectors for the diseases listed in the FDA proposal. There has never been evidence that HIV or other infectious diseases have been transmitted through IVF or other assisted reproductive procedures. IVF has proven its safety. Since the first IVF birth in 1978, there has never been a single transmission of HIV through this technique.

Freezing embryos results in a **significant** decrease in viability and reduction in pregnancy rates. In our own program, we have about a 35-40% conception rate in good prognosis patients. After cryopreservation and thaw of embryos, rates go down to less than 10%. Additionally, a larger percentage of embryos do not survive freezing, therefore, mandated freezing is a death sentence for some embryos which would, otherwise, have achieved live birth.

In summary, IVF using donor oocytes is a very different procedure than is insemination with donor sperm, in which the volume of biological material is significantly higher and there is an inability to reduce the risk of viral transmission. The FDA is interfering with the practice of medicine by attempting to require quarantining of embryos resulting from donor egg IVF. There is no scientific

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justification for these recommendations. Quarantining would increase costs, decrease success rates, increase the death rate of embryos and results in subsequent decline in pregnancy rates, as well as increased anxiety and cost for patients.

Thank you, so very much, for your attention to this matter.

Sincerely,

Charla M. Blacker MD

Charla M. Blacker, M.D.

Assistant Professor and Associate Director

Assisted Reproductive Technologies

Division of Reproductive Endocrinology and Infertility

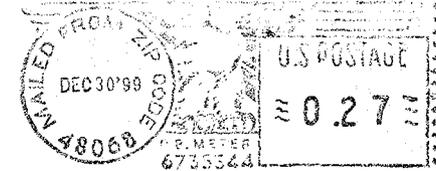
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