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December 8, 1999,

Docket Management Branch (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, Room 106 1,
Rockville, MD 20852

Reference: Comments on the proposed rule for suitability determination for donors of human cellular and tissue-based products (docket no 97N-484S).

Dear Sir or Madam:

My comments are mainly directed to Sec. 1271.60. Quarantine pending determination of donor suitability.

I will discuss at length why mandating to store embryos for six months in quarantine is not a good idea. The rule will have extremely detrimental effect on donor oocyte programs in general and the oocyte recipients in particular.

The patients who opt to receive oocyte donation are usually those women who failed to have children during their childbearing years. They have suddenly come to the realization that they are running out of time to bring up children and put them through school. The only option they have is to use donor oocytes; a difficult decision made after a lot of thinking. They have to come up with a great deal of money since the insurance does not pay for these cycles. Now we require them to freeze these embryos for six more months before they can implant them! Most women will not go for oocyte donation. I know this to be the truth because of my experience. We have for last many years given the recipients the option of freezing the embryos and using them after six months quarantine. Despite the fact that the patients

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clearly understood that it would be safest to ascertain that the donor was not infected at the time of oocyte donation, NONE of the hundreds of recipients who went through the program agreed to go for this option.

This rule will do disservice to the patients and their interests. If you really want to help them and do what is in their best interest why not poll all the recipients that go through the program. Find out what are their wishes rather than imposing this requirement on them.

Semen quarantine makes sense because semen can be frozen successfully and is available from sperm banks on demand. When the technology for successfully freezing oocytes becomes available, and it will, you can make donor oocyte quarantine mandatory. Furthermore, kidney and liver donations are not required to be quarantined. Why discriminate against embryos?

Then again there are potential recipients whose beliefs and/or religion does not allow them to freeze embryos. Why are they being penalized? This is not a hypothetical scenario. We who deal with oocyte donation cases come across such instances all the time.

One little fact not considered by the lawmakers is how are you going to force the donors to come and be retested? We regularly have problems tracking down the donors. They move, they change their mind about cooperating with the donor programs. What will you do with the embryos if such is the case? What happens if the donor dies before she can be tested? Sperm and oocytes can be discarded but what about embryos? A couple has invested money and emotions in those embryos and the husband considers them his potential offspring (after all his sperm was used in fertilizing the donor oocytes). The law is going to make a great deal of unhappiness and trouble for everyone involved.

To-date thousands and thousands of oocyte donations have been performed. No center has reported sero-conversion in a single case. Furthermore, many donors are in the donor program for about 2 to 3 years and retested every six months. We have not seen any donor become positive for any of the screened diseases mandated by the state of New York. This strongly implies that the present method is highly effective in selecting safe donors for the oocyte donor programs. Surely there is a slight risk involved

but the answer does not lie in mandating embryo quarantine. We have to wait until successful oocyte freezing becomes available.

Sincerely:

Kantilal H Thanki Ph.D.

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