



National Embryo Donation Center

November 18th, 2004

Tommy G. Thompson
U.S. Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Mr. Thompson,

The FDA is planning to mandate that all embryos developed after May 1, 2005 fall under the regulations for all HCT/P's (human, cellular, and cellular and tissue-based products). These new regulations will have the effective impact of shutting down the practice of embryo donation and adoption in this country. The document which will mandate these changes is published in the Federal Register at <http://www.fda.gov/cber/rules/suitdonor.pdf>.

The number of infertile couples who would be denied treatment by these regulations is large, and there is at present no evidence of a public health hazard which needs to be addressed concerning embryo donation.

A careful review of this issue and the proposed regulations allows one to suggest a number of better alternatives. Unfortunately, once the regulations are final, it will be extremely difficult to implement these alternatives.

The National Embryo Donation Center is a nonprofit organization formed through an alliance of one of the nation's largest medical groups (the Christian Medical Association), the country's largest provider of adoption services (Bethany Christian Services), and Baptist Health Systems of East Tennessee. *We urgently request that you assist us in delaying the implementation of the proposed guidelines as they apply to human embryos until we can determine a satisfactory solution to this issue.* I would like to request a meeting with you or a staff member at your earliest convenience to discuss this matter. I look forward to your response.

Sincerely,

Jeffrey A. Keenan, M.D.
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Nov 19, 2004 15:19:55 WS# 06
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Problems with the proposed FDA guidelines as they apply to human embryo donation

- 1) There have been no documented cases of infectious disease transmission after transfer of cryopreserved human embryos. Therefore, a danger to public health has not been shown. It is unreasonable to eliminate a viable healthcare alternative for infertile women based simply on "biologic plausibility".
- 2) It would be virtually impossible for healthcare practitioners to perform the testing and screening outlined in the proposed guidelines from both a time and cost perspective.
- 3) Most couples who donate embryos only do so years after the initial IVF procedure. It is unreasonable to ask them to undergo extensive testing and screening for a process that may never be an option for them, i.e. embryo donation.
- 4) It has never been shown that some of the infectious agents in the proposed guidelines can even survive liquid nitrogen, and it is most likely that they cannot.
- 5) As for the other agents, most of them are exceedingly rare in IVF patients. It would appear that the risk of serious harm or death from embryo donation/adoption would be far less than the risk of alternative infertility treatments, and far less than pregnancy and childbirth. It is not reasonable to restrict a procedure based on potential 'risk' when the outcome of the procedure carries even more risk but is not restricted.
- 6) Rather than implement the proposed guidelines, centers which perform embryo donation should be required to monitor all patients for a period of years after the procedure to determine if a risk is present. Other precautions can also be taken during that period to minimize potential risk.

Endorsed by the Christian Medical & Dental Associations