

## ALLEGHENY GENERAL HOSPITAL IVF PROGRAM

One Allegheny Square Suite 280 Pittsburgh, PA 15212 412/359-1900

Anthony N. Wakim, M.D., Medical Director

1999 JAN -5 AIO :44

December 27, 1999

To: Whom it May Concern

Re: Docket # 97N-484S: "Suitability Determination for Donors of Human Cellular and Tissue-Based Products"

From: Anthony N. Wakim, M.D.

Medical Director; Director of Reproductive Endocrinology and Infertility  
Allegheny General Hospital IVF Program

I would like to respond to the new rules proposed by the FDA in the above referenced docket, which would dictate how reproductive medicine practices choose to treat patients undergoing embryo transfer from donated oocytes. These new rules are clearly unnecessary, and would represent a significant intrusion by the government in our medical practice which would increase expense and cause poorer outcomes among couples already reproductively challenged.

In 21 years of IVF, with 15 of them using donated oocytes, there has never been a documented case of transmission of an infectious disease such as Hepatitis B or C or HIV. In our practice, as I believe it is customary in most, patients are informed of the as yet theoretical risk of infectious disease transmission with the transfer of fresh embryos from donated oocytes, and given the option of quarantining frozen embryos and recalling the donor for testing. To date, not a single couple has chosen this option, and for good reason: there are no reported cases of transmission of Hepatitis B or C or HIV in this country as a result of these procedures; and, transfer of frozen embryos provides a lower pregnancy rate, which is unacceptable to couples spending in excess of \$12,000 for donated oocytes. Many assisted reproductive technologies are still uncovered by medical insurance, meaning most couples pay large sums of money out of pocket for the "privilege" of creating a family, a basic function which most Americans take for granted. To have the FDA invade this private matter in this way is yet another slap in the face for these couples, inflicting additional emotional and financial stress.

In our practice, transfer of fresh embryos from donated oocytes affords approximately a 50% chance of pregnancy. If these embryos are frozen, the pregnancy rates drop to the low 30% range (variable according to what type of insemination technique is used, for those couples also suffering from male infertility). Embryos will die in the freeze/thaw process, representing an unnecessary loss of potential human lives. In our practice, we would estimate the financial cost of this intrusion, by legislating a 6 month waiting period and rescreening the oocyte donor to be about \$750.00. However, there are costs to be considered which are not only financial. The added stressor of time, for couples who are already on the fringe of "normal" reproductive ages, making these women older at the time of pregnancy and childbirth, must be a consideration. Most of these couples are long-term

97N 484S

C399

infertility patients who have exhausted all their other options for creating a family from their own genetic material. Also, please consider what would happen if a donor were to die unexpectedly during the quarantine period, or was lost to follow up and not able to be retested? These couples would have spent an enormous amount of money and emotional energy which would be for naught, because according to the proposed rules, without retesting, the embryos would not be considered "suitable for transfer." I personally, from working with these couples on a daily basis, cannot imagine a situation as tragic.

If the government insists on enacting these objectionable, unnecessary, and unacceptable rules to "protect" these citizens who have no use for these rules, then we must also enact legislation to help these couples: mandatory insurance coverage for infertility (since the government is going to make it more expensive, more difficult, and more time-consuming to achieve results) and greater access for all couples, including those over 40 years old, who wish to adopt infants to create a family.

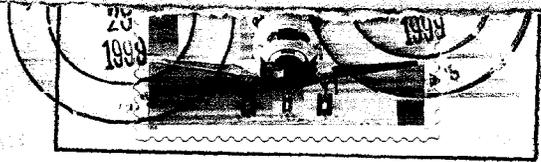
Our government has time and again shown a deaf and unsympathetic ear to the plight of infertile couples. Not until one must travel this difficult path, can one understand the intense pain and difficulty of achieving this basic life function. It is not reasonable, humane, or appropriate, that the government should intervene in the medical treatment of these couples, especially when there is not one shred of proof that this intrusion is warranted. Please, please reconsider these proposed rules and do away with the requirement to quarantine embryos from donated oocytes until the donor is retested for infectious diseases.

Sincerely,



Anthony N. Wakim, M.D.  
Medical Director  
Allegheny General Hospital IVF Program  
Director, Division of Reproductive  
Endocrinology and Infertility  
Associate Professor,  
MCP/Hahnemann University Medical School  
Allegheny University of the Health Sciences  
Allegheny Campus

0-222-1811



www.usps.gov

AGH-IVF PROGRAM  
1 ALLEGHENY SQ. SUITE 280  
PITTSBURGH PA 15212

DOCKETS MANAGEMENT BRANCH (HFA-305)  
FOOD AND DRUG ADMINISTRATION  
5360 FISHERS LANE ROOM 1061  
ROCKVILLE, MD 20852

**The efficient FLAT RATE ENVELOPE.**

You don't have to weigh the envelope... Just pack all your correspondence and documents inside and pay only the 2 lb. Priority Mail postage rate.

**We Deliver.**