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Risks to women in embryo cloning

By Judy Norsigian | February 25, 2005 Boston Globe

THERE IS a disturbing lack of attention to the risks to women's health posed by the advent of embryo cloning. Media coverage continues to convey the idea that the only ethical debate is over the issue of destroying embryos and that the primary voices in this debate are the antiabortion advocates (who usually oppose all embryo stem cell research) and those who endorse all types of stem cell research, including embryo cloning. When women's health advocates are mentioned, their positions are usually misstated.

In fact, women's health advocates like us *do* support most embryo stem cell research and also support the use of otherwise-discarded embryos from fertilization clinics. However, we have deep reservations about the embryo stem cell research that involves somatic cell nuclear transfer. Also referred to as embryo cloning, research cloning, or "therapeutic" cloning, this type of research is specifically called for in the recent legislation introduced in Massachusetts.

Omitted from the polarized debate is any discussion of the thousands of women who will need to undergo egg extraction procedures for such embryo cloning. A primary concern is the substantial risks to women's health posed by the extraction procedure and the inability to obtain true informed consent from egg donors given the current lack of adequate safety data.

These concerns are shared by a former chief medical officer of the Food and Drug Administration, Dr. Suzanne Parisian, a former researcher in genetics and developmental biology. Her position emphasizes that "many of the drugs used during these procedures have not been adequately studied for long-term safety, nor do some of these drugs have FDA approval for these specific indications. This is not widely understood and has led to significant misunderstanding about the risks involved for women who donate eggs," whether for reproductive purposes or for research cloning.

Pharmaceutical firms have not been required by either the government or physicians to collect safety data for in-vitro fertalization drugs on risk of cancer or other serious health conditions -- despite the drugs having been available in the United States for several decades. Lack of FDA approval or review of these drugs as part of egg extraction procedures should be a major concern of anyone considering embryo cloning research.

A woman undergoing IVF stimulation in order to become pregnant (or to help another woman become pregnant) is usually informed of "unknown" and potential long-term health risks, but she accepts these risks because of the demonstrated possibility that a baby will result from her efforts. The risk versus benefit calculation for a healthy woman providing her eggs for stem cell research is not the same.

Stimulation drugs may cause ovarian hyper-stimulation syndrome in 3 to 8 percent of patients. Based on symptoms, it is classified as mild or moderate to severe and can progress rapidly to a life-threatening condition days after completion of egg collection. The syndrome has been associated with death and has been reported in younger women.

Risks associated with leuprolide acetate (Lupron) -- a drug used to "shut down" the ovaries before stimulation with other drugs -- include depression, memory loss, liver disorders, bone loss, and severe muscle, joint, and bone pain. Some of these problems persist long after the drug is first used, and the FDA has not yet been able to follow up on the thousands of reported adverse reactions, including hundreds of hospitalizations. For a number of years, many of the women adversely affected by Lupron shared their experiences on the Internet as part of the "Lupron Victims Network."

Given recent attention to the harm that can result when clinical trial data are withheld -- consider the track record with Vioxx, Celebrex, and the antidepression drugs known as selective serotonin reuptake inhibitors, or SSRIs -- the public should demand that companies release all safety data for drugs used in egg extraction. This would include the release of unpublished data on leuprolide acetate collected some years ago by TAP Pharmaceuticals.

Because we have such an incomplete picture of the risks to women's health, any responsible stem cell research plan would specifically postpone embryo cloning research with human eggs until better data make true informed consent possible for any woman considering the donation of eggs for research.

There are other concerns about embryo cloning as well, such as the potential for commodification of eggs and embryos, embryo cloning's gateway role in germ line genetic modification of future generations, and the possibility of utilizing this technique for "enhancement" rather than "medical" purposes. These are issues needing much further discussion by all of us.

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