September 4, 2001

Committee on Health, Education, Labor, and Pensions
Dennis O'Donovan
Room 428
Dirksen Senate Office Building
Washington D.C., 20510

re: Comments for Hearing on Stem Cell Research,
September 5, 2001

Dear Mr. O'Donovan,

Attached please find pertinent comments for the Committee's review regarding human embryonic stem ceil research.. I would like to request that these 2 comments be included in this discussion and entered into the record of the hearings, and have enclosed a disk per protocol.

Sincerely,

Lynne Millican

To: Committee on Health, Education, Labor, and Pensions
From: Lynne Millican, R.N.
Date: September 4, 2001
Re: Human Embryonic Stem Cell Research

Embryonic Stem Cells (ESC): Alteration of embryos and women's health

1) Genetically Modified Human Embryonic Stem Cells

The human embryonic stem cell debate, in actuality, should be termed the genetically modified human embryonic stem cell debate - since, as reported by Geron (holder of several US patents on embryonic stem cells), a telomerase gene was cloned and transferred into the stem cell. The former mortality of the stem cell, thus being altered, allegedly leads to an immortal cell line - but results in a genetically altered embryonic stem cell line. This critical point is inexplicably left out of this discussion. Public debate has been raised on genetically modified foodstuffs - there needs to be identification and discussion of the genetic modification(s) involved with human embryonic stem cells.

2) The Process Of Producing These Embryos Has latrogenically **CAUSED** The Very Diseases That Are Being Claimed As Those Diseases Necessitating Embryonic Stem Cell Research For A Cure

And as one who underwent superovulation in fertility treatment (the administration of drugs to produce numerous eggs/embryos), and subsequently developed multiple health problems - it astounds me that the debate on human embryonic stem cell research has been conducted without addressing the serious health risks and adverse events experienced by women who have been superovulated to produce these multiple eggs and embryos.

One commonly used agent in many superovulation regimes is Lupron, which is labeled by the FDA as a pregnancy category X drug ("should not be taken by any woman who is or who may become pregnant"), and classified by the National Institutes of Health (NIH) and Occupational Safety and Health Administration (OSHA) as a "hazardous drug". NIH and OSHA recommend that healthcare workers wear protective gear (including, but not limited to, 2 pairs of chemotherapy gloves and chemotherapy gown) when handling and administering lupron, and that healthcare workers considering conceiving or fathering a child should abstain from handling lupron for 3 months prior to conception attempts. Lupron is also listed as a reproductive and developmental toxicant. While lupron was initially approved by the FDA for palliative treatment of prostate cancer in 1985, its initial patent was for claims of ovulation induction - yet, according to the sponsor, clinical trials for lupron's use in fertility treatment were "discontinued", and lupron has never gained FDA approval for fertility treatment..

Nonetheless, according to fertility industry figures, by 1990, 97% of assisted reproductive technology cycles utilized "GnRH analogs" in superovulation - with lupron being the most frequently prescribed GnRH analog. Lupron has also been the major subject of a US

Commerce Committee and several US Attorney probes for billing fraud in its prostate cancer usage, as well as being the subject of numerous civil litigations (and product liability litigation looms on the horizon). On the web alone there are numerous message boards and websites dedicated to exposing the post-lupron health problems; i.e., the 'National Lupron Victims Network' (www.lupronvictims.com), 'Julie's Lupron Page' (www.delphi.com/afterlupron), the 'Lupron Petition' (www.planetkc.com/lupronsurvivor), 'Assistance for People Affected by Lupron' (www.angelfire.com/ma2/APAL), and 'lupron: Serious Unanswered Questions' (www.lupronSUQS.com).

The chairman of this Committee, Senator Kennedy, was quoted on November 24, 1999 in a FOX 25 News' piece, entitled "Dangers of Lupron", stating: "FOX 25's report on possible side effects of Lupron was troubling. Physicians have an obligation to inform patients of the risks of drugs they prescribe, and promotion of potentially risky "off-label" uses of products by manufacturers is illegal and unethical...." A 1999 request by this writer for a congressional investigation into the alleged safety of lupron and the very troubling numbers and health status of lupron victims remains unanswered.

Thousands of women have experienced a gamut of health problems and diagnoses, including, but not limited to, diabetes, Parkinsonian-like disorders, memory loss, (and spousal reports of Alzheimers), arthritic disorders, cardiac problems, immune abnormalities - the very same diseases that embryonic stem cell research proponents claim as the compelling reasons to conduct such experimentation. The devastating effect lupron has had on many women's health and lives must be recognized and the risk for adverse events involved with superovulation MUST be addressed in this debate. The risks and benefits of anything cannot be weighed if vital information and the existing casualties are ignored.

Ethics momentarily aside, how legally valid is the contract these women/couples sign to relinquish their embryos for experimentation if informed consent of the risks in producing these embryos have been withheld from the decision-making process? According to the nation's largest volume fertility clinic (as quoted in the Boston Globe, 8/4/96) "women do not need to know about the lack of FDA approval" for lupron's use in fertility treatment "since Lupron is so widely used". Laws and 'reproductive rights' have resulted in access to procure, implant, destroy, share and/or sell women's eggs, embryos, and fetal tissue for a variety of purposes - but there's been no marches or legislation for a woman's right to access safe, informed, fertility treatment.

The aforementioned nation's highest volume fertility clinic has just entered into an arrangement to provide Harvard University with "left over" embryos for private research enterprise (and, incidentally, Harvard has a patent on assessing egg and embryo quality). As the egg donor ads proliferate, and fertility clinics pop up everywhere, there are no celebrities, politicians, scientists, or physicians stepping forward to call for research into lupron-induced diseases. 'Reprotech' is a profitable business, and the provision of informed consent and the recognition of lupron victims would not be good eggonomics. This fact is well illustrated by the fertility industry's opposition to Massachusetts House 3308, a bill which would mandate informed consent of the risks of the fertility drugs/procedures. All vested interests have opposed this bill and it has languished, unpassed, for 10 years - as tens of thousands of women are prescribed an off-label, hazardous drug without their knowledge or consent, and while hundreds of lupron victims turned into thousands. Massachusetts has, however, passed legislation (like many other states) that

mandates insurance coverage for fertility treatment - a result of heavy lobbying by RESOLVE, an alleged 'grassroots' infertility organization that receives, according to their Annual Reports, thousands upon thousands of dollars from fertility drug companies (including thousands from the manufacturer of lupron, at least as early as 1989).

The 1994 NIH Human Embryo Research Panel Hearings heard testimony from numerous experts identifying serious problems within the fertility industry; i.e. Dr. Van Blerkom stated "This field is based on methodologies being introduced into clinical practice based on a few papers, based on a few studies, based on exchanges of information at meetings, without a thorough evaluation ... I think the quality of science in this field has been awful", and C.A. Taer stated "I think we need to say something about the detrimental things that have occurred in the last 15 years, the fact that clinical work has gone on without the basic science to underlie it... I think the fact that the research enterprise has gone on out there without peer review and without the appropriate safeguards is something very bad that has happened."

In this alleged fair land, the promise of profit, conflicts of interests, lack of informed consent, human experimentation, and the suppression of information and the casualties, have polluted this entire arena - and the harmed consumer has no voice. Since women who were prescribed lupron during superovulation have developed the very diseases that are being cited as the reasons to further embryonic research (and thus, further the use of lupron) — and these victims are being ignored in the midst of this debate — the premise that 'this research will be conducted cautiously and truthfully' falls flat on its face.

Something very bad, indeed, has happened. Where once humankind "searched for life" (uni- and multi-cellular) in moon and Mars dirt and rock, now on earth a human embryo is a 'challenge' to the definition of life. Where once and foremost medicine did no harm, now thousands are being harmed from 'treatment' - right under everybody's nose. Perhaps those who thirst for the hundreds of thousands of human embryo$ that are "destined to be discarded anyway" feel that women are also a dispensable means to justify these ends.

Respectfully submitted,

Lynne Millican, R.N.