MASS HB2039 2005 Stem Cell Cloning, Problematic Portions

By Sharon Quick, MD

From SECTION 1, Sec. 2:
"Donated to Research", when, in the absence of valuable consideration, and after fulfillment of the requirements of informed consent, the person or persons from whose cells the preimplantation embryo has originated or will originate gives the pre-implantation embryo or cells to another person provided that the recipient(s) shall use the extant or resultant pre-implantation embryo in biomedical research, and shall not transfer the pre-implantation embryo to a uterus or uterine like environment or nurture the pre-implantation embryo beyond fourteen days development.

Comment: "Donated to Research" *section mandates destruction of human life when that life is an embryo produced by asexual means or a sexually-produced embryo whose "owner" has signed a consent form to donate the embryo to research. This sets a very dangerous precedent by requiring destruction of human life and also by treating human life as property without inalienable rights.*

What if the parents change their mind about donating to research? There are no waiting periods or other time constraints given about how soon an embryo can be destroyed once it is donated. In Ohio, parents are suing for wrongful death of a frozen embryo that was inadvertently destroyed in an in vitro fertilization (IVF) lab.

In addition, regulation of the fate of cloned human embryos presents a legal problem. IVF labs have the capability to produce cloned human embryos. Whether an embryo is formed through asexual or sexual reproduction, they appear identical under the microscope. Once formed, it is impossible to tell how the embryo was produced. There have been embryo mix-ups in IVF labs already. What if a woman has a cloned embryo implanted? Is she then forced to have an abortion? What if it isn't discovered until birth? Allowing creation of human cloned embryos will likely result in pregnancies of cloned humans. The state would have the impossible task of monitoring biotechnology institutions to make sure that none of these tiny developing humans escapes alive. This bill violates the state's traditional responsibility to protect the weak and vulnerable from those who would exploit them for profit. (Testimony of Richard Doerflinger before the Health and Human Development Committee of the Delaware House of Representatives concerning Senate Bill No. 55, "Cloning Prohibition and Research Protection Act"; January 14, 2003.)

"Valuable Consideration", any consideration, excluding reimbursement for reasonable costs incurred in connection with a donation, including costs associated with the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of gametes, embryonic or cadeveric tissue.

Section 8 (c). No person shall knowingly and for **valuable consideration** purchase, sell, transfer, or otherwise obtain human embryos, gametes, or cadaveric tissue for research purposes. Nothing in this section shall prohibit a person from banking or donating their gametes for personal future use, or from donating their gametes to another person or from donating their gametes for research. Nothing in this chapter shall be deemed to prohibit or regulate the use of in vitro fertilization for reproductive purposes.

Comment: "Valuable Consideration" is used in the definition of Donated to Research and in Section 8 (c). Donation of human embryonic or fetal tissue for research purposes is allowed and "reasonable payment" for various parts of processing is permitted (Sec. 8(c)). Even though the wording seems to outlaw purchase of human tissue, the "reasonable payments" could be profit-producing and encourage destruction of human embryos. A decade-old federal law already prohibits the sale of human embryonic

or fetal tissue (42 USC 289g-2), although it has not been completely effective. For example, in 1999 a tissue procurement company called Opening Lines distributed a long list of fetal organs of various types and stages, with prices (e.g., "Eyes (>8 weeks) – 40% discount for single eye - $50," "Spinal Column - $150," etc.). The company evaded the federal law by presenting this list as a "Fee for Services Schedule," taking advantage of the law's provision allowing "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue." HB 2039 contains essentially the same loophole. (See Doerflinger R. Congressional Testimony to House Health and Government Operations Committee of the Maryland Legislature; Mar. 12, 2003)

One could imagine what "reasonable payment" might be offered a woman for the time and health risks involved in "donating" eggs required for somatic cell nuclear transplantation (cloning). It is estimated that each patient that undergoes therapeutic cloning (treatment that is purely hypothetical at this point) theoretically might require 50-100 human eggs. There are 60 million women of child-bearing age in the US, and each woman can produce about 10-20 eggs per superovulation cycle. There are not enough women to donate eggs for all potential benefactors. Because of the inefficiency of cloning and the large number of eggs that would be required to produce even one human cloned embryonic stem cell line, poor and disadvantaged women will be exploited if cloning is allowed.

"Human Reproductive Cloning", the asexual genetic replication of a human being by transferring a pre-implantation embryo that has been created by somatic cell nuclear transfer, parthenogenesis, or by other asexual means into a uterus or uterine like environment with the purpose of creating a human fetus or a human child.

Comment: Would possibly allow implantation of a cloned embryo into a uterus, and growing it up to 8 weeks (the time at which an embryo is classified as a fetus), as long as it is aborted by that time for its parts and tissues.

It is a bit unclear how courts might interpret "fetus" in this clause. Section 12J of Chapter 112 of the General Laws (http://www.mass.gov/legis/laws/mgl/112-12j.htm) currently protects a fetus from destructive research, and defines fetus as including an embryo or neonate. An embryo has been created when the initial one-celled cloned embryo is formed, and should be protected from destructive research by this section of law as it currently is written. This current law is appropriate as cell biology and human embryology texts are very clear that human life begins with the one-celled embryo. However, SECTIONS 2 and 3 of this bill amends section 12J to exclude pre-implantation embryos or parthenotes as defined in section 2 of chapter 111L from such protection. It is possible that courts might then use the accepted scientific definition of fetus (beginning at 8 weeks of gestation) in any rulings on "reproductive cloning." If so, then implantation of a cloned embryo into a uterus would not be prohibited as long as it was aborted to harvest its parts prior to 8 weeks.

Section 3. (a) Research and clinical applications involving the derivation and use of human embryonic stem cells, including somatic cell nuclear transfer, human adult stem cells from any source, umbilical cord stem cells, parthenotes, and placental cells shall be permitted.

Comment: The phrase "adult stem cells from any source" would allow harvesting of adult stem cells from cloned humans. With the limitations placed on "reproductive cloning" in Sec. 2, this excerpt from Sec. 3 (a) would allow a cloned embryo to be implanted in a uterus and cultivated for his or her stem cells up to 8 weeks of age at which time the law would mandate abortion of this cloned individual.

Section 4. A physician or other health care provider who provides a patient with in vitro fertilization therapy shall provide said patient with timely, relevant and appropriate information sufficient to allow that patient to make an informed and voluntary choice regarding the disposition of any pre-implantation embryos or gametes remaining following said treatment. The physician shall present the patient with the options of storing, donating to another person, donating for research purposes, or otherwise disposing of or destroying any unused pre-implantation embryos, as appropriate.

Comments: This bill has NO conscience clause, yet it requires physicians to give patients undergoing infertility treatment options for the disposition of human embryos including destroying them or donating them for research purposes. Some infertility centers do not create excess embryos. Human life begins with the one-celled embryo. Should this bill become law it would require a physician to authorize the killing of a helpless human. Many physicians still ascribe to the ethical tenets outlined in the Hippocratic Oath sworn to by doctors for over 2000 years and, thus, will not destroy the unborn or suggest to their patients that they do so. Some infertility centers in the US do not create excess embryos; they only create the ones they will implant. It is wrong to coerce physicians to advocate to their patients conduct they consider unethical and unprofessional.

This lack of a conscience clause in Sec. 4 is interesting when compared to:
Section 5. (e) Nothing in this section shall impose a requirement upon any employee, physician, nurse, or other medical staff that is directly affiliated with a sincerely held religious denomination that includes as an integral part of its beliefs and practices the tenet that blood transfer is contrary to an essential part of its doctrine or beliefs.

Collecting umbilical cord or placental blood is not generally considered an ethically contentious practice, yet the bill protects a person from doing so if it is against their religion. However, the bill provides no such protection for physicians who have religious objections to authorizing the destruction of a human embryo! Section 7 (a) exempts an employee from conducting "scientific research, experimentation, or study that involves the creation or use of pre-implantation embryos in relation to human embryonic stem cell research to the extent that such research conflicts with the sincerely held religious practices or beliefs of the employee." *This clause doesn't appear to apply to the mandated requirements for physicians in providing options to infertility patients.*

Under Section 4 "donating to another person.... or otherwise disposing of" *is unclear and could potentially lead to abuses of human embryos. The purpose for such a donation is not indicated. If it is supposed to mean that unused embryos can be donated to another individual for the purpose of adoption and implantation into a uterus, then that should be made clear. However, it is hard to understand how a male recipient might accomplish this. As currently written, the recipient could do anything they want with the embryos, including abuses such as black market sales which might be listed as "processing fees."*

SECTION 2. Subsection (a) I of section 12J of Chapter 112 of the General Laws, as appearing in the 2002 Official Edition, is hereby amended by adding at the end thereof the following:- For the purposes of this section, fetus shall include a neonate and an embryo, but shall exclude a pre-implantation embryo or parthenote as defined by section 2 of chapter 111L, and obtained in accordance with said chapter 111L.

Comment: Massachusetts law currently protects an unborn human, including embryos, from destructive research (except for abortion) or sale of parts. This bill would add an exception to this protection of unborn humans by allowing research on human embryos if they are produced by cloning or have been abandoned by their natural parents (so they are now "left-over"). It challenges logical thinking to comprehend why the value of human life should depend on the route by which it was created or the

attitude of the parents toward the embryo. Neither of those conditions changes the status of the embryo itself—it is a unique living human. This bill discriminates against human embryos.

This is especially evident under Section 19 where the following is proposed: "an analysis of the feasibility of granting the Commissioner of Public Health, upon a declaration by a court of competent jurisdiction that said embryos have been abandoned, the authority to accept legal custody of the embryos and to provide consent to their use for purposes of biomedical research or medical care or treatment." *Human embryos are living individuals and possess the inalienable rights of our Declaration of Independence and US Constitution; otherwise they cannot be offered "legal custody" to determine their future medical care.*

SECTION 18 ...the biomedical research advisory council.... shall investigate the feasibility of permitting companies' whose stock is publicly traded to use an alternative method of approval in lieu of the requirement of having to acquire the approval of an Institutional Review Board before conducting embryonic stem cell research pursuant to the provisions of this chapter. Said investigation shall include a recommendation as to whether the approval of a duly appointed bioethical advisory board is a suitable alternative to the approval of an Institutional Review Board.

Comments: It presents an ethical bias to allow a company or institution that may financially benefit from some research to appoint its own ethics committee to approve such research, unless there are stipulations for assuring adherence to external standards and appointment of unbiased ethical advisory members.