Regulation of Human and Therapeutic Cloning

• The purpose of this bill is to establish and regulate what types of cloning technologies and processes will be legal in the United States; furthermore, the bill stipulates the rights of illegally generated clones or immigrating clones.

• This bill will undergo a review every 5 years, and necessary revisions can be made at that time only. In the event of discovery of new genetic technologies with respect to human reproductive cloning and human therapeutic cloning, the bill will undergo further review and necessary revisions to accommodate the new technology.

Definitions:

Clone: Making a genetic copy of an entire organism, cell, or gene. Specifically, the cloned entity will have the same genetic information (DNA) as its parent.

Zygote: A cell that is the result of fertilization of an egg. In the context of this bill however, we refer to zygote as merely being a cell with all necessary genetic information to grow; for no fertilization is used in cloning (see below). Instead, our zygote results from fusing an enucleated egg with the nucleus from a somatic cell.

Human Somatic Cell: Any cell in the body excluding sex cells—eggs or sperm in females and males respectively.

Egg Donor: In the context of this bill, the egg donor refers to a woman donating her eggs for the purposes of human therapeutic cloning.

Somatic Cell Donor: A person who donates a cell from their body to be used for cloning. As defined above, somatic cells can be any cells in the body except sex cells (eggs and sperm).
Human Therapeutic Cloning Technologies: The bill classifies these as all technologies associated with any aspect of human therapeutic cloning (as described above). These technologies are involved in: chemical treatment of somatic cell nucleus, removal of nucleus from egg, fusion of enucleated egg with somatic cell nucleus, treatment of blastocyst, removal of inner mass cells from embryo, growth hormones required to allow cells to grow into specific cells, etc.

Human Reproductive Cloning: The process of taking a somatic cell from a donor and removing the nucleus (through chemical treatment in lab). This nucleus is then fused with a donor egg (which has also had its nucleus removed—"enucleated egg") to create a cloned zygote. The cloned zygote is then implanted into a surrogate mother, and carried to term like a normal baby. *Please note, in this process…the somatic cell donor can act as the surrogate mother too. The surrogate mother, egg donor, and somatic cell donor can be the same person or different people. The somatic cell donor can be male or female, but the egg donor and surrogate must be a female.*

Human Therapeutic Cloning: Similar to the process of human reproductive cloning, except the last stage. A somatic cell nucleus is removed and planted into an enucleated egg (see above for more detailed explanation), resulting in a cloned zygote. However, the cloned zygote is not put into a surrogate mother; rather the cloned zygote’s cells are removed and grown in a culture and differentiated into embryonic stem cells. Embryonic stem cells are taken from the “inner cell mass” of a 5 day old zygote (embryo). These cells are then cultured, and continually differentiate. These cells can be treated with growth factors to allow them to develop into cells for the heart, liver, etc. However, upon removing the inner cell mass, the embryo is destroyed.

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1 For our definitions and purposes, we classify a “blastocyst” or 5 day old zygote as an embryo; this is the stage in which cells begin developing around the sphere (become placenta, amniotic fluid, etc) and within the sphere (inner cell mass—become embryos).
Human Reproductive Cloning-Policy

1. Reproductive human cloning is illegal, in any application (including research). Specifically, the implantation of a cloned human zygote into a uterus is illegal.
   a. Any person who knowingly: 1) Acts as a surrogate mother to a cloned zygote. 2) Implants a cloned zygote into a uterus. 3) Funds the technology required to implant cloned zygote into the uterus. will face up to $100,000.00 in fines and/or jail time of up to 5 years; the specific amounts of jail time and fines will be decided by state governments.

2. Any clone\textsuperscript{1} that is born on United States’ soil will be treated as an American citizen and will receive all the rights and liberties associated with citizenship (including social security). They will face no punishment or prosecution.

3. Any foreign clone\textsuperscript{2} wishing to enter the United States will be treated the same as any other foreigner. All immigration laws are in effect, and the clone will receive no discrimination.
   a. Violation of compliance with immigration laws will result in punishment as stated by existing immigration laws. The only punishable party, in cases of violation of immigration laws, will be the clone.

\textsuperscript{1} Here we use “clone” in reference to a cloned organism (specifically a human).

\textsuperscript{2} Here we use “clone” in reference to a cloned organism (specifically a human).
Human Therapeutic Cloning

1. Human Therapeutic Cloning is legal, but only by institutions/parties that have legally obtained a license—this includes research that involves the use of Human Therapeutic Cloning technologies. This license will be granted by the federal government health department’s Human Therapeutic Cloning Committee (HTCC). The institution must qualify under all provisions of the HTCC to operate legally. These provisions include: operation of a sanitary and clean facility, funding to self sustain operations (federal funding will not be granted), safety and approval of technologies, certification and appropriate training of staff, and payment of annual licensing fees. These provisions will be regulated by the HTCC through annual inspections, which the institution must pass to continue operation. All therapeutic cloning experiments and use of technologies will be reported to the HTCC.
   a. Failure to pass inspection, pay annual fees, or report therapeutic cloning will result in fines up to $40,000.00 and/or license revocation. Using Human Therapeutic Cloning technologies without a legal license will result in fines up to $100,000.00 and/or jail time up to 3 years. The penalties apply to all parties involved in the illegal operation of human therapeutic cloning technologies.

2. Full consent of egg donor(s) and somatic cell donor(s) is required before therapeutic cloning can take place. This will be regulated through compulsory consent forms from the HTCC that must be signed by all donors before therapeutic cloning can take place. These forms must also specify potential dangers and risks of during the therapeutic cloning process to the donor(s).
   a. Failure to obtain signature on disclosure forms will result in fine up to $40,000.00 and/or license revocation of involved institution.

3. The use of the cells created from therapeutic cloning will be decided exclusively by the somatic cell donor. All other parties involved in the therapeutic cloning process will not be allowed to decide what purposes the cells are used for.
a. Using therapeutically cloned cells\(^3\) in a manner not specified by the somatic cell donor will result in revocation of license and/or fines up to $40,000.00 for the involved institution.

\(^3\) Here we are referring specifically to human cloned cells. Thus, only the cells are cloned, there is no organism cloning.