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PH: 202-347-6840 Fax: 202-347-6849 www.stemcellresearch.org "As to diseases ,make a habit of two things — to help, or at least *do no harm*."

Hippocrates, The Epidemics —

IT CAN HAPPEN HERE

Senate must act now to prevent fetus farming

"Cloning embryos for producing embryo stem cells will, by failing to deliver on its promises, inevitably lead to calls to extend the life span of clonal embryos so as to permit harvesting developmentally more advanced cells and tissue for research and potential therapies... And once stem cell harvesting from two-month clonal embryos is in place, who could resist the pleas to extend the time frame so that liver and bone marrow could be obtained from six-month clonal fetuses... This is my prediction... frustration over lack of progress in producing safe and effective therapeutics from embryo stem cells will lead to calls to permit harvesting of embryo germ cells from two to three month clonal embryos..."

-- Testimony of Dr. Stuart Newman, professor of cell biology and anatomy, New York Medical College, before the Senate Subcommittee on Health, 3/5/2002

But if the goal is tissue...why stop research at 14 days? Once you say we can do this much of it, what's the difference?...We can't produce some tissues precisely or efficiently outside the embryo, because the embryo is what produces them...We already condone harvesting of cells from cloned human embryos for the first two weeks. Why stop there? ...Why did we draw this limit in the first place? ...Having pushed the line to 14 days, can we push it further? Sure we can."

--William Saletan, "The Organ Factory," *Slate*, five-part series published online July 25-29, 2005

The U.S. Senate is poised to consider S. 3504, "The Fetus Farming Prohibition Act."

The legislation would ban the solicitation or acquisition of human fetal tissue obtained from a fetus that was deliberately gestated in a human or non-human womb for the purpose of acquiring such tissue (current federal law includes an embryo that has been implanted under the definition of "fetus").

Some argue that the bill is unnecessary, as there is currently no clamor to carry out such activities.

However, certain "proof of principle" experiments, the ongoing failure of researchers to produce usable tissue from embryonic stem cells *in vitro*, and state legislative proposals governing embryonic stem cell research, all point to disturbing trends that argue for this legislation now:

In April 2002, researchers offered as "Proof of Principle" for "therapeutic" cloning an experiment that only succeeded when the researchers implanted and grew cloned mouse embryos, brought them to live birth, and then harvested their (adult) bone marrow cells; these adult stem cells were transplanted successfully back to reverse the disease in the original mice that had been cloned. The researchers were forced to

grow embryos to live birth for their tissue because they failed to develop therapeutically useful, non-rejected, differentiated tissue from cloned embryonic stem cells in the dish (William M. Rideout III et al., "Correction of a Genetic Defect by Nuclear Transplantation and Combined Cell and Gene Therapy," *Cell* 109 (April 5, 2002): 17-270).

- In July 2002, researchers failed to obtain therapeutically useful kidney cells from bovine (cow) embryonic stem cells in the lab, reporting that "bovine ES cells capable of differentiating into specified tissues *in vitro* have not yet been isolated." To solve this problem, they resorted to fetus farming: implanting cow embryos, growing them to the fetal stage and then aborting them and harvesting developed kidney tissue. This research was done by Massachusetts-based Advanced Cell Technology (ACT) (Robert Lanza et al., "Generation of histocompatible tissues using nuclear transplantation," *Nature Biotechnology* 20 (July 2002): 689-696; www.nature.com/nbt/journal/v20/n7/pdf/nbt703.pdf).
- ➤ In 2003, Israeli researchers found that kidney precursor cells, obtained from both a 7-8 week gestated human fetus and a 3-4 week gestated pig fetus, could give rise to a functioning organ. The authors of this paper concluded that this presented "a window of human and pig embryogenesis that may be optimal for transplantation in humans"(B. Dekel et al., "Human and porcine early kidney precursors as a new source for transplantation," *Nature Medicine* 9 (January 2003): 53-60; http://www.nature.com/nm/journal/v9/n1/full/nm812.html).
- ➤ In February 2004, ACT again resorted to fetus farming in order to obtain differentiated tissue to treat heart damage in mice. After failing to differentiate cloned embryonic stem cells into useable tissue, the researchers implanted and grew cloned mouse embryos to a later fetal stage and then aborted them to harvest fetal liver cells: "Cloned fetuses recovered at 11 to 13 days of gestation were used as source of liver cells." (Robert Lanza et al., "Regeneration of the Infarcted Heart With Stem Cells Derived by Nuclear Transplantation," *Circulation Research* 94 (April 2, 2004): 820-827; and http://circres.ahajournals.org/cgi/reprint/94/6/820).
- ➤ In July 2005, ACT farmed cloned cow fetuses then aborted them to obtain differentiated liver tissue (Robert Lanza et al., "Long-Term Bovine Hematopoietic Engraftment with Clone-Derived Stem Cells," *Cloning and Stem Cells* 7 (June 2005): 95-106). In a press release, ACT medical director Robert Lanza hailed this technology, expressing hope that it would be used "in the future to treat patients with diverse diseases" (http://www.advancedcell.com/press-release/somatic-cell-nuclear-transfer-gives-old-animals-youthful-immune-cells).

While all these studies claim to offer proof of the therapeutic efficacy of embryonic stem cells, they show the opposite. Translating these studies into a human gestational time frame, the studies instead suggest that if cells from human cloning are to have any therapeutic use in treating human patients, then fetus farming – implanting and growing human embryos up to or even beyond the fetal stage -- may be necessary.

Moreover, at least one state -- New Jersey -- has adopted language governing cloning and stem cell research that explicitly allows for fetus farming. The New Jersey law claims to ban human cloning, but defines cloning as "the replication of a human individual by cultivating a cell with genetic material *through the egg, embryo, fetal and newborn stages into a new individual*" (emphasis added). Thus, under the guise of "banning" human cloning, the New Jersey law actually provides for creating a cloned human embryo, implanting that embryo, and growing the embryo up to the point of birth, before destroying the fully developed child and harvesting his or her tissue.

Similar language has been proposed as model language for legislatures in at least 9 other states.

Just a few years ago, politicians and scientists promoting embryonic stem cell research cynically assured the American people that the research would be limited to using only those "spare" or "leftover" frozen embryos that were "going to be destroyed anyway". Many explicitly stated they would reject the creation of human embryos just to be used in research.

Soon many abandoned those assurances. They have led a political and propaganda push to allow (and in many cases to provide state or federal funding for) the creation of embryos solely for research purposes.

Researchers and their political allies may assure us *now* that they do not wish to harvest tissue from embryos beyond a 14 day limit. But similar assurances that the research would be conducted with some semblance of ethical restraint have been easily discarded in the past.

Congress should pass S.3504, "The Fetus Farming Prohibition Act," before this happens again.

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