



Federal Funding for Embryonic Stem Cell Research Position Statement

Approved by the ASCO Board of Directors, March 2005

Background

- Embryonic stem cell (ESC) research offers the potential for unprecedented advances in the regeneration of a multiplicity of human tissue for the treatment of chronic diseases, including cancer.
- At present, federal funding through the National Institutes of Health (NIH) or otherwise is quite limited. At the outset of his presidency, President George W. Bush established a policy to allow federal funding of ESC research, but only with respect to the cell lines that were in existence at that time. It was thought that there were more than 60 separate cell lines, but the available cell lines now number only around 20, and they are regarded as less than ideal for research because they may be contaminated by the mouse cell media in which they were grown.
- In addition, the State of California passed a 2004 ballot initiative to provide state-supported ESC research in the amount of \$3 billion over 10 years. The availability of substantial funding and a free environment for ESC research there will shift the focus of activity to California and even further away from the minor federal role played by NIH.

Ethical Considerations

- The Bush Administration's decision to fund research on existing cell lines, but not on new ones, represented a perceived "compromise" between the ardent supporters of unfettered stem cell research and those who believe just as ardently that destruction of embryos, even in the cause of finding cures, is tantamount to the taking of human lives.
- That compromise should be re-examined in light of the evolving environment for ESC research, including the following: (1) the roughly 20 federally approved cell lines are proving to be inadequate for any meaningful research portfolio; (2) the private sector has continued to support creation of new cell lines, so lack of federal involvement has not significantly impeded the destruction of embryos for ESC research; (3) with the California initiative, there likely will be a tremendous expansion of ESC research; and (4) under current law, the ESC research activity pursued in the private sector and under auspices of California or other states will not have the benefit of federal review, guidance, and ethical oversight. The federal government should not abrogate its responsibility for leadership and quality control in this essential research area.
- Most existing stem cell lines as well as those being newly developed by researchers on an ongoing basis derive from embryos created for in vitro fertilization but not used for that purpose. These surplus embryos, if not used for ESC research, would eventually be discarded. Ethicists thus reasoned that their

- use in potentially life-saving research was justified, notwithstanding the destruction of embryonic life, since their destruction is inevitable.
- Now it appears that ESC lines derived from fertility-clinic embryos may lack the necessary qualities of flexibility and adaptability to be optimal for ESC research. Moreover, those embryos would pose the risk of rejection in any person treated with their cell lines because of incompatibility of their immune systems.
 - The problem of rejection can be addressed through a technique called somatic cell nuclear transfer in which the nucleus of a cell from the patient is inserted into an egg from which the cell nucleus has been removed. Theoretically, the result of this process is an embryo with the identical genetic and immune system profiles to those of the patient. This embryo would then be utilized to create a compatible ESC line for the patient, but in the process the embryo would be destroyed.
 - Somatic cell nuclear transfer, also known as therapeutic cloning, has not been aggressively pursued because some ethicists believe it is less justifiable to destroy an embryo that has been created for research purposes than to destroy the fertility-clinic embryos that would be discarded eventually in any event.
 - In light of the limits of other options, the ethical questions related to therapeutic cloning should be examined anew, and some research institutions have commenced such an ethical review.
 - At the same time, federal law should ban the use of cloning techniques for the purpose of reproducing human clones, an outcome that would be both unethical and medically inappropriate.

ASCO Position

- Congress should enact legislation that clearly prohibits human reproductive cloning with appropriate criminal and civil penalties, but also clarifies that therapeutic cloning is permissible within specified ethical limits to be determined by qualified ethicists.
- The Administration should reconsider its policy on funding of ESC research, taking into account current circumstances that are serving to marginalize the contribution of NIH. At the very least, the policy should permit research on any cell lines existing at the time of the grant, and, with appropriate ethical review, consideration should also be given to federal funding for creation of new ESC lines, although this step would not be possible without legislative relief from the so-called Dickey Amendment.
- The Administration should also support international conventions that would ban reproductive cloning, but leave the question of therapeutic cloning to the legislatures of each country.
- Through legislation, through funding policy, and through international organizations, the Administration must assert a leadership role that incorporates the ethical and scientific expertise of NIH in the vital area of ESC research to address serious and life-threatening diseases like cancer.