American Stem Cell Research

Politics and Policies

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Overview

In February of 1997, Dr. Ian Wilmut announced the creation of the first cloned mammal. The report, published in the science journal *Nature*, described a lamb, "Dolly," which was cloned using somatic cell nuclear transfer (SCNT). This landmark paper and the media attention it received created an immediate reaction from the public and politicians in Washington, D.C. who were concerned about the potential cloning of humans using this technique. Since Dolly's creation, congressional leaders have been trying to find a way to prevent human cloning and other allegedly unethical medical procedures while still allowing medical research to proceed unhindered.

In late 1998, the issue was further complicated by the announcement from researchers at the University of Wisconsin-Madison, led by Dr. James Thomson, who derived the first human embryonic stem cells from blastocysts. This marked the beginning of a new area of medical science, human embryonic stem cell research. With this new breakthrough, the issue of human cloning became considerably more complex, since SCNT was now linked to potential disease-curing research.

With each congressional session, a new crop of conflicting bills arises from both the House and the Senate, and congressional hearings are called to bring witnesses in to validate either side, but no resolution appears to be in sight. Although many polls have shown that the vast majority of Americans disapprove of research which could produce a cloned human (83% in a 2002 poll by Research!America), there is still much public debate about the ethics of embryonic stem cell research. This debate resonates in the Congress and generates the current stalemate where lawmakers are unable to reach a consensus about medical research relating to embryonic stem cells.

Pre-"Dolly" Regulation

In the 1970s, rules were developed to govern the federal funding of research on human embryos for *in vitro* fertilization (IVF). The rules specified that all federally funded research on human embryos would need to be approved by a congressionally appointed ethics advisory board. Although the board met once, it was dissolved in 1980 without ever federally funding embryonic research. In 1993, this rule was rescinded, but the Dickey Amendment, a **Department of Health and Human Services** (DHHS) 1996 appropriation rider, subsequently banned any federal funding of human embryo research and each year this amendment has been attached to the appropriation bill for the DHHS. Since that time, no federal funds have been allowed for embryo (and therefore embryonic stem cell) research, but private funding of research on embryos has been allowed and is completely unregulated.

Post-"Dolly" Debate

In February of 1997 after the public announcement about "Dolly", President Clinton charged the **National Bioethics Advisory Council** (NBAC) to study the issue of human cloning. In June of that year, NBAC released a report which determined that reproductive cloning was immoral and requested that a moratorium should be established until subsequent laws prohibiting it were passed (with a sunset period of 3-5 years). The members also suggested that the law be written so it would not interfere with biomedical research. Taking their suggestions, President Clinton offered a legislative proposal to bar anyone (either federally or privately funded) from attempting to clone a human through SCNT for 5 years. President Clinton's proposal was announced after several bills in the House and Senate had already been introduced (see Table 1). However, due to the fear that Congress was acting too quickly and might bar valid research, the majority needed to pass these bills was never attained and thus no legislation limiting such cloning was ever successfully passed into law.

In November of 1998, after Dr. Thomson announced the creation of the first human embryonic stem cell line, President Clinton asked NBAC to specifically address human embryonic stem cell research, which had not been discussed in 1997. In 1999, the

Table I - Bills Introduced in 1997-98 (105TH Congress)

Bill	Sponsor	Action
S. 368	Sen. Bond (R-MO)	The government would be permanently banned against using federal funds for cloning an individual.
H.R. 922	Rep. Ehlers (R-MI)	*Human Cloning Research Prohibition Act*. The government would be permanently banned against using federal funds for cloning an individual.
H.R. 923	Rep. Ehlers (R-MI)	*The Human Cloning Prohibition Act of 1997.* Cloning a human being through SCNT would be illegal and with a $5000 civil penalty for violations.
H.Doc. 105-97	Pres. Clinton	*The Cloning Prohibition Act of 1997*. It would bar everyone in the country, both private and publicly funded, from attempting to create a baby through SCNT. The ban would only last 3-5 years and proposed a $250,000 fine for anyone in violation.
S. 1574	Sen. Campbell (R-WY)	*Human Cloning Prohibition Act.* The bill would bar federal funding of research designed to clone a human or create a human embryo. It would also make it illegal and subject it to a $5000 fine.
S. 1601	Sen. Bond (R-MO)	*Human Cloning Prohibition Act.* The government would be permanently banned against using federal funds for cloning an individual. It would make the creation of a human embryo through SCNT a criminal act with a 10-year prison sentence. It would also prohibit the importation of human embryos which were created by SCNT. They would create a National Commission to Promote a National Dialogue on Bioethics.
S. 1602	Sen. Feinstein (D-CA) Sen. Kennedy (D-MA)	*Prohibition of Cloning Human Beings Act of 1998.* The bill would forbid creating a human by SCNT and bar federal funding for 10 years. It provided a $1 million fine for violations.

NBAC recommended that federal funding should be used to support both the research and creation of human embryonic stem cells. They also suggested amending the ban on embryo research (the Dickey Amendment) to allow the derivation and use of embryonic stem cells.

However, before the results of the NBAC deliberations were announced, the **National Institutes of Health** (NIH), specifically the legal council for the DHHS, determined that federal law (the Dickey Amendment) prohibited the use of federal funds to create human embryonic stem cell lines, but they did believe that it was legal to fund research on already existing lines. Private sources were never barred from deriving their own human embryonic stem cell lines and were actively pursuing this area of research. The NIH released guidelines for the federal funding of human embryonic stem cell research for public comment in 1999, followed by an updated version in 2000 in the *Federal Register*. Before NIH was able to grant money in response to research proposals, a new administration (President George W. Bush) took office and the previous rulings by the DHHS and NIH were set aside.

Meanwhile in the Senate, the Specter-Harkin bill (S.2015) was introduced as the *Stem Cell Research Act of 2000*. It called for the federal funding of the derivation and use of human embryonic stem cells from spare donated embryos (IVF), as long as the research did not lead to "reproductive cloning of a human being." This marked the first of many bi-partisan bills that Congress would see on this issue. The Specter-Harkin bill, like many future bills, was not passed into law.

When President Bush took office, one of his first actions was to temporarily stop all federal funding of human embryonic stem cell research (no grant had been given) while his administration considered their actions. On August 9, 2001, after several months of deliberation, President Bush announced that he would allow the federal funding of the research of human embryonic stem cells, but only those that had been derived before the date of the announcement could be used. Thus, no new embryonic stem cells could be created with federal funds, nor could federal funds be used to do research on new lines create after the August 9, 2001 deadline. NIH estimated at the time that there were as many as 60-75 cell lines available for research. However, since that time, NIH has revised its numbers downward. By the 2004 presidential campaign, NIH had only 22 lines available (see insert “Effect of President Bush’s Stem Cell Policy”).

Since the President’s August 9, 2001 decision, embryonic stem cell policy has remained unchanged. In November 2001, President Bush established the **President’s Council on Bioethics** (PCB), a group of experts (similar the NBAC), to address the issues of human cloning, embryonic stem cell research and other bioethical issues. In Congress, new bills were introduced in the 107th and 108th congress, and the Weldon-Stupak bill was passed in House in 2001 and 2003 to ban all forms of cloning and the use of SCNT, but neither passed in the Senate (see Table II and III). Almost every year we see each political side introduce their version of a law which would outlaw all human cloning or only reproductive cloning and either outlaw or permit the use of embryonic stem cells, but nothing has been signed into law.

Perhaps, the most interesting part of the congressional debate is the fact that views on the topic do not necessarily follow traditional party lines or a person's opinion on abortion or right to life. This new debate has produced the most unlikely bipartisan partnerships and has resulted in a deadlock in Congress, which has sharply constrained federally funded research on embryonic stem cells and human cloning. At the same time, the

deadlock has virtually left the privately funded research involving embryonic stem cells and human cloning completely unregulated.

Momentum for expanding federal funding for embryonic stem cell research began to build again as the 2004 presidential campaigns kicked into gear. In April of 2004, 206 members of the House of Representatives (out of 435) signed a letter to President Bush urging him to expand the current federal policy on embryonic stem cell research to include new lines developed after August 9, 2001. Following the House's lead, the Senators that advocated embryonic stem cell research also wrote a letter to President Bush with 58 signatures (out of 100). On May 10, 2004, former First Lady, Nancy Reagan publicly supported embryonic stem cell research at a fundraiser for juvenile diabetes. Although, privately she had supported the research with personal letters to congressmen, this was her first public statement on the topic. Nancy Reagan and the Reagan family are often thought of as icons for the Republican Party and conservative ideals. This public acceptance led the way for other Republicans to support the issues. One month later, President Reagan, a victim of Alzheimers, passed away. Stem cell research was immediately brought into the forefront as a campaign issue for the 2004 election. Senator Kerry supported the expansion of the research, while the President Bush explained his current policy and promised to maintain the status quo.

With the return of President Bush to office in 2005, the possibility for changing the current federal policy seems unlikely. However, in May 2005, the U.S. House of Representatives passed the *Stem Cell Research Enhancement Act*, perhaps the most significant legislative advance in the support of stem cell research (see Table II). Its passage was the result of initiative from the leaders in both parties. The bill amends the Public Health Service Act to provide for stem cell research by stating that cells donated from excess supplies from IVF clinics are viable for use. It stipulates that these donations are to be made from embryos determined never to be implanted in a woman and under informed consent without any financial inducements. The bill goes on to say that reports of research carried out under these guidelines should be presented each fiscal year. The Stem Cell Research Enhancement Act needed to be passed by the U.S. Senate, and although the Senate Majority Leader, Senator Bill Frist (R-TN) promised to bring it forward in 2005, the vote did not occur until July 2006. As he promised a year before, President Bush vetoed the bill on July 19, 2006.

Table II – Bill from 109th Congress

Bill	Sponsor	Action
H.R. 810	Rep Castle (R-DE) Rep DeGette (D-CO)	*Stem Cell Research Enhancement Act.* This bill authorizes federal funding of research on human embryonic stem cells regardless of the date they were derived. All embryos must be from donated excess from IVF clinics. Passed in the House in May 2005.
S. 471	Sen. Specter (R-PA) Sen. Hatch (R-UT) Sen. Feinstein (D-CA) Sen. Kennedy (D-MA) Sen. Harkin (D-IA)	*Stem Cell Research Enhancement Act.* Companion bill to H.R. 810. Passed in the Senate July 2006.

With or without the expansion of federal funding, some states (such as California, Michigan, and Arkansas) are beginning to pick up the reigns by passing their own laws related to embryonic stem cell research (see page 15 "State Cloning Legislation"). In

November 2004, Californians (with 59% of the vote) approved Proposition 71, or the *California Stem Cell Research and Cures Initiative*, which called for the creation of a California Institute for Regenerative Medicine (CIRM) and authorized $3 billion of state funds to support the effort over the next five years. The proposal also established the right to conduct embryonic stem cell research in California, but prohibits reproductive cloning. President Bush's policy only limits federal funding, but does not make the research itself illegal therefore the states are able to determine how they wish to regulate and fund research using state funds. California's proposition allowed the use of state funds to support embryonic stem cell research regardless of the date the cells were generated, to create new cell lines, and to use SCNT to create cell lines with specific genes. This new institute is expected to attract stem cell researchers and investors to California allowing it to corner the market on any promising findings.

Despite the passage of Proposition 71, several legal obstacles have delayed its implementation in California. In November 2005, a California judges refused to dismiss a lawsuit by taxpayer groups and organizations opposed to research on human embryonic stem cells. The group contended that CIRM could not sell bonds backed by taxpayer money to fund research, because it is not under direct state control. Bond sales that would be used to fund the institute are on hold until the lawsuit is settled. In April 2006, the court ruled in favor of CIRM, but the case is still in appeals. Furthermore, CIRM needed time to determine the rules for awarding grants, conducting research, and handling patent rights before it started funding grants. However, in April 2006 CIRM was still able to award their first round of grants, which totaled $12.1 million.

Summary

The debates on stem cell research essentially started in 1997, after the first mammal, "Dolly," was cloned. Through the past decade, the United States government has not been able to agree on the best policy. The Bush Administration put into place a policy that allows some research to proceed, but at the same time it fails to address the research that is taking place with private and other non-federal funds. The issue has also produced a stalemate in Congress on whether to allow the federal funding of embryonic stem cell research to be expanded. Whether we should fund embryonic stem cell research and therapeutic cloning and how to regulate the current research done with private funds are questions Congress and Bush Administration will need to address.

Effects of President Bush's Stem Cell Policy

In an effort to appease the advocates for embryonic stem cell research, but still stay true to his conservative base, President Bush allowed federal funding of research on human embryonic stem cells derived on or before August 9, 2001. At the time of the announcement, the NIH believed that there were 60-75 lines which met the qualification for federal funding. Since the announcement, scientists have found several problems with the cell lines which were approved:

1. Currently there are only 22 lines available for distribution by the NIH (the other lines were unavailable for distribution). Many of the other cell lines were either unavailable to researchers or had contamination problems, chromosomal abnormalities, or were unstable.

2. All the cells had been created using mouse cells; therefore, they cannot be used in humans for fear of spreading mouse viruses in humans. It also has been shown recently that all the lines tested contained mouse proteins on their surface which causes them to be rejected by the immune system in a human. This means the cells are unlikely to ever be used for medical purposes.

3. Older cell lines are more susceptible to chromosomal abnormalities than newer lines. So over time, the current stem cell lines will degrade and are not medically viable.

4. Several of the lines have been difficult to grow, giving them very limited uses.

5. Each approved cell line has the propensity to grow into only one specific cell-type. This decreases the breadth of research opportunities for scientists.

6. The cell lines lack genetic diversity necessary to create therapeutic treatment for a broad number of patients

7. There is an absence of disease-specific cell lines, thereby limiting stem cell research on genetic diseases.

Improvements in how scientists can grow the cells *in vitro* have made new cell lines created in other countries and from private funding (now numbering over 150 lines) more appealing than the lines approved for federal funding. This discourages scientists from using the cell lines, applying for the federal funds, or even entering the field. Most scientists, especially new faculty and graduate students, rely heavily on public funding during their careers.

This policy also limits the availability of subsequent discoveries to the general public. Since private firms will own any therapies derived from such research and may charge heavily to recoup their investments, they have no incentives to publicly release their data.

References and Further Suggested Readings

Introduction to Stem Cells

(1) International Society for Stem Cell Research: http://www.isscr.org
(2) NIH, Stem Cell Basics: http://stemcells.nih.gov/info/basics/
(3) National Research Council and Institute of Medicine. (2002) Stem Cells and the Future of Regenerative Medicine. Washington D.C.: National Academy Press: http://www.nap.edu.
(4) Embryonic Stem Cell Research at the University of Wisconsin-Madison: http://www.news.wisc.edu/packages/stemcells/facts.html#1
(5) National Parkinson Foundation: http://www.parkinson.org.
(6) Juvenile Diabetes Research Foundation: http://www.jdrf.org.
(7) Wilmut, I., et. al. (1997) Viable Offspring Derived from Fetal and Adult Mammalian Cells. Nature 385:810-13.

American Politics and Policies

(1) Thomas, Legislative Information on the Internet: http://thomas.loc.gov
(2) American Association for the Advancement of Science. (2003) Regulating Human Cloning. Washington D.C.: AAAS: http://www.aaas.org/spp/cstc/briefs/cloning/index.shtml
(3) California Institute for Regenerative Medicine: http://www.cirm.ca.gov/.
(4) National Research Council and Institute of Medicine. (2002) Stem Cells and the Future of Regenerative Medicine. Washington D.C.: National Academy Press: http://www.nap.edu.
(5) National Research Council and Institute of Medicine. (2002) Scientific and Medical Aspects of Human Reproductive Cloning. Washington D.C.: National Academy Press: http://www.nap.edu.
(6) National Research Council and Institute of Medicine. (2005) Guidelines for Human Embryonic Stem Cell Research. Washington D.C.: National Academy Press: http://www.nap.edu.
(7) President's Council on Bioethics. (2004), *Monitoring Stem Cell Research*: http://www.bioethics.gov/reports/stemcell/index.html
(8) Bonnicksen, A.L. (2002) Crafting a Cloning Policy, From Dolly to Stem Cells. Washington D.C.: Georgetown University Press.
(9) Thomson, J.A. et. al. (1998) Embryonic Stem Cell Lines Derived from Human Blastocysts. Science 282:1145-7.Wilmut, I., et. al. (1997) Viable Offspring Derived from Fetal and Adult Mammalian Cells. Nature 385:810-13.

State Legislation

(1) National Conference of State Legislatures: http://www.ncsl.org/programs/health/genetics/rt-shcl.htm, http://www.ncsl.org/programs/health/genetics/embfet.htm and http://www.ncsl.org/programs/health/genetics/geneticsDB.cfm
(2) California Institute for Regenerative Medicine: http://www.cirm.ca.gov/
(3) Connecticut Legislature: www.cga.ct.gov/2005/BA/2005SB-00934-R01-BA.htm.
(4) Maryland Legislature: http://mlis.state.md.us/2006rs/bills/sb/sb0144t.pdf.
(5) Illinois Governor's Office: www.illinois.gov/gov/execorder.cfm?eorder=39.
(6) State of New Jersey: www.state.nj.us/scitech/stemcell/.

World Human Cloning Policies

(1) The Database of Global Policies on Human Cloning and Germ-line Engineering: http://www.glphr.org/genetic/genetic.htm
(2) Global Lawyers and Physician for Human Rights: http://www.glphr.org
(3) Stem Cell Policy: World Stem Cell Map: www.mbbnet.umn.edu/scmap.html
(4) European Commission, Directorate General – Research: Survey on opinions from National Ethics Committees or similar bodies, public debate, and national legislation in relation to human embryonic stem cell research and use. Volume I: EU Member States, July 2004: http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm, Volume II: Countries associated to FP6 and Third Countries, July 2004: http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm
(5) UNESCO (United Nations Educational, Scientific, and Cultural Organization). National Legislation Concerning Human Reproductive and Therapeutic Cloning, July 2004: http://unesdoc.unesco.org/images/0013/001342/134277e.pdf
(6) The Hinxton Group Consensus Statement, March 2006: http://www.hopkinsmedicine.org/bioethics/finalsc.doc.
(7) The Phoebe R. Berman Bioethics Institute. (March 2006) International Policy Trends: Embryonic Stem Cell Research.

Advocacy Organizations

(1) Texans for Advancement of Medical Research: http://www.txamr.org
(2) Coalition for the Advancement of Medical Research (National Coalition): http://www.camradvocacy.org
(3) National Parkinson Foundation: http://www.parkinson.org
(4) Juvenile Diabetes Research Foundation: http://www.jdrf.org
(5) Research!America: http://www.researchamerica.org
(6) Genetic Policy Institute: http://www.genpol.org.

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