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Bush Stem-Cell Restrictions Hamstring Vital Health Research

Stem-cell research promises significant medical advances. It may lead to treatment for diseases and disabilities such as Parkinson's and Alzheimer's, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis and rheumatoid arthritis.¹ The possibilities are endless.

However, at the behest of anti-choice forces, President Bush has placed nearly insurmountable constraints on this vital research. President Bush has decided that the federal government may only conduct or fund research on stem-cell lines derived before the arbitrary date of August 9, 2001. This policy is both ethically incoherent and seriously damaging to this critical medical research.

The existing stem-cell lines simply are not sufficient to allow researchers to develop the cures that could otherwise be anticipated. Thus, time is running out for millions of disease sufferers, and much research that would otherwise be undertaken in the public sector has been forced into the private realm, where it does not receive the benefit of the strict ethical scrutiny and oversight that comes with public funding.

What Are Stem Cells?

Stem cells are cells that can develop into almost any type of cell. There are both *embryonic* stem cells and *adult* stem cells. The controversy surrounding stem-cell research and President Bush's policy concerns only embryonic stem cells. Research using adult stem cells is not controversial, but adult stem-cell research is not an adequate substitute for embryonic stem-cell research. Embryonic stem cells have the greatest potential to create cures for a number of diseases, as they have the ability to become the widest range of cells. (This is known as "pluripotency.") While adult stem cells also show promise for certain diseases, such as liver disease and multiple sclerosis, studies have shown they are less likely to be useful in many other areas, such as diabetes or diseases of the brain and nervous system.² The National Institutes of Health (NIH) has stressed the importance of pursuing research with both embryonic and adult stem cells – and now, even President Bush's own appointed NIH director has broken publicly with his own administration's policy.³

In embryonic stem-cell research, a cluster of cells is isolated from an embryo that was created in the laboratory through in-vitro fertilization. Typically, these embryos are created as part of fertility treatments, but are no longer needed and would otherwise be discarded. The stem cells then are allowed to regenerate into a "line" of cells that have the potential to create healthy new

cells that may be able to replace tissue that has been damaged by disease or injury.⁴ Stem cells do not have the capacity to develop into a full human being.⁵

The Promise of Stem-Cell Research

Stem cells are a unique medical and scientific resource. Scientists at respected medical and educational institutions, from the members of the National Bioethics Advisory Committee (NBAC) to the over 9,000 members of the American Society for Cell Biology to the National Academy of Sciences, anticipate that stem-cell research may lead to significant advances in medical science, including the following:

- Tissue transplantation, to replace damaged or diseased tissue, such as heart tissue following a heart attack.
- Generation of neurons to cure Parkinson's disease.
- Growth of cartilage-forming cells to alleviate arthritis.
- Research into curing diseases such as Alzheimer's, osteoporosis, cancer, and juvenile diabetes.⁶
- Drug research and testing, allowing the testing of the safety and efficacy of drugs directly against human tissues, rather than relying on animal models for research.⁷

History of Federal Funding for Stem-Cell Research

Since 1996, federal law has banned federal funding of human-embryo research.⁸ However, in 1999 the Department of Health and Human Services concluded that the congressional ban on funding research using human embryos did not extend to stem-cell research, since stem cells are not embryos and do not have the potential to develop into a fetus or a person.⁹ Following extensive public discussions involving scientists, doctors, patients, lawyers, and ethicists, the NIH issued guidelines for federally funded stem-cell research. The guidelines set limits on stem-cell research funding; for instance, federal funding could not have been used to *derive* stem cells from embryos; it could only have been used for research involving stem cells that were derived using private funds.¹⁰ Moreover, the stem cells could only have been derived from frozen embryos that were created for fertility treatment and were in excess of those needed for the treatment. The guidelines also included thorough informed-consent requirements for the donors, ensured that there was a clear separation between the fertility treatment and decision to donate, and ensured that the donors could expect no direct benefit from the decision to donate.¹¹

The Controversy

During the 2000 presidential campaign, then-Gov. George Bush indicated he would review and probably reverse the Clinton administration's policies on stem-cell research. Bush had "consistently opposed federal funding for research that requires embryos to be discarded or

destroyed," his spokesman said.¹² Many in the anti-choice movement oppose stem cell research because they wish to ascribe to every fertilized egg in a petri dish the moral and legal status of a person.¹³ This position, however, is impossible to reconcile with well-accepted practices of assisted-reproductive technologies, and even contraception. For instance, in-vitro fertilization typically requires the creation and transfer to the uterus of many embryos for every live birth. Embryos are also commonly discarded after a successful pregnancy or when a couple decides not to continue to attempt to get pregnant. Furthermore, almost all forms of modern contraception (the pill and the intra-uterine device (IUD), for example), including emergency contraception, work, among other ways, by preventing a fertilized egg from implanting in the uterine wall.

On the other side of the debate are the scientists, clinicians, patients, and their families who hope to be able to take full advantage of this promising new technology. More than 80 Nobel laureates wrote to President Bush arguing against regulations that would limit research to those stem cells derived from adult tissues.¹⁴ The prestigious NBAC declared, "In our view, the ban [on research using human embryos] conflicts with several of the ethical goals of medicine and related health disciplines, especially healing, prevention, and research." Patient advocacy groups ranging from the American Diabetes Association to the Parkinson's Action Network support stem-cell research.¹⁵ In addition, many in the religious community strongly support the research.¹⁶ Even a number of anti-choice politicians, including Sens. Harry Reid (D-NV), Gordon Smith (R-OR), and Orrin Hatch (R-UT) have voiced their support for the potentially life-saving research.¹⁷ After long opposing the research, even former Senate Majority Leader Bill Frist (R-TN) reversed his position and ultimately supported a repeal of the Bush restrictions.

The Bush Policy: Politically Expedient, Morally Incoherent

Caught between an American public that strongly supports federally funded stem-cell research and an anti-choice political constituency, President Bush sought a way out. In trying to find a middle ground, the administration developed a politically expedient but morally incoherent policy. The Bush policy allows federal funding for stem-cell research only with cell lines that were derived (1) with the informed consent of the donors; (2) from the excess embryos created solely for reproductive purposes; (3) without any financial inducements to the donors; and (4) from a derivation process initiated prior to 9:00 p.m. EDT on August 9, 2001.¹⁸

The key point to the president's policy is that it refuses to allow any stem-cell lines created after an arbitrary date. However, it fails to justify why research conducted before this date is acceptable, while research conducted after this date is not. According to Arthur Caplan, head of the Center for Bioethics at the University of Pennsylvania, "The problem with the president's policy is that it is hopelessly arbitrary and illogical. Why is it ethical to use stem cells made from human embryos before August 9, 2001, but not after?"¹⁹

Inadequacy of Pre-Existing Stem-Cell Lines

Aside from its moral incoherency, the Bush policy has a number of practical limitations, most of which relate to the adequacy of the cell lines derived before the policy's arbitrary deadline. The National Institutes of Health initially identified 78 cell lines worldwide that were derived in

accordance with the administration's new policy.²⁰ However, the NIH has acknowledged that "[t]here are serious issues about when the cells will be practically available."²¹ According to the NIH, in the third quarter of 2004, there were just 22 human embryonic stem cell lines available to researchers.²²

Concerns about the adequacy of stem cell lines available under the Bush restrictions center on (1) quality; (2) longevity; (3) genetic diversity; (4) ownership; and (5) compliance with ethical standards.

1. *Quality.* Little is known about the quality or viability of the cell lines in the NIH registry.²³ Each stem-cell line is unique and will differ in many characteristics, including its ability to generate into other types of cell lines. Perhaps of greatest concern, many existing cell lines were cultured with animal cells or serum, which could pose health risks if used in humans.²⁴ However, newer methods allow stem cells to be cultivated with other human cells, avoiding the chance of contamination with animal viruses.²⁵
2. *Longevity.* Although stem-cell lines are sometimes referred to as being "immortal" most scientists expect that they will in fact degrade over time.²⁶ Thus, replacement cell lines will need to be derived from time to time if any meaningful research is to be undertaken.
3. *Genetic Diversity.* Many researchers are concerned about the lack of genetic diversity among existing lines. The great majority of the stem cells on the NIH registry appear to have been derived from white couples, meaning they may be of limited use to those from a non-European background.²⁷ If stem cells are to be used to treat injury and disease, the tissues and cells that are produced must be injected into the body. As with blood transfusions or organ transplants, these cells must "match" the patient to minimize the extent to which the patient's body rejects the foreign tissue. Harold Varmus, former head of the NIH and current director of Memorial Sloan-Kettering Cancer Center, and Douglas Melton, leading Harvard cell biologist, have cautioned that "even 100 good lines will likely be inadequate to treat our genetically diverse population without encountering immune rejection."²⁸
4. *Ownership.* All the cell lines on the NIH registry were derived with private funds and/or in foreign nations. The availability of these cell lines to U.S. researchers, and the rights to any products that are derived from the lines, are very much in doubt. For example, obtaining living material from foreign sources requires "material transfer agreements," which can take months or even years to execute.²⁹
5. *Ethical Considerations.* The Bush ethical guidelines for researchers are weaker than both those under the Clinton policy and those required by many universities and other research institutions. Thus, some of the cell lines on the NIH register may not be available to many U.S. researchers if they don't meet the ethical guidelines required by the researcher's home institution. The NIH has acknowledged that it did not study the adequacy of the informed consent forms completed by donors, but that the standard would be whatever was in place in the country or facility where the work was

performed. The American Association for the Advancement of Science has noted that “[t]oo often we have learned that procedures used in other parts of the world in research with human subjects do not measure up to the ethical standards we embrace in this country.”³⁰

These concerns have prompted a renewed debate about the president’s stem cell policy. In 2003, Sen. Arlen Specter (R-PA) asked the Bush administration to allow for more human stem-cell lines to be generated after confirming a potential supply of safer stem cells that were not grown on mouse cells.³¹ Also in 2003, a medical ethics panel comprised of scientists, philosophers, ethicists and lawyers, met at John Hopkins University and echoed the same sentiments. According to the panel, treating patients with the embryonic stem cells approved by President Bush for federal funding would be “unethical and risky.” There are safer stem cells that exist and are currently being used around the world, but the administration refuses to make them eligible for federal funding.³²

Finally, after years of building pressure from scientific experts and American public opinion, in 2006 anti-choice congressional leaders relented and allowed a vote on legislation to repeal the president’s policy. Both chambers passed the legislation, with votes from pro-choice and pro-life members alike, but President Bush vetoed it anyway.³³ Subsequently, in 2007, Sens. Tom Harkin (D-IA) and Specter included language in the FY’08 health-spending bill to make more cell lines eligible for federally funded research. But faced with a veto threat from the White House, they ultimately relented and withdrew the provision.³⁴ Thus, for the time being, the restrictive, morally incoherent policy remains in force.

A Stem-Cell Brain Drain?

The United States is the worldwide leader in biomedical research, but with ever-tightening politically motivated restrictions, its future position remains uncertain. At least one leading scientist, Roger Pedersen, formerly of the University of California, San Francisco, has left the United States for the University of Cambridge where he can pursue his work under the more rational British regulations.³⁵ Jeffrey Kahn, director of the Center for Bioethics, believes that Dr. Pedersen is only the first in what will become a “brain drain” as American scientists relocate in order to pursue their research away from what many see as “overly puritanical restrictions from Washington.”³⁶

Paul Berg, Cahill Professor of Cancer Research at Stanford University and Nobel laureate, worried the United States is losing ground: “I’m absolutely amazed at how little has been accomplished. . . following the president’s announcement. . . . If you look at what’s happening elsewhere, in Australia, Israel and England. . . they are rushing into this area of science because they see its promise. But here there’s just no evidence of urgency.”³⁷ Keith Yamamoto, vice dean for research at the University of California, echoed Dr. Berg’s concerns stating, “Normally. . . many young people would be diving into this field. . . . It’s clear to me there’s been a chilling effect.”³⁸

Conclusion

The federal government plays the most critical role in driving biomedical research. Because marketable products from stem-cell research are still years away, the private sector simply will not make the level of investment that is needed if we are to see the treatments and cures that this technology promises. Furthermore, government funding ensures appropriate oversight and public scrutiny of research. The limited and weak compromise on federal funding for stem-cell research holds the health – indeed, the lives – of millions of Americans hostage.

Before his untimely death caused by complications arising from a paralyzing spinal-cord injury after a horse-riding accident, actor Christopher Reeve gave a poignant perspective: “It is painful to contemplate where we might be today if embryonic stem cell research had been allowed to go forward with full support of the government.”³⁹

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Notes

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- 7 National Institutes of Health (NIH), *Stem Cell Information: Stem Cell Diseases*, at <http://stemcells.nih.gov/info/health.asp> (last visited Dec. 17, 2007).
- 8 Federal funds must not be used for the “(1) creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero. . .” P.L.108-447; P.L. 108-199; P.L. 108-7; P.L. 107-116; P.L. 106-554; P.L. 106-113; P.L.105-277; P.L. 105-78; P.L. 104-208. Research activity involving a fetus in utero, when not undertaken for the fetus’ own health, must pose a minimal risk to the fetus and must seek to “develop[] important biomedical knowledge which cannot be obtained by other means.” 45 C.F.R. § 46.208. The “risk standard” for fetuses in utero must be the same, regardless of whether they will be aborted or carried to term. 42 U.S.C. § 289g(b).
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- 10 Department of Health and Human Services (HHS), *Human Pluripotent Stem Cell Research Guidelines*, at <http://www.hhs.gov/news/press/2001pres/01fsstemcells.html> (last visited Dec. 17, 2007); see also Memorandum from Harriet S. Rabb, General Counsel, HHS, to Harold Varmus, M.D., Director, NIH, Jan. 15, 1999 (on file with NARAL); NIH Press Release, *NIH Publishes Final Guidelines for Stem Cell Research*, Aug. 23, 2000; 65 Fed. Reg. 51976, 51979, 51981 (Aug. 25, 2000), as corrected 65 Fed. Reg. 69951 (Nov. 21, 2000).
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- 18 President George W. Bush, *President Discusses Stem Cell Research*, Aug. 9, 2001, transcript at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html> (last visited Dec. 18, 2007); Press Release, NIH, *Update on Existing Human Embryonic Stem Cells*, Aug. 27, 2001 at <http://www.nih.gov/news/pr/aug2001/od-27.htm> (last visited Dec. 17, 2007).
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