President Obama's Executive Order and Stem Cell Research

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On March 9, 2009, President Barack Obama issued an executive order that rescinded the letter of former President George W. Bush, issued August 9, 2001, that limited Federal support of human embryonic stem cell research.

Although the details of what human embryonic stem cell research will be supported by Federal funds awaits "new NIH guidance on such research," to be made known by July 7, 2009, President Obama's new Executive Order was welcomed by stem cell scientists. The burdensome and expensive bookkeeping and research practices to separate "non-presidential" stem cell research from "presidential" stem cell research will no longer be necessary for some studies, but will continue for other studies because of long standing federal regulations not over-turned by the Obama order. As with all biomedical research break-throughs, private funding remains essential.

As it stands now:

Because of a long-standing prohibition on federal funding for research on human eggs and embryos (described below), the ability of the National Institutes of Health to fund research to study the newly derived human embryonic stem cells was murky in 1999. Moreover, the House of Representatives had passed legislation that would have made the derivation of human embryonic stem cells from human embryos illegal, and with criminal penalties. Because such legislation was not passed by both the House and the Senate, it never became the "law of the land."

To both clarify and restrict the scope of Federal funding for human embryonic stem cell research, former President Bush issued guidelines on August 9, 2001, that limited Federal funding to research on those human embryonic stem cell lines that had already been created with private funding. At the time, his belief, based on information from the National Institutes of Health Stem Cell Registry, was that there were 60 genetically diverse human embryonic stem cell lines that could be studied with Federal funding.

Unfortunately, the real number of stem cell lines available for study proved to be fewer than a dozen, severely limiting the research possible with Federal funding. Moreover, none of the stem cell lines were from embryos diagnosed with deadly genetic diseases, such as Tay Sachs, Huntington's Disease and sicle cell anemia. Scientists believe genetically diseased stem cell lines will be powerful tools to better understand the disease and develop treatment approaches.

On June 20, 2007, former President Bush issued an executive order (#13435) expanding Federal funding for stem cell research from sources other than human embryos. Although the ultimate goal of stem cell research is to NOT need human embryos, the science is not yet that advanced. Scientists have attempted for decades to expand adult stem cells to the trillions needed for therapy without success. Research on embryonic stem cells is needed to fill the knowledge gaps that are preventing the use of all sources of stem cells for regenerative medicine treatments.

President Obama's new Executive Order also rescinds Bush's Executive Order 13435. Therefore, for the first time since human embryonic stem cells were developed in Wisconsin in 1998, Federal funding will be available for research on many more useful human embryonic stem cell lines than before.

Importantly, however, Federal funding will still NOT be available for the derivation of new stem cell lines from discarded human embryos, including those diagnosed with serious diseases. Nor will Federal funding be available for the derivation of parthenote stem cells from unfertilized human eggs. Many scientists will, therefore, need private or state sources of funding to continue their research.

The history:

Federal concern with human embryo research began over 25 years ago with the advent of assisted reproduction technologies, i.e. in vitro fertilization (IVF) or "test tube babies." Although the first report of laboratory studies in Brookline, Massachusetts, of human fertilization appeared in Science in 1944, clinical IVF was successful first in Great Britain in 1978 for couples with infertility. IVF became standard of care in the United States in the early 1980's. As with all other forms of clinical treatment, the medical community began to look to basic science

research to improve the safety and efficacy of IVF for mothers and babies. Such research was not possible with Federal funds.

In 1979, an Ethics Advisory Board for the National Institutes of Health issued guidelines for research on earlly human embryos, but no action was taken, and no new Ethics Advisory Board was convened after 1980. For these reasons, the Federal Policy for the Protection of Human Subjects enacted in 1977 remained in place: 45CFR § 46.204(d), "No application or proposal involving human in vitro fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint." Since there was no Ethics Advisory Board, federally funded research was not possible.

Throughout the 1980's, public debate about conducting research on early human embryos took place in Great Britain. Many were in favor, many were opposed. The debate ultimately led to the formation of a regulatory body to oversee research on human fertilization. That regulatory body remains active today, which is why embryonic stem cell research was first possible in England.

In 1993, former President Clinton initiated the National Institutes of Health Revitalization Act (Pub. L. No. 103-43), section 121(c) of which simply eliminated 45CFR § 46.204(d), paving the way for Federal funding of grant applications to study human fertilization without the need for additional review by an Ethical Advisory Board.

When this possibility became known to the U. S. Congress in 1996, Representatives Dickey and Wicker authored a rider for the budget of the National Institutes of Health: Balanced Budget Downpayment Act, I, Public Law No 104-99, § 128, 110 Stat. 26, 34 "...none of the funds appropriated shall be used to support any activity involving: 1) the 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 under 45 C.F.R 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 USC 289g(b)." Further, "For purposes of this section, the term 'human embryo or embryos' includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this ACT, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."

The Dickey-Wicker amendment to the budget of the National Institutes of Health has been renewed each year since 1996. President Obama's new Executive Order does not change this Federal moratorium on funding studies that will destroy human embryos, artifically activated unfertilized eggs ("parthenogenesis"), or eggs following nuclear transplantation of somatic cells.

For additional information, see the Connecticut Law Review, Vol 36, #4, 2004 that contains 8 essays on "What is an Embryo?" and the Rejoinder, Connecticut Law Review, Vol 37, #1, 2004.

The need for private funding:

Although there are federal restrictions on the use of taxpayer dollars for human embryo research, the federal government continues to encourage taxpayers and corporations to support research they deem important by providing tax deductions for contributions to qualifying research institutions. The over-dependence on the federal government to support biomedical research has grown ten-fold in the past two decades. For example, prior to that, when President Roosevelt launched the campaign to cure Polio, he did so not by increasing funding to the National Institutes of Health, but by creating a public charity, the National Foundation for Infantile Paralysis, which for two decades accepted private donations to fund the research that led to the development of the polio vaccine.

The recent federal moratorium on funding embryonic stem cell research emphasized the pitfalls in over-dependence on centralized federal funds for biomedical advances, markedly increased the need for private funding, and stimulated several states to establish state-sponsored research resources. Such de-centralization of research resources helps to ensure that no good idea goes unfunded, and that all citizens have the ability to support research they feel is meritorious.

President Obama's rescindment of research funding restrictions enacted during the Bush administration will help speed the discovery of regenerative medicine treatment strategies with stem cells, but in no way replaces the need for private and/or state funding. Women with serious diseases such as Huntington's Disease, spinal cord injury and Crohn's disease have volunteered to donate their eggs for parthenote (from unfertilized eggs) stem

cell research, which can only be carried out with non-federal funds. Scientists agree that parthenote stem cells provide a valuable alternative to embryonic stem cells both for studies of diseases and for potential therapies.

In addition to increasing Federal funds for biomedical research, President Obama and the U. S. Congress need to ensure and strengthen the tax benefits for all citizens who donate to the research program of their choice.

The Bedford Research Foundation is currently raising funds to support the Parthenote Stem Cell Program.