



Memo to HHS/NIH Transition Team

NEXT STEPS FOR STEM CELL RESEARCH AND RELATED POLICIES CONSIDERATIONS FOR THE NEW ADMINISTRATION

Center for Genetics and Society
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Over the past eight years, public understanding and discussions of embryonic stem cell research have been marked by deep polarization. The new administration has an opportunity to help put this divisive past behind us. It can begin immediately to craft a pro-research stand that simultaneously affirms the need for consistent and enforceable regulation, for hope without hype, and for ensuring that stem cell research and applications accord with principles of equity, social justice and human rights.

This memo recommends new federal policies on embryonic stem cell research; grounds these recommendations in a framework of widely shared social values; and calls attention to related human biotechnology issues that the new administration is likely to confront during its first term. A fuller treatment of these topics, *Responsible Federal Oversight of the New Human Biotechnologies: Opportunities for the New Administration*, will be available on January 14, 2009 at <http://www.geneticsandsociety.org/opportunities>.

NEW FEDERAL POLICIES ON EMBRYONIC STEM CELL RESEARCH

1. Lift restrictions on federal funding

A presidential directive, issued at the earliest opportunity, should lift current restrictions on federal funding for embryonic stem cell research. It should clearly establish that federal funds will be available for work on stem cell lines that have been derived in accordance with established guidelines. Most important among these are that the stem cell lines be produced using embryos created but not needed for reproductive purposes, and that informed consent for stem cell derivation is given by those whose gametes were used in the creation of the embryos.

2. Ensure comprehensive federal oversight

The new administration should work with Congress on legislation that codifies federal funding for stem cell research along the lines outlined above, and, in broad terms, requires effective regulatory oversight of stem cell research. The Congressional directive should inform regulations to be subsequently developed by the National Institutes of Health. These may be based on the voluntary National Academies guidelines issued in 2005 and amended in 2007 and 2008. Legislation should specify that stem cell research standards are enforceable rather than voluntary, and that they apply to all research. The Stem Cell Research Oversight (SCRO) committees recommended by the National Academies should be made accountable to a federal oversight authority, as are the Institutional Review Boards that currently oversee human subjects research. Proposals for stem cell research involving somatic cell nuclear transfer should be subject to particular scrutiny, given the special risks involved and the likely availability of induced pluripotent stem cell techniques for deriving disease-specific and patient-specific stem cell lines.

OPPORTUNITIES TO RESHAPE THE DEBATE ON STEM CELL RESEARCH

The new administration can begin to reshape the public debate on stem cell research not just through its policy initiatives, but also through the values in which it grounds them, the messages with which it communicates about them, and the constituencies it brings together to help develop and support them.

1. Encourage deeper understanding of the individual and societal benefits and risks of stem cell research and other human biotechnologies, grounded in widely shared values

Although Americans may hold differing views about embryo research, they share common ground in the desire to safely and effectively treat disease and alleviate suffering. They are supportive of medical and scientific advances, but are aware that these can also have unanticipated and undesired social consequences. The majority of Americans support stem cell research using embryos created but not needed for fertility treatments, providing this research is carefully regulated. At the same time, Americans do not support reproductive cloning or inheritable genetic modification, and are wary of many non-medical applications of genetic and biomedical technologies.

As the new administration prepares its stem cell policies, it should continue to emphasize the importance of effective regulatory oversight of research and applications. Special effort must be made to protect the scientific integrity of stem cell and related medical research by preventing conflicts of interest involving stem cell researchers and commercial ventures. Exaggerated promises about near-term stem cell-based cures must be avoided. The public interest – including equitable access to the benefits of stem cell research – should be a priority value in decisions about broad funding directions, patent policies, and commercialization policies.

2. Engage a wider range of constituencies in public dialogue

Public and policy discussions of stem cell research and other human biotechnology issues must involve a wider range of voices than has been heard to date. Debate on these topics has been largely driven by religious conservatives, biomedical researchers, research advocacy groups, and the commercial biotechnology sector. Additional constituencies, including women's and children's health advocates; public health leaders; advocates for civil rights and racial justice; human rights leaders; and representatives of people with disabilities, need to be represented if the ensuing policies are to have broad support.

RELATED HUMAN BIOTECHNOLOGY ISSUES

1. Prohibit human reproductive cloning

The new administration should work with Congress to quickly enact legislation prohibiting human reproductive cloning. Opposition to reproductive cloning is nearly unanimous among scientists, health professionals and the general public. As of December 2008, 59 countries have adopted legislation banning it, including those with the most robust biomedical research sectors and every member of the Organization of Economic Cooperation and Development except the United States. Bills to prohibit reproductive cloning have been introduced by Senators Dianne Feinstein (D-CA), Edward Kennedy (D-MA) and Tom Harkin (D-IA), among others. A clear, permanent ban on reproductive cloning, including explicit sanctions for those who seek to violate it, is needed now to help build public confidence in the responsible development of stem cell and other biomedical technologies.

2. Establish comprehensive federal oversight of other human biotechnologies

The new human biotechnologies have potential for both great good and great harm. If properly used, they could lead to advances in medical knowledge and new ways of treating disease. If misused, however, they could harm research subjects and patients and reinforce societal inequities, discriminatory beliefs and practices, and inequality. During the next few years the administration will likely be called on to address increasingly controversial human biotechnology issues, including the prospect of athletic "gene doping," the rapid expansion of commercial genetic testing and of commercial trade in reproductive tissues and services, the development of powerful neuro-pharmaceuticals for altering cognitive functions, the creation of animal-human chimeras for research, the expansion of DNA forensic databases, embryo screening to select the sex and other non-medical traits of future children, and more.

Many countries, including the United Kingdom, Canada, France and Germany, have established comprehensive national policies that allow valuable medical research and applications to proceed while proscribing others. The new administration should begin a review of new and controversial biotechnologies, with an eye towards the development of appropriate federal oversight policies for the United States.

ABOUT THE CENTER FOR GENETICS AND SOCIETY

The Center for Genetics and Society is a nonprofit public affairs organization working to encourage responsible uses and effective societal governance of the new human biotechnologies. The Center works in a context of support for the equitable provision of health technologies domestically and internationally; for women's health and reproductive rights; for the protection of our children; for the rights of the disabled; and for precaution in the use of powerful new technologies. For information on this memorandum, please contact CGS Associate Director Dr. Marcy Darnovsky at mdarnovsky@geneticsandsociety.org or 510-625-0819 x 305.

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