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U.S. STEM CELL POLICY – UNINTENDED CONSEQUENCES

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U.S. Stem Cell Policy – Unintended Consequences

Over the past decade, the U.S. human embryonic stem cell (hESC) policy has become a hodgepodge of difficult-to-understand and easily misinterpreted legislation and regulations. By a 2001 executive order, President George W. Bush defined official federal policy to restrict federal funding of research to the hESC lines that were created before August 9, 2001 (the date of his speech). No hESCs created after that date, regardless of the source, could be used in federally funded research. Federal policy is also guided by the Dickey-Wicker Amendment, which applies to all federal biomedical research and bans the use of federal monies for the creation of hESC lines. In addition to the federal policy, states have moved forward with their own policies. Some states banned all research or portions of research, while others such as California and Connecticut encouraged it with state funding. Also, in contrast to many other countries, there are no federal restrictions on hESC research carried out by private companies or any other nonfederal entity.

This piecemeal policy has prompted medical researchers to call for a clearly defined and all-inclusive national stem cell policy, specifically for federal oversight and funding of expanded hESC research. This includes expanding federal funding for research on hESC lines created with leftover donated *in vitro* fertilization (IVF) embryos (as provided for in bills passed in Congress in 2006 and 2007 that were later vetoed). With proposed oversight through the National Institutes of Health (NIH), the public would be involved in the policymaking process, and research would progress at a pace that would allow the United States to continue as a leader in this important area of medical research.

To achieve this goal, however, there are many obstacles to overcome. In recent years the administration has discovered that it had accidentally banned research it supported. The problem stemmed out of the 2001 executive order, which was worded in such a way that it banned federal funding on all new hESC lines, no matter how they were created. Thus, methods of creating an hESC line without destroying a human embryo (i.e., methods the administration has deemed “morally acceptable”) were also effectively banned by this directive.

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Efforts to change the federal policy have been unsuccessful. In 2006 and 2007, President Bush vetoed bills to increase the number of hESC lines available for federally funded research – lines that would have been taken from donated embryos that were to be discarded at IVF clinics around the country. Instead, in June 2007 the administration passed a new executive order to allow additional hESC lines to be eligible for federal funding, but only those that were created without “destroying, discarding, or subjecting to harm a human embryo,” adding another regulation to an already large collection of policies affecting hESC research. Scientists have developed methods to create hESC lines by removing one cell from an eight-cell human embryo without destroying it, a process similar to methods used in IVF. However, the method still carries a risk for the embryo, as it may not survive the procedure. Thus, even with the 2007 executive order, NIH may not be able to fund this new, “morally acceptable” research.

This conundrum highlights the unintended consequences that often result from efforts to regulate scientific research. While the administration hoped to promote new research that protected human embryos from destruction, it ended up inhibiting this research altogether. Words like “harm” or “injury” in regulations cause confusion – and stifle research, because the legal repercussions of misinterpreting regulations are severe.

To research these complex policy issues, the Baker Institute’s International Stem Cell Policy Program was established in November 2006. The goal of the program is to bring together scientists, ethicists, policymakers, media experts, and community and business leaders to find new ways to engage the general public and policymakers in a dialogue on this important issue. It is our hope that the discussions and publications of the program will contribute to the resolution of the federal-level stalemate concerning oversight and regulation of hESC research and promote hESC research which offers a real hope for better understanding of many debilitating diseases and injuries as well as new treatments and cures.