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Stem Cells: Growth and Development...in Policy

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Many scientists and patient advocates cheered earlier this summer when the National Institutes of Health (NIH) released new guidelines for human embryonic stem cell (hESC) research. The guidelines came after President Obama's March 2009 executive order lifting the restrictions on federal support for research using embryonic stem cells.

Obama's directive revoked the Bush administration's restrictions and funding ban on hESC research, which had limited scientists to using only 21 approved cell lines out of about 700 in existence. The directive also ordered the NIH to issue new guidelines for hESC research, which were released in July 2009. These new guidelines specify that NIH funding can be provided for research on hESCs derived from human embryos "that were created using *in vitro* fertilization for reproductive purposes [but] were no longer needed for this purpose," and were donated by individuals who were fully informed about embryo treatment and gave their voluntary, written consent to use the embryos for research. The guidelines also stipulate that there can be no financial inducements for embryo donations, and that NIH-funded research must remain separate from privately funded research. Additionally, the NIH will establish a working group of scientists and ethicists to review existing cell lines, determine their eligibility for federal funding, and post those hESCs eligible for federal funds in an online registry.

The presidential directive greatly expands the research potential in this field, but Obama noted in his remarks about the order that the "full promise of stem cell research remains unknown, and it should not be overstated." Many advocates of stem cell research agree: Much more stem cell research will take place, yet much more policy work still awaits action.

The spotlight is currently on the NIH working group. This is because until the NIH determines which cell lines are eligible for federal funding, hESC research remains on hold and, as of early September 2009, the NIH registry was still empty. Alan Smith, senior research scientist at Stemina Biomarker Discovery (a metabolomics company in Madison, Wisconsin), says that this void in the registry is a major concern for industry because it is slowing efforts to build new collaborations with other companies that are using yet-to-be-approved cell lines and to spur innovations in stem cell research. It is unclear when new stem cell lines will be entered into the registry—no timeline has been announced—but some researchers are concerned that the addition of the new lines may take years.

Other pressing policy issues remain. Some analysts have suggested that the government focus on developing a coalition among all the entities that work on stem cells, perhaps by supporting the formation of geographic innovation hubs. Such a large-scale collaboration between universities and industries could be transformative for the field of regenerative medicine. Other experts, such as Jonathan Moreno, a senior fellow at the Center for American Progress, believe that the next grand policy challenge will be to develop guidelines for safe human trials. The pharmaceutical company Geron was set to begin the first-ever human clinical trial of stem cell therapy on spinal cord injury patients in August. However, in the last round of animal trials, researchers found a larger-than-expected occurrence of cysts, and the US Food and Drug Administration (FDA) halted the trial. Moreno argues that stem cell advocates ought to proceed to clinical trials with caution, as human trials with tragic results would cause a change in the tide of public support for stem cell research.

Proponents of stem cell research are hopeful that the Obama administration policy will allow US scientists to remain leaders in stem cell science and technology. More research should soon be eligible for federal funding, and making more lines available for research, as Smith says, will "open up the vast range of hES lines derived from genetically diverse embryos." Stem cell advocates remain hopeful that the pace of research will accelerate as scientists collaborate and eliminate some of the delays associated with past requirements for separate and dedicated stem cell research laboratories, equipment, and personnel. Many believe that once the public sees the first positive results from hESC research, much of the tension surrounding the stem cell debate will disappear, and stem cells will truly grow.

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