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## Obama overturns stem-cell ban

President's executive order will allow US human embryonic stem-cell research to thrive at last.

#### Erika Check Hayden

Scientists and research advocates worldwide are celebrating the removal of rules limiting research on human embryonic stem cells in the United States, which they say have restricted the field's progress for seven and a half years.

The National Institutes of Health (NIH) in Bethesda, Maryland, is now working out policies that will allow researchers to apply for grant money from the agency to study some of the hundreds of cell lines created since 9 August 2001, when President George W. Bush limited federal funding to research on lines in existence at that time. Some scientists are already proposing to use the new lines in applications for \$200 million in NIH 'Challenge' grants, which will be funded by the economic stimulus package signed into law last month. Details of these grants were unveiled last week (see NIH website).

Estimates of the number of new lines range from 400 to 1,000. Unlike the 21 lines previously eligible for federal funding, many of the lines have been made from embryos that had genetic predispositions to specific diseases, or were derived using 'animal-free' preparations, and thus could be more relevant to laboratory research and preclinical studies.



Heather Melichar (left) and Ou Li at the University of California, Berkeley, can now use the federally funded equipment in their main lab to do embryonic stem-cell research.

P. Skorpinski

President Barack Obama signed the executive order on 9 March at a White House ceremony attended by scientists, lawmakers, patients and patient advocates. "We will vigorously support scientists who pursue this research," Obama said. "And we will aim for America to lead the world in the discoveries it one day may yield."

The new order asks the NIH to develop guidelines and regulations within 120 days to govern federally funded human embryonic stem-cell research. Work is already under way at the NIH to develop guidelines covering the eligibility of cell lines for federal funding. These will be based on issues such as the kind of informed consent given by couples who donated the leftover embryos from which the cells were collected. Such cells can develop into any type of tissue in the body, and are thus thought to hold enormous promise as tools for dissecting disease processes, screening possible treatments and developing new therapies.

Legislation to codify the change has already been introduced into both the House of Representatives and the Senate. It explicitly permits federal funding for research on stem-cell lines derived with parental permission from embryos left over at fertility clinics and otherwise slated for destruction. At least one observer has suggested that legislation explicitly approving federal funding for stem-cell research is needed to address the Dickey-Wicker amendment, a law first enacted by Congress in 1996 and renewed every year since, that prohibits federal funding of research in which embryos are created or destroyed (see <u>Nature 457</u>, 1068–1069; 2009).

Scientists and advocates say the change will speed up research on stem cells and the development of possible treatments around the world, and will help remedy what they see as the Bush administration's legacy of political interference in science. "This is the first time that the key decisions and guidelines on this issue are going to be made in Bethesda and not at 1600 Pennsylvania Avenue," says Larry Soler, executive vice-president of the Juvenile Diabetes Research Foundation International, based in New York City. "That is what the scientific community and the patient community have been asking for."

But there was a bittersweet taste to the victory, as scientists lamented almost a decade of delays to the research. "There's no doubt that this federal policy has really slowed the rate of progress of stem-cell research in the United States, and the impact of the change in policy would have been greater if it had happened years ago," says Arnold Kriegstein, director of the Eli and Edythe Broad Center of Regeneration Medicine and Stem Cell Research at the University of California, San Francisco.

Those who oppose the research because it involves the destruction of embryos criticized Obama's decision. They say that the NIH should support research only on cells that are not derived from embryos, such as induced pluripotent stem cells (iPS cells), which are derived from adult cells but have many properties of embryonic stem cells.

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But iPS cells, first created in 2006, are not a substitute for embryonic stem cells, Kriegstein says. "iPS technology and its ongoing improvement will likely eclipse embryonic stem-cell lines for diagnostic and therapeutic applications, but for now, embryonic stem cells are clearly needed. And it's still not clear how iPS cells will ultimately compare for therapeutic purposes."

Obama's action will begin to level the playing field for researchers in the United States, where some states — most notably California, which created the \$3-billion California Institute for Regenerative Medicine (CIRM) in 2004 — have leapfrogged ahead of others by funding stem-cell research themselves. And it will have ripple effects around the world, some predict. "This type of science is international, and the whole world has suffered from the previous short-sighted and rather bizarre policy," says Robin Lovell-Badge of the National Institute for Medical Research in London.

For instance, Lovell-Badge collaborates on one project with NIH-funded scientists who have had to limit their work to the previously approved cell lines. More broadly, the lack of policy guidance from the NIH — normally a global science-policy leader — "has contributed to the morass of different rules adopted around the world, which in turn inhibits collaboration, goodwill and progress", Lovell-Badge adds.

Indeed, CIRM president Alan Trounson says that other nations with restrictive stem-cell research policies, such as Germany, now seem to be rethinking their stance, and he predicts that the Obama administration's support for the research will accelerate this trend. Such support may also encourage wary investors and pharmaceutical companies to become more involved in funding the research, and this could benefit both the biotechnology industry and the development of new treatments.

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"Since Obama was elected, the pharmaceutical industry is clearly much more interested in stem

cells," Trounson says. "That will be a really big help when we're working through costly and difficult clinical trials to get treatments to patients."

For more images of a US lab working with human embryonic stem cells the day the ban was lifted, see our slideshow

A video interview with members of the lab is available **here** 

See Editorial, page 125

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This is excellent news, even if iPS cells fulfill their promise there is still an need for continued human ESC research to guide the development of stem cell medicine. Scientists shouldn't let their guard down though, the so-called "Republican War on Science" may be over for now, but other threats to science and science based medicine remain as strong as ever. We need to redouble our efforts to make the best use of the window of opportunity that has just opened. http://speakingofresearch.com/2009/03/10/restoring-science-to-its-rightful-place/

Report this comment Posted by: Paul Browne 10 Mar, 2009

I welcome this overturn because it will give stem cell researchers better opportunities to learn the developmental process of NATURAL stem cells rather than ALTERED stem cells such as iPSCs. In addition, with more ESCs available for comparison with iPSCs, more and more distinctions may be found between them for overturning an ?indistinguishable? claim made earlier. The promise of iPSCs for therapeutic cloning and regenerative medicine rests on the capability of completely removing the introduced factors and avoid the cancer-forming tendency as repeatedly shown in various published studies on iPSCs. In addition, whether the reprogramming in iPSCs has been done correctly or not is still an open question. Understanding the normal development program of ESCs will help us in reaching an answer to this question. So ESCs are much needed, indeed. (see more at http://im1.biz and http://blog.sina.com.cn/im1).

Report this comment Posted by: Shi Liu | 10 Mar, 2009

With all respect to the excellent news, the public should keep in mind that just having embryonic stem cells research with adequate funding is not a guarantee for near future embryonic stem cells remedies. Legitimate embryonic stem cells research has been conducted in a number of countries around the world where such restrictions were not imposed for more than a decade. Cell lines were produced and many problems in maintaining such cells were solved. Nevertheless, major technical and biological obstacles make the translation of the use of such cells into a component of tissue regeneration

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therapies still exist. These include the adoption of the donor histocompatibility profile upon differentiation of the stem cells, which may result in their rejection as a mismatch organ transplant, the tendency of such cells to form teratomas and other cancers and, more importantly, the lack of adequate techniques to engineer the cells in the tissues to reach adequate therapeutic outcome. In many ways one could compare the way to go in the application of embryonic stem cells to invention of the single transistor on the road to the currently used integrated circuits, when you do not know yet if this is the actual component on which the integrated chips will be based on eventually.

Report this comment Posted by: rafi gorodetsky | 10 Mar, 2009

Science (knowledge) is indeed a powerful and effective tool, in itself neither good nor bad. By necessity, ethical considerations will arise at every instance when the human person is using this powerful tool. Therefore, any use of science must be subject to the ethical standards of the community. A mere lack of community (ethical) control does not mean an absence of ethics in doing science (every human behavior is governed by and expresses some kind of ethical consideration). It only means an absence of commonly agreed upon and accepted ethical standards and the presence of ethical standards that serve the interest of some. Interestingly, this is how dictatorships work also: some own and use powerful tools that serve their interest, at the expense of others. There is no such thing as apolitical science, as President Obama claims. Every human activity happens within the community (polis? city, community), it impacts the community and as such it is intrinsically political. Therefore, President Obama?s statement about a science not influenced by politics and ?ideology? is inconceivable and as such, totally illogical. He just happened to have a different political and/or ideological standard than his predecessor had. The question remains, who and what authority will decide which one is more ethical? The practice of science (not science?s inner logic) has to be governed by ethical considerations. Otherwise we end up with a ?scientific barbarism,? of which we have sadly experienced the consequences during the Second World War, and afterwards during the nuclear crisis. This cannot happen again. A lack of open and frank ethical debate on life issues (such as the ethical and legal status of the human embryo) was not encouraged by the previous administration. Sadly enough, this new administration seems to be set to repeat the same mistake.

Report this comment Posted by: A. Prokecz | 10 Mar, 2009

If Jack is fatally injured and Jill volunteers to give up her life to save Jack's, we applaud her selflessness. But if Jack is fatally injured, and Jill kills a nearby baby to save Jack's life, what do we do? In the US, we fund more research on Jill's technique. This is what Embryonic Stem Cell Research is.

Report this comment Posted by: Jeff Harvey | 11 Mar, 2009

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