



# Rapid Public Health Policy Response Project

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## Embryonic Stem Cell Research: What are the Next Steps?

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### About this Paper

On March 9, 2009, President Barack Obama signed an executive order lifting the ban on federal funding for embryonic stem cell research. The National Institutes of Health (NIH) has been asked to revise its existing guidelines within 120 days. While these steps alone will undoubtedly expand research significantly, choices made in Congress and NIH actions could promote further research activity, or change its direction.

For example, Congress could codify the President's action — or countermand it — so that it could not be as readily altered by future administrations. Legislators could also overturn existing law so that federal funding can be used not only to study any available stem cell lines, but to create new ones. Likewise, the NIH has substantial leeway in deciding whether to support research that uses so-called “custom-made” embryos created exclusively for research, or derived through the techniques of therapeutic cloning, or to limit its support to embryos created at *in-vitro* fertilization clinics.

This paper reviews the issues likely to be debated over the coming months as embryonic stem cell research begins to expand.

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### About the Rapid Health Policy Response Project

The Rapid Health Policy Response Project of the School of Public Health and Health Services at The George Washington University presents data and other background information on breaking public health stories. The goal is to educate the public, policymakers, legislators, health care providers, the media and others in order to promote informed decisionmaking.

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On March 9, 2009, President Barack Obama signed an executive order lifting the ban on federal funding for embryonic stem cell research.<sup>1</sup>

His remarks at the signing ceremony were eloquent. Those “tiny cells,” he said might be used “to regenerate a severed spinal cord and lift someone from a wheelchair; to spur insulin production and spare a child from a lifetime of needles; to treat Parkinson’s, cancer, heart disease and others that affect millions of Americans and the people who love them.”<sup>2</sup>

But the President acknowledged that the scientific breakthroughs necessary to achieve these goals are uncertain, and that other changes to the existing policy and legal framework governing stem cell research now need to be considered. This paper explains how the recent executive order has changed the landscape, and the decisions confronting Congress and the National Institutes of Health (NIH).

## The Science and the Controversy

The International Society for Stem Cell Research, the leading scientific society in the field, likens stem cells to a “blank microchip that ultimately can be programmed to perform particular tasks.”<sup>3</sup> The most versatile type of stem cell research uses “pluripotent” stem cells isolated from human embryos. Known as embryonic stem cells, they can develop into any other type of cell in the human body, and may not provoke a risky immune response when placed into a patient. The great hope of stem cell research is that it will allow scientists to understand how cells develop into their many specialized functions and perhaps ultimately allow them to be used to repair or replace cells that become damaged in a host of diseases.

President Obama’s executive order declares that the NIH “may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law” and calls for NIH guidance on how such research can be conducted.

Possible next steps:

- Congress can enact legislation allowing (or banning) the use of federal funds for embryonic stem cell research so that future presidents can not act solely by executive order.
- Congress can remove legal restrictions that currently prohibit the use of federal funds to create new embryonic stem cells. If it does not, federal funding will be available only for research on embryonic stem cells created with private funds.
- Congress can allow federal funding only to create new embryonic stem cell lines derived from embryos that were used as part of an *in-vitro* fertilization process and that would otherwise be discarded. Alternatively, it can allow funding to create embryos specifically for research purposes.
- The National Institutes of Health can issue guidelines limiting federal support to research involving embryonic stem cell lines created from the leftover *in-vitro* fertilization embryos. Or, it could also fund research on cell lines developed from embryos created solely for research purposes or with the techniques of therapeutic cloning.

Stem cells were first isolated from human embryos in 1998 by Dr. James A. Thomson, a biologist at the University of Wisconsin in Madison. Once a stem cell line is successfully established, those cells can be replicated in the laboratory, perhaps indefinitely, and shared with other researchers.

**Restrictions on research funding:** Thomson conducted his scientific investigations with private corporate and foundation funding because a 1995 law banned federal support for any research “in which human embryos are created, destroyed, [or] discarded.”<sup>4</sup> That ban, known as the Dickey-Wicker amendment, has been attached to congressional appropriations bills every year since then, and remains in place today.

In 1999, a year after Thomson’s discovery, the Department of Health and Human Services (HHS) concluded that the Dickey-Wicker amendment did not ban the use of federal funds for all human embryonic stem cell research, as long as the cell lines themselves were created with private funding. In August 2000, the National Institutes of Health released guidelines to allow some public support for the research.<sup>5</sup>

But presidential elections soon followed, the political climate changed, and research was largely stalled. On Aug. 9, 2001, President George W. Bush announced that federal funds could be used for embryonic stem cell research, but only if the cells had been derived from human embryos prior to that date. Researchers could not study any subsequently created cell lines in laboratories that had any federal funding whatsoever. So stringent was the firewall that no scientific equipment paid for by other NIH grants, not even a test tube, could be used.

According to Bush’s August 2001 statement, 71 lines of embryonic stem cells had already been created and were available for use.<sup>6</sup> While this cracked open the door to some public funding, many of those cell lines turned out to be merely “in development,” and not viable for research.<sup>7</sup> As of March 2009, 18 stem cell lines on the National Institutes of Health Federal Registry were deposited in the National Stem Cell Bank and available to researchers.<sup>8</sup> This limited supply posed a number of potential difficulties, including possible contamination with cell lines from other animals or viruses, which could block their use in human clinical studies. The embryonic stem cell research that took place during this period continued to be financed mostly by private sources, and later by some of the states, including California.

**Other stem cell research:** With limited funds available for embryonic stem cell research, scientists sought other sources of stem cells for their experiments. Adult stem cells — something of a misnomer because they can be derived from fetal tissue or the bodies of infants, children, and adults — are undifferentiated cells isolated from mature tissues in the body. Induced pluripotent stem cells are differentiated cells that have been turned back into “blank” cells.

While work with these cells has moved forward, their capacity to surpass the potential of embryonic stem cells is unknown. Indeed, given the many technical challenges and limitations of any approach, many scientists believe that investigations into embryonic stem cells, adult stem cells and induced pluripotent stem cells should proceed in parallel.

**The shift under Obama:** With its promise that federal funds can be used to support a much broader range of research, Obama’s executive order is likely to launch a significant

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amount of new scientific activity in the field. Scientists will be able to seek federal funding to study any available embryonic stem cell line, and the complex firewall that had to be erected between private and public research funding will be removed. However, the new executive order does not permit the use of federal funding to *create* new stem cell lines, only to use those created by others. Any change in that regard will have to come from Congress.

The President has given the National Institutes of Health 120 days to review and revise its existing guidelines, describe the research it will be willing to support, and establish appropriate safeguards.

### Next Steps in Congress

As the swing of the pendulum from President Bush to President Obama suggests, some of the fundamental policies guiding embryonic stem cell research remain subject to the policy preferences of the White House occupants. Congressional legislation could codify the President's action — or countermand it — so that it could not be as readily altered by subsequent administrations. It could also go further to lift the Dickey-Wicker amendment and allow federal funding for the creation of new embryonic stem cell lines, and other research involving embryos.

Among the bills pending before Congress:

- ▶ The Stem Cell Research Enhancement Act of 2009, introduced into the U.S. House of Representatives by Reps. Diana DeGette (D–CO) and Michael Castle (R–DE), would require the federal government to support research on embryonic stem cells, regardless of when they were created, as long as those cell lines were derived from *in-vitro* fertilization clinics, were in excess of the needs of the individuals seeking fertilization treatment, and would otherwise be discarded.<sup>9</sup>
- ▶ The Stem Cell Research Improvement Act of 2009, introduced in the House by the same bipartisan sponsors, establishes the same criteria for federal funding, and also mandates the NIH to issue research guidelines to ensure appropriate oversight.<sup>10</sup>
- ▶ Like the other bills, the Senate version of the Stem Cell Research Enhancement Act of 2009 would provide federal support for embryonic stem cell research if the cells were donated from *in-vitro* fertilization clinics. Under the leadership of Senators Tom Harkin (D–IA) and Arlen Specter (R–PA), that bill also has bipartisan support. The proposed legislation also requires HHS to pursue research to develop techniques for isolating and testing stem cells that were not derived from human embryos and requires the HHS Secretary to prioritize research with the greatest potential for near-term clinical benefit.<sup>11</sup>

None of these bills would permit funding for research that used embryos created specifically for research purposes. For now, Congress seems more comfortable limiting federal support to embryonic stem cells derived from the surplus embryos that are routinely created as part of fertilization treatments, and then discarded. While the technique used is the same — eggs are fertilized with sperm in a laboratory, the stem cells are extracted and the embryo is destroyed — the motive is different.

Ethicists argue about the justification for permitting the use of “excess” embryos while prohibiting embryos from being created specifically so that stem cells can be taken from them:

- “Custom-made embryos raise questions about the ethics of using human embryos solely and explicitly as a means to some end,” writes one bioethicist. “They are created solely as laboratory materials; they are used in a sense that many find incompatible with the concept of human dignity.”<sup>12</sup>
- Others consider the moral distinction between using “spare” embryos and creating them to be “weak . . . . Whatever the basis is on which defenders of this viewpoint accord intrinsic value to the embryo, once they accept the creation and sacrifice of embryos to benefit infertile people with a child-wish, they do not have a sound moral argument to condemn the creation and sacrifice of embryos to benefit ill and injured people.”<sup>13</sup>

Two other bills in Congress would maintain the restrictions of the Dickey-Wicker amendment while encouraging other avenues of stem cell research:

- The Patients First Act of 2009, introduced in the House by Reps. Randy Forbes (R–VA) and Daniel Lipinski (D–IL), would bar federal support for stem cell research involving the destruction or discarding of an embryo, or creating one for research purposes. The legislation calls for intensified research to identify cells that “have the flexibility of embryonic stem cells,” but is not explicit about their source.<sup>14</sup>
- The Senate bill, Ethical Stem Cell Research Tax Credit Act of 2009, introduced by Sen. David Vitter (R–LA), proposes a tax credit to encourage stem cell research that does not involve the destruction of a human embryo or its creation for research purposes.<sup>15</sup>

### Therapeutic Cloning

One technique for deriving embryonic stem cells is known as somatic cell nuclear transfer.<sup>16</sup> In this process, the nucleus is removed from an unfertilized egg and replaced with the nucleus of a donor somatic cell (by definition, a somatic cell is any cell of the body except the sperm and the egg). Once the egg contains the genetic material of the donor somatic cell, it is coaxed into dividing as if it had been fertilized; five or six days later, the stem cells are ready to be harvested.

The unique feature of these stem cells is that they are genetically identical to the donor somatic cell. In theory, they can be turned into any needed cell and then transplanted back to the donor, where they would be recognized as “self,” lessening the risk of immune system rejection. While still mostly hypothetical, the technique has been successfully used to treat Parkinson’s disease in an animal model.<sup>17</sup>

Somatic cell nuclear transfer is also known as *therapeutic* cloning, because it makes multiple identical copies from a single cell with the goal of treating diseases. The intent is completely different from *reproductive* cloning, which could theoretically be used to create genetically identical populations of human beings, although the capacity to do this currently does not

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exist. The National Academy of Sciences,<sup>18</sup> the American Association for the Advancement of Science<sup>19</sup> and most other scientific bodies agree that reproductive cloning should be banned, and President Obama called it “dangerous [and] profoundly wrong” in his remarks when he lifted the stem cell research ban.<sup>2</sup>

Nonetheless, therapeutic cloning is also controversial, in part because the early steps would be the same as those taken in reproductive cloning, and therapeutic cloning could provide knowledge that gets put to use for other purposes. It also raises concerns about the ethics of developing treatments likely to be prohibitively expensive for most people and about the potential risks of harvesting eggs.

To date, both reproductive and therapeutic cloning remain lawful under federal law, although a number of bills to ban human cloning are pending in Congress.<sup>20</sup> The states have been more active here, with 15 disparate laws on the books, according to the National Conference of State Legislatures — some states ban all forms of cloning, others ban reproductive cloning while specifically permitting therapeutic cloning, and still others prohibit the use of public funds for cloning but do not ban the research.<sup>21</sup>

### Guidelines for Conducting Research

The patchwork regulatory approach to somatic cell nuclear transfer has parallels with the framework currently in place for the entire embryonic stem cell field. A number of states specifically protect the research and some, including California, Massachusetts, and New Jersey, have allocated billions of dollars to fund it. Other states, including Arkansas, Indiana, Louisiana, North Dakota, and South Dakota, have imposed significant restrictions on any research involving embryos.<sup>22</sup>

Federal guidelines will neither replace state laws nor the requirements established by Institutional Reviews Boards at universities and laboratories, but they will be binding on researchers who seek federal funding and may ultimately provide a framework for other statutes. To meet President Obama’s 120-day deadline for developing guidelines for embryonic stem cell research, the National Institutes of Health may rely heavily on two non-binding documents that have already been designed to promote responsible practices in the field:

- ▶ The National Academy of Science’s (NAS) *Guidelines for Human Embryonic Stem Cell Research*, issued in April 2005, along with subsequent amendments, emphasize a dual system of oversight at the institutional and federal government levels. The document also spells out approaches to appropriate cell procurement processes, donor protections, standards of clinical care, and uniform tracking systems.<sup>23</sup>
- ▶ The International Society for Stem Cell Research guidelines, issued in 2007, have a similar emphasis on oversight, although the society recommends a single, rigorous review process. The guidelines prohibit the use of human embryos after they have been cultured beyond 14 days so they are in their most primitive stage of development. They also define permissible and impermissible research in ways that are subtly different from the National Academy.<sup>24</sup>

The NAS guidelines explicitly cover research using human embryo stem cells secured in a variety of ways — not only those donated by *in-vitro* fertilization clinics, but those produced specifically for research and developed with the techniques of somatic cell nuclear transfer.

In his March announcement, President Obama surprised some observers because he did not suggest that federal funding be restricted only to research involving stem cells derived from surplus embryos.<sup>25</sup> The NIH must now decide whether or not it will also support work on stem cell lines derived from embryos created for research purposes, or via therapeutic cloning.

“He left it wide open,” Thomas Murray, director of the bioethicists Hastings Center told the Washington Post. “Now we are going to have to face a host of morally complicated, politically charged questions.”<sup>25</sup> Congress and the NIH are in the midst of doing just that.

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