

[Alerts and Updates]

Anticipated Policy Changes for Embryonic Stem Cell Research: Funding Under the Obama Administration

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Soon after the November 2008 election, then-President-elect Obama signaled his intention to issue executive orders to repeal decisions made by the Bush administration on diverse policies, including the limitations imposed on embryonic stem cell research. Less than a week after Election Day, John Podesta, transition chief for the Obama administration, stated that they were "looking at virtually every agency to see where we can move forward, [including] on stem cell research."¹ Podesta further stated that executive orders on stem cell research could be easily repealed without congressional action. President-elect Obama later confirmed his intention to pursue legislation to permit federal funding on stem cell research, and overturn the limits imposed by President Bush.²

Embryonic stem cells are primitive cells from early-stage embryos capable of developing into almost any tissue in the body. Medical researchers seeking treatments for a wide range of diseases, including paralysis, heart ailments, cancer, diabetes and Parkinson's disease, believe embryonic stem cells may help cure these conditions, and may eventually extend human life.³

In 2001, President Bush issued an executive order limiting federal funding for medical research using human embryo stem cells.⁴ His executive order resulted in a limitation in federal funding to approximately 60 stem cell lines created from embryos destroyed prior to August 2001, even though some scientists said that of those, only 20 eligible cell lines were useful for research and that many of those lines were problematic.⁵ The executive order did not preclude the use of private funds to finance embryonic stem cell research, but rather imposed limitations on the use of federal funds for such research.

The restrictions imposed by the Bush administration on stem cell research were criticized by many as devastating to research efforts.⁶ However, scientists believe that under a pro-research Obama administration, money is likely to flow to all promising avenues of research based on scientific merit.⁷ George Daly, Associate Director of the Stem Cell Program at Children's Hospital in Boston, stated that "[w]ith an administration more supportive of science in general, and stem cell research in particular, I predict that the field will expand dramatically."⁸ In California, voter approval of Proposition 71 in 2004 led to state funding of basic science and laboratory construction. As a result, universities and research institutes in that state may be well poised to benefit from federal funding increases, which may in turn attract scientists and biotechnology companies to relocate to California. Bush administration restrictions on the use of federal funds for embryonic stem cell research also precluded the use of equipment or labs for such research, requiring acquisition of duplicate equipment and research space to conduct embryonic stem cell research. Robert Klein, chairman of the California Institute for Regenerative Medicine, recently stated, "[a]t a time of scarce resources, this country doesn't need to pay twice for critical and expensive equipment to advance medical research. . . . Now, hundreds of millions of dollars, if not billions of dollars, worth of tools and equipment would immediately become accessible to all researchers."⁹ In Klein's view, "[t]his is cause for tremendous optimism that a new generation for science has started."¹⁰

As a possible signal of a new level of support by the federal government for stem cell research, on January 23, 2009, the FDA approved a clinical trial request for human-based embryonic cell research, which was submitted by Geron Corp., a California-based biotech company. The trial approval is likely to pave the way for the study of effects from implantation of embryonic stem cells in human paraplegic patients suffering from spinal cord injuries. The embryonic stem cell line used by Geron Corp. was one of the oldest cell lines, and was therefore eligible for federal financing under the Bush administration guidelines set in 2001.¹¹ ¹² While Klein called the approval "an extraordinary benchmark," Dr. John A. Kessler, chairman of Neurology and director of the Stem

Cell Institute at Northwestern University, cautioned that if the therapy proves unsafe, or even if it is safe but does not work, it could cause a backlash that would set the field back for years.¹³

It may not come as a surprise that the FDA's approval of the Geron Corp. clinical trial was good news for the company's shareholders. The financial impact of this approval is not limited, however, to Geron Corp.'s increase in stock prices, as stock prices for other companies engaged in stem cell research have also risen.¹⁴

While researchers have cautioned that the Geron Corp. clinical trial approval is the first step of many in determining whether the treatment can provide therapeutic benefits to humans, many are optimistic about the insight to be gained from this trial. David Scadden, co-chair of the International Society for Stem Cell Research (ISSCR) Clinical Translation Committee, director of the Massachusetts General Hospital Center for Regenerative Medicine, and co-director of the Harvard Stem Cell Institute, has stated that "[t]he FDA has signaled that the safeguards are now in place to begin testing embryonic stem cell therapies. If the White House follows through with lifting restrictions on federal funding, we could see a great flowering of new research and an opportunity to see if these cells can deliver for patients."¹⁵

The Obama shift in federal stem cell policy has also spurred tangential businesses to announce program expansion. For example, Cord Blood America, Inc., an umbilical cord blood stem cell preservation company, announced this week that it intends to pursue rapid expansion of its health insurance partnership program to new locations this year. Matthew Schissler, CEO and founder of Cord Blood America, Inc., predicts that 2009 will be a milestone year for stem cell storage companies generally, and that the announced expansion of his company will pave the way for the company to double its current health insurance provider base. As stated, "[w]ith a national health insurance plan and stem cell agenda as two of the primary topics from the new administration, we see a marriage of the insurance companies possibly paying for stem cell storage on the horizon. . . . By developing the insurance sales channel, we feel we are positioning ourselves for long term success in becoming a globally dominant stem cell storage company."¹⁶

President Obama has pledged to support increased stem cell research and allow "greater federal government funding on a wider array of stem cell lines."¹⁷ This statement is consistent with Obama's pre-election promise that "as president, [he would] lift the . . . ban on federal funding of research on embryonic stem cell lines. . . through executive order. . . ." ¹⁸ An executive order meeting this description will no doubt be good news for the stem cell research community, and may lead to increased revenue in states where research centers are located, such as California, Wisconsin and Massachusetts. In turn, new federal funding for research is likely to result in substantial growth in the scientific research community in terms of employment and construction of facilities. Given the economic woes the United States now faces, whether such a significant shift in White House policy will be coupled with the requisite federal funding to support a broader scope of embryonic stem cell research remains to be seen. With the hope that the new administration will approve a 3-percent to 4-percent increase in NIH funding, and the potential for an additional \$1 billion from the economic stimulus package, the scientific community is applauding the prospect of new opportunities, the scope of which have not occurred since the formation of Medicare 40 years ago.¹⁹

For Further Information

If you have any questions about the anticipated stem cell policy changes or would like more information, please contact Karen Shichman Crawford, any member of the Life Sciences Practice Group or the attorney in the firm with whom you are regularly in contact.

Footnotes

1. "Obama Could Reverse Bush Orders on Drilling, Stem Cells," *AFP*, November 9, 2008.
2. "Obama Wants Congress to Act on Lifting Stem Cells Ban," Yahoo News, January 16, 2009; "Obama Win 'Sigh of Relief' for Stem Cell Research," ABC News, November 11, 2008.
3. "White House Stem Cell Shift Expected," BBC News, January 14, 2009.
4. "Obama to Reverse Bush Decisions," BBC News, November 10, 2008.
5. "White House Stem Cell Shift Expected," BBC News, January 14, 2009.
6. *Id.*
7. "Obama Plans to Sweep Bush Stem-Cell Restrictions Aside," *New Scientist*, November 12, 2008.
8. *Id.*

9. "Federal Shift in Stem Cell Policy Could Benefit State," *San Diego Union Tribune*, January 23, 2009.
10. *Id.*
11. "FDA Approves a Stem Cell Line," *The New York Times*, January 23, 2009.
12. "FDA OKs 1st Embryonic Stem Cell Trial," www.washingtonpost.com, January 23, 2009.
13. *Id.*
14. "Geron Shares Rise on Potential Stem Cell Policy," www.forbes.com/feeds/ap/2009/01/26/ap5966269.html, January 26, 2009.
15. "Scientists See Progress in FDA Stem Cell Trial Approval; ISSCR Cautions Clinical Research Still at an Early Stage," www.isscr.org/press_releases/fda.html, January 26, 2009.
16. *Id.*
17. White House Website, www.whitehouse.gov/agenda/technology, January 28, 2009.
18. "Obama Win 'Sigh of Relief' for Stem Cell Research," ABC News, November 11, 2008.
19. "Special Report: Barack to Business in 2009," *Genetic Engineering & Biotechnology News*, <http://www.genengnews.com/news/bnitem.aspx?name=48226965>, January 21, 2009.