

# Modern Healthcare

## Crossing the line?

As Obama clears path for embryonic stem-cell research, Catholic healthcare finds itself at crossroads of religion and medicine

By Melanie Evans  
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The White House opened the nation's \$29 billion medical research budget to embryonic stem-cell research last week and dealt a blow to Roman Catholic hospitals, which have rejected such science because it is banned by the church.

President Barack Obama last week lifted the 2001 limits placed on embryonic stem-cell research by his predecessor and vowed the nation would seek cures and treatments "with the urgency required to make up for lost ground." For scientists, the policy shift removes one major restriction to federal tax support for studies of embryonic stem cells and does so just as the nation's research arm, the National Institutes of Health, is racing under a two-year deadline to spend \$8.4 billion in federal economic stimulus aid.

For Catholic healthcare, Obama's decision was a disappointing setback that risks diverting research dollars from alternatives deemed ethical under church doctrine.

As a practical matter, said Jeff Schaub, a healthcare analyst with Fitch Ratings, shifting federal research dollars won't significantly hurt Catholic hospitals because major academic health centers are not affiliated with the church.

Embryonic stem cells, found in a pinpoint-sized cluster of cells on the fifth day of development of a fertilized egg, are able to churn out copies as well as morph into any of the body's cell types. Scientists see enormous potential in the cells for medical research and understanding how heart, nerve and other cells develop. But opponents of the research say extracting the cells destroys human life.

Adult tissue harbors stem cells, but they are harder to find and less versatile than their embryonic counterparts. Another option: adult cells that can be switched to resemble embryonic stem cells by tinkering with a recently discovered combination of genes. In December, the Vatican condemned the use of embryonic stem cells in research and said adult stem-cell studies "should be encouraged and supported."

"In effect, the order sanctions and encourages the destruction of human life in its earliest stages, offending the consciences of millions of Americans by using their tax dollars to fund research they find morally unacceptable," said Sister Carol Keehan, president of the Catholic Health Association, a St. Louis-based trade group that represents Catholic hospitals and other providers, in a written statement.

The newly available federal funds stand to add significant resources to the privately backed efforts and state-funded investments in embryonic stem cells that flourished under rules that strictly limited

support from the NIH. President George W. Bush banned federal funding for research on stem cells taken from embryos after Aug. 9, 2001, and issued his first veto nearly five years later when Congress sought to remove the restrictions. “Crossing this line would be a grave mistake and would needlessly encourage a conflict between science and ethics that can only do damage to both and harm our nation as a whole,” Bush’s veto message read.

Obama’s administration expressed no such concerns and scientists praised the move as long overdue support for science with the potential to unlock how devastating diseases develop and how best to treat them.

“It’s certainly about time,” said Marie Csete, chief scientific officer for the California Institute for Regenerative Medicine. The institute was created after California voters agreed in 2004 to pour \$3 billion into stem-cell research and gave scientists the constitutional right to use embryonic stem cells. Csete said that the effort is aggressively pursuing results that will reach patients. The institute last month unveiled at least 10 grants worth up to \$20 million each for research reasonably likely to land before the Food and Drug Administration as a new therapy within four years. “We have been trying very hard to look at the bottlenecks to developing these kinds of therapies,” she said.

Catholic leaders declined to say whether the potential for useful discoveries from embryonic stem cells could leave Catholic hospitals on the sidelines of significant medical advances.

Keehan and Catholic health ethicists said that they could not evaluate such a scenario as long as such results remain hypothetical. “Just because there is money there doesn’t mean there will be great breakthroughs,” Keehan said in an e-mail. More pressing is the use of embryonic stem cells in research; Keehan said the CHA has worked to connect scientists and Catholic hospitals to promote adult stem-cell research. “What we are grappling with is the fact that this research destroys embryos, which we believe is human life,” she said.

How much will be spent on the newly available avenue of research, and how quickly, is unclear.

The acting head of the NIH said last week that officials would move quickly to adopt necessary policies to fund embryonic stem-cell research and stressed that Obama’s executive order underscored the field’s “enormous potential” for scientists.

“Researchers will now be able to pursue new knowledge about human development, regenerative medicine and the origins of many of our most devastating diseases,” said Lawrence Tabak, the NIH acting deputy director.

Stem cells rank among 15 research priorities that will share at least \$200 million of \$8.4 billion the NIH received for research under the Obama administration’s economic stimulus plan, all of which must be divvied up before the end of September 2010.

Tabak said that officials do not have a projected NIH budget for embryonic stem cells. In 2008, the NIH spent \$938 million on stem-cell research, including \$88 million to fund research on stem cells from human embryos (See chart, above). New guidelines for embryonic stem-cell research funding must be final within 120 days of Obama’s order, but grant approval can take nine months or longer, he said.

Obama’s move will allow scientists to seek federal funding for embryonic stem cell research, but law continues to ban the use of federal money to create or destroy an embryo. Nonetheless, scientists

said the broader policy will open research on embryonic stem cells that were previously off-limits to scientists with salaries or equipment funded by the NIH.

“There is a lot of pent-up demand,” said Eric Bouhassira, director of the Albert Einstein College of Medicine’s Center for Human Embryonic Stem Cell Research. The New York college received \$3 million from the NIH in 2005 to study approved embryonic stem cells and opted not to work with any cells not eligible for federal funds, a decision that “restricted our research in several ways,” Bouhassira said. He added that he hopes Obama’s reversal will attract young scientists to studying the promising cells. “It’s very scary to be working in a field that might disappear because of federal restrictions,” he said.

Researchers stressed the need for continued private donations and state-funded efforts despite greater access to federal funds.

In 2006, the New York Stem Cell Foundation established a privately funded laboratory to allow scientists to work without running afoul of federal rules. The foundation has since raised more than \$15 million and recently received two awards from New York’s stem-cell initiative totaling roughly \$6 million.

#### **Some remains off-limits**

With federal rules relaxed, the growing laboratory can now work with scientists whose time is paid for by federal grants and other researchers can work on stem-cell lines used in the laboratory, which better enables scientists to compare results as studies progress since everyone starts with the same material, said Scott Noggle, director of the foundation’s lab.

But some of the work in the foundation’s Manhattan laboratory remains off-limits to federal aid. Scientists are searching for a method to use a human egg to reset an adult cell’s genetic instructions to those of an embryonic stem cell. Noggle said that the laboratory would also like to create its own stem-cell lines, which cannot be federally funded. Plus, private money can be more readily invested in promising research, he said. “Federal funding is great, but it’s slow,” Noggle said. “We can make things that need to happen fast happen fast.”

Researchers admittedly eager for a share of the influx of stimulus funds also said they fear many projects will fold after federal spending to boost the economy dries up.

Jeffrey Pessin, a professor of medicine and molecular pharmacology at the Albert Einstein College of Medicine and director of its diabetes research and training center, described the potential bust following the stimulus boom as “feast and famine.”

But that won’t stop Pessin from seeking some of the aid. The infusion means an opportunity for more research that may yield promise and attract further funds, he said. “We’ll take the money.”

Pessin is also one of dozens of New York scientists to share \$101 million in state grants for stem cell research announced last week. In 2007, New York pledged to spend \$600 million on stem-cell research, including those taken from embryos. Pessin received a little more than \$1 million to explore how embryonic and adult stem cells morph into fat cells, research that could help scientists understand the mechanics of obesity and prevent it.

Pessin turned to New York for the money to study embryonic stem cells and avoid the constraints that Obama removed. Still, the president’s action does not eliminate need for state stem-cell support, he said. Demand for federal research funds may only grow more competitive should budgets

stagnate as scientists step forward to pursue research made possible under Obama's order. "Where is the money going to come from?" he asked.

Officials with major stem-cell initiatives said last week's shift in federal policy won't curb state spending. In New York, one of nine states that has moved to fund stem-cell research since 2004, according to the National Conference of State Legislatures, Health Commissioner Richard Daines said Obama's action did not undermine the state's 11-year commitment.

California voters agreed in 2004 to borrow \$3 billion for stem-cell research to give the state's economy and healthcare system an edge by investing where others could not, said the California Institute for Regenerative Medicine's Csete. "We feel strongly that the \$600 million that we've distributed has really put us way in the lead in this area," she said. To keep that edge, the institute will need to communicate with federal officials to avoid overlap, she said.

Catholic health officials responded to Obama's move with a call for increased funding to study adult stem cells found in the body's tissue or umbilical cord blood.

"We must pursue progress in ethically responsible ways that respect the dignity of each human being," Catholic Health Initiatives, a Denver-based system with 60-hospitals, said in a written statement. Michael Panicola, corporate vice president of ethics for SSM Health Care, said in a written statement "adult stem-cell research holds great promise in achieving the very same therapeutic goals of human embryonic stem-cell research without crossing an important ethical line of using and destroying human embryos."

The nation's largest Catholic health system, Ascension Health, which owns 77 hospitals in 16 states and Washington that adhere to Catholic religious and ethical directives for medical care, declined to comment on Obama's reversal and referred questions to the CHA.

U.S. Catholic bishops denounced Obama's broader stem-cell policy as political maneuvering in light of embryonic stem-cell research that flourished under Bush's more-restrictive policy—with or without federal funds—and scientific advances among alternatives to embryonic stem cells, such as a 2007 discovery that used genetic manipulation to convert a fully formed cell into one able to become any number of cells.

Richard Doerflinger, the U.S. Conference of Catholic Bishops' associate director of pro-life activities, said such induced stem cells rapidly stand to eliminate any need for those taken from embryos.

Scientists said research has yet to bear that out. Furthermore, the claim cannot be confirmed without embryonic stem cells to use for comparison, said Richard Marchase, vice president for research at the University of Alabama at Birmingham and president of the Federation of American Societies for Experimental Biology, who praised Obama's decision.

He was also heartened by the president's call for an examination of the scientific integrity of government policies. "It's a really important recommitment to the idea that science should drive public policy," Marchase said, "and that science should be interpreted fairly without regard to its political implications."