

# Federally Funded ‘Stem Cell’ Research: New Hope, Renewed Controversy

By Rebekah Saul

Recent breakthroughs in “stem cell” research—biomedical research utilizing human unspecialized, early embryonic cells—have reopened a long-standing debate around governmental involvement in embryo research. In 1998, two groups of scientists announced that they had successfully isolated and cultivated stem cells, which are widely considered to hold enormous promise in treating a range of human diseases—from Parkinson’s disease to diabetes to cancer. The scientists’ work, which was privately funded, prompted key members of Congress to hold hearings on the new research and, in doing so, to reexamine the impact of a four-year-old prohibition on federal funding for research involving human embryos. At the same time, the breakthroughs spurred National Institutes of Health (NIH) Director Harold Varmus to request a legal opinion from the Department of Health and Human Services (DHHS) as to whether research utilizing stem cells is proscribed by the funding ban.

In the midst of the congressional hearings, DHHS attorneys declared that federal funds could, in fact, be used to support stem cell research because the cells are not a “human embryo” within the statutory definition of that term. The opinion was received with open arms by medical researchers and patient advocacy groups alike, while the staunchest antiabortion factions in Congress rallied to oppose it as a violation of the “letter and spirit of the federal law.”

Reproductive health advocates responded to the opinion with some

ambivalence. While praising the decision to support this critical research, they also expressed concern that permitting stem cell research to go forward with federal funding would take whatever steam there might be out of the already uphill battle to repeal the embryo research funding ban altogether. And that, many argue, will be necessary to make real progress in the areas of contraceptive technology, infertility and birth defects prevention.

## The Breakthroughs

In 1998, scientists at the University of Wisconsin and another group of scientists at Johns Hopkins University isolated and cultured one of several types of stem cells—“pluripotent” stem cells, which have the potential to become many, but not all, of the cell types in the human body. The scientists at the University of Wisconsin obtained the cells from embryos originally created in the course of in vitro fertilization to treat infertility, but unused by the

## According to the director of NIH, the ability to isolate and culture stem cells brings medical research ‘to the edge of a new frontier.’

couples undergoing treatment. The embryos were donated for research, and the scientists allowed them to develop in a laboratory for a few days, to the so-called blastocyst stage, when the embryo is a hollow ball of cells. The stem cells were then extracted from the blastocyst.

Once isolated, the cells were able to replicate indefinitely—so the scientists’ work produced not just a group of cells but, at least theoretically, an unlimited source of them. The scientists at Johns Hopkins used a different method and source, deriving the cells from fetal tissue following an induced abortion, to achieve a similar end—the cultivation of an endless supply of pluripotent stem cells.

According to Varmus, these breakthroughs “bring medical research to the edge of a new frontier.” Varmus and other scientists maintain that the potential for the use of these pluripotent stem cells in research and treatment for human diseases and conditions is almost limitless. One important use of the cells, they say, would be for the development of tissue transplantation therapies—for example, to grow cells to replace damaged heart tissue, neurons for use in treating Parkinson’s or cartilage-forming cells to treat arthritis. In addition, they say, studying the cells could offer general insight into human developmental biology—by learning how cells divide and differentiate, a better understanding of what goes wrong to cause cancer or birth defects could be achieved. Scientists further maintain that the use of stem cells could revolutionize pharmaceutical research and development, because new therapies could be tested for safety on stem cells before being used on animals or human subjects.

## Rethinking Federal Support

These discoveries have inspired a critical reappraisal of the current federal law that prohibits the use of federal funding for “the creation of a human embryo...for research purposes” or for “research in which...human embryos are destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero.” The prohibition, which has been included in an annual spending bill

for four years running, was originally advanced by antiabortion lawmakers who believe that a full human being begins and is owed full legal protection from the point of fertilization; accordingly, they oppose all research using human embryos, no matter the timing or potential benefit.

Removing the funding ban, meanwhile, has been the goal of a large, loose coalition of health and research organizations that have long recognized the benefits of

### **The benefits of stem cell research for reproductive health-related research remain unclear.**

embryo research—and the importance of federal funding for such research, which, they say, helps guarantee that research priorities are made in the public interest and ensures ethical oversight and coordination of research efforts. However, lifting the ban has been a virtual impossibility in light of the political stronghold antiabortion forces have maintained in recent Congresses.

The new stem cell research, however, brings groundbreaking health advancements much closer to hand—a fact that apparently prompted the chair and ranking minority member of the key Senate subcommittee that funds DHHS to hold a series of hearings over the last few months. In December 1998 and January of this year, Sens. Arlen Specter (R-PA) and Tom Harkin (D-IA) and their colleagues heard testimony from researchers, representatives of biotechnology companies, patients' advocates and government officials, as well as from a representative of the National Conference of Catholic Bishops. The witnesses presented information on the science and implications of stem cell research, addressed the need for the federal government's involvement in the research as well as in other

biotechnology developments, and raised ethical issues.

At the same time, the Senate panel anxiously awaited DHHS's response to Varmus's inquiry on whether stem cell research even falls within the existing ban on embryo research funding. The opinion, which was issued on January 15, stated that it did not, because pluripotent stem cells cannot be considered human embryos within the statutory definition. In her opinion, DHHS General Counsel Harriet Raab stressed that "human embryo" is defined in federal law as an "organism," but that pluripotent stem cells are not, scientifically speaking, organisms. In addition, she pointed out that stem cells are not tantamount to human embryos because—even if implanted in the uterus—they are not capable of becoming a human being.

Upon reviewing the DHHS opinion, NIH announced that it "plans to fund research using these stem cells." At the same time, NIH acknowledged that this type of research has unique ethical, legal and moral issues and stated that it would need "stringent oversight...beyond the traditional rigorous NIH scientific peer review process." As a result, NIH will delay funding until stem cell-specific guidelines are developed and issued. The National Bioethics Advisory Commission—a commission appointed by the president to study this and other biotechnology issues—will participate in developing the guidelines.

### **Reactions All Around**

The DHHS opinion and NIH's response were applauded by a wide range of health care and research organizations. Within days of the announcement, over 60 medical and science groups signed a letter to key members of Congress expressing their support and reviewing the

potential benefits of federal funding. "The federal government has an important role in funding and in overseeing the conduct of this research," they wrote, "so that the talent and creativity of the nation's scientists—both privately and federally funded—can be applied to this valuable line of research."

Meanwhile, reproductive health advocates—though supportive of the decision to allow federal funding for this critical research to go forward—worry that the DHHS decision does not go far enough. The American Society for Reproductive Medicine was one of the groups that signed the letter of support, but in an interview, Director of Public Affairs Sean Tipton was less than optimistic about the benefits of stem cell research for reproductive health-related research. "Unfortunately," he said, "the stem cell decision is not going to do anything to help research on infertility or contraception." Tipton points out that much of the progress made in assisted reproductive and contraceptive technologies came from studying the process of fertilization and intact embryo development—neither of which can be achieved through stem cell research. For this reason, the Society and other reproductive health supporters remain committed to repealing the embryo research funding ban altogether.

Others haven't ruled out *any* potential benefits of stem cell research, in reproductive health or any other area. In fact, at the Senate hearings, the scientists from both the University of Wisconsin and Johns Hopkins research teams specifically mentioned the contribution stem cell research could make to maternal and child health. James Thomson of the University of Wisconsin, for example, asserted that stem cells "will offer insights into developmental events that cannot be studied directly in the intact

*(Continued on page 7)*

## *Stem Cell Research...*

*Continued from page 4*

human embryo, but which have important consequences in clinical areas, including birth defects, infertility and pregnancy loss.”

For their part, Congress’s hard-line abortion opponents—those who believe that stem cells are full human persons and that research on them is murder—protested the DHHS opinion almost immediately. Led by stalwarts Chris Smith (R-NJ) and Henry Hyde (R-IL), 70 members of the House of Representatives wrote DHHS Secretary Shalala, charging that the agency’s opinion is “a carefully worded effort to justify transgressing the law” and that it unravels federal policy that has been a “bulwark against government’s misuse and exploitation of human beings in the name of medical

research.” Sam Brownback (R-KS) organized a similar letter in the Senate a week later.

### **For now, a serious attempt to repeal the embryo research funding ban entirely is likely off the table.**

It is widely expected that, barring any change in course by DHHS or NIH, antiabortion leaders this year will spearhead an effort to expand the current embryo research funding prohibition specifically to include stem cell research. And that, in turn, likely takes off the table any serious effort to repeal the embryo research funding ban entirely, at least in the short run. Dave Moore, associate

vice president of the Association of American Medical Colleges, admitted as much in a recent interview. “We still support repealing the ban,” Moore said, “but we recognize the political environment and need to focus our attention on holding the ground—maintaining and securing the DHHS position.”

For reproductive health advocates, only time will tell how federally funded stem cell research—assuming the DHHS position is allowed to stand—might actually impact reproductive health, especially the extent to which it might specifically benefit contraceptive and infertility research. For now, with both the scientific and the political outlook up in the air, they can only hope that half a loaf, indeed, will be better than none. ☩