Embryonic Stem Cell Research–Old Controversy; New Debate

By Rachel Benson Gold

The debate over federal funding of research involving fetuses and material derived from fetuses has ranged far and wide over the course of three decades. Its common thread, however, is an enduring controversy over work that is portrayed by its proponents as holding immense scientific promise and by its opponents as devaluing human life in its most basic form.

The debate's most recent incarnation centers on the use of stem cells derived from embryos in the very earliest stages of development; these cells have long been thought by scientists to have an extraordinary potential for alleviating the suffering caused by conditions ranging from diabetes to Alzheimer's disease to spinal cord injury. In a rare break with its political base, the Bush administration in 2001 enunciated a policy that would permit some research to go forward with federal funds, albeit with very stringent restrictions. Three years later, that compromise approach has garnered little support, either among the scientific community or the public at large.

Long-standing Debate

Research involving human embryos and fetuses has yielded an impressive array of results over the years. As far back as 1954, the Nobel Prize for Medicine was awarded to scientists whose work on cultures of human fetal kidney cells led to the development of the polio vaccine. But balanced at the intersection of science, politics and personal ethics, fetal and embryo research also has been the subject of long-standing controversy that has led to a complex web of policymaking—involving administration officials, Congress and a string of specially created expert review panels ("Human Embryo and Fetal Research: Medical Support and Political Controversy," *TGR,* February 2001, page 3). The current state of federal policy setting forth when and under what circumstances such research may be conducted with federal funds is summarized in the chart on page 5.

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In the 1970s, the controversy focused on research involving fetuses in utero, aimed at developing techniques such as amniocentesis and improving the understanding of conditions such as congenital heart disease, as well as on research involving tissue from aborted fetuses of the type that led to the polio vaccine. Federal funding of this research was halted until guidelines and safeguards were established by a blue-ribbon, congressionally mandated commission and later codified into federal law.

In the 1980s, the controversy shifted to research involving the transplantation of fetal tissue into adults with an array of serious conditions—including diabetes, Parkinson's disease and spinal cord injuries. Federal funding of this work, which involves material derived from a fetus following an abortion, was halted by the Reagan administration in 1988, only to be resumed under a 1993 executive order issued by President Clinton. Only months after Clinton's action, Congress adopted legislation codifying into federal law guidelines for such research that had been proposed by yet another special NIH review panel. Significantly, Congress was spurred to action by sustained pressure by the research community and the support of key senators with solid antiabortion records, including former Sens. Robert Dole (R-KS), a longtime advocate for disability issues, and Strom Thurmond (R-SC), whose daughter suffers from diabetes.

The latest chapter in this long saga involves embryonic stem cell research—research using cells derived from days-old "spare" embryos, which were created in the process of infertility treatment but never implanted and slated to be discarded. Even before embryonic stem cells were first isolated in 1998, scientists were eager to work with them because they have the potential to generate the different kinds of tissue a body may need. According to a special committee established by the National Academy of Sciences (NAS), researchers hope that "harnessing the capabilities of stem cells…could then help repair damaged and diseased organs or provide alternatives to organ transplants. Stem cell therapy could offer hope for the millions who suffer from spinal-cord injuries, cardiovascular disease, autoimmune disease, diabetes, osteoporosis, cancer, Alzheimer's disease, Parkinson's disease and other disorders."

Just as the promise of stem cell research predated the reality, so did the political controversy and the active involvement of antiabortion activists. In 1995, Congress moved to prohibit the use of federal funds to create human embryos solely for research purposes or to destroy

RESEARCH INVOLVING HUMAN EMBRYOS AND FETUSES			
	Definition	*Use*	*Status of Federal Funding*
Fetal research	An umbrella term encompassing the study of fetuses (*in utero* or *ex utero*) or the use of fetal cells and tissues generally obtained from induced abortions.	Used in the development of vaccines and to study aspects of cell physiology and human development.	Allowed in accordance with 1975 regulations, as codified by 1985 law, which prohibit researchers from having any involvement in the decision to terminate a pregnancy or assessing fetal viability and forbid altering the timing or method of abortion for the sake of research and the payment of any inducements that might encourage a woman to have an abortion.
Fetal tissue transplantation research	Research involving transplantation of "multipotent" cells ("differentiated" cells that give rise to more specialized cells) and tissues generally obtained from aborted fetuses.	Used to develop potential treatments for a variety of conditions, such as diabetes and Parkinson's disease.	Allowed in accordance with 1993 law, which ensures informed consent, forbids the woman providing the tissue from being paid or knowing the identity of the recipient, forbids altering the timing or method of abortion for the sake of research and attempts to avoid the commercialization of fetal tissue.
In vitro fertilization research	Research on reproduction in which sperm and egg are combined in a laboratory dish, where fertilization occurs.	Used to understand and develop treatments for infertility; IVF also used for deriving stem cells (see below).	Effectively prohibited by 1995 law, which blocks funding for any research in which human embryos are destroyed, discarded or knowingly subjected to serious risk.
Stem cell research	The study of "undifferentiated," or "pluripotent," stem cells, which are able to divide and form into many different cell types. Stem cells can be derived from aborted fetuses, from embryos created through IVF for the sole purpose of research, from embryos created through IVF but not implanted in women being treated for infertility and through a cloning technique called somatic cell nuclear transfer.	Used to understand factors in abnormal human development. Considered potentially useful in treating genetic disorders or organ failure and, through transplantation, Parkinson's disease, Alzheimer's disease, spinal cord injury, stroke, burns, heart disease and diabetes.	In accordance with 2001 executive order, federal funds may be used to support research only on embryonic stem cell lines created on or before August 9, 2001.

them (which effectively prohibited federally funded research into in vitro fertilization). Because of the extraordinary promise of the research, the National Institutes of Health (NIH) sought guidance from the general counsel of its parent agency, the Department of Health and Human Services (DHHS), on the exact applicability of that congressional ban to stem cell research.

In January 1999, the general counsel determined that federal funds could be used for research involving stem cell lines as long as the actual derivation of those cells had been conducted with private funds. Armed with this opinion, NIH issued guidelines in August 2000 for research involving the use of existing cell lines and solicited research applications. As applications began arriving, NIH appointed a committee to review the proposals.

A New Moratorium

When the Bush administration took office in January 2001, many expected it to move quickly to block NIH's steps toward funding stem cell research, in line with what opponents intended with the passage of the 1995 ban on using federal funds to destroy embryos. However, President Bush instead directed DHHS Secretary Tommy G. Thompson to review the issue. With the policy in limbo, NIH canceled the first scheduled meeting of the review committee, which had been set for April.

Even while the president was deliberating, support for stem cell research began building among antiabortion Republicans. That spring, long-standing abortion foes Sens. Connie Mack (R-FL) and Thurmond announced their support for the research. In June, Sen. Orrin G. Hatch (R-UT), who had led the fight in Congress *against* fetal tissue transplantation research, announced his support for stem cell research.

The administration finally announced its policy in August 2001. In a statement delivered from his Texas ranch, Bush attempted to walk a fine line between those clamoring for funding for stem cell research and those—including many of the administration's most steadfast allies—wanting a complete ban on the work. In crafting his policy, the president used the date of the speech as a major, albeit arbitrary, demarcation point, and prohibited the use of federal funds for research on stem cell lines created after that point. In an attempt to be seen as not impeding science, Bush announced that funds could be used, however, for work on the 64 cell lines estimated by the administration to be in existence as of that point ("Bush Okays Some Stem Cell Research Funding; Debate Continues," *TGR,* August 2001, page 12).

Reaction was swift. Interestingly, much of the strongest criticism came from opponents of the research, who had wanted no federal involvement whatsoever. "President Bush," said the press statement released by the American Life League the next morning, "has stepped aside and cleared the path for those who demand unrestricted freedom to dissect and discard the tiniest and most vulnerable of our fellow human beings." Proponents, meanwhile, were more measured in their response, applauding even the limited research possibilities the president's policy afforded but questioning whether enough research material would be available. "While we are pleased that the President supports the research," said the president of the Juvenile Diabetes Research Foundation, "we are concerned about the limitations he has placed on it."

A bipartisan group of 206 House members and 58 senators sent letters to the president urging him to ease the restrictions on stem cell research.

Even cautious optimism faded quickly, however. Only a month after the president's announcement, a report released by the NAS concluded that additional stem cell lines would be necessary if the promise of the research were to be fulfilled. And, indeed, just this year, the *Washington Post* cited an unpublished NIH analysis concluding that only 15 stem cell lines are available to federally funded researchers, a far cry from the number that had originally been promised when the administration's policy had been announced in 2001.

Moreover, the restrictions, according to the NAS, force stem cell research into the private market, both here and in other countries, beyond the reach of federal ethical oversight and where it is likely to be controlled by the private sector's need for profit rather than the goals of basic science. "NIH money is the engine for biomedical research in this country," Johns Hopkins researcher John Gearhart said in the *Baltimore Sun.* "In this area, that engine is limited. And that has a major, major impact."

A Developing Wedge

Research supporters, concerned about the impediments posed by the Bush administration's policy, have mounted an aggressive campaign to allow NIH to assume its traditional role by both providing research dollars and setting critical ethical standards for work involving embryonic stem cells. Throughout, the campaign seeks to emphasize the potential benefits of the work while giving the issue a human face, in the form of policymakers' constituents—or even family members—whose suffering might be alleviated or prognosis improved.

This effort has borne fruit this year, as what had been a somewhat arcane biomedical research issue has received unparalleled national, and political, prominence. This spring, a bipartisan group of 206 House members and 58 senators sent letters to the president urging him to ease the restrictions on stem cell research. Notably, the bipartisan group of signatories include such antiabortion stalwarts as Reps. Dana Rohrabacher (R-CA) and Charles W. Stenholm (D-TX) and Sens. Trent Lott (R-MS) and Kay Bailey Hutchinson (R-TX).

But the real sea-change came from the events surrounding the death of former president Ronald Reagan from Alzheimer's disease, which thrust the issue directly into electoral politics. While Nancy Reagan had been known to have supported stem cell research privately, she spoke out publicly for the first time in May. As a result of her husband's ordeal, "I'm determined to do whatever I can to save other families from this pain," Mrs. Reagan told attendees at a dinner for the Juvenile Diabetes Research Foundation. "I just don't see how we can turn our backs on this." Democratic presidential hopeful Sen. John Kerry (D-MA), a long-standing stem cell research supporter, pledged to expand federal support for the research days after Ron Reagan Jr. touted its enormous promise in a prime-time address at the Democratic National Convention.

The impact registered quickly. A Harris poll conducted in August found 73% of Americans saying they support the research, with support outpolling opposition by a ratio of six to one, including majority support among Republicans. The proportion believing that the research should be banned because it is unethical and immoral fell from 32% to 15% over the last three years.

All of this seems to have painted the administration into a corner, albeit one of its own making. As the presidential election nears, political pundits are speculating as to whether and what extent public opinion in support of the stem cell issue might actually be reflected at the polls. At the same time, speculation also is rising that no matter who is elected, the issue may have reached a tipping point—that even a second Bush administration would have difficulty clinging to its increasingly unpopular position.

Meanwhile, apparently unwilling to wait for policy to be sorted out at the federal level, two states are stepping into the breach. In a bid to establish the state as a center for cutting-edge research, New Jersey put $11.5 million for stem cell research in its budget for the current fiscal year. And in California, voters are being asked to approve a budget

(Continued on page 14)

Courts Strike 'Partial-Birth'…

Continued from page 3

fertilization to read an almost 200-word script to the pregnant woman stating that "the Congress of the United States has determined" that her "unborn child" can feel pain and that the abortion will cause it pain, and that by law she has the option of choosing to have anesthesia or other pain-reducing drugs administered directly to the "pain-capable unborn child." The bill would require the pregnant woman to accept or reject the pain medication for the fetus in writing.

Certainly, the issue of whether and at what point fetuses experience pain is an important one that should inform best medical practice and is currently the subject of active discussion within the medical community. Given the uncertainty, proponents of the legislation once again aim to dictate medical practice from the position of ideology, rather than science. Whether they will heed the admonishments of the three judges in this latest round of "partial-birth" abortion cases, and conduct balanced fact finding before acting, remains to be seen.

Embryonic Stem Cell Research…

Continued from page 6

initiative in November to establish a similar state-funded research effort; the initiate would authorize the state to issue $3 billion in bonds to finance research over a 10-year period. The campaign in support of the California initiative has received critical financial backing from a wide array of supporters, including businessman and philanthropist Bill Gates, Sen. Jon S. Corzine (D-NJ), actor and Parkinson's patient Michael J. Fox and George P. Schultz, secretary of state in the Reagan administration. Because of its potential to rejuvenate the state's lagging high-tech sector, it is also supported by the California Chamber of Commerce.

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