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US deliberates on embryonic stem cells, cloning

In a speech televised in August from his Texas home, US President George W. Bush endorsed a plan for funding human embryonic stem (ES) cell research in the public sector, while imposing sharp restrictions on the cell lines eligible for such studies and also establishing a special Council on Bioethics to oversee the research. In a related move barely more than a week earlier, members of the US House of Representatives voted by a substantial majority in favor of a broad measure to ban public and private human cloning research and medical procedures, and to impose criminal sanctions on anyone who fails to heed those restrictions. So far, however, the Senate has not deliberated over this issue, but seems unlikely to agree to comparably broad anti-human cloning measures.

In terms of federal policy at least, the issues of human ES cell and cloning research became ever more tightly interwoven during the public and political debate of July and August. The spotlight—along with widespread skepticism and sharper criticism from much of the scientific establishment—often focused on the cloning of a donor nucleus into an enucleated human egg as a potential means for aiding individuals to reproduce (reproductive cloning). However, the main tie of current ES cell research involves a more limited approach to such cloning—not to produce babies but for eventual use as a source in clinical procedures using tailored ES cells (therapeutic cloning).

"I strongly oppose human cloning," Bush said in his August speech, reiterating his distaste for that branch of experimental biology. He has been unusually outspoken on the issue. For instance, at the end of July, he quickly congratulated House members for passing anti-human cloning bill HR 2505, noting that the "overwhelming and bipartisan House action to prohibit human cloning is a strong ethical statement, which I commend. We must advance the promise and cause of science, but must do so in a way that honors and respects life." In yet another statement on cloning, he also pointed out that he "strongly approves of the development of cell- and tissue-based therapies based on research involving the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans."

In giving officials at the National Institutes of Health (NIH; Bethesda, MD) his okay to begin funding human ES cell research, Bush said that he will allow such research only on those "existing stem cell lines, where the life-and-death decision has already been made"—effectively, some 60 or so "genetically diverse" stem cell lines derived from "excess" embryos held at private-sector in vitro fertilization clinics.

NIH officials appear relieved to have the matter of moving forward settled. "Using the more than 60 existing cell lines from around the world, many more researchers will now be able to explore the potential of human embryonic stem cells, in addition to the extensive work already sponsored by NIH using human adult stem cells," says NIH Acting Director Ruth Kirschstein.

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Bush's strictures appear not to apply to human ES cell research, including the derivation and use of new ES cell lines, conducted in the private sector. However, representatives of the biotechnology industry, although pleased with the go-ahead for federal funding of such research, are cautiously critical of Bush's restrictions on cell-line usage in such research. "Placing a limit on the number of cell lines available for this research may place roadblocks to medical progress, some of which may take years to overcome," says Carl Feldbaum, president of the Biotechnology Industry Organization (BIO; Washington, DC). "This is a relatively new area of medical research and to pre-emptively limit the pathways in which researchers are able to work so early in this process may well be detrimental, may cost years, even lives."

Similarly, BIO and Feldbaum carefully criticized Bush and other supporters of HR 2505, calling the House vote in favor of sweeping measures against all human cloning research "a step backwards" that, if passed into law, "will reverse progress toward new medical treatments." With the Senate yet to debate the issue, BIO's Feldbaum is urging its members to "reflect more carefully on the potential medical benefits from this technology—and to separate the technology's therapeutic use from its use for reproductive cloning, a concept the biotechnology industry finds…repugnant and unsafe."

Questions about separating those two potential applications of human cell cloning technology are also at issue among university researchers. For instance, during a day-long meeting in August convened by the National Academy of Sciences (NAS; Washington, DC), scientists, clinicians, and bioethicists evaluated results from recent animal cloning experiments as well as partly disclosed plans to conduct cloning procedures as a way toward producing genetically related offspring in infertile couples.

In that context, Alan Trounson of Monash University (Melbourne, Australia) points out that cloning procedures would not be essential for the next phase of human ES cell research because many lines from several sources are available and they are generally stable. However, he and others note, the eventual move from purely experimental to therapeutic applications with human ES cells will likely be accompanied by a dramatic increase in demand for such cells.

Even during the next phase of basic studies, it would be helpful to use cloned cells from individuals with specific diseases as a safe and efficient way of studying those diseases in vitro, says Irving Weissman, who chairs the NAS cloning review panel, is a professor at Stanford University (Stanford, CA), and co-founded StemCells (Palo Alto, CA). Moreover, he adds, studies of cloned human ES cells would likely provide valuable insights about early human development and, eventually, many kinds of therapeutic applications will likely depend on producing cells through cloning procedures that carry the precise immunologic signature of the individuals in whom they will be used.

Despite considerable public confusion over the nuanced differences between linked issues of ES cell and cloning research, recent opinion polls and a steady drumbeat from groups that represent patients and families with various specific diseases indicate widespread support for ES cell research. Although Bush broke an important logjam in permitting federal support for restricted ES research, political tensions remain high. Indeed, in the immediate aftermath of his go-ahead, vocal opposition to federal support for such research remains intact in some circles, including among some groups on whose political support Bush depends.

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