

New Jersey Passes Law Supporting Stem Cell Research

SUSAN KERR BERNAL

From North Wales, Pennsylvania.

Between the wars on terror and in Iraq, the ubiquitous presidential politics, and the celebrity trials, little else has recently engendered notable television or print news attention. One such unfortunate victim of this media denial was New Jersey stem cell legislation signed into law by Governor James E. McGreevy on Sunday, January 4, 2004. New Jersey became only the second state, California being the first, to explicitly protect intrastate stem cell research (SCR). In light of the vast potential of SCR and President Bush's August 9, 2001, restrictions on federal funding for such research, this law is not only newsworthy, but may also signal changes to come.

I. President Bush's Edict Limiting Federal Funding for SCR.

In November 1998, 2 separate research teams declared they had isolated, cultivated, and grown stem cells from donated embryos and fetuses. Quickly, shouts of human cloning and the destruction of human life (human embryos) usurped the life-altering medical possibilities of the accomplishment. Under pressure to regulate or make such research illegal, the Department of Health and Human Services (DHHS) reviewed the 1995 federal financing ban on research in which human embryos are destroyed. In January 1999, the DHHS declared that the 1995 financing ban did not apply to embryonic SCR (ESCR). However, these were not the government's last words on the topic. Nineteen months after the 1999 announcement, the National Institutes of Health (NIH) issued specific guidelines for the federal funding of SCR. These Clinton

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Administration guidelines came at the height of the 2000 presidential campaign. In response, then-Governor George W. Bush, the Republican presidential nominee, unabashedly averred his ardent opposition to federally financed research that destroys human embryos.

By January 2001, George W. Bush was President of the United States, and because of tremendous public interest, his administration reviewed the policy regarding the federal funding of SCR. In May 2001, President Bush deftly walked a tightrope by opposing SCR that involved the destruction of human embryos but supporting promising SCR that used adult tissue or existing stem cell colonies where the embryos had already been destroyed. Finally, on August 9, 2001, the White House issued a press release detailing the Bush Administration's position. The press release began with the following quotation from the President:

As a result of private research, more than 60 genetically diverse stem cell lines already exist. I have concluded that we should allow federal funds to be used for research on these existing stem cell lines where the life and death decision has already been made. This allows us to explore the promise and potential of SCR without crossing a fundamental moral line by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life.¹

The press release went on to stress the President's belief in the "fundamental value and sanctity of human life" and "his desire to promote vital medical research." Furthermore, it explained that federal funds would only be available for research using the then-existing 60 cell lines, if they were derived 1) with the informed consent of the donors; 2) from excess embryos created solely for reproductive purposes; and 3) without any financial inducement to the donors. Regarding the potentially usable 60 existing cell lines, the NIH was ordered to examine them and create a registry of those lines that met the Administration's criteria. The press release also stated that no federal funding would be allotted for 1) the derivation of stem cell lines derived from newly destroyed embryos; 2) the creation of any human embryos for research purposes; or 3) the cloning of human embryos for any purpose. Of note is that the President's edict affected only federal

Correspondence to: Susan Kerr Bernal, JD, MPH, PhD(c) (e-mail: bernal@erols.com).

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¹ Office of the Press Secretary, White House Press Release: Fact Sheet Embryonic Stem Cell Research, August 9, 2001.

funding, not the private funding of SCR. Lastly, the press release stated that a President's Council on Bioethics, headed by Dr Leon Kass of the University of Chicago, was to be established to "study the human and moral ramifications of developments in biomedical and behavioral science and technology with a focus on ESCR, adult SCR (ASCR), cloning and assisted reproduction."

Following this press release, specific legislation to make all ESCR illegal was introduced in both Houses of Congress and in several states. None of these bills has yet become law. However, 8 states, in addition to New Jersey and California, have limited laws relating to SCR. For example, Arkansas, Iowa, Michigan, Missouri (only as to state funding), North Dakota, Rhode Island, and Virginia have all passed laws prohibiting reproductive cloning. Similarly, Arkansas, Iowa, Michigan, North Dakota, and Virginia have banned somatic cell nuclear transfer (SCNT), also known as therapeutic cloning, although admittedly Virginia's law is somewhat unclear.

II. The New Jersey and California SCR Laws.

The New Jersey bill, S1909, signed into law by Governor James E. McGreevy on January 4, 2004, and 2 California measures, SB322 and SB771, signed into law by then-Governor Gray Davis on September 24, 2003, are essentially broad legal affirmations by these states that support the use of private funding for all types of SCR, explicitly including SCNT. The legislators purposely included SCNT after hearing scientific testimony convincing them "that such cells will prove more effective than other stem cells in treating disease because they can generate tissue matching the donor's."² The laws do not include support for reproductive cloning,³ nor do they provide state funding for this research. Neither the New Jersey nor the California law makes anything legal that was not previously legal, nor do they conflict with the President's proclamation concerning federal funding and SCR. Thus, what the governors did by signing their laws was to extend a welcoming hand to the private funding of SCR and ensure the funding recipients that they are in a legally safe and encouraging environment.

Although the center of the nation's pharmaceutical industry and home to numerous biotech companies, research institutions, and universities, New Jersey followed California's legal lead. It did so after witnessing a substantial influx of private funding to Stanford University to establish a major SCR center, as well as after noting that several prominent researchers in the SCR field had relocated to California. Given the potential benefit to a

state economically and through job growth, it is likely that more states will pass such supportive SCR laws.

III. Despite Increases in Private Funding, the Restrictions on Federal Funding Constrains SCR Advancement.

Even though the amount of private funding and the quantity of SCR continue to rise, the restrictions on "the world's single largest supporter of biomedical science" a/k/a NIH funding, puts US scientists at a significant disadvantage in their efforts to find therapies or cures for diseases such as spinal cord injury, diabetes, Alzheimer disease, and Parkinson disease. Furthermore, of the 78 cell lines that the NIH ultimately determined met all the President's requirements, only 6 are widely available for study. There are other obstacles to the fruitful use of these lines as well. First, the 6 approved and available cell lines were cultured using mouse cells as nutrients. As such, safety concerns would exclude them from future human therapeutic use because of the potential for passing rodent viruses to the recipient, which could not be fought by the human immune system. Second, most of the permissible and available cell lines are controlled by private companies. Therefore, academic laboratories are reticent to license the lines because doing so would subject the laboratory to the corporation's dictates and possibly require them to pay huge royalties, should a successful therapy or cure come to fruition.

IV. A Change in Federal Funding for SCR May Be on the Horizon.

In response to the SCR controversy, the Hastings Center, an independent medical ethics think tank in Garrison, NY, released a report in November 2003 claiming that the Bush Administration's restrictions on SCR are "stifling important research" and "agree[ing] with arguments by an increasing number of scientists . . . that the stem cells President Bush said could be studied with NIH funds are not very useful." The report goes on to suggest federal funding of ESC that uses additional lines but that is subject to continuing government oversight. Also offered in the report is the notion that research conducted with private funding should be monitored by the government as well. The panel of experts at the Hastings Center borrowed their ideas from the way the federal government presently, and generally successfully, regulates gene-therapy research conducted with and without federal funding.

Even if President Bush does not implement any of the suggestions contained in the Hastings Center report, changes may still take place. After all, it is once again an election year, and some of the Democratic presidential candidates do not agree with the President's decision to padlock the federal funding of ESCR on new lines. For

² Laura Mansnerus, In Stem-Cell Law, Supporters See Opportunity for New Jersey, NYT, January 6, 2004.

³ New Jersey makes reproductive cloning a First Degree Felony punishable by 20 years in jail and a \$200,000 fine.

example, former Democratic presidential candidate Senator Joseph Lieberman issued a statement on SCR and SCNT, saying that “the first day that I am privileged to enter the Oval Office (presumably as President of the United States), I will rescind George W. Bush’s restrictions on SCR. I will also ensure that promising research on SCNT is not hindered by right-wing efforts.” Former Democratic presidential candidate Senator John Edwards issued a less-decisive statement than Senator Lieberman on the subject, but he, too, has “come to support ethical, regulated stem cell research” and believes “[t]he federal government must play a thoughtful role in regulating [such] research.” Democratic presidential candidate Senator John Kerry supports ESCR and the use of SCNT in medical research and claims that he “will ensure we (the government) unleash all of our technology and scientific potential to use stem cell research to develop cures.” Former Democratic presidential candidate Dr Howard Dean’s

statement includes an annual 8% increase in NIH funding “to advance life saving medical research and foster the discovery of cures and new therapies, . . . rescind[ing] the current restrictive SCR policy . . . and allow[ing] SCNT to move forward with federal oversight.” Finally, former Democratic presidential candidate Representative Richard Gephardt as President would “seek to reverse [President Bush’s] short-sighted policy and dedicate the full support of the federal government to advancing SCR.” He also “strongly support[s] SCNT technology” and opposes “any attempt to ban therapeutic cloning.” Each of these presidential candidates would encourage a ban on human or reproductive cloning. Specifically, Edwards and Dean would sign the Harkin, Hatch, Specter legislation known as the Human Cloning and Stem Cell Research Act of 2003 into law, if presented to him as President.

So, even though New Jersey’s having enacted an SCR law was not “front page news,” a change in SCR policy could be “front page news” before the year’s end.