



At the end of 2005, the 109th Congress could boast of a great deal of maneuvering on bioethics issues—but only one significant action, in the very last days of the session. A federal bill to support public banking of umbilical cord blood stem cells, held hostage to disagreements on embryonic stem cell research for many months, was finally signed into law on December 20.

### **Congressional Impasse on Stem Cell/Cloning Bills**

In the summer of 2005, Senate Majority Leader Bill Frist (R-TN) tried to broker a deal allowing six or more bioethics bills to come up for debate and vote in quick succession. The proposal was to bring up some bills favored by proponents of cloning and embryonic stem cell research, some favored by opponents of these practices, and some trying to chart a middle course, so every senator would have an opportunity to stake out a position on the issues. But Senate Democrats (and some Republicans) reportedly rejected the offer, and these bills remained at an impasse.

Any bill brought up in the U.S. Senate without such a “unanimous consent” agreement faces two barriers: first, the possibility of a filibuster by opponents, requiring a sixty-vote margin to invoke cloture (the process by which the Senate can vote to limit debate) and proceed to a vote on the bill itself; second, the prospect that any controversial bill can be attacked with numerous hostile amendments. Each amendment would also have to be considered, since the Senate is not governed by the kinds of rules that can limit debate and amendments on the floor of the House of Representatives. Factors like these make it much easier to stall legislation than to pass it in the Senate.

### **A Victory for Patients on Cord Blood Stem Cells**

One innocent victim of this impasse was the bill to promote banking of umbilical cord blood stem cells, the Stem Cell Therapeutic and Research Act of 2005, sponsored by Rep. Chris Smith (R-NJ) in the House (H.R. 2520) and Sen. Orrin Hatch (R-UT) in the Senate (S. 1317). The House passed it almost unanimously, 431 to 1, on May 24, the same day it approved H.R. 810, a bill to promote federally funded embryonic stem cell research. Some Senate supporters of H.R. 810 rejected the

Senate majority leader's offer to bring up a number of bills relating to stem cell research together, but also insisted that the cord blood bill should not be brought up independently of H.R. 810. In essence, this unopposed bipartisan bill, cosponsored by both supporters and opponents of embryonic stem cell research, was held hostage to the debate on the far more problematic and controversial H.R. 810.

This situation was especially surreal because everyone involved knew that H.R. 810 would not be enacted into law. President Bush had pledged to veto the bill, and the House's approval fell fifty votes short of the margin needed to override that veto. The result was a partisan game of "chicken": Democrats wanted to embarrass the President by forcing him to cast his first-ever presidential veto against what they perceive as a very popular bill; Republicans wanted to deny them that political advantage; and the loser would be the party that flinched or wavered first.

In the end, what forced the Senate's hand was the charge that further delay would do irreparable harm to suffering patients. In recent months, public recognition of the benefits of cord blood stem cells has grown.<sup>1</sup> Recent scientific literature has documented the potential benefits of cord blood even for patients with severe neurological problems: Hurler's syndrome,<sup>2</sup> Krabbe's disease,<sup>3</sup> and spinal cord injury.<sup>4</sup> In the Washington, D.C., area, the affiliates of two major television networks featured human interest stories at the end of November about local families benefiting from innovative cord blood stem cell treatments; the NBC broadcast described the common practice of discarding umbilical cords after live births as "throwing away the future," and reported that a bill to alleviate this tragedy was pending in the Senate.<sup>5</sup>

At the same time, fearing public backlash against the hyped promises made for embryonic stem cells, proponents of the research in recent months had been trying to lower public expectations, conceding that treatments from these cells might take

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<sup>1</sup> See Ronald Kotulak, "Medical Hope in Umbilical Cord Blood: Researchers Find Its Healing Powers May Provide Cures for Many Deadly Maladies," *Chicago Tribune*, October 23, 2005, final edition, 26, <http://www.stemcellnews.com/articles/stem-cells-medical-hope-in-umbilical-cord-blood.htm>.

<sup>2</sup> Susan L. Staba et al., "Cord-Blood Transplants from Unrelated Donors in Patients with Hurler's Syndrome," *New England Journal of Medicine* 350.19 (May 6, 2004): 1960–1969.

<sup>3</sup> Maria L. Escolar et al., "Transplantation of Umbilical-Cord Blood in Babies with Infantile Krabbe's Disease," *New England Journal of Medicine* 352.20 (May 19, 2005): 2069–2081.

<sup>4</sup> K. S. Kang et al., "A 37-Year-Old Spinal Cord-Injured Female Patient, Transplanted of Multipotent Stem Cells from Human UC Blood, with Improved Sensory Perception and Mobility, Both Functionally and Morphologically: A Case Study," *Cytotherapy* 7.4 (2005): 368–373.

<sup>5</sup> Kathy Fowler, "Stem Cell Surgery in S. Korea," ABC 7 Medical, November 30, 2005, <http://www.wjla.com/news/stories/1105/281912.html>; "Cord Blood Stem Cells Key to Saving Lives," NBC 4, November 30, 2005, <http://www.nbc4.com/health/5438374/detail.html>.

years or even “decades” to materialize.<sup>6</sup> Also garnering extensive media attention in December was the South Korean cloning scandal, indicating that the only published studies claiming the creation of embryonic stem cell lines from cloned human embryos were tainted by deception, unethical practices to obtain women’s eggs for the research, and even falsified scientific data.<sup>7</sup> This public “black eye” for embryonic stem cell research could not have helped the credibility of those claiming that H.R. 810 offers the royal road to cures.

Finally, Majority Leader Frist took the Senate floor on December 15 to ask for unanimous consent that the cord blood banking bill be brought up and passed. Sen. Tom Harkin, a cosponsor of the Senate version of H.R. 810, rose to speak against bringing this measure up separately. In response, he was chided by Frist and other Republicans for blocking expanded access to “a technology that is producing cures and saving lives now,” in the name of a proposal that could take decades to benefit anyone.<sup>8</sup> After further maneuvering, and a repeated promise from Sen. Frist that the embryonic stem cell bill will be considered early in 2006, all holds were dropped and the Stem Cell Therapeutic and Research Act was unanimously approved on December 16.<sup>9</sup> The House, required to take up the bill again because the Senate had made technical amendments in committee, quickly approved the final version 413 to 0 on December 17.<sup>10</sup>

Signing the bill into law on December 20, surrounded by congressional sponsors and by representatives of cord blood banks, President Bush said he was glad to be signing legislation to promote science in an ethical manner. This writer, speaking for the U.S. Conference of Catholic Bishops, said that “Congress and the President have given a wonderful Christmas present to patients in need.”<sup>11</sup>

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<sup>6</sup> For a sampling of such recent statements, see Do No Harm: The Coalition of Americans for Research Ethics, “The ‘Political Science’ of Stem Cells, Lesson 11: Not Months or Days, But Decades,” December 5, 2005, <http://www.stemcellresearch.org/polisci/lesson11.pdf>.

<sup>7</sup> See Richard M. Doerflinger, “Cloning Chaos,” *National Review Online*, December 13, 2005, <http://www.nationalreview.com/comment/doerflinger200512130824.asp>; Erika Check, “Where Now for Stem Cell Cloners?” *Nature*, News (December 20, 2005), <http://www.nature.com/news/2005/051219/full/4381058a.html>.

<sup>8</sup> Senators Frist, Harkin, Brownback, Enzi and Hatch, 109th Cong., 1st sess., *Congressional Record* 151.161 (December 15, 2005): S13636–S13640; the quotation is from Senator Frist, at S13636.

<sup>9</sup> Senator Frist, *Congressional Record* 151.162 (December 16, 2005): S13930–S13931.

<sup>10</sup> *Congressional Record* 151.163 (December 17, 2005): H12063–H12072 (Floor debate and full text of legislation) and H12142–H12143 (House vote).

<sup>11</sup> USCCB Office of Media Relations, “USCCB Official Hails Enactment of Cord Blood Stem Cell Legislation,” December 20, 2005; <http://www.usccb.org/comm/archives/2005/05-290.shtml>. The full text of a July 11, 2005, letter to the Senate from Cardinal William Keeler, Chairman of the USCCB Committee for Pro-Life Activities, urging Senate approval of the cord blood bill, is available at <http://www.usccb.org/prolife/issues/bioethic/stemcell/keelercord.pdf>.

### Legislation Carried over into 2006

The bills considered as part of Senate Majority Leader Frist's proposed legislative package this year, except for the cord blood bill, will carry over into 2006 and may well be the subject of continued negotiations.<sup>12</sup> They include:

- The Stem Cell Research Enhancement Act, sponsored by Sen. Arlen Specter (R-PA) in the Senate (S. 471) and Rep. Mike Castle (R-DE) in the House (H.R. 810). This bill would end the Bush administration's policy of funding only research using stem cells that were derived from human embryos before August 9, 2001. If the bill is passed, federal funds could be used to encourage researchers to destroy new embryos for their stem cells, if the embryos are considered "spare" by fertility clinics and "would otherwise be discarded." H.R. 810 was approved by the House on May 24, by a vote of 238 to 194, but President Bush has vowed to veto the bill, and the House's support falls far short of the margin needed to override a veto.
- The Human Cloning Prohibition Act, sponsored by Sen. Sam Brownback (R-KS) in the Senate (S. 658) and Rep. Dave Weldon (R-FL) in the House (H.R. 1357). This is a genuine ban on the use of the "somatic cell nuclear transfer" cloning technique to make human embryos for any purpose. It allows the use of cloning techniques to produce plants, animals, or cells other than human embryos. A similar bill (108th Congress, H.R. 534) was approved by the House in 2003 by a vote of 241 to 155, but the issue has been at an impasse in the Senate ever since. Supporters of "therapeutic cloning" (more accurately known as human cloning for research purposes) would prefer to vote on the Human Cloning Ban Act sponsored by Sen. Dianne Feinstein (D-CA) in the Senate (S. 1520) and Rep. Mary Bono (R-CA) in the House (H.R. 3932). It would ban only "implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus." The latter bill would allow the cloning of human embryos without limit, but ban the later *survival* of these embryos by prohibiting the act of placing them in the nurturing environment of the womb.
- The Human Chimera Prohibition Act, sponsored by Sen. Brownback (S. 1373). This would ban the creation and use of certain human-animal chimeras (e.g., embryos created by uniting animal sperm with human egg or vice versa, or by placing a human cell nucleus in an animal egg or vice versa). It would also forbid the creation of "a nonhuman life form engineered such that it contains a human brain or a brain derived wholly or predominantly from human neural tissues." The timeliness of this proposal became apparent on December 13, when researchers announced progress in getting human neural cells to grow in a mouse

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<sup>12</sup> The bills described here that have not been enacted will remain active, under these bill numbers, as the current Congress has only reached the middle of its two-year span; 2006 is the second session of the 109th Congress. The text and legislative history of each bill discussed here can be obtained from the congressional Web site THOMAS, at <http://thomas.loc.gov>.

brain as a model for studying human neurological diseases.<sup>13</sup> The current research stopped very far short of making a mouse with a predominantly human brain, but it immediately raised questions as to how far researchers might go before they risk creating and exploiting an animal with something comparable to a human brain.<sup>14</sup>

- The Respect for Life Pluripotent Stem Cell Act, sponsored by Sen. Tom Coburn (R-OK) in the Senate (S. 1557) and Rep. Roscoe Bartlett (R-MD) in the House (H.R. 3144). This would encourage federal funding of “research in the derivation and use of human pluripotent stem cells by means that do not harm human embryos.” This could include investigating the versatility of adult and cord blood stem cells, experiments in dedifferentiating adult cells to a more “pluripotent” state, and efforts to obtain embryonic-like stem cells without creating or harming live human embryos.

Pro-life groups have generally welcomed the effort to explore options that avoid harming embryos, but are also cautious about some of the proposed avenues.<sup>15</sup> The complexity of this issue was illustrated by letters published October 16 in the online edition of *Nature*, in which two different research teams claimed to have made progress in obtaining embryonic stem cells without destroying embryos. One team, led by Dr. Rudolf Jaenisch of MIT, produced mouse embryos that were engineered to lack a gene necessary for full embryonic development, known as *Cdx2*; they said they had grown the resulting entity to a stage where embryonic stem cells could be obtained.<sup>16</sup> The question raised here is whether “knocking out” this one gene produces an entity that is not an embryo, or is simply a very damaged and short-lived embryo that cannot develop past a certain point. Another team, led by Dr. Robert Lanza of Advanced Cell Technology, said it had obtained viable embryonic stem cells by performing a biopsy on very early mouse embryos without visibly harming them.<sup>17</sup> Here the argument is that a child conceived by in vitro fertilization could have stem cells picked off at a very early stage of development, for research and for creating that particular child’s own “repair kit” for the future. But the biopsy technique used to obtain the cells poses uncertain risks to the embryo, and is generally now used to harvest cells for genetic analysis (with subsequent discarding of any embryo found to

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<sup>13</sup> Alysson R. Muotri et al., “Development of Functional Human Embryonic Stem Cell-Derived Neurons in Mouse Brain,” *Proceedings of the National Academy of Sciences* 102.51 (December 20, 2005): 18644–18648; published online December 13.

<sup>14</sup> See Paul Elias, “Scientists Create Mice with Human Brain Cells,” Associated Press, December 12, 2005, <http://msnbc.msn.com/id/10441350/>.

<sup>15</sup> For example, see the Colloquy discussion in *National Catholic Bioethics Quarterly* 5.1 (Spring 2005): 9–22.

<sup>16</sup> Alexander Meissner and Rudolf Jaenisch, “Generation of Nuclear Transfer-Derived Pluripotent ES Cells from Cloned *Cdx2*-Deficient Blastocysts,” *Nature* 439.7073 (January 12, 2006): 212–215.

<sup>17</sup> Young Chung et al., “Embryonic and Extraembryonic Stem Cell Lines Derived from Single Mouse Blastomeres,” *Nature* 439.7073 (January 12, 2006): 216–219.

have a genetic defect). Making stem cell research dependent on this problematic technique for eugenic selection, and on IVF itself, with its risks and ethical problems, does not seem a promising way to resolve ethical concerns.

Other bills on this issue have also been discussed, but not yet introduced. Some Senate Republicans, such as Kay Bailey Hutchison (R-TX) and Norm Coleman (R-MN), want to reverse President Bush's policy of using only embryonic stem cells obtained from embryos before August 9, 2001, but do not want to go as far as H.R. 810. Other senators have shown an interest in slightly different bills to promote alternative ways to obtain pluripotent stem cells. We can be sure that this debate will continue into 2006 in all its bewildering complexity.<sup>18</sup>

### **President's Council on Bioethics: *Taking Care***

As reported in the Winter 2005 *Washington Insider*, Dr. Leon Kass has stepped down as Chairman of the President's Council on Bioethics; he will remain on the council, and is succeeded as chairman by Dr. Edmund Pellegrino. The final council report developed under Dr. Kass's leadership, *Taking Care: Ethical Caregiving in our Aging Society*, was published in October 2005.<sup>19</sup>

End-of-life issues have long been a mainstay of bioethics debate. But the new council report deserves careful attention from ethicists, lawmakers, and others because of its fresh perspective.

First, the authors recognize that much medical and ethical attention has been lavished on the plight of terminally ill patients and their need for palliative care, due in part to the societal debate on physician-assisted suicide. Far less attention has been devoted to the more daunting challenge of an aging population that includes millions of long-term patients, who may live for many years in declining health and often with various degrees of dementia. This can involve far more complex judgments about life-sustaining treatment, and significantly more demanding psychological and financial commitments simply to provide care for patients we cannot cure.

Second, the authors recognize that in addressing the needs of patients with dementia, the "personal autonomy" model favored by many modern bioethicists is of very limited use. These patients are increasingly unable to make informed decisions for themselves, and models of "substituted judgment" create the illusion of autonomy while actually imposing the views of others. What is needed is a consensus, or at least some attempt at consensus, on a basic level of care we owe to all helpless patients due to their perduring human dignity.

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<sup>18</sup> For an astute and challenging analysis of the controversy from a secular viewpoint, see William Saletan, "Stem-Cell Shakeup," *Slate*, October 20, 2005, <http://www.slate.com/id/2128306/>.

<sup>19</sup> The President's Council on Bioethics, *Taking Care: Ethical Caregiving in Our Aging Society* (Washington, DC: Government Printing Office, 2005), available at [http://www.bioethics.gov/reports/taking\\_care/taking\\_care.pdf](http://www.bioethics.gov/reports/taking_care/taking_care.pdf).

Third, the council carefully explains why one proposed solution—encouraging all patients while they are competent to sign advance directives such as “living wills”—has severe limitations. *Taking Care* contains the most thoughtful and extensive critique of the craze for living wills this writer has seen in many years. That craze has only intensified in the wake of the highly publicized Terri Schindler Schiavo tube-feeding case; all involved in promoting living wills as the obvious solution to such problems should read Chapter 2 of this report.

The report’s final recommendations are necessarily rather general. The council firmly rejects legalization of euthanasia and assisted suicide as solutions to the plight of these patients. (On this issue one member, Janet Rowley, M.D., filed a dissenting statement, which calls the majority view “draconian” and rails against the “greedy” seniors who are using up more than their fair share of social resources.) The report promotes a model of “best care,” whereby every human person will receive the care due to his or her human dignity but will not have needlessly burdensome life-prolonging care imposed on him or her. (While most council members and staff are not Catholic, Catholic ethicists will be on familiar ground here.) Finally, the council recommends the establishment of a “Presidential Commission on Aging, Dementia, and Long-Term Care” to discuss how the health-care system must change to accommodate the urgent needs of our increasingly aging population.

Whether these worthwhile recommendations will be taken up by policy makers in Washington and around the country as a guide to action remains to be seen. “A mature and caring nation,” concludes the report, “concerned about staying human in a technological age, will not shy away from its responsibilities. If asked, ‘Who cares?’ the answer must be, ‘We do.’”<sup>20</sup>

Are we indeed such a nation? And do we care enough to meet these needs?

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<sup>20</sup> Ibid., 222.