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The November 2004 elections produced two results of direct significance for public policy on bioethics. However, those results push in opposite directions.

Nationally, the voters returned President Bush to office and produced slightly increased margins of support in both the House and Senate for pro-life legislation, including a ban on all human cloning. In California, however, by a 59 percent to 41 percent margin, voters approved a massive bond proposal for devoting three billion dollars over ten years to embryonic stem cell and cloning research. California's proposal has belatedly garnered local criticism as journalists and others discover its real implications; yet it is also being used to pressure other states to initiate embryonic stem cell proposals of their own, so their top scientists will not "go west" to seek their fortunes in California.

The Elections and Congress: A Continued Stalemate on Embryo Research?

The issue of embryonic stem cell research came up during the presidential campaign, including an exchange during the October 8 televised debate between President Bush and Senator Kerry. The President defended his policy of funding only research using stem cells obtained by destroying embryos before his policy announcement of August 9, 2001. He affirmed his support for scientific progress while insisting on a need to "be very careful in balancing the ethics and the science."

Senator Kerry, by contrast, made his unqualified support for embryonic stem cell research into a key element of his campaign. The issue was emphasized many times during the Democratic Convention in July 2004—especially during the featured speech by young Ron Reagan, who was given a brief spotlight of increased

¹John M. Broder, "California's New Stem-Cell Inititative Is Already Raising Concerns," *New York Times* (November 27, 2004): A10.

²CBS News transcript of the October 8, 2004 debate: http://www.cbsnews.com/stories/2004/10/08/politics/main648311.shtml.

fame by the recent death of his father, former President Ronald Reagan. Ron Reagan exploited his father's death from Alzheimer's disease to present himself as a concerned family member committed to curing this and other devastating diseases. He then essentially equated embryonic stem cell research (and scientific progress in general) with a strong commitment to the cloning of human embryos for research purposes, suggesting that this agenda could provide each viewer with "your own personal biological repair kit." That Ron Reagan's endorsement of such "therapeutic cloning" was no accident was dramatized by the fact that Senator Kerry on July 13 had become a co-sponsor of S. 303, the pending federal bill to authorize human cloning for research nationwide. Paraplegic actor and director Christopher Reeve also campaigned for the Kerry-Edwards ticket, citing the stem cell issue. After Reeve suddenly died from an infection on October 10, Kerry running mate John Edwards declared in a campaign speech: "If we do the work that we can do in this country, the work that we will do when John Kerry is president, people like Christopher Reeve are going to walk, get up out of that wheelchair and walk again."

This situation was rich in irony, for significant facts were left unmentioned in young Reagan's convention speech and Senator Edwards' campaign speech. First, Ronald Reagan, while president, had firmly opposed federal funding of any research harming human embryos, and had even issued a presidential proclamation promoting respect for "the unalienable personhood of every American, from the moment of conception." Second, the emerging scientific consensus is that Alzheimer's disease is extremely unlikely to be one of the diseases influenced by treatment using embryonic stem cells. In fact, young Reagan himself had admitted this in other forums. Third, even Christopher Reeve, in one of his final interviews, admitted that embryonic stem cells could not treat chronic spinal cord injuries like his own.

Days before the November election, a group of fifty-seven scientists and medical experts released an open letter to Senator Kerry, decrying the exaggerated and

³Ron Reagan's speech at the Democratic Convention, July 27, 2004: http://www.dems2004.org/site/apps/nl/content3.asp?c=luI2LaPYG&b=125925&ct=159643.

⁴The bill carries the misleading title, "Human Cloning Ban and Stem Cell Research Protection Act of 2003." See Terence P. Jeffrey, "Cloning By Any Other Name Still Smells," *Human Events Online* (August 11, 2004): http://www.humaneventsonline.com/article.php?id=4765.

⁵Charles Krauthammer, "An Edwards Outrage," *The Washington Post* (October 15, 2004): A23, http://www.washingtonpost.com/wp-dyn/articles/A34167-2004Oct14.html.

⁶President, Proclamation 5761, "National Sanctity of Human Life Day, 1988," *Federal Register* 53, no. 11 (January 19, 1988).

⁷Rick Weiss, "Stem Cells an Unlikely Therapy for Alzheimer's," *The Washington Post* (June 10 2004): A3, http://www.washingtonpost.com/wp-dyn/articles/A29561-2004Jun9.html.

⁸A few days before the convention, Reagan had said on the television show "Hardball with Chris Matthews," "Alzheimer's is a disease, ironically, that probably won't be amenable to treatment through stem cell therapies." See National Right to Life, "National Right to Life Responds to Ron Reagan's Pro-Cloning Speech at Democratic National Convention," press release, July 28, 2004, http://www.nrlc.org/press_releases_new/Release072804.html.

⁹James Kelly, "The Wrong Path: Mourning Christopher Reeve," *National Review Online* (October 21, 2004), www.nationalreview.com/comment/kelly200410210859.asp.

irresponsible claims for embryonic stem cells that had been publicly disseminated by Kerry and other public figures. "Because politicians, biotechnology interests and even some scientists have publicly exaggerated the 'promise' of embryonic stem cells," notes the letter, "public perceptions of this avenue have become skewed and unrealistic." That letter received almost no public attention.

In the end, it is not clear how many voters were swayed by blatant and exaggerated appeals to the self-interest of families facing serious illness. Instead, the most widely noted feature of the final vote was the rise of "values voters" who gave President Bush his re-election victory. National exit polls showed that 22 percent of voters cited a concern for "moral values" as the most important issue in their vote—more people than cited the economy, terrorism, the war in Iraq, or any other single factor. And 80 percent of these voters opted for President Bush. 11

Congressional elections also produced net gains on some moral issues, with both the House and Senate slightly increasing their margins of support for abortion restrictions and a complete ban on human cloning. 12

The impact of this perceived mandate for morally based policies was visible even before the newly elected Congress was to convene in January. In a November 2004 "lame duck" session seeking to complete action on an omnibus appropriations bill for fiscal year 2005, Congress renewed the previous year's appropriations rider banning the patenting of human organisms at any stage of development.¹³ This provision, opposed by biotechnology advocacy groups, had earlier been seen as having an uncertain fate, because it had been excluded from the Senate's version of the new spending bill; but it was ultimately accepted by a House-Senate conference committee and then by both chambers. Also approved as part of this omnibus bill was a House-approved conscience protection amendment, forbidding federally funded government bodies to discriminate against physicians, hospitals, and other health-care providers who decline to participate in abortion.¹⁴

¹⁰The October 27, 2004, letter with list of signatories is posted on the web site of Do No Harm: The Coalition of Americans for Research Ethics, at www.stemcellresearch.org/pr/kerry.pdf.

¹¹See the national exit poll at www.cnn.com/ELECTION/2004/pages/results/states/US/P/00/epolls.0.html. For one commentary, see Jim Malone, "Issue of Moral Values Crucial in US Election Outcome," *Voice of America* (November 9, 2004), www.voanews.com/english/2004-11-08-voa63.cfm.

¹²Douglas Johnson, "What the Election Results Mean for the New Congress," Statement at National Right to Life Committee press conference, November 4, 2004, http://www.nrlc.org/Post/Johnson110404.html.

¹³Consolidated Appropriations Act of 2005, Sec. 626 of Division B, Pubic Law 447, 108th Cong. For the debate over this provision in the previous year, see Richard M. Doerflinger, "Washington Insider," *The National Catholic Bioethics Quarterly* 4.1 (Spring 2004), 20–24.

¹⁴Consolidated Appropriations Act of 2005, Sec. 508(d) of Division F, Public Law 447, 108th Cong. See United States Conference of Catholic Bishops, "Bishops' Official Applauds Pro-Life 'Conscience Protection' Provision of Appropriations Bill," press release, December 9, 2004, www.usccb.org/comm/archives/2004/04-242.htm.

Nevertheless, efforts to rescind the President's policy on limited embryonic stem cell research are expected to continue in the new Congress. By the end of the 2004 congressional session, a bill to authorize funding for research using new embryonic stem cell lines had gathered 191 House sponsors, and had clear majority support in the Senate.¹⁵ It seems very likely, however, that the President will be able to retain his policy as long as he is willing to make clear that he would veto any more expansive policy.

Less clear is the fate of S. 245, the complete federal ban on human cloning, which has twice been approved by the House but never taken up by the Senate. By most accounts, the election results increased Senate support for the ban by at least three votes—which may be enough to give it majority support, but not the sixty votes needed to overcome a filibuster.

California's Proposition 71 and New Battles in the States

California voters' approval of Proposition 71, to provide massive state funding for embryonic stem cell and cloning research, can be attributed to several factors. First, California has long been a stronghold of pro-abortion sentiment, with leading Republicans as well as Democrats giving short shrift to any claims for the dignity of unborn human life. Second, the biotechnology industry is both well developed and politically powerful in the state, and has been positioning itself for years to take over from the computer experts in Silicon Valley as a driving engine for the state's economy. Third, the political clout and readily available cash of Hollywood were placed at the service of this initiative, as actors and producers with serious illnesses in their families joined the coalition. The campaign in support of Proposition 71 raised over \$20 million, compared to about \$400,000 raised by opponents. ¹⁶

Most importantly, the advertising purchased with that \$20 million disseminated extremely misleading claims about the initiative, while suppressing important facts that were widely reported by news media only after the voters had approved it. Among these key facts:

- The initiative authorizes a three billion dollar bond issue to fund stem cell research over ten years; California's already shaky economy has given it such a bad credit rating that top interest rates will be applied to this loan, costing the state six billion dollars to pay off the debt with interest.¹⁷
- While many voters thought the proposal would fund whatever area of "stem cell research" is most promising at a given time, the proposal itself discourages funding any research avenue eligible for federal funding (supposedly to avoid dupli-

¹⁵Stem Cell Research Enhancement Act, HR 4682, introduced June 24, 2004, by Rep. Michael Castle (R-DE).

¹⁶Broder, "California's New Stem-Cell Initiative."

¹⁷Scott Gottlieb, "California's Stem Cell Follies," American Enterprise Institute—News and Commentary, November 1, 2004, www.aei.org/news/filter.,newsID.21485/news_detail.asp.

cation of effort). The result is that the state funds will not be spent on the most clinically promising areas of stem cell research, using umbilical cord blood and other non-embryonic stem cells, but on the most ethically controversial research requiring the creation and destruction of new human embryos.¹⁸

- The initiative creates a state constitutional right to conduct embryonic stem cell research, including research in human cloning. The proposal does forbid research in "human reproductive cloning." But it defines this as "the practice of creating or attempting to create *a human being* by transferring the nucleus from a human cell into an egg cell from which the nucleus has been removed for the purpose of implanting the resulting product in a uterus to initiate a pregnancy" (emphasis added). Because current state and federal constitutional jurisprudence refuse to recognize the child prior to birth as a human being in the abortion context, implanting a cloned embryo in order to abort the child later for his or her tissues (sometimes called "fetus farming") may not be prohibited. Supporters of the initiative consistently denied that it had anything to do with cloning, and even sued their opponents in state court (unsuccessfully) to forbid them to use the word "cloning" to describe what the initiative allows.²⁰
- The allocation of funds is to be determined by an "Independent Citizens Oversight Committee," which turns out not to be independent at all. Rather, it is to be made up of the very activists, researchers, wealthy entrepreneurs, and for-profit companies that funded the successful political campaign to get the initiative approved. Robert Klein, a wealthy financier who was instrumental in crafting and funding the initiative, has already been nominated as chairman of this oversight committee. Far from guarding against conflicts of interest, the committee itself seems designed to serve the interests of those with a professional and financial stake in profiting from the unfettered pursuit of this research.
- In one way, the oversight committee will be very "independent" indeed. Its activities and rules of operation are immune to correction or oversight by the state legislature for at least three years, and both critics and supporters now say it has few safeguards to prevent conflicts of interest and ensure that the funds are used for the public good. Perhaps unwittingly, the voters have created and lavishly funded a separate little government within the state of California that is answerable chiefly to itself.

¹⁸Wesley J. Smith, "An Indecent Proposition: Do Californians Really Want to Subsidize Stem Cell Research?" *The Weekly Standard* (October 18, 2004), www.discovery.org/scripts/viewDB/index.php?command=view&id=2237.

¹⁹For the text of the law created by Proposition 71, see www.ss.ca.gov/elections/bp_nov04/prop_71_text_of_proposed_law.pdf.

²⁰See Americans to Ban Cloning, "California's Proposition 71: Deposition in Lawsuit Regarding Impact of Ballot Initiative," at www.cloninginformation.org/congressional_testimony/newman_prop71.htm.

²¹Ryan Rose, "Arnold Taps Klein to Lead Stem Cell Research Board," *The Sacramento Union* (December 13, 2004), www.sacunion.com/pages/state_capitol/articles/1030.

• The payoff for this unprecedented grant of power is supposedly the discovery of miracle cures, and the associated economic gains such discoveries would bring to the state. Campaign ads for the initiative declared that it would soon pay for itself. Yet scientists candidly admit that "cures" from embryonic stem cell research may not be developed for decades—long after the loan and interest come due.²² Too late, state legislators found that even the supporters' claim that the state would share in all profits arising from the research was misleading.²³

None of these glaring problems has prevented supporters from lobbying other states to follow California's lead.²⁴ Some supporters have even argued to other states' legislatures that they must immediately place large investments of state money in embryonic stem cell research and cloning, lest they lose their top scientists and biotechnology companies to California. The fact that this area of research is a tiny segment of the biotechnology industry, and has never yet created a marketable product, has not prevented these scare tactics from being used or from having an impact.

Since the approval of Proposition 71 in California, efforts to pass a human cloning measure were renewed in the Illinois legislature, and fell short by only two votes. The state comptroller has come forward with his own plan to devote \$1 billion to embryonic stem cell research, funded through a tax on plastic surgery. Proponents in New Jersey are declaring that this state's support for embryonic stem cell research and cloning should be boosted to the same amount. Other states are being asked to consider similar initiatives.

²²Wisconsin researcher James Thomson, who first isolated human embryonic stem cells, says that "a lot of money will be spent badly" under the initiative, and it cannot be expected to pay for itself in less than fifteen to twenty years. Brian E. Clark, "Thomson Warns California May Lure Wis. Researchers," *WisBusiness.com* (December 2, 2004), www.wisbusiness.com/index.iml?Article=28010.

²³See Editorial, "Proposition 71 Needs Reform," *The Examiner* (San Francisco; December 7, 2004), www.sfexaminer.com/article/index.cfm/i/120704op_editorial.

²⁴See Claudia Kalb, "Welcome to the Stem-Cell States," *Newsweek*, December 6, 2004, 52, 54–55.

²⁵Megan Garvey, "California Stem Cell Project Energizes Other States to Act," *The Los Angeles Times* (November 22, 2004): A1. The measure, HB 3589, would have authorized research using embryonic, fetal, and adult stem cells "from any source, including somatic cell nuclear transplantation." See www.ilga.gov/legislation/fulltext.asp?GAID=3&SessionID=3&GA=93&DocTypeID=HB&DocNum=3589&LegID=6165&SpecSess=&Session=.

²⁶Paul Gores, "Illinois Looks at \$1 Billion Plan for Stem Cell Research," *Milwaukee Journal Sentinel Online* (November 24, 2004), www.jsonline.com/bym/news/nov04/278364.asp.

²⁷New Jersey Right to Life, "1 Billion Stem 'Sell' Push Self-Serving and Misleading," press release, November 10, 2004, www.politicsnj.com/njrtl101104.htm.

A Time for New Ideas?

The apparent political impasse over embryonic stem cell research has prompted some to ask whether there is any way to resolve the underlying moral problem in this research—the fact that it requires destroying human embryos.

Two proposals for addressing this problem were discussed at the December 2–3, 2004, meeting of the President's Council on Bioethics, chaired by Dr. Leon Kass. ²⁸

One proposal, offered by Drs. Howard Zucker and Donald Landry of Columbia University, involves trying to select the frozen embryos that one can determine have already died—that is, have lost so many viable cells that they are irreversibly incapable of integrated functioning as a human organism. It is well known that individual cells and even organs may be alive after an adult human being has died; these researchers suggest that this is even true at the embryonic stage, so that viable stem cells may be obtained from embryos which are already dead.²⁹

The other proposal, offered by Council member Dr. William Hurlbut of Stanford University, is to alter the somatic cell nuclear transfer technique so that this cloning technique produces an entity lacking the basic developmental potential of the human embryo. The goal of this "altered nuclear transfer" (ANT) would be to produce something akin to a teratoma or hydatidiform mole, which may contain usable embryonic stem cells but never become an integrated human organism. This could presumably provide embryonic stem cells of whatever genetic profile is needed, without destroying a true human organism.³⁰

A proposal superficially similar to this was offered in 1998 by Dr. Michael West, president of the Advanced Cell Technology company in Massachusetts that has pursued human cloning for research purposes. West said he might be able to alter his technique, to create an embryo so damaged that it could not implant in a womb or produce a placenta; in this way, he claimed, he could avoid destroying human entities with the potential to become (what he would recognize as) human beings, and pursue cloning for research without any risk of producing a cloned infant. That proposal was rejected by pro-life spokespersons.³¹

²⁸See the transcript of the Council's December 3 session, at www.bioethics.gov/transcripts/dec04/session6.html.

²⁹Donald W. Landry and Howard A. Zucker, "Embryonic Death and the Creation of Human Embryonic Stem Cells," *Journal of Clinical Investigation* 114.9 (November 2004): 1184–1186.

³⁰William B. Hurlbut, "Altered Nuclear Transfer as a Morally Acceptable Means for the Procurement of Human Embryonic Stem Cells," Commissioned Working Paper for the President's Council on Bioethics, December 3, 2004. See p. 145 of this issue.

³¹Rick Weiss, "Can Scientists Bypass Stem Cells' Moral Minefield?" *Washington Post* (December 14, 1998): A3; Richard M. Doerflinger, testimony before the Senate Appropriations Subcommittee on Labor, Health and Education, January 26, 1999, www.usccb.org/prolife/issues/bioethic/test99.htm.

The Hurlbut proposal is strikingly different, however. First, it is offered not by a cloning proponent, but by an opponent who shares the pro-life community's regard for nascent human life. Second, his proposal is not to make a damaged embryo that would then die, but to produce an entity containing embryonic stem cells that from the beginning does not have the status of an embryo at all. Third, he has invited Catholic and other pro-life ethicists and scientists to help him refine his concept, to ensure that it would not involve destroying an organism of the human species, and he would test the concept only in animal models until it is clear that this goal has been achieved.

Initial reactions from the pro-life community have been mixed. Many are concerned that the proposal may only lead to the creation of severely damaged embryos, which would develop normally for a short time and then expire due to an engineered genetic defect. Many Catholic philosophers and scientists, however, are open to the proposal, having been trained in a Thomistic philosophy that emphasizes the distinction between the raw materials of life and its organized development. What is agreed upon by all is that the idea should not be pursued in humans without thorough testing in animal models to establish the validity of the concept.

Interestingly, one of the harshest condemnations of the Hurlbut proposal has come from Dr. Robert Lanza, Dr. West's associate at ACT. Declaring that "A human embryo is a human embryo whether or not this or that gene is knocked out," he said that "to genetically manipulate human life for religious reasons is wrong and without scientific justification." ³²

In other words, Dr. Lanza assumed that this new proposal is actually identical to the one his own company offered just six years ago—to make a very damaged embryo that cannot survive past the blastocyst stage. But why would he then condemn it, aside from his distaste for the "religious" motives of those offering it? One answer may lie in Lanza's own "therapeutic cloning" research, which has succeeded in repairing damaged tissue in animals only by developing cloned animal embryos to the *fetal* stage and then aborting them for their more developed tissues. In his most recent published trial, he had to gestate cloned mouse embryos in a mouse's womb for eleven to thirteen days (well over half the usual gestational period for a mouse) to obtain usable stem cells to repair cardiac damage.³³

The Hurlbut proposal may be rejected by some embryonic stem cell enthusiasts precisely because it does not allow for such extension into "fetus farming." If that is the case, one of the proposal's virtues may be to force such enthusiasts to

³²Robert Lanza, letter to the editor, Washington Post (December 13, 2004): A20.

³³Robert Lanza et al., "Regeneration of the Infarcted Heart with Stem Cells Derived by Nuclear Transplantation," *Circulation Research* 94.6 (April 2, 2004): 820–827. Actually the "fetus farming" aspect of Lanza's experiment is not apparent unless one reads the online data supplement accompanying his journal article: "Cleaved (2-cell) embryos were transferred ... to the oviducts of pseudopregnant CD1 surrogate mothers. Cloned fetuses recovered at 11 to 13 days of gestation were used as source of liver cells." Online Data Supplement, http://circres.ahajournals.org/cgi/data/94/6/820/DC1/1.

become more candid about their real agenda, which does not stop with the manipulation of early embryos.

The Bottom Line: Who Is Helping Patients?

Largely ignored in these debates, as usual, is the ever-growing clinical evidence that it is non-embryonic stem cell research that is moving forward to provide real treatments for human beings. A few of the recent developments in this field are worth noting:

- In South Korea, a woman unable to stand for nineteen years due to a spinal cord injury has taken her first steps, due to a stem cell transplant using umbilical cord blood ³⁴
- As reported by the *Baltimore Sun*, several teams in Europe and the United States are making rapid progress toward the use of adult stem cells as sources of cardiac repair for heart attack victims.³⁵
- In Germany, researchers recently used adult stem cells from fat tissue to repair extensive skull damage in a seven-year-old girl.³⁶
- In the United Kingdom, researchers are using patients' own bone marrow stem cells to repair severe liver damage after conducting successful animal trials in this therapy.³⁷

One can only hope that state and federal legislators will pay more attention to such advances in the months to come, and will recall that therapies for suffering patients—not embryo destruction for its own sake—was supposed to be their goal.

³⁴Kim Tae-gyu, "Korean Scientists Succeed in Stem Cell Therapy," *Korea Times* (November 26, 2004), http://times.hankooki.com/lpage/200411/kt2004112617575710440.htm.

³⁵Jonathan Bor, "Scientists Try to Heal Heart with Stem Cells," *The Baltimore Sun* (December 13, 2004): A1, A7.

³⁶Malcolm Ritter, "Stem Cells from Fat Used to Repair Skull," Associated Press (December 17, 2004), http://apnews.myway.com/article/20041217/D871A54G0.html.

³⁷"Stem Cells 'To Treat Liver Harm,'" *BBC News* (December 16, 2004), http://news.bbc.co.uk/2/hi/health/4097795.stm.