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Stephen R. Latham

PREFACE

The Once and Future Debate on Human Embryonic Stem Cell Research

Stephen R. Latham*

In one Petri dish are scores, perhaps hundreds, of thrombocytes: human platelets, the cells that circulate in our bloodstream and help us stop bleeding when we're cut. Normally, platelets are produced when they bud off from megakaryocytes, their parent cells, in our bone marrow. The newly formed platelets circulate around our bodies for about a week, and then—if they haven't been used in clotting—they are destroyed in the spleen and liver, to be replaced by freshly created cells. But the platelets in this Petri dish have never been inside a bone or traveled through a vein or an artery; they will never encounter a spleen or a liver; they will never be a part of a human body or pumped by a heart. Only a few weeks ago, these cells were undifferentiated human embryonic stem cells,

* J.D., Ph.D., Deputy Director, Yale's Interdisciplinary Center on Bioethics; Member, CT Stem Cell Research Advisory Committee. This collection of papers began as a conference at Yale University. Many more people contributed valuable papers and discussion to that conference than are represented in this collection. Original contributors, not included in this selection, were as follows: Jennifer Beste, Assistant Professor of Theological Ethics, Xavier University; John Booss, Professor of Neurology and Laboratory Medicine, Yale University; Carolyn Brokowski, Research Assistant, Yale Interdisciplinary Center for Bioethics; Thomas Duffy, Professor of Medicine and Director of The Program for Humanities in Medicine, Yale University; Margaret Farley, Gilbert Stark Professor of Christian Ethics, Yale University; Arthur Galston, Eaton Professor Emeritus of Biology, Yale University; Myron Genel, Professor Emeritus of Pediatrics, Yale University; Jeffrey Kocsis, Professor of Neurology and Neurobiology, Yale University; Robert Lanza, Vice President of Research and Scientific Development, Advanced Cell Technology; Karen Lebacqz, Robert Gordon Sproul Professor Emeritus of Theological Ethics, Pacific School of Religion, Graduate Theological Union, Berkeley; William May, Cary M. Maguire Professor of Ethics Emeritus, Southern Methodist University; and John Young, Clinical Professor of Psychiatry, Yale University. Earlier versions of these and other Articles were compiled and edited by Marguerite Strobel Robinson, Biomedical Ethics Program Manager, Mayo College of Medicine; Susan Owen, Medical Ethicist, National Center for Ethics in Health Care, Veterans Health Administration; and Brian Sorrells, Visiting Lecturer in Ethics, Harvard Divinity School. Brian Sorrells took the lead in selecting and pulling together the essays for this special issue.

floating in this same Petri dish like clouds in a tiny sea of gel. Now, having been bathed by a researcher in the right combination of materials, they have become platelets.

In a neighboring Petri dish there are still clouds floating: human embryonic stem cells from the same line as those that have already been transformed into platelets. These cells are being cultivated, divided, and multiplied. They will supply the researcher with an essentially limitless number of genetically identical cells on which to test and re-test techniques for inducing thrombocytic differentiation—for making specialized human blood cells without blood, bone marrow, or a human body.

In these two Petri dishes we see the twofold magic of stem cells: they have the ability to replicate themselves repeatedly, and they can transform into a diverse range of specialized cells. So-called "embryonic" stem cells are taken from what is in fact the pre-embryonic blastocyst stage of development (i.e., a fertilized egg that has divided into a small cluster of cells).[1] They have the capacity to develop into every kind of cell. So-called "adult" stem cells are found at numerous sites around the body at every post-embryonic stage of development. They have the capacity to differentiate into a range of specialized cell types found in their organs of origin; this permits them selectively to repair and replenish specialized tissue.

Both adult and embryonic stem cells have tremendous potential for exploitation in the development of therapies for disease. The fact that they can self-replicate indefinitely means that they are of great utility in testing and comparing cellular responses to different drugs and biological materials. Moreover, if scientists can master the mechanisms by which stem cells can be made to differentiate into specialized cell types, stem cells may become a source of replacement cells for people with cellular diseases like diabetes, Parkinson's and Alzheimer's.

There is considerable doubt, though, about scientists' ability to attain that mastery. Some kinds of adult stem cells have already been used successfully in therapies (most familiarly in bone-marrow transplants for leukemia).[2] For the adult stem cell types with the most limited potential for differentiation, however, it can be challenging to harvest and grow sufficient numbers of cells to conduct research into the mechanisms by which they differentiate. Embryonic stem cells can be propagated easily, but researchers are only at the very beginning stages of understanding their differentiation and the mechanisms by which that differentiation is maintained. Differentiated stem cells have a disturbing tendency that scientists do not well understand to revert to an undifferentiated state,

1. *See, e.g.*, National Institutes of Health, Stem Cell Basics, Chapter III: What are embryonic stem cells?, http://stemcells.nih.gov/info/basics/basics3.asp (last visited Apr. 21, 2009).

2. *See, e.g.*, National Institutes of Health, Stem Cell Basics, Chapter IV: What are adult stem cells?, http://stemcells.nih.gov/info/basics/basics4.asp (last visited Apr. 21, 2009).

higgledy-piggledy, thus generating tumors.

In addition, the problem of rejection remains. Even if scientists could reliably cause embryonic stem cells to differentiate into exactly the sort of specialized cell required for a therapy, it is likely that just as with donated organs, the differentiated cells will be rejected by the immune system of nearly anyone into whom they were introduced.

One possible solution to this rejection problem involves therapeutic cloning. To illustrate this solution, suppose you need replacement cells of a certain sort. A scientist could remove the nuclear genetic material from one of your readily sampled cells—a skin cell, say. She could then enucleate (pop the nucleus out of) a donated human egg and pop your own nuclear material in. This would result in a clone of your cell: the equivalent of a fertilized egg with your exact genetic material in its nucleus (though it would have different mitochondrial DNA—the DNA in what we might think of as the "white" part of the egg surrounding the nuclear "yolk").[3] Scotland's famous Dolly the sheep was cloned in just this fashion. But the aim of therapeutic cloning is not to implant the egg into a woman's uterus and bring your cloned offspring to term. (That would be "reproductive cloning.") Instead, scientists permit the fertilized ovum to develop in a Petri dish for only a few days, until it reaches the blastocyst stage, and then harvest the embryonic stem cells. These cells are then influenced to differentiate *in vitro*—the Latin phrase means "in glass" and indicates that the process is occurring in a Petri dish rather than in the body—into the sort of specialized cell that you need. (This is called "therapeutic" cloning because it is undertaken for the sake of generating a therapy.) If all has gone well, your body will not reject the new replacement cells, because they contain your very own nuclear DNA (and thus produce identifying "tags" identical to the other cells in your body). While this procedure is still highly theoretical in terms of its therapeutic benefits, in 2008, some American scientists reported the successful cloning and development of a human embryo to the blastocyst stage using a donated egg and nuclear material taken from the researchers' skin cells.[4]

Over the past several years, the type of research described above has been the subject of a vigorous national debate. Adult stem cell research (and, for the most part, embryonic stem cell research conducted in laboratory animals) has been fairly uncontroversial. But human embryonic stem cell research involves

3. *See, e.g.*, Genetics Home Reference, Mitochondrial DNA, http://ghr.nlm.nih.gov/chromosome=MT (last visited Apr. 21, 2009) ("Mitochondria are structures within cells that convert the energy from food into a form that cells can use. Although most DNA is packaged in chromosomes within the nucleus, mitochondria also have a small amount of their own DNA. This genetic material is known as mitochondrial DNA . . . .").

4. Andrew Pollack, *Cloning Said To Yield Human Embryos*, N.Y. TIMES, Jan. 18, 2008, at A15.

the destruction of human embryos, and research using therapeutic cloning not only creates embryos that will eventually be destroyed in research, but also brings us uncomfortably close to human *reproductive* cloning—though there have not been known attempts to bring an actual human clone to term. The national debate has been concerned predominantly with the question of whether it is morally permissible to conduct human embryonic stem cell research at all. In general, that debate pits concerns about the moral status of the human embryo *in vitro* against the potential of embryonic stem cell and cloning research to deliver lifesaving and life-enhancing cures.[5]

One argument in this debate holds that the research is morally impermissible no matter what its potential therapeutic upside might be. This argument assimilates the destruction of the embryo to murder. For example, when White House spokesman Tony Snow was asked why President Bush vetoed federal funding for embryonic stem cell research, he replied, "The simple answer is he thinks murder is wrong."[6] According to a frequently used version of this argument, once fertilization has occurred, the resulting embryo is a human being like any other, and it deserves our full moral regard and protection.[7] Following this argument, no amount of benefit from research can justify what is seen as the conduct of mass murder in stem cell labs. Of course, many who advance this claim also attempt to undercut others' positions by arguing that the medical potential of stem cell research has been exaggerated—but the core of the argument is that the embryo *in vitro* has full moral status as a human being.

On the opposite side of the debate, another argument holds that genetic material notwithstanding, the early embryo either is not yet a human being, or is not yet (in developmental terms) the kind of human being who deserves our full moral regard.[8] According to this view, an early human embryo is merely a collection of cells with no strong moral claims upon us. For this position, too, the

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5. A secondary debate, relating only to therapeutic cloning, concerns the fact that cloning research relies upon women to volunteer to donate eggs via an invasive surgical procedure. For example, Dr. Leon Kass, Chairman of President Bush's Council on Bioethics, has questioned the morality of therapeutic cloning in part because it "exploits women as egg donors not for their benefit." Gina Kolata, *Koreans Report Ease in Cloning for Stem Cells*, N.Y. TIMES, May 20, 2005, at A1.

6. *Bush Spokesman Retracts Stem Cell Comment*, N.Y. TIMES, July 25, 2006, at A16. Press Secretary Snow later retracted this comment, clarifying that President Bush believes that human embryonic stem cell research involves "the destruction of human life." *Id.*

7. *See, e.g.*, PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 76 (2004), *available at* http://www.bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf ("This view holds that only the very beginning of a new (embryonic) life can serve as a reasonable boundary line in according moral worth to a human organism, because it is the moment marked out by nature for the first visible appearance in the world of a new individual.").

8. For a summary of versions of this argument, see *id.* at 78-84.

actual efficacy of the cloning and embryonic stem cell research programs is not terribly important, since hardly any justification is required for what is seen as the mere destruction of some cells. Supporters of this argument attempt to bolster their pro-research position by touting the medical potential of embryonic stem cell research; however, the core of the argument is that the tiny group of cells in the dish has no moral status.

Between these opposites is a third position that casts the issue as involving the balancing of serious and competing moral claims. According to this argument, human embryos *in vitro* enjoy substantial moral status. Their destruction in research may nonetheless be permissible, however, if either or both of the following conditions are fulfilled: 1) the embryos' moral claims are outweighed by the potential of the research to alleviate human suffering; or 2) the embryos, if not used in research, would languish in the freezers of fertility clinics and eventually be destroyed.

Though this debate continues to rage in journals and on the Internet, as a policy matter it has been resolved in favor of permitting research on embryos, including embryos specifically cloned for research. Pursuant to a statement made by President Bush in August 2001,[9] the Bush administration restricted federal funding only to research on a limited number of previously existing human embryonic stem cell lines; on March 9, 2009, President Obama formally lifted that funding restriction.[10] At this writing, it seems likely that federal funding will begin to flow toward broader embryonic stem cell research in only a few months. Pursuant to the Dickey-Wicker Amendment, the federal government has been prohibited annually from funding the cloning or destruction of any human embryo,[11] but that amendment has been construed as permitting federal funding for subsequent research on cell lines created from embryos cloned or destroyed with non-federal funds.

States and private organizations have also taken a central role in funding embryonic stem cell research. Aside from a few states that impose more restrictive laws, both embryonic research and human cloning for research

9. For the full text of President Bush's speech on human embryonic stem cell research, see Press Release, Office of the Press Secretary, White House, President Discusses Stem Cell Research (Aug. 9, 2001), *available at* http://georgewbush-whitehouse.archives.gov/news/releases/2001/08/20010809-2.html.

10. *See* Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 9, 2009).

11. The Dickey (or Dickey-Wicker) Amendment is actually a rider that Congress has attached to the appropriations bill for Health and Human Services annually since 1996. "[T]he Dickey Amendment prohibits federal engagement in a field of research pertaining to the nature of the human embryo, its disorders of development, and the derivation of new human embryonic stem-cell lines." George Q. Daley, *Missed Opportunities in Embryonic Stem-Cell Research*, 351 NEW ENG. J. MED. 627, 628 (2004).

purposes remain permissible in most of the country.[12] Further, taking advantage of the vacuum left by the temporary absence of federal funding, a number of state governments have decided to fund human embryonic stem cell research and cloning.[13] By offering their own funding, those states hope to gain a competitive advantage over unfunded states in university and industry development, while also satisfying disease-group constituencies who were anxious to see stem cell research generate cures. Private money has also flowed generously toward such research; Harvard University's prominent stem cell research program, for example, is mostly funded by private philanthropy.[14]

Although for the moment stem cell research has widespread public appeal and growing support from the federal government, states, and private institutions, there is reason to believe that this broad consensus will not be terribly stable. The funding and methods of stem cell research have generated a new round of debates, and underlying moral questions regarding the status of the embryo are far from resolved. The public's support for embryonic stem cell research seems not to be concentrated at the stable ends of the above tripartite division of arguments. When asked blankly whether they support or oppose stem cell research, a substantial majority of Americans say they support it.[15] But that apparent support erodes considerably when the question stresses that the research involves the destruction of human embryos.[16] Support increases, however, when the question instead highlights the high human and economic costs of the diseases that stem cell research might one day treat or cure.[17] In light of this rather confused and confusing data, it seems reasonable to conclude that a sizeable chunk of Americans take a moral balancing approach, namely the third view listed above. This moral balancing approach leads to different conclusions when the weights on different sides of the scale (embryonic destruction and research potential) are called to attention. At the moment, most of the public seems to have resolved the balance in favor of research, if it has resolved the conflict at all. But if anything occurred to alter its perception of the weight either

12. For a periodically updated chart summarizing state laws governing the treatment of fetuses and embryos in research, see National Conference of State Legislatures, Stem Cell Research, http://www.ncsl.org/programs/health/Genetics/embfet.htm (last visited Apr. 21, 2009).

13. States currently funding embryonic stem cell research include California, Connecticut, Illinois, Maryland, Massachusetts, New Jersey, New York, and Ohio. *See id.*

14. *See* Harvard Stem Cell Institute, Frequently Asked Questions, http://www.hsci.harvard.edu/faq#FAQ14 (last visited Apr. 21, 2009) ("HSCI is supported primarily by private philanthropic donations.").

15. Yuval Levin, *Public Opinion and the Embryo Debates*, 20 NEW ATLANTIS 47, 50 (2008).

16. *Compare id.* (showing that 69% of people surveyed supported stem cell research) *with id.* at 52 (finding that only 33% of people believed an embryo should be destroyed for scientific or research purposes).

17. *Id.* at 52 (finding that 54% of people surveyed agreed that the economic and personal costs of disease are greater than the risks associated with the destruction of embryos).

on the research-progress side of the scale or on the moral status side, the existing consensus could easily shift.

To be sure, a new round of debate on stem cell and cloning research is not apt to culminate in either a wholesale reversal or a solid reaffirmation of the core position about the moral permissibility of human embryonic stem cell and cloning research. The next debates are likely, instead, to have decentralized and seemingly marginal effects. As different groups find their moral balances shifting, some funding may be expanded or cut; particular research techniques may be banned while others are underwritten; priorities will shift; the caché of different research programs and institutions may be evaluated differently. Collectively, these dozens of small and decentralized political and financial adjustments could enhance the research, hinder it, or dramatically alter its scope and quality.

The Articles in this book are ideal reading material for someone who wants to follow and understand the significance of these new debates.

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One thing that will not change is the urgent desire of many Americans for the development of cures for devastating diseases. That urgent desire made itself known throughout the first national debate; every state that considered funding stem cell research heard impassioned pleas from mothers of diabetic children, from men dying of Parkinson's disease, and from Alzheimer's caregivers.

But urgent desires can lead to unrealistic expectations, and unrealistic expectations easily lead to disappointment. There is strong evidence that expectations for stem cell research are already unjustifiably high. Recent polls suggest that nearly a third of Americans believe, incorrectly, that embryonic stem cell research has already delivered usable cures or treatments for human disease.[18] And this incorrect belief is more common among those who claim some familiarity with the stem cell research issue![19] Many more people expect or demand cures soon. At a recent public meeting of Connecticut's Stem Cell Research Advisory Committee—at which the committee was reviewing one-year progress reports from university investigators who had received research grants in the first round of state funding—the leader of the state chapter of a national spinal-injury lobby group spoke of his disappointment that researchers were not yet making progress toward cures.[20] He spoke also of his own personal desire to

18. *Id.* at 44.

19. *Id.* (noting that 40% of those who claimed to have some knowledge about the research believed, incorrectly, that embryonic stem cells had yielded therapeutic results, compared to only 23% of those who said they were unfamiliar with the research).

20. David Meneker, Remarks at the Meeting of the Connecticut Stem Cell Research Advisory Committee 141 (May 20, 2008) (transcript available at http://www.ct.gov/dph/lib/

rise one day and walk away from his wheelchair.[21] Such high hopes may easily be dashed—and if they are, stem cell research may be abandoned by some of those who were originally its greatest supporters.

From where did those high hopes come? **Daniel Callahan** argues that the stem cell research "juggernaut" was the deliberate creation of a coordinated public relations campaign. That campaign, he argues, hyped research potential and then used that hype to undergird a supposed "moral obligation" to conduct the research.

Researchers have been enthusiastic and optimistic about therapeutic research programs before. For a dose of humility, we need only remember the hype surrounding gene therapy a few decades ago. In the 1980s, even those who opposed gene therapy took it for granted that it would radically alter medicine; indeed, their primary objections were based on the assumption of its success.[22] Gene therapy was thought dangerous precisely because it was going to be too powerful, that it was going to transform us into eugenicists or demigods, altering our genes and our gene pool before we had thought carefully about the results. Today, gene therapy is still in its infancy. Only a handful of therapies have ever been tested in humans, and in more than one high-profile case, that testing has resulted in the deaths of research subjects.[23] It may well be that the development of stem cell cures will take longer, much longer, than many of its proponents anticipate. There may be dramatic bumps in the road—bumps that cause substantial delay and disappointed expectations. This could turn the tide against stem cell research, or at least against public funding for it.

Jane Maienschein is concerned with a different and more subtle sort of hype that pervades the national debate on stem cell research. That debate, she laments, is comprehensively polluted by an idea of genetic determinism inspired

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dph/Transcript_5-20-08.doc). I attended this meeting and heard these comments as a member of the Connecticut Stem Cell Research Advisory Committee.

21. *Id.*

22. *See, e.g.*, Clifford Grobstein & Michael Flower, *Gene Therapy: Proceed with Caution*, HASTINGS CENTER REP., Apr. 1984, at 13.

23. For a brief summary of the current status of gene therapy research, including summary discussion of some of its major setbacks, see Human Genome Project Information, Gene Therapy, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetherapy.shtml (last visited Apr. 21, 2009). For an extensive review of the case of Jesse Gelsinger, who died during a gene transfer experiment at the University of Pennsylvania, see Robert Steinbrook, *The Gelsinger Case*, *in* THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 110 (Ezekiel J. Emanuel et al. eds., 2008). *See also* Jocelyn Kaiser, *Gene Transfer an Unlikely Contributor to Patient's Death*, 318 SCIENCE 1535, 1535 (2007) (describing an investigation into the death of a gene therapy trial participant, which "concluded that the gene transfer was unlikely to have contributed . . . but that this 'cannot definitively be ruled out'") (citations omitted); *Panel Urges Limits on X-SCID Trials*, 307 SCIENCE 1544, 1544 (2005) (noting the death of one child during a gene therapy trial for immunodeficiency disease in France).

by earlier debates about cloning and by the well-publicized Human Genome Project. The basic view that our genetic structure is the core of our being, and that we do and become what our genes command, is pervasive even among scientists—and yet, Maienschein argues, this view is importantly incorrect. Maienschein, a historian and philosopher of biology, shows us how this view obtained its cultural authority and how it is that the biology with which the public is most familiar is a limited biology of genetic determinism. She then makes some recommendations for the conduct of a more scientifically informed debate about cloning and human development going forward.

If one danger to the current stem cell consensus comes from disappointed expectations in the research, a second danger comes from dramatic new progress in that research. Key arguments in the debate about embryonic stem cell research concern the availability of alternative means to create cell lines that would be as useful as embryonic cells—means that might bypass the core ethical debate because they do not involve the creation or destruction of human embryos. If scientists could only find an adequate substitute (or a set of adequate substitutes) for embryonic stem cells, then the entire stem cell research program could proceed without the moral worries about embryo destruction and therapeutic cloning. In the past, opponents of embryonic stem cell research argued that adult stem cell research was a fully adequate substitute for embryonic stem cell research, and indeed that adult stem cells held greater therapeutic promise. Few scientists were willing to concede this, however, given the comparatively limited ability of adult stem cells to differentiate and the difficulties of culturing adequate numbers of adult cells for research. Some argued, also, that the opponents of embryonic stem cell research were over-hyping the therapeutic potential of adult stem cells. In a different effort to square the ethical circle, William Hurlbut of the President's Council for Bioethics argued for the creation of a "biological artifact," a kind of deliberately "disabled" embryo that was incapable of developing into a human being, specifically because it had been engineered to lack the capacity to generate a placenta.[24] Since destruction of such an embryo would not involve the destruction of a potential human being, Hurlbut reasoned, the ethical problem would be solved. Critics pointed out, however, that the creation of the "disabled" embryo would itself involve the destruction of an embryo.

But in the past few years, stem cell science has progressed considerably, and there are more, and perhaps more realistic, alternatives to embryonic stem cell and cloning research in the offing. Most dramatically, in 2007, scientists in the

24. For a detailed discussion of Hurlbut's proposal, see PRESIDENT'S COUNCIL ON BIOETHICS, ALTERNATIVE SOURCES OF HUMAN PLURIPOTENT STEM CELLS: A WHITE PAPER 36-50 (2005), *available at* http://www.bioethics.gov/reports/white_paper/alternative_sources_white_paper.pdf.

United States[25] and Japan[26] demonstrated their ability to use viruses to introduce certain changes in the genetic content and expression of specialized somatic (adult) cells, rendering them pluripotent (able to differentiate into different specialized cells), in a manner similar to embryonic stem cells. In 2008, similar "induced pluripotency" was achieved in mice without the use of the viral vectors.[27] Induced pluripotency is not yet a real substitute for embryonic stem cell research because the exact mechanism by which pluripotency is induced is imperfectly understood even by the researchers. It also remains unclear whether induced pluripotent stem cells will share identical characteristics with their embryonic counterparts. But there is considerable potential here for doing research on cell specialization without embryonic destruction. **Rajesh Rao** reviews this and a host of other potential substitutes for embryonic stem cell and cloning research, including parthenogenesis (which involves the development of stem cells from an unfertilized egg) and cellular reprogramming via cell fusion and other techniques.

For many, the moral permissibility of embryonic destruction in research turns on the idea that the embryos being destroyed "would have been destroyed anyway." The question of using "spare" embryos from assisted reproduction is returning to the forefront of the debate for a number of different and mutually reinforcing reasons. First, the Roman Catholic Church has recently released a formal instruction on bioethics, which comprehensively opposes assisted reproduction, the creation of supernumerary embryos, and the use of such embryos in research.[28] Second, recent scholarship has questioned the quality of consent given by infertile couples who permit their "spare" embryos to be used in research: one scholar has revealed that some of the federally fundable stem cell lines were secured with inadequate parental consent;[29] other scholars have questioned the propriety of asking couples to consent to research use of their embryos at the same time as, and in the same document as, their consent to fertility treatment;[30] and others have questioned whether the burdens of non-

25. Junying Yu et al., *Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells*, 318 SCIENCE 1917 (2007).

26. Kazutoshi Takahashi, *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861 (2007).

27. Keisuke Okita et. al., *Generation of Mouse Induced Pluripotent Stem Cells Without Viral Vectors,* 322 SCIENCE 949; *see also* Matthias Stadtfeld et al., *Induced Pluripotent Stem Cells Generated Without Viral Integration*, 322 SCIENCE 945 (2008).

28. CONGREGATION FOR THE DOCTRINE OF THE FAITH, INSTRUCTION *DIGNITAS PERSONAE* ON CERTAIN BIOETHICAL QUESTIONS (2008), *available at* http://www.usccb.org/comm/Dignitaspersonae/Dignitas_Personae.pdf.

29. *See, e.g.*, Robert Streiffer, *Informed Consent and Federal Funding for Stem Cell Research*, HASTINGS CENTER REP., May-June 2008, at 40.

30. *See, e.g.*, Ellen A. Waldman, *Disputing Over Embryos: Of Contracts and Consents*, 32 ARIZ. ST. L.J. 897, 918-32 (2000).

fertility-related stem cell research should fall solely upon infertile couples.[31] Given this kind of debate, state legislatures will likely be revisiting the question of the provenance of research embryos.[32] **Gene Outka**'s Article is a sophisticated philosophical defense of the use of "spare" embryos in research, based on the principle that "nothing is lost."[33] The latter part of **Daniel Callahan**'s paper effectively engages Outka in debate on this point, rejecting the "nothing is lost" principle.

State and federal legislatures have repeatedly flirted with some sort of ban on reproductive and/or therapeutic cloning—not always sharply distinguishing between the two. Calls for such legislation have followed closely on the heels of disclosures by scientists that they have succeeded in cloning human embryos for therapeutic purposes. **Robert Burt**'s paper takes a look at the possible constitutional limits of any effort to regulate or ban research cloning. His analysis examines a number of challenges to such a ban, including a possible constitutional right to free scientific inquiry; a claim that such regulation might interfere unconstitutionally with couples' reproductive freedom; a claim that executive branch restrictions on research funding might be unconstitutional; and the claim that only states, and not the federal government, have constitutional authority to regulate in this area.

Robert Levine offers a critical view of the Bush administration's research funding policy and an argument for expanded federal regulation of federally funded stem cell research. In Levine's view, the federal refusal to fund embryonic stem cell research, but to permit it to proceed with private funding, was a political cop-out, a way to appear to satisfy parties on both sides of a tough moral question. But the politically safe decision to permit research to proceed without government funding may have had negative collateral consequences for research subjects. Funding, Levine argues, has commonly come hand-in-hand with regulatory oversight and protections for research subjects. He illustrates his point by comparing stem cell research with federal regulations governing the oversight of research on human subjects, and with the largely privately funded, and largely unregulated, field of assisted reproductive technology. He offers some timely recommendations for federal regulation of stem cell research, which will take on increasing importance as funding restrictions lessen.

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31. *See, e.g.*, Angela Ballantyne & Sheryl de Lacey, *Wanted—Egg Donors for Research: A Research Ethics Approach to Donor Recruitment and Compensation*, 1 INT'L J. FEMINIST APPROACHES TO BIOETHICS 145 (2008).

32. The NIH has also recently considered the sources of embryos used in research. *See* Draft National Institutes of Health Guidelines for Human Stem Cell Research Notice, 74 Fed. Reg. 18,578 (proposed Apr. 23, 2009)

33. This is an updated version of the argument that he first presented in a discussion paper before the President's Council on Bioethics.

Finally, **James Fossett**'s Article shifts the focus away from federal policy in the embryonic stem cell and cloning area, and toward the question of state and private funding for that research under the new administration. Fossett summarizes the roles of state governments and private philanthropies in funding stem cell research, and predicts that, though the federal government may move to fund more embryonic stem cell research, major federal funding is unlikely. He predicts, also, that the advent of such funding will do little to diminish the state's role in sponsoring and regulating embryonic stem cell research. He argues that robust federalism is not only desirable, but necessary, in this research sector.

Taken together, these Articles offer a thorough and up-to-date overview of the fields of embryonic stem cell and cloning science, ethics, and policy.