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FUNDING STEM CELL RESEARCH: THE CONVERGENCE OF SCIENCE, RELIGION & POLITICS IN THE FORMATION OF PUBLIC HEALTH POLICY

Edward A. Fallon*

Public health policy in the United States has long been influenced by three factors: the imperfect and evolving state of scientific knowledge about human biology, the far less changeable status of religious doctrine concerning the human body, and the constant compromises and accommodations made by elected officials in an attempt to garner the support of divergent political interest groups. Scholars have even developed a new term to describe this field of inquiry: “public bioethics.”¹ The current debate over the funding of stem cell research, in particular human embryonic stem cell (hESC) research, is but the most recent convergence of these three influences on public policy. Advocates of federal and state government funding of embryonic stem cell research argue that our democratic government should foster and promote the path of discovery, especially where that inquiry focuses on the causes and cures of disease. Opponents of federal and state funding argue that our democratic government should reflect the moral values of our population, a portion of which object to embryonic

* Associate Professor, Marquette University Law School. In my private life, I am the president of a nonprofit organization that advocates in support of all forms of stem cell research. I would like to thank Professor Aaron D. Levine for his comments and suggestions. I would also like to thank my daughter Emma and my son Andrew, both of whom inspire me every day.

1. O. Carter Snead, *Science, Public Bioethics, and the Problem of Integration*, 43 U.C. DAVIS L. REV. 1529, 1532 (2010) (defining “public bioethics” as the “the governance of the practice of medicine, biotechnology, and biomedical research in the name of ethical goods”).

stem cell research on religious grounds.²

Differing conceptions of knowledge contribute to this debate. Scientific knowledge follows an uncertain path, and those who are engaged in scientific research assume that complete and final knowledge is an unattainable goal.³ New discoveries are episodic and tentative. While impressive additions to the universe of human knowledge have been made since 1998, when Dr. Jamie Thomson successfully isolated human embryonic stem cells for the first time,⁴ today there still remains much that we do not understand about cell biology.

Religious doctrine, in contrast, rests upon the assertion that certain truths are unassailable and are not subject to change regardless of the results of scientific inquiry.⁵ The doctrines of the Catholic Church, in particular, historically have opposed both contraception and abortion. These doctrines are based upon Church teachings in regards to human sexuality and reproduction that have evolved little since the time of Saint Augustine.⁶

Some observers assert that it is inevitable for scientific and

2. An October 2010 Harris Interactive poll found strong support for embryonic stem cell research among the public. According to the poll, 73% of respondents support stem cell research "as long as the parents of the embryo give their permission, and the embryo would otherwise be destroyed." Among the poll's findings: 58% of Republicans support stem cell research (with 24% of Republicans opposed), while the research is supported by 69% of Catholics and 58% of born-again Christians. In contrast, the poll found that embryonic stem cell research is opposed by 16% of Catholics and 22% of born-again Christians. See Amanda Gardner, *Most Americans Back Embryonic Stem Cell Research: Poll*, BLOOMBERG BUSINESSWEEK (Oct. 7, 2010), <http://www.businessweek.com/lifestyle/content/healthday/644026.html>.

3. BERTRAND RUSSELL, *RELIGION AND SCIENCE* 14 (Oxford University Press 1997) (1935).

4. James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 *SCIENCE* 1145, 1145 (1998).

5. See RUSSELL, *supra* note 3, at 13-17.

6. See generally JOHN T. NOONAN, JR., *CONTRACEPTION: A HISTORY OF ITS TREATMENT BY THE CATHOLIC THEOLOGIANS AND CANONISTS* (1965). There is, however, a vigorous debate concerning the extent to which Catholic doctrine on these matters has in fact changed in meaningful ways over the centuries. See generally Christine E. Gudorf, *Contraception and Abortion in Roman Catholicism*, in *SACRED RIGHTS: THE CASE FOR CONTRACEPTION AND ABORTION IN WORLD RELIGIONS* 55 (Daniel C. Maguire ed., 2003).

religious viewpoints to come into direct conflict.⁷ Others believe that it is possible for the government to craft policies that advance both scientific and religious perspectives.⁸ Indeed, the very concept of public bioethics as a field of inquiry assumes that it is both necessary and possible for government policymakers to accommodate these two differing attitudes towards the acquisition of knowledge.⁹

The convergence of science, religion and politics in the health care context has engendered controversy in the past. In the 1980s, a newly identified communicable disease known as Acquired Immune Deficiency Syndrome (AIDS) gave rise to fears of an epidemic and prompted calls for a public health response. Medical researchers criticized the federal government for being slow to develop and adopt a national AIDS strategy. In addition, many scientists questioned Congress' decision to fund research for a vaccine through supplemental appropriations rather than by increases to the budget of the National Institutes of Health (NIH).¹⁰

The early (and incomplete) scientific understanding of the disease led some persons to conclude that the illness was primarily spread through immoral conduct. Other segments of the public objected to using tax dollars to fund public education and prevention programs that advocated the use of condoms.

7. See RUSSELL, *supra* note 3, at 13-17.

8. See GARRY WILLS, HEAD AND HEART: A HISTORY OF CHRISTIANITY IN AMERICA 547-52 (2007).

9. See Snead, *supra* note 1, at 1602 (concluding that the question of federally funding embryonic stem cell research "should be decided by politically accountable public officials, applying the humanistic concepts of moral reasoning").

10. Much of the controversy over the appropriate role of the federal government in responding to the AIDS crisis played out as a funding debate:

From June 1981 to June 1982, a period generally considered to be the first twelve months of the epidemic, the Centers for Disease Control and Prevention (CDC) spent \$1 million on AIDS, compared with \$9 million in response to the much smaller problem of Legionnaires' disease. In late 1982, Congress allocated \$2.6 million to be targeted for the CDC's AIDS research, but the Reagan administration claimed that the CDC did not need the money and opposed any congressional supplemental appropriations designed to fund federal governmental AIDS policy efforts.

ENCYCLOPEDIA OF AIDS: A SOCIAL, POLITICAL, CULTURAL, AND SCIENTIFIC RECORD OF THE HIV EPIDEMIC 164 (Raymond A. Smith, ed., Penguin Reference 2001) (1998).

Meanwhile, on the other end of the political spectrum, gay rights advocates objected to the utilization of traditional public health powers, such as quarantine, as a means of combating the spread of AIDS. Liberal groups feared that these "archaic" police powers would inevitably be used to target homosexuals in general rather than the affected population.¹¹ As a result, the public health response to the AIDS crisis was hampered by the need to accommodate religious and political interest groups.

The funding of medical research¹² using stem cells provides a contemporary opportunity to examine the intersection of science, religion and politics in the formation of public health policy. In Section I, this article reviews the science of stem cell research. Section II addresses religious and ethical perspectives relating to stem cell research. In Section III, the current funding landscape for stem cell research is examined. Interest group litigation seeking to influence federal and state funding policies is discussed in Section IV. Finally, in Section V, this article articulates two neutral principles that should guide policymakers in future situations where public health decisions implicate science, religion and politics.

THE SCIENCE OF STEM CELL RESEARCH

A BRIEF HISTORY OF REGENERATIVE MEDICINE

Researchers and their advocates believe that stem cell research has the potential to greatly alleviate human suffering.

11. See generally Edward A. Fallone, *Preserving the Public Health: A Proposal to Quarantine Recalcitrant AIDS Carriers*, 68 B.U. L. REV. 441 (1988).

12. Medical research takes place in three stages. Basic medical research (sometimes called the "discovery phase") typically takes place at academic institutions and is usually funded by the state and federal governments rather than by for-profit corporations. Preclinical research, the second stage, focuses on applications that build off of basic research discoveries and on "proof of concept" testing. Academic institutions engage in this second stage of research, along with biotech and pharmaceutical companies seeking to develop patentable technologies. The third stage of medical research is clinical research. Clinical research is performed in order to verify the safety and efficacy of treatments on human patients, and it is typically conducted by both academic institutions and by large corporations developing a marketable product.

Numerous diseases and chronic medical conditions, including Diabetes, ALS, Multiple Sclerosis, Parkinson's Disease, Alzheimer's, and spinal cord injury, may be susceptible to treatment or even cures using stem cells. Many of these diseases disproportionately affect the elderly, an important factor in consideration of the rapidly aging American population.¹³ Supporters argue that the development of therapies for chronic health conditions would also be beneficial to the economy, because costs associated with the treatment of chronic disease are a significant contributor to the steady rise in health care spending in our nation. However, stem cell research is merely the latest stage in the long and often controversial history of regenerative medicine.¹⁴

For hundreds of years, medical research has sought treatments for human tissue and organs that have been damaged, whether by accident, genetic defect, or degenerative disease.¹⁵ One consistent focus of this research has been the possibility of replacing the non-functioning body part with a healthy alternative. The earliest blood transfusions in the eighteenth century became the template for the first organ transplants – the replacement of damaged or diseased organs with healthy organs from a donor. As the transplantation techniques advanced over the decades, transplants involving kidneys, hearts, lungs and other types of organs have become commonplace.

One drawback to organ transplantation is the need to suppress the recipient's immune system in order to prevent the rejection of foreign tissue. However, a far more significant drawback has proven to be the limited supply of donated organs

13. See Cynthia M. A. Geppert, *Stem Cell Research*, in *ENCYCLOPEDIA OF AGING AND PUBLIC HEALTH* 760, 760-61 (Sana Loue & Martha Sajatovic eds., 2008) ("Stem cell research offers enormous potential to improve the quality of life of older people and even to extend the life span.").

14. The term "regenerative medicine" applies to treatments intended to repair damaged or diseased tissues and organs in the human body, whether via tissue engineering, stem cell therapy, the use of mechanical devices or other techniques.

15. "Tissue" refers to specialized human cells that perform a specific bodily function. "Organs" refer to body parts containing multiple related types of tissue.

for transplantation. In response to this shortage, researchers have explored the use of mechanical devices that function as artificial organs and, in certain instances, the use of organs obtained from animal sources. These developments led to objections by some to the introduction of non-human material into the recipient's body, on religious grounds. Nonetheless, a majority of the public favored the use of these alternative sources of organs so long as ethical guidelines were followed.¹⁶

Neither mechanical nor animal organs are an exact substitute for the healthy human organs that they are designed to replace, however. In addition, despite recent advances in nanotechnology, researchers still struggle to create machines that can perform biological functions at a cellular level. Therefore, the finite supply of donated human organs continues to be the primary limitation on the use of transplantation as a treatment for disease and chronic injury.

In the 1970s, significant progress was made in the field of recombinant DNA. Researchers inserted strands of human DNA into bacteria in order to manufacture proteins and artificial hormones that exactly mimic their parallels in the human body. An entire new branch of the pharmaceutical industry developed in order to produce drugs designed to trigger natural responses within the patient's body.¹⁷ These advances in recombinant DNA were initially controversial, and some persons viewed the combination of human DNA with a bacterial host as evidence of a scientific community run amuck.¹⁸

16. For a discussion of religious perspectives on the bodily incorporation of mechanical devices, see generally Courtney S. Campbell et al., *The Bodily Incorporation of Mechanical Devices: Ethical and Religious Issues (Part 2)*, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 268 (2007).

17. For example, diabetics today inject artificial insulin that is genetically identical to human insulin. The patient must still inject the artificial insulin several times a day, so it is not the equivalent of replacing the patient's damaged pancreas. Nonetheless, the genetically manufactured insulin is considered superior to insulin harvested from slaughtered pigs, which was the previous source of injectable insulin. Similarly, drugs created using recombinant DNA can be used to trigger an increase in the body's red blood cell production during chemotherapy.

18. See ROGER SHATTUCK, *FORBIDDEN KNOWLEDGE: FROM PROMETHEUS TO PORNOGRAPHY* 186-195 (1996).

Stem cell research is the most recent stage in the historical progress of regenerative medicine. Stem cell research focuses on the process of human biology at a cellular level, and is therefore one way that researchers hope to learn how to repair or replace human organs and tissues. The ultimate goal of this science is to create new adult human cells, either by growing them from undifferentiated stem cell lines or by transforming one type of adult cell directly into another type. One potential use of these newly created cells is to test experimental drugs on human tissue without having to conduct clinical trials on human subjects. However, a second potential use, which is of particular interest to millions of Americans with chronic medical conditions, is to create a new source of organs and tissues that can be used for transplantation.

STEM CELL RESEARCH: A VARIETY OF APPROACHES

Stem cells are “unspecialized” cells that can generate healthy new cells, tissues, and organs. They are the master cells of the human body and, when isolated outside of the body, they can be manipulated to transform into more specialized cells that perform specific bodily functions. A stem cell “line” is formed by extracting stem cells from their source and placing them in a growth culture in a petri dish. The stem cells are then induced to self-replicate, generating a colony of stem cells that continually replaces itself. Researchers then apply factors to the stem cell line that cause the stem cells to transform into specialized adult cells.

Adult Stem Cell Research

After birth, small amounts of stem cells remain in many mature human organs, where they continue to create specialized cells that replace cells that have become damaged or worn out. Researchers have long known that it is possible to use these adult stem cells in order to generate different types of specialized replacement cells. Adult stem cells are characterized

as "multipotent,"¹⁹ meaning that they can be transformed into a limited number of specialized cell types. Replacement cells created using adult stem cells are usually closely related to the types of cells that reside in the tissue where the adult stem cells were located. In other words, adult stem cells derived from blood-producing bone marrow can be used to produce different kinds of specialized blood cells, but it is unclear whether they can be used to produce nerve or muscle cells.

Embryonic Stem Cell Research

After the union of sperm and egg, the fertilized egg undergoes several stages of development. The fertilized egg divides into two cells, then four, eight, and so forth, until it reaches a stage where it is called a morula ("berry" in Latin).²⁰ Approximately four days after fertilization, this solid mass of cells begins to transform from a compressed morula into a hollowed-out ball called a blastocyst.²¹ The blastocyst is about the size of the period at the end of this sentence, and its interior contains a thin ridge of cells.²² These are the embryonic stem cells, and they can be extracted from the blastocyst and grown in culture. Embryonic stem cells are the progenitor cells that serve as precursors of every cell type that will later be necessary for human development.

Prior to extraction from the blastocyst, the embryonic stem cells are "totipotent," meaning that they possess the ability to develop into any of the three types of human tissue (endoderm, mesoderm, or ectoderm) and also to develop into the placental tissues needed for the blastocyst to implant in the uterus.²³ An embryonic stem cell line is created by removing the embryonic stem cells from the blastocyst and inducing them to reproduce in

19. See Ralph Dittman, *Latest Developments in Stem Cell Research*, THE HUFFINGTON POST (Nov. 21, 2007, 6:10 PM), http://www.huffingtonpost.com/ralph-dittman/latest-developments-in-st_b_73783.html?view=screen.

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*

a cultured petri dish. Once removed from the blastocyst, the embryonic stem cells are “pluripotent,” meaning that they have the ability to develop into any of the 210 or so different cell types of a human body²⁴ but that they no longer possess the ability to form placental tissues.

The extraction of the embryonic stem cells from the blastocyst typically occurs between five and ten days after fertilization.²⁵ Extraction is performed during this early time frame because, as the blastocyst continues to develop, the cells become even more differentiated and specialized. Until about day fourteen, the cell mass could be divided in two segments, and it would result in two viable identical cell masses. However, after day fourteen the cells become differentiated to the point that, if one were to attempt to divide them, the entire cell mass would arrest and stop developing. In addition, by day fourteen the cells have become so specialized that they cease to be pluripotent, but are merely multipotent instead.²⁶

Self-perpetuating embryonic stem cell lines were first successfully isolated from humans and cultured by Dr. James Thomson at the University of Wisconsin in 1998.²⁷ In the United States, hESC research uses eggs that have been fertilized in vitro and then donated for research purposes with the informed consent of their donors. These eggs were not fertilized in a woman’s body, but rather were created at an in vitro fertility clinic. They exist because the in vitro fertilization (IVF) process

24. *Id.*

25. Extraction of the stem cells from the blastocyst collapses the outer line of cells and renders the blastocyst incapable of implantation in the uterine wall. It is the destruction of the blastocyst at this stage that has engendered opposition to hESC research. It should be noted that at this stage in the development of the blastocyst, were it located in the human body, it would still be traveling through the fallopian tubes and would not yet have reached the uterus. It is estimated that fewer than one third of fertilized eggs successfully implant in the uterus during human reproduction and proceed to develop to term. Instead, the majority of eggs that are fertilized within the woman’s body pass through the uterus or, after implantation, spontaneously abort. Biologists do not consider conception to occur until implantation in the womb. See HAROLD J. MOROWITZ & JAMES S. TREFIL, *THE FACTS OF LIFE: SCIENCE AND THE ABORTION CONTROVERSY* 51 (1992).

26. See Dittman, *supra* note 19.

27. See Thomson et al., *supra* note 4, at 1145.

typically results in the creation of excess blastocysts, and if not used for research purposes the majority of these fertilized eggs would be destroyed.²⁸ Federal funding of hESC research is currently limited to research using excess blastocysts obtained from IVF clinics. In addition, federal dollars may only be used to support research using pre-existing hESC lines and not for the derivation of new hESC lines from blastocysts.

Induced Pluripotent Stem Cells (iPS cells)

In November 2007, both Dr. James Thomson of the University of Wisconsin and a separate team under the direction of Dr. Shinya Yamanaka in Japan announced that they had discovered how to create cells that behave like embryonic stem cells by adding a “cocktail” of four gene transcription factors to an adult skin cell.²⁹ This technique converts routine body cells, or somatic cells, into pluripotent stem cells. In technical terms, the technique “de-differentiates” the adult cell. These re-programmed somatic cells are called “induced pluripotent stem cells” or iPS cells.

The breakthrough involved using four factors — including cancer genes — that were inserted into human adult skin cells using retroviruses as a vehicle. These factors “re-programmed” the skin cells with the result that they began to behave like embryonic stem cells. These iPS cells appear to have a plasticity similar to embryonic stem cells, although it is unknown whether they are an exact equivalent. One potential advantage of using stem cells created via the iPS technique is that there would be no immune system issues should those cells be transplanted back into the patient that donated the skin cells. Early concerns expressed over the use of cancer genes and retroviruses to do the

28. A 2004 study found that eighty-four percent of fertility clinics routinely destroyed unused blastocysts created for implantation. See Andrea D. Gurmankin et al., *Embryo Disposal Practices in IVF Clinics in the United States*, 22 POL. & LIFE SCI. 4, 6 (2004) (In a survey, 175 out of 208 IVF clinics reported that they had policies permitting the disposal of excess embryos.).

29. See Kazutoshi Takahashi et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861, 868 (2007).

reprogramming — the introduction of which might “switch on” cancer genes already present within the body — were addressed through the development of new methods of re-programming which do not utilize cancer genes.

Direct Cell Re-Programming

The expanded knowledge of cell biology that has been gained from stem cell research has also led to techniques that transform one type of specialized adult cell directly into another type of adult cell. Using this approach, researchers can side-step the entire process of creating any stem cell lines. This process has been labeled “direct reprogramming.”

In 2008, Dr. Douglas Melton at the Harvard Stem Cell Institute announced successful experiments in mice where he transformed normal pancreas cells into more specialized insulin producing cells.³⁰ He achieved these results by using a “cocktail” of three transcription factors to transform one type of adult mouse cell directly into a different type of adult cell. This advance allowed the creation of new adult mouse cells without first creating a stem cell line. If this technique can be replicated using human cells, it would also seem to avoid potential problems with the extraction of adult stem cells or the rejection of transplanted cells by the immune system. Similar to iPS research, the initial direct re-programming results involved the use of a virus as the vehicle for introducing the genes into the cells. A non-viral approach needs to be developed to avoid the risk that the virus will induce the growth of cancerous tumors.

Comparability and Equivalency Among Different Types of Stem Cell Research

Because human embryonic stem cells are able to differentiate into any cell type in the body, scientists believe that they hold great promise – both as a source of replacement cells

30. See Qiao Zhou et al., *In Vivo Reprogramming of Adult Pancreatic Exocrine Cells to β -Cells*, 455 NATURE 627, 630-31 (2008).

for transplantation and for use in testing drug interactions in human tissue. Their plasticity, and their durability as self-sustaining cell lines that self-replicate over long periods of time, are the primary advantages of embryonic stem cells. For example, researchers have used embryonic stem cells to create large quantities of red blood cells, raising the prospect that one day blood drives may be unnecessary.³¹ In addition, because embryonic stem cells have developed only once from their embryonic state, tissue created using embryonic stem cells is considered to be the closest equivalent to naturally occurring human tissue. Immunosuppression issues remain one of the primary concerns in regards to hESC research.

In contrast, adult stem cells extracted from the patient's own body do not trigger an immune system response when used to create specialized cells that are re-introduced into the patient's body. However, there are currently several disadvantages associated with the use of adult stem cells. First, researchers have yet to find a collection of adult stem cells throughout the body that can give rise to *all* of the various types of cells and tissues present in the human body. In addition, in some instances adult stem cells may be present in mature organs but the extraction of these adult stem cells is difficult or dangerous to the patient. This is currently the case with adult stem cells located in the heart and the brain.

Second, adult stem cells are often present in only minute quantities in mature tissues in the body.³² They can therefore be difficult to isolate, purify and replicate in large quantities. This is an important drawback, as large numbers of cells are likely to be necessary for stem cell replacement therapies. In contrast, hESC derived cells are relatively easy to grow in cultures and can multiply perfectly for long periods of time.

Finally, it is still unclear whether adult stem cells contain

31. See Shi-Jiang Lu et al., *Biologic Properties and Enucleation of Red Blood Cells from Human Embryonic Stem Cells*, 112 BLOOD 4475, 4475 (2008).

32. *Stem Cell Information Frequently Asked Questions*, NAT'L INSTS. HEALTH, <http://stemcells.nih.gov/info/faqs.asp> (last updated Aug. 2, 2010).

more DNA abnormalities than hESC cells. It is thought that “sunlight, toxins, or errors in making more DNA copies during the course of a [cell’s] lifetime” may increase the incidence of abnormalities among adult stem cells.³³ While researchers may eventually overcome some or all of the above limitations, adult stem cells cannot currently be considered a complete substitute for embryonic stem cells.

There are also uncertainties associated with the derivation of iPS cell lines. For example, there is evidence that iPS cell lines are less efficient than embryonic stem cell lines in self-replicating, and that the tissue developed using iPS cell lines differs in noticeable ways from tissue derived from hESC lines.³⁴ In addition, the process of reversing an adult cell to its embryonic state creates not only iPS cells but also non-iPS cell colonies and “pseudo-iPS cells” that fail to regress completely.³⁵ Therefore, it can be challenging for researchers to differentiate among iPS cells sharing the same petri dish with potentially cancerous cells. Scientists need to continue to work on the purification techniques necessary to identify and isolate the true iPS cells. There also remains considerable uncertainty concerning the stability of iPS cells over time. Some researchers believe that the re-programming process renders iPS cells less stable than embryonic stem cells, and there are indications that iPS cells are more prone to develop tumors than embryonic stem cells.³⁶ It is necessary to conduct equivalency studies comparing iPS and embryonic stem cells in order to definitively answer

33. *Id.*

34. See Sergio Pistoï, *Do We Still Need Human Embryonic Stem Cells?*, INT’L SOC’Y STEM CELL RESEARCH (Oct. 1, 2010), http://www.isscr.org/public/briefings/human_embryonic_stem_cells.html (citing studies).

35. Paul Knoepfler, *Some Inconvenient Truths About iPS Cells*, KNOEPFLER LAB STEM CELL BLOG (Dec. 12, 2010, 4:41 PM), <http://www.ipscell.com/home.php?s=some-inconvenient-truths-about-ips-cells>. There is also evidence that the regressed cells retain a “memory” of their original state. Jose M. Polo et al., *Cell Type of Origin Influences the Molecular and Functional Properties of Mouse Induced Pluripotent Stem Cells*, 28 NATURE BIOTECHNOLOGY 848, 851 (2010).

36. See Louise C. Laurent et al., *Dynamic Changes in the Copy Number of Pluripotency and Cell Proliferation Genes in Human ESCs and iPSCs During Reprogramming and Time in Culture*, 8 CELL STEM CELL 106, 106-08 (2011).

these questions, but in the meantime we simply don't know whether cells created using iPS lines will function in an identical manner as cells created using hESC lines over long periods of time.

Another consideration in the comparison of iPS cell lines and hESC lines is the cost associated with therapies. The advantage of iPS cell lines is that they are derived using the patient's own somatic cells, and therefore avoid the need for immunosuppressant drugs.³⁷ However, the disadvantage to the individualized iPS approach is that there are no economies of scale. Each patient needs to have a distinct iPS cell line created using their unique cells, and each cell line needs to be individually tested for efficacy and safety before it can be used for therapy.³⁸ In addition to being expensive (one estimate places the cost of creating an individual iPS cell line suitable for therapeutic use at \$100,000 or more), this process is also time consuming and may make it impracticable to use iPS cell lines to

37. It is likely that at least some immunosuppression drugs are necessary in connection with therapies using embryonic stem cells. This is because embryonic stem cells are derived from blastocysts created in vitro and not from the patient's own cells. However, the degree of immunosuppression required, and the ability of the human body to tolerate stem cells derived from a foreign source, will not be known until more clinical trials using embryonic stem cells are conducted.

One possible method for resolving the immunosuppression issue is through the process of therapeutic cloning, also called Somatic Cell Nuclear Transfer ("SCNT"). This process creates a blastocyst by combining an unfertilized egg with a cell nucleus containing the DNA of the patient. The egg is then given a charge of electric current to induce cell division and an embryonic stem cell line is then created through the normal process. The result is to create a stem cell line that shares the patient's DNA. Therapeutic cloning is perhaps the most controversial form of stem cell research due to the fear, among some segments of the public, that the embryos created via this process would not be used for research but would rather will be implanted in a woman's uterus and brought to term (so-called "reproductive cloning"). Supporters of hESC research typically favor a ban on reproductive cloning, but resist efforts to ban therapeutic cloning. Under current guidelines at the National Institutes of Health (NIH), no federal dollars are available to fund research using stem cell lines derived through therapeutic cloning. See 107th Congress Stem Cell Research, NAT'L INSTS. HEALTH RES. STEM CELL RESEARCH, <http://stemcells.nih.gov/policy/legislation/archive107.htm> (last modified Feb. 18, 2009).

38. Paul Knoepfler, *Not Ready For Prime Time: The Three Critical Challenges for iPS Cells*, KNOEPFLER LAB STEM CELL BLOG (Oct. 27, 2010, 1:55 PM), <http://www.ipsell.com/home.php?s=not-ready-for-prime-time-the-three-critical-challenges-for-ips-cells>.

treat fast moving diseases.³⁹ In contrast, embryonic stem cell lines can be used to create “batches” of clinically tested and approved stem cells that would be available “off the shelf” at a lower per patient cost. The clinical trial begun by the company Geron in the fall of 2010, to treat spinal cord injuries, uses a hESC-based drug that was created in this latter fashion.⁴⁰

Finally, direct re-programming, while promising, possesses many of the same disadvantages as adult stem cells and iPS cells. The direct re-programming process is both expensive and time consuming as compared to the hESC process. Similar to the case with iPS cell lines, relatively small amounts of replacement cells are produced by direct re-reprogramming, whereas large quantities of cells are needed for transplant therapies. Finally, the long term behavior of cells created via direct re-programming is unknown. More study is necessary in order to determine the degree to which this type of cell shares the same worrisome characteristics as iPS cells, such as the retention of a “memory” of its prior state or a tendency towards tumor formation.

Taken in combination, the disadvantages of each particular type of stem cell research may be less significant than when viewed in isolation. It is quite possible that any “cure” that results from stem cell research may result from the use of a combination of the above approaches being employed to address different components of a single disease. It is also possible that therapies derived from adult stem cells may prove superior to treat certain diseases, while hESC-based therapies turn out to be the optimal means of treating a different class of diseases.

The existence of the alternatives of adult stem cells, iPS cells and direct reprogramming do not render embryonic stem cell research unnecessary or obsolete. The replacement cells created by these four different techniques are not identical. At this point in time, researchers don’t know enough about iPS cells or about

39. *Id.*

40. *Id.*

cells created via direct reprogramming to know whether they are exactly equivalent to the hESC and adult cells that have been studied for a decade or more. The comparability and equivalency of these various types of cells will continue to remain unknown unless parallel experiments are conducted that compare their longevity and malleability. Therefore, research on all four types of cells should continue.

Moreover, there are substantial costs associated with the abandonment of hESC experiments that are already underway. Important knowledge is being gained every day that will be lost or delayed for decades if researchers abandon these ongoing projects. It is striking that the advances that led to both the iPS and direct reprogramming breakthroughs were made by researchers applying knowledge obtained from the study of embryonic stem cell lines. All four types of stem cell research are related, and all four contribute to a common base of knowledge that is mutually beneficial.

In summary, there is no scientific rationale that argues in favor of giving preferential treatment to one type of stem cell research over another. In light of the science's rapid progress upon multiple fronts, it is simply premature to declare that any one form of stem cell research is more likely to lead to therapies or cures than another, or that any particular type of stem cell research is unworthy of public funding. Arguments in favor of directing public funding towards one form of stem cell research and away from another are premised upon religious or political agendas.⁴¹

41. See JOHN DANFORTH, FAITH AND POLITICS: HOW THE "MORAL VALUES" DEBATE DIVIDES AMERICA AND HOW TO MOVE FORWARD TOGETHER 93 (2006). Former Senator Danforth writes:

Unlike the issue of abortion, where a fetus in the womb will, with the passage of time, become a breathing human being, these cells in a petri dish have no potential other than what scientists can do with them to find cures for diseases. Calling these blastocysts human life can only be understood as a statement of religious doctrine, and advancing legislation to protect them can only be understood as attempting to enforce religion by resorting to the criminal law.

Id.

RELIGIOUS AND ETHICAL PERSPECTIVES ON STEM CELL RESEARCH

THE MORAL STATUS OF THE EMBRYO

Different faith traditions have different beliefs regarding the moral status of the embryo.⁴² The Catholic perspective is the religious point of view that is perhaps the most strongly opposed to hESC. Official Catholic doctrine holds that life begins at the moment that the sperm and egg unite, and that the human embryo is therefore a person entitled to the same rights and dignity as any other person.⁴³ The destruction of an embryo, under this view, is the equivalent of the taking of a life. Catholic doctrine also opposes the creation of an embryo for purposes other than procreation, and is critical of embryos being used for research on the grounds that it treats human life as the mere means to an end.

Protestant opposition to hESC research has come from the Southern Baptist Convention and from fundamentalist Protestant denominations. These Christian churches emphasize a strict interpretation of biblical language, focusing on passages that suggest that God recognizes the pre-born. In addition, these denominations emphasize that embryonic stem cell research is

42. Although it is common in public debate to refer to the blastocyst as an "embryo," the technical meaning of the word "embryo" applies only to a blastocyst that has attached to the uterus and has subsequently developed a structure called the "primitive streak" which lays out the body plan of the developing fetus. In the human body, the developing fetus reaches this stage approximately fourteen days after fertilization. Prior to this point, it is more accurate to refer to the blastocyst as a "pre-embryo." See EVE HEROLD, *STEM CELL WARS: INSIDE STORIES FROM THE FRONTLINES* 121-22 (2006). However, despite the technical meaning of the word "embryo," commentators outside of the medical profession typically use the word "embryo" to refer to the fertilized egg at every stage of its development subsequent to the union of sperm and egg. The discussion in this section will employ the word "embryo" as it is commonly used by the public rather than in its more limited technical meaning.

43. Norman Ford, *The Human Embryo as Person in Catholic Teaching*, 1 THE NAT'L CATH. BIOETHICS Q. 155, 159-60 (2001).

incompatible with the Christian mandate to protect the most vulnerable members of society, a group which they believe includes the embryo. The National Association of Evangelicals has issued the following policy statement explaining its opposition to embryonic stem cell research:

All humans, male and female, are made in the image of God (*Genesis* 1:27) and, therefore, have intrinsic dignity that should be respected and honored. Indeed, the breath of life in all human beings is a gift from God (*Genesis* 2:7) and thus inherently holy. The NAE has pledged to protect the sanctity of human life and to safeguard its nature. Thus, the NAE opposes all human cloning, including cloning human embryos for laboratory experimentation, as well as discrimination based on genetic identities. The NAE welcomes and supports medical research that uses stem cells from adult donors and other ethical avenues of research.⁴⁴

In contrast, many mainline Protestant denominations have issued statements in support of embryonic stem cell research. One of the basic tenets of the Protestant Reformation was the embrace of the family as the basic unit of society, and this has found expression in a more accepting attitude towards non-procreative sexual relations between husband and wife than under Roman Catholicism.⁴⁵ In the United States, many mainline Protestant denominations have accepted contraception and abortion as questions of child-bearing that are appropriately left to the individual conscience of the woman.⁴⁶ These Christian denominations focus on implantation in the womb as a more significant event than fertilization in the formation of personhood; the development of the fetus is seen as a process whereby personhood is attained gradually. Protestant denominations that support embryonic stem cell research

44. *Respecting Human Dignity in Biotechnology*, NAT'L ASS'N OF EVANGELICALS (2009), <http://www.nae.net/fthn/respecting-human-dignity-in-biotechnology>.

45. Gloria H. Albrecht, *Contraception and Abortion Within Protestant Christianity*, in *SACRED RIGHTS: THE CASE FOR CONTRACEPTION AND ABORTION IN WORLD RELIGIONS* 79, 89-91 (Daniel C. Maguire ed., 2003).

46. *Id.* at 94-96.

include the Episcopal Church,⁴⁷ the Presbyterian Church (USA),⁴⁸ the United Church of Christ,⁴⁹ United Methodist Church,⁵⁰ and the Unitarian Universalist Association of Congregations.⁵¹

Jewish scholars also have been supportive of embryonic stem cell research. The traditions of Judaism recognize that personhood begins with the child's birth, and not before. Therefore, Judaism does not accord the embryo a moral standing outside of the womb independent of the mother.⁵² All of the major Jewish denominations support medical research using hESC: Reform,⁵³ Conservative,⁵⁴ Orthodox,⁵⁵ and the Reconstructionist Rabbinical Association.⁵⁶ In addition, Islamic scholars have been supportive of embryonic stem cell research when it is conducted for purposes of curing disease.⁵⁷

47. Episcopal Church, *Resolution 2003-A014: Support Human Embryonic Stem Cell Research*, THE ARCHIVES OF THE EPISCOPAL CHURCH (2003), http://www.episcopalarchives.org/cgi-bin/acts/acts_resolution.pl?resolution=2003-A014.

48. *Presbyterians Vote in Favor of Fetal, Embryonic, and Stem Cell Research*, SCIENCE BLOG (2001), www.scienceblog.com/community/older/2001/D/200114185.html.

49. Twenty-Third Synod of the United Church of Christ, *Support for Federally Funded Research of Embryonic Stem Cells*, UNITED CHURCH OF CHRIST (2001), <http://www.ucc.org/synod/resolutions/SUPPORT-FOR-FEDERALLY-FUNDED-RESEARCH-ON-EMBRYONIC-STEM-CELLS.pdf>.

50. *Ethics of Embryonic Stem Cell Research*, THE UNITED METHODIST CHURCH (2004), <http://archives.umc.org/interior.asp?ptid=4&mid=6560>.

51. *Pass the Stem Cell Research Enhancement Act*, UNITARIAN UNIVERSALIST ASS'N OF CONGREGATIONS, <http://www.uua.org/socialjustice/socialjustice/statements/8064.shtml> (last updated June 3, 2010).

52. See Yoel Jakobovits, *Judaism and Stem Cell Research*, TORAH.ORG (2002), <http://www.torah.org/features/secondlook/stemcell.html>.

53. *Urge the Senate to Support Stem Cell Research and Save Lives*, RELIGIOUS ACTION CTR. OF REFORM JUDAISM, <http://rac.org/advocacy/issues/stemcell/#rjm> (last updated July 26, 2005).

54. *Stem Cell Research and Education*, THE UNITED SYNAGOGUE OF CONSERVATIVE JUDAISM (2003), http://www.uscj.org/Stem_Cell_Research_a6675.html.

55. *Union of Orthodox Jewish Congregations Welcomes U.S. House Passage of Stem Cell Research Enhancement Act*, ORTHODOX UNION INST. FOR PUB. AFFAIRS (May 25, 2005), <http://www.ou.org/public/statements/2005/n11.htm>.

56. *Resolution on Educational and Political Support of Stem Cell Research*, RECONSTRUCTIONIST RABBINICAL ASS'N (March 15, 2005), <http://www.therra.org/members/conv2005/Res-StemCell-2005.pdf>.

57. Muzammil Siddiqi, *An Islamic Perspective on Stem Cells Research*, ISLAM101,

Other faith traditions have taken no official position either in favor of or against embryonic stem cell research. Religious faiths that have not expressed an official position include the Church of Jesus Christ of Latter Day Saints,⁵⁸ Hinduism⁵⁹, and the American Baptist Churches.⁶⁰

THE CALL TO HEAL THE SICK

In addition to the moral status of the embryo, there is a separate faith tradition that is implicated by stem cell research. Many religious denominations teach that society has an affirmative obligation to heal the sick and to comfort those afflicted with disease. For example, the Jewish faith includes a calling to pursue medical research as an affirmative duty, one that is often cited by Jewish supporters of stem cell research. In addition, the more "liberal" Protestant denominations traditionally have embraced the benefits of scientific progress, and have accepted human reason and new discoveries as a force for good in the world.⁶¹ Persons from these Christian denominations who express support for embryonic stem cell research often point to Jesus' miracles in healing the sick, and call on mankind to follow Jesus' example.

Bioethicist Laurie Zoloth has summarized the challenge presented by these alternative moral perspectives on medical research:

I argue that the free inquiry of research science can be understood as a sort of free speech. It is protected by the larger social polity, and it has to be responsive to

<http://www.islam101.com/science/stemCells.htm> (last visited March 14, 2011).

58. *Embryonic Stem-Cell Research*, THE CHURCH OF JESUS CHRIST OF LATTER-DAY SAINTS, <http://beta-newsroom.lds.org/official-statement/embryonic-stem-cell-research> (last visited March 14, 2011).

59. Pankaj Mishra, *How India Reconciles Hindu Values and Biotech*, N.Y. TIMES, Aug. 21, 2005, at WK4.

60. See generally *Religious Groups' Official Positions on Stem Cell Research*, THE PEW FORUM ON RELIGION & PUB. LIFE (July 17, 2008), <http://pewforum.org/Science-and-Bioethics/Religious-Groups-Official-Positions-on-Stem-Cell-Research.aspx>.

61. See Albrecht, *supra* note 45, at 84.

the larger civic discourse, and to the meaning of the moral gesture of medicine. If medicine's future lies in genetics knowledge, how will such terrain shape our view of the self? If medicine's future lies in transgression of boundaries understood as natural, how will we reconstruct a robust sense of morality and of a connection to the narrative past?

We live in the world as we find it, but medicine is, in a sense, about the world as we imagine it could be. The task of the next century in medicine will be a complex and difficult freedom, for with emerging, transformative powers will come serious and vexing challenges. Creating a duty-based response in research as well as in medicine will be needed if the calling at the heart of medicine continues to guide the work of the physician. . . .

Different faith traditions—Buddhist, Hindu, Sikh, Muslim, and Jewish as well as Christian sensibilities—will need to be considered now, and in most of these, the duty to heal the sick and the need for free scientific inquiry will be the primary considerations in this work. For many whose religion now prohibits any use of the early embryo, no matter how it is created, much of this research will be impermissible. But others will argue that this opens the door to a critical research direction. Each member of the clergy and each lawmaker must think: how do we balance the many competing moral appeals?⁶²

Much of the controversy surrounding stem cell research can be traced to the existence of distinctive moral perspectives among persons of different faith traditions.

GUIDELINES FOR ETHICAL RESEARCH

Because stem cell research uses human tissue, it raises many of the same ethical issues involved in any other type of medical research involving humans. Most, if not all, research institutions have adopted guidelines to ensure that embryonic stem cell research progresses in an ethical manner. For example, before

62. Laurie Zoloth, *Living Under the Fallen Sky: Science and Religion Meet Naturally, if Uneasily, in Healing*, 36 HARV. DIVINITY BULL. (Spring 2008), available at http://www.hds.harvard.edu/news/bulletin_mag/articles/36-2/zoloth.html.

engaging in embryonic stem cell research, scientists at the University of Wisconsin entered into contracts with the donors of blastocysts created for in vitro fertilization purposes, in order to establish a system of informed consent.⁶³ These contracts also provided that only blastocysts that had previously been frozen would be made available for research and that no financial compensation would be paid to the donors.⁶⁴ In addition, researchers at the University of Wisconsin sought and received approval from the university's twenty-four person institutional review board, which concluded that the research could be conducted ethically after reviewing the work of national review boards in both the United Kingdom and Canada, as well as the report of the NIH's Human Embryo Research Panel.⁶⁵

Since 2005, the National Academies of Sciences has maintained guidelines that call on all research institutions conducting embryonic stem cell research to establish a committee charged with Embryonic Stem Cell Research Oversight (ESCRO).⁶⁶ The ESCRO Committee would be charged with the oversight of all issues related to the derivation and use of embryonic stem cells. The current guidelines also call for institutions to document the provenance of stem cell lines utilized for research in order to verify that they were obtained with informed consent,⁶⁷ and to prohibit any payment to the donors of blastocysts beyond direct expenses.⁶⁸ In addition, the guidelines state that no embryonic stem cell research should be conducted that involves the use of blastocysts beyond the

63. See Sanjay Jain & Gerard George, *Technology Transfer Offices as Institutional Entrepreneurs: The Case of Wisconsin Alumni Research Foundation and Human Embryonic Stem Cells*, 16 INDUS. & CORP. CHANGE 535, 546 (2007).

64. *Id.*

65. *Id.* at 545.

66. HUMAN EMBRYONIC STEM CELL RESEARCH ADVISORY COMMITTEE, NAT'L RESEARCH COUNCIL AND INST. OF MED. OF THE NAT'L ACADS., 2008 AMENDMENTS TO THE NATIONAL ACADEMIES' GUIDELINES FOR HUMAN EMBRYONIC CELL RESEARCH, Appendix A Guideline 2.0 (2008), available at http://books.nap.edu/openbook.php?record_id=12260&page=21#p20015de59970021001.

67. *Id.* at Guideline 3.6.

68. *Id.* at Guideline 3.4.

fourteenth day of development, or after the formation of the primitive streak, whichever occurs first.⁶⁹

In July 2009, the NIH adopted new guidelines that state which embryonic stem cell lines currently are eligible to receive federal funding. The NIH guidelines largely parallel the National Academies of Sciences recommendations on the issues of informed consent and the prohibition of compensation. However, under the current NIH guidelines, federal funding is limited to hESC lines derived from blastocysts created for purposes of in vitro fertilization.⁷⁰

THE CURRENT FUNDING LANDSCAPE

Depending upon one's perspective, the current funding landscape for stem cell research in the United States can either be applauded as an experiment in federalism or else decried as having caused the balkanization of medical research. Currently, funding for stem cell research is provided in various forms and in various amounts by the federal government (through the NIH), by several state governments, and by private actors such as philanthropic foundations and investors in biomedical companies. This funding landscape has developed over time, not due to any plan or conscious design, but rather as a result of the fact that "[f]or the past thirty years the political branches have been locked in a stalemate on the issue."⁷¹

A BRIEF HISTORY OF FEDERAL FUNDING

A brief summary of the history of federal funding of embryonic stem cell research is helpful at this point. The 1993 National Institutes of Health Revitalization Act removed legal

69. *Id.* at Guideline 4.5.

70. Raynard S. Kingston, 2009 *Guidelines on Human Stem Cell Research*, THE NAT'L INSTS. OF HEALTH, <http://stemcells.nih.gov/policy/2009guidelines.htm> (last visited April 4, 2011). For an analysis of the current NIH guidelines, see Wise Young, *Analysis of 2009 NIH Human Stem Cell Research Policy*, WISE YOUNG@CARECURE (July 9, 2009), <http://wiseyoung.wordpress.com/2009/07/15/287/>.

71. Snead, *supra* note 1, at 1545.

impediments that had previously prevented the NIH from awarding federal funds to support research using human embryos.⁷² In September 1994, the NIH Human Embryo Panel, responding to a charge from President Clinton, issued a report recommending that some areas of human pre-embryo research receive federal funding, and making no distinction between excess blastocysts created during the in vitro fertilization process and blastocysts created expressly for research.⁷³ President Clinton, however, directed the NIH not to allocate any resources that supported the creation of blastocysts expressly for research purposes.⁷⁴

However, before any regulations were adopted authorizing the federal funding of stem cell research, Congress passed the Dickey-Wicker Amendment. Attached as a rider to an omnibus appropriations bill, and signed into law by President Clinton, the Dickey-Wicker Amendment prohibits the use of federal funds for the creation of a "human embryo" for research purposes or for research "in which a human embryo or embryos" are destroyed.⁷⁵ The Dickey-Wicker Amendment has been reauthorized every year subsequent and is currently in force.

In 1998, the Department of Health and Human Services issued an interpretation of the Dickey-Wicker Amendment concluding that the law did not prohibit the federal funding of research using stem cell lines that were derived from blastocysts that had been previously destroyed using private funding.⁷⁶ However, the Clinton Administration came to an end before any federal funds were allocated to support embryonic stem cell research under this interpretation. President Bush agreed with the Clinton Administration's interpretation of the Dickey-Wicker Amendment, however, and under his administration the NIH

72. *Id.*

73. *Id.* at 1546.

74. *Id.*

75. *Id.*

76. *Id.* at 1546-47.

awarded federal funds to support embryonic stem cell research for the first time.⁷⁷ However, President Bush directed that the only embryonic stem cell lines eligible to receive federal funding would be those that were already in existence on August 9, 2001, the date on which his policy was announced.⁷⁸ The reason for this limitation was to ensure that federal funding did not create incentives for the “further destruction of human embryos.”⁷⁹ As the months passed after President Bush announced his policy, it became apparent that only twenty-one embryonic stem cell lines were both suitable for research purposes and eligible to receive federal funding.⁸⁰

On two separate occasions, Congress passed legislation that would have broadened federal funding of embryonic stem cell research to allow research using any blastocyst that was created during the in vitro fertilization process and that had been donated for research purposes with informed consent, but on both occasions Congress failed to override President Bush’s veto.⁸¹ The Bush Administration guidelines remained in place from 2001 until March 9, 2009 when they were rescinded by President Obama.⁸²

In July of 2009, the NIH issued new guidelines that permitted the use of federal funds for embryonic stem cell research so long as the blastocyst had been originally created for reproductive purposes and were donated with informed consent.⁸³ The new NIH guidelines do not permit federal funds to be used for research that involves therapeutic cloning. In

77. *Id.* at 1550.

78. *Id.*

79. President George W. Bush, Announcement to Allow Federal Funding for Research on Existing Stem Cell Lines (Aug. 9, 2001) (transcript available at <http://www.speakout.com/activism/apstories/10048-1.html>).

80. Snead, *supra* note 1, at 1550.

81. *Id.* at 1551.

82. See President Barack Obama, Remarks Prepared for Delivery Signing of Stem Cell Executive Order and Scientific Integrity Presidential Memorandum (March 9, 2009) (transcript available at http://www.whitehouse.gov/the_press_office/Remarks-of-the-President-As-Prepared-for-Delivery-Signing-of-Stem-Cell-Executive-Order-and-Scientific-Integrity-Presidential-Memorandum/).

83. Snead, *supra* note 1, at 1552-53.

promulgating the new NIH guidelines, the Obama Administration joined the Clinton and Bush Administrations in interpreting the Dickey-Wicker Amendment to allow such funding.

*ANALYSIS OF CURRENT FEDERAL AND STATE FUNDING
ALLOCATION*

Currently, the federal funding of embryonic stem cell research lags well behind federal funding for alternative methods of stem cell research. The Fiscal Year 2010 budget for the NIH allocated \$126 million to hESC research, and it is estimated that \$125 million will be allocated to embryonic stem cell research by the end of Fiscal Year 2011.⁸⁴ The current estimate of hESC funding in the Fiscal Year 2012 NIH budget is approximately \$128 million.⁸⁵ In contrast, the Fiscal Year 2010 budget for the NIH allocated \$341 million for non-embryonic forms of human stem cell research, and it is estimated that the Fiscal Year 2011 NIH budget will fund non-embryonic research in an equal amount.⁸⁶ In addition, funding of non-human (animal) stem cell research in Fiscal Year 2010 equaled \$745 million, and it is expected that in Fiscal Year 2011 the NIH will fund research using non-human (animal) stem cells in the amount of \$744 million.⁸⁷ In summary, between 2007 and 2010 the NIH budget has never allocated more than 11% of the annual research budget for stem cell research to hESC research. This trend is set to continue in 2011 when hESC research will constitute a mere \$125 million out of a total budget of \$1.098 billion.⁸⁸

Federal funding of embryonic stem cell research is also being outpaced by state funding. Between December 2005 and

84. Nat'l Insts. Health Research Portfolio Online Reporting Tools, *Estimates of Funding for Various Research, Condition, and Disease Categories*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Feb. 14, 2011), <http://report.nih.gov/rcdc/categories/>.

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

the end of 2009, six states⁸⁹ awarded a total of \$1.25 billion in grants to support all types of stem cell research.⁹⁰ Within the individual states, funding priorities vary among adult, embryonic, or iPS research. A full 75% of California's grants went to support hESC research, as did 97% of Connecticut's grants.⁹¹ In contrast, New York only awarded 21% of its grants to support hESC research, with the bulk of its research dollars awarded for the study of iPS cells.⁹² Maryland and Illinois have funded a varied mix of adult and hESC research.⁹³ Among them, these six states governments – and not the federal government – have provided the majority of research dollars spent on hESC research.⁹⁴

While some private foundations, such as the Juvenile Diabetes Research Foundation, are known to be significant funders of embryonic stem cell research, there is no national data that reveals the total amount of private dollars spent on stem cell research or that identifies the allocation of those dollars among hESC, adult or iPS cells. Philanthropic funding can shrink during economic downturns, and it is unknown what impact the recent recession has had on research funding by private foundations. Some experts predict that for-profit corporate funding will become an increasingly significant contributor to the funding of stem cell research, due to the uncertainties of philanthropic and government funding.⁹⁵ However, close ties between medical researchers and for-profit biotech companies raise their own distinct concerns. Some fear that an increased reliance on corporate funding means that

89. These states are California, Connecticut, Illinois, Maryland, New Jersey, and New York. Ruchir N. Karmali et al., *Tracking and Assessing the Rise of State-Funded Stem Cell Research*, 28 NATURE BIOTECHNOLOGY 1246, 1247 tbl.1 (Dec. 2010).

90. *Id.* at 1246.

91. *Id.* at 1247 tbl.1.

92. *Id.*

93. *Id.*

94. *Id.* at 1247 (noting that state funding of hESC research on a cumulative basis from 2005 through 2009 exceeded NIH funding for hESC research during the same period).

95. See Jessica Reaves, *Stem Cell Research Skirts Hurdles, but Raises Ethics Issues, Too*, N.Y. TIMES, Oct. 22, 2010, at A23.

financial results will dictate the course of research, rather than purely scientific considerations.⁹⁶

It appears unlikely that the traditional paradigm of the National Institutes of Health serving as the single funding mechanism for basic medical research will ever be attained in the case of stem cell research. Despite the efforts of the Obama Administration to expand the types of stem cell lines that are eligible to receive federal funding, future congressional restrictions and future legal challenges to administrative rulemaking will almost certainly continue, and any hope of an uninterrupted stream of NIH funding is slim. In such an environment, it is doubtful that states will abandon their parallel funding schemes, while other alternatives to federal funding, such as state-private funding partnerships, will be explored.

While it is unfeasible to dismantle state funding schemes for stem cell research at this time, it is nonetheless worth examining the reasons why a unified federal funding scheme administered through the NIH is the preferred mechanism for funding medical research. First of all, unified funding through the NIH promotes an allocation of resources that directs research dollars to the most meritorious projects. This is because channeling grant requests through a single funder allows that funder to use uniform application guidelines and a rigorous peer review process in order to select the most promising projects. It is inefficient for individual states to replicate this administrative infrastructure, and, by splitting the application pool among multiple funding sources, it is also possible that worthy applications will fall through the cracks.

Another advantage of federal funding of medical research is that it promotes collaboration among researchers nationwide. The NIH can impose uniform guidelines and ethical standards concerning the derivation, donation, and cultivation of stem cell lines. By creating a set of research data where all projects comply with the same standards, researchers can more easily

96. *Id.*

share their data and compare results. In addition, collaboration is more easily fostered by a single nationwide funder, both because the NIH can give preference to joint projects and because state boundaries need not constrain where the funds are spent.

The expected high demand among the public to participate in clinical trials for stem cell therapies provides another reason to prefer channeling research funding through the NIH. State funded clinical trials are likely give priority to state residents, given that state tax dollars were used to fund the underlying research. However, patients outside of the funding state might be superior candidates to participate in a clinical trial. A federal funding scheme ensures that only medical criteria are used to determine access to clinical trials.

In addition, the federal government is in the best position to ensure transparency, so that the public is fully informed about what researchers are doing. By accepting federal dollars, research institutions agree to comply with the NIH's ethical guidelines and to report on their activities. In contrast, state funded research operates outside of any federal oversight, and, while California researchers operate under extensive state guidelines, other states employ varying degrees of supervision over the use of state dollars.⁹⁷ Meanwhile, privately funded research occurs without any government oversight at all. The use of federal funding serves an important function both as a means of imposing ethical limits on the research and also in ensuring a level of public oversight. Without federal funding, a greater percentage of this research will occur outside of the public eye.

Finally, federal funding of research also helps to promote industry standards and practices that eventually will be adopted by for profit entities. An absence of federal funding is the

97. See generally Lori P. Knowles, *State-Sponsored Human Stem Cell Research: Regulatory Approaches and Standard Setting*, in *STATES AND STEM CELLS: A SYMPOSIUM ON THE POLICY AND ECONOMIC IMPLICATIONS OF STATE-FUNDED STEM CELL RESEARCH* 75-111 (Aaron D. Levine ed., 2006).

equivalent of an absence of federal rules. Already, overseas stem cell clinics are marketing their services to residents of the United States. The growth of "stem cell tourism" is of great concern, especially given the wild claims and unproven therapies that are being touted by many foreign companies. At some point in the future, companies will team with scientists in order to offer stem cell based therapies to the public domestically. Without federal research grants and standards, practices in the field will be driven by market forces rather than government created guidelines. The infertility industry is an example of a medical specialty that has grown largely independent of federal funding and oversight throughout its history, leading bioethicist Arthur Caplan to refer to in vitro fertilization clinics as "the wild, wild west of medicine."⁹⁸

While the federal funding of medical research offers several advantages, a scheme that relies on multiple state funders presents several disadvantages. First, state funding sources typically impose legal restrictions that limit the use of state funds to research that is conducted within the state's borders. For example, money granted to researchers by the California Institute of Regenerative Medicine must be spent in California.⁹⁹ These restrictions make it difficult for researchers in different states to collaborate with each other.

Second, various forms of regulatory inconsistency are created where there are multiple funders of basic research, even beyond restrictions on the use of research dollars.¹⁰⁰ Perhaps the

98. Tamara Audi & Arlene Chang, *Assembling the Global Baby*, WALL ST. J., Dec. 20, 2010, <http://online.wsj.com/article/SB10001424052748703493504576007774155273928.html>

99. CALIFORNIA INST. FOR REGIONAL MEDICINE, CIRM GRANTS ADMINISTRATION POLICY FOR ACADEMIC AND NON-PROFIT INSTITUTIONS 13 (April 28, 2009), http://www.cirm.ca.gov/files/Regulations/NPGAP_042809a.pdf ("CIRM-funded research must be conducted in California."). Private funders of stem cell research, such as the Juvenile Diabetes Research Foundation, also place restrictions on the use of their funds.

100. See generally Geoffrey Lomax & Susan Stayn, *Similarities and Differences Among State Stem Cell Policies: Opportunities for Policymakers, Patients, and Researchers*, 7 MED. RES. L. & POL'Y REP. 695 (2008), reprinted in BUREAU OF NAT'L AFFAIRS INC., 4 (2008).

most vexing inconsistencies involve intellectual property rights. For example, when universities and research institutions license patented technology that they have developed using private funds, these institutions will often assert the right to exercise control over any discoveries that result from the use of the patented technology.¹⁰¹ In patent law, this is called a “reach through,”¹⁰² and critics assert that the aggressive assertion of patent rights on basic scientific methods can chill future research that seeks to build on the prior discoveries.

The NIH has used its influence as a funder of embryonic stem cell research to address concerns over “reach through” patent rights. The patent rights to the methods used to isolate human embryonic stem cell lines are owned by the Wisconsin Alumni Research Foundation (WARF). Many scientists objected to the license agreements by which WARF originally made embryonic stem cell lines available to researchers around the country, on the grounds that the agreements contained a provision retaining “reach through” rights for WARF covering any commercial applications developed by licensees. The NIH and WARF were able to negotiate an agreement that clarified the extent and timing of any “reach through” rights in cases where stem cell research is funded by the federal government. The existence of this agreement largely satisfied the concerns of researchers.¹⁰³ However, state funding regimes create additional

101. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-03-536, TECHNOLOGY TRANSFER: AGENCIES' RIGHTS TO FEDERALLY SPONSORED BIOMEDICAL INVENTIONS 3, 4 (2003), available at <http://www.gao.gov/new.items/d03536.pdf>.

102. See generally, Stephen G. Kunin et al., *Reach-Through Claims in the Age of Biotechnology*, 51 AM. U. L. REV. 609, 618 (2002).

103. In 2001, WARF negotiated a Memorandum of Understanding with the NIH that permits academic researchers to have broad access to hESC for “upstream” research while preserving WARF’s interest in “downstream” commercial applications. See Rebecca S. Eisenberg & Arti K. Rai, *Proprietary Considerations*, 1 HANDBOOK OF STEM CELLS 793, 793 (2004); see also Jain, *supra* note 63, at 548.

In general, the NIH utilizes a Resource Sharing Plan that gives researchers an incentive to waive certain intellectual property rights in exchange for receiving federal funding. See Office of Extramural Research, *NIH Data Sharing Policy and Implementation Guidance*, U.S. DEPT OF HEALTH & HUMAN SERVS., http://grants2.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm (last updated March 5, 2003).

and perhaps conflicting rules that govern the exercise of "reach through" rights in the context of research funded by the states rather than by the federal government.¹⁰⁴ It is unclear whether the existence of inconsistent state rules regarding intellectual property rights has had a detrimental effect on the progress of embryonic stem cell research to date, but it is indisputable that the legal rights attached to new discoveries are more likely to promote innovation when they are uniform and predictable rather than conflicting and uncertain.¹⁰⁵

There are also indications that the balkanized funding landscape itself has influenced the types of stem cell research that have received government funding. First of all, evidence shows that a substantial amount of hESC research currently being funded by the states would have qualified for federal funding even under the Bush administration's 2001 NIH guidelines.¹⁰⁶ This fact suggests that there is a greater demand for federal dollars to support embryonic stem cell research than the NIH has been able to satisfy. It also suggests that the total amount of federal funding is insufficient even to support research using the original twenty-one hESC lines, much less to support research on all four types of stem cells.¹⁰⁷

Moreover, the funding data shows that the majority of those receiving state grants have not previously received NIH funding

104. Owen Hughes, Pfizer, Remarks at the World Stem Cell Summit 2008 (Sept. 23, 2008) (transcript available at http://worldstemcell08.blogspot.com/2008_09_01_archive.html (speaking at the 2008 World Stem Cell Summit in Madison, Wisconsin, he stated:

Nobody quite knows yet how it will play out . . . and it will get more complicated if the NIH decides to enter the funding arena. The trigger points for the reach through events will be different for feds and states, and we don't clearly know what they are.).

105. See generally Roger G. Noll, *Designing an Effective Program of State-Sponsored Human Embryonic Stem Cell Research*, 21 BERKELEY TECH. L. J. 1143, 1149-53 (2006).

106. See Karmali, *supra* note 89, at 1247.

107. On average, only twenty percent of applications for grants to support biomedical research receive NIH funding. Nat'l Insts. of Health Research Portfolio Online Reporting Tools, *Research Project Success Rates by NIH Institute for 2010*, U.S. DEP'T OF HEALTH & HUMAN SERVS. http://report.nih.gov/award/success/Success_ByIC.cfm (Last updated Dec. 14, 2010).

for stem cell-related research.¹⁰⁸ It appears that the existence of state funding schemes has drawn new researchers into the field.¹⁰⁹ However, it is not clear that expanding the universe of grant recipients will necessarily lead to better research results, especially when scientists with more experience working with stem cells are struggling to obtain funding. Those who receive state funds may not always have submitted the best research proposals. Rather, a particular state may be funding mediocre proposals submitted by inexperienced researchers simply because those are the best applications received from a resident of that state. At the same time, experienced researchers are losing out on funding opportunities as a result of inadequate federal funding combined with simply being a resident in the wrong state. This geographic disparity in funding creates a strong incentive for scientists to relocate away from states that lack a funding mechanism and to move to states where a stable source of research funding is available.¹¹⁰

LITIGATION AS A STRATEGY TO DISRUPT GOVERNMENT FUNDING

Research projects involving embryonic stem cell lines require an uninterrupted stream of funding in order to succeed. While the uncertain and changeable nature of governmental funding policies can impact this stream, funding is also vulnerable to disruption by non-governmental sources. In two high profile instances, groups with religious objections to embryonic stem cell research have used litigation in an attempt to disrupt the

108. See Karmali, *supra* note 89, at 1247.

109. *Id.*

110. See Aaron D. Levine, *Research Policy and the Mobility of U.S. Stem Cell Scientists*, 24 NATURE BIOTECHNOLOGY 865, 866 (2006) (concluding that stem cell scientists are more likely to receive job offers to move to new positions in states and foreign countries than are scientists in other biomedical fields, and stating that this data "lend[s] credence to the claim that federal funding restrictions are negatively affecting the field's development in the United States"); see generally Aaron D. Levine, *Policy Considerations for States Supporting Stem Cell Research: Evidence from a Survey of Stem Cell Scientists*, 68 PUB. ADMIN. REV. 681 (2008).

financing of research.¹¹¹

THE CALIFORNIA EXPERIENCE

In November 2004, the voters of California approved a state-wide referendum to amend the state Constitution known as Proposition 71. The terms of Proposition 71 authorized the state to issue \$3 billion in general obligation bonds in order to support stem cell research.¹¹² It also created the California Institute of Regenerative Medicine (CIRM) to serve as the vehicle for the award and supervision of research grants using this fund.¹¹³

However, almost immediately after Proposition 71 was passed, a series of lawsuits were filed in California state courts seeking to prevent the state from issuing the bonds. These lawsuits challenged the impartiality of the governing board of CIRM, alleged that the lack of state oversight over the operations of CIRM violated the California Constitution, and charged that the language of Proposition 71 violated the single subject requirement for state-wide initiatives.¹¹⁴ Funding for these lawsuits was provided by pro-life organizations seeking to overturn Proposition 71 or to delay its implementation for as long as possible.¹¹⁵ The ongoing litigation prevented California from issuing the bonds authorized by Proposition 71 for over two years, and bond sales did not occur until May 2007.¹¹⁶ In order to award research grants in the interim, CIRM was forced to borrow \$45 million and obtain \$150 million in bridge financing from the state treasury.¹¹⁷ The California Court of

111. See Noll, *supra* note 105, at 1156-57.

112. David Gollaher, *The California Experiment*, J. OF LIFE SCIENCES, Sept. 2007, at 48, 50.

113. *Id.*

114. See Joel W. Adelson & Joanna K. Weinberg, *The California Stem Cell Initiative: Persuasion, Politics, and Public Science*, 100 AM. J. PUB. HEALTH 446, 448 (2010).

115. *Id.*; see also Gollaher, *supra* note 112, at 51.

116. See Gollaher, *supra* note 112, at 51.

117. *Id.*

Appeals ruled in CIRM's favor in February 2007.¹¹⁸

SHERLEY V. SEBELIUS

In August 2009, a lawsuit styled *Sherley v. Sebelius*¹¹⁹ was filed in federal district court challenging the NIH guidelines issued one month previously by the Obama administration. Among the named plaintiffs were two faith-based organizations. The plaintiffs argued that the July 2009 NIH guidelines, which expanded federal funding of hESC research beyond the twenty-one lines approved under the prior guidelines, violated the Dickey-Wicker Amendment. Judge Royce Lamberth granted the preliminary injunction sought by the plaintiffs, preventing the NIH from expending any federal funds until the completion of a trial on the merits.

Judge Lamberth concluded that the language of the Dickey-Wicker Amendment unambiguously prohibited the use of federal funds for research purposes if a blastocyst had been destroyed at any stage leading up to the federally funded portion of the research:

The language of the statute does not support defendants' alternative definition of research as 'a piece of research.' Indeed, the Dickey-Wicker Amendment does not contain any language to support such a limited definition of research. Rather, the language of the statute reflects the unambiguous intent of Congress to enact a broad prohibition of funding research in which a human embryo is destroyed. This prohibition encompasses all 'research in which' an embryo is destroyed, not just the 'piece of research' in which the embryo is destroyed. Had Congress intended to limit the Dickey-Wicker to only those discrete acts that result in the destruction of an embryo, like the derivation of ESCs, or to research on the embryo itself, Congress

118. Cal. Family Bioethics Council v. Cal. Inst. for Regenerative Med., 55 Cal. Rptr. 3d 272, 312 (Cal. Ct. App. 2007).

119. Shirley v. Sebelius, 704 F. Supp.2d 63, 66 (D.D.C. 2010), vacated by No. 10-5287, 2011 U.S. App. LEXIS 8686 (D.C. Cir. April 29, 2011).

could have written the statute that way.¹²⁰

Judge Lamberth also ruled that the destruction of human embryos necessarily occurs when embryonic stem cell lines are created, thereby triggering the prohibition of the Dickey-Wicker Amendment:

ESC research is clearly research in which an embryo is destroyed. To conduct ESC research, ESCs must be derived from an embryo. The process of deriving ESCs from an embryo results in the destruction of the embryo. Thus, ESC research necessarily depends upon the destruction of a human embryo.¹²¹

Therefore, Judge Lamberth granted the motion for a preliminary injunction.

Judge Lamberth's ruling can be criticized on several fronts. First of all, his interpretation of the "unambiguous" language of the Dickey-Wicker Amendment is contrary to the interpretation adopted by three separate presidential administrations. This suggests that the contrary interpretation is at least a permissible reading of the statutory language and that therefore the federal courts should defer to the agency interpretation. Second, under Judge Lamberth's interpretation of the Dickey-Wicker Amendment, even the Bush administration's 2001 funding guidelines are unlawful. At no time during the Bush administration did Congress express such understanding of the law. Finally, by granting a preliminary injunction, Judge Lamberth necessarily found that the plaintiffs would suffer irreparable harm if the NIH guidelines were not immediately enjoined.¹²² However, as discussed above, there is absolutely no evidence that the availability of federal funds for embryonic stem cell research has limited or detracted from the availability of funds for research using adult stem cells or iPS cells. The federal government currently funds far more research using

120. *Shirley*, 704 F. Supp.2d at 70-71.

121. *Id.* at 71.

122. *Id.* at 72 (Judge Lamberth held as follows: "The guidelines, by allowing federal funding of ESC research, increases [sic] competition for NIH's limited resources. This increased competition for limited funds is an actual, imminent injury.").

adult stem cells than embryonic stem cells, and to date the primary financial support for embryonic stem cell research has come from state governments.

In other words, the plaintiffs did not demonstrate a likelihood of success on the merits of their claim, nor could they show that they were likely to suffer irreparable harm in the absence of a preliminary injunction halting the future funding of embryonic stem cell research. The United States Court of Appeals for the District of Columbia Circuit held as much on April 29, 2011, when it vacated Judge Lamberth's order granting the preliminary injunction.¹²³ The litigation remains ongoing as this article goes to press.

The decision of the Court of Appeals allows the National Institutes of Health to continue funding embryonic stem cell research for the time being. However, while the Circuit Court expressed skepticism over the plaintiffs' interpretation of the Dickey-Wicker Amendment, it is still possible that Judge Lamberth will rule for the plaintiffs on the merits of the case. Future appeals are likely in either event, perhaps all the way to the United States Supreme Court. The uncertainty generated by legal challenges to state and federal funding of embryonic stem research has had a measurable negative impact on the development of stem cell science.¹²⁴

THE NEED FOR NEUTRAL PRINCIPLES TO GUIDE MEDICAL RESEARCH

As the foregoing discussion illustrates, the rapid progress of scientific knowledge concerning human stem cells, as well as religious and political considerations, have worked in combination to influence the funding landscape for stem cell research. The result, whether intended or not, has been to turn

123. *Sherley v. Sebelius*, No. 10-5287, 2011 U.S. App. LEXIS 8686, at *30 (D.C. Cir. April 29, 2011).

124. See generally Aaron D. Levine, *Policy Uncertainty and the Conduct of Stem Cell Research*, 8 CELL STEM CELL 132 (2011).

the method of funding medical research into a force that impedes progress. The seeds were sown when the Bush administration decided in 2001 to limit federal funding to twenty-one pre-existing hESC lines, thereby creating a de facto incentive for scientists to develop an over reliance on a limited subset of hESC lines. Now, in 2010, researchers who have devoted years to working with these specific hESC lines are understandingly hesitant to abandon this knowledge base in order to pursue iPS research or cell reprogramming research. Nor is it obvious that our society is better off if scientists cease studying hESC lines, since future progress in the entire field will benefit from the knowledge gained concerning embryonic stem cell lines.

It is not surprising that individual states have sought to fill the gap in available federal funding by acting strategically and focusing on funding a narrow range of stem cell research. It is logical to use specialization as a means of seeking the maximum impact from limited dollars, because state governments lack the resources of the federal government. Thus, California has become a center of embryonic stem cell research while New York has taken the lead in funding research using iPS cells.¹²⁵ However, as states compete against each other for researchers, seeking to attract top talent to relocate within their borders, the current funding landscape creates an incentive to build off of their existing subject area strengths rather than to seek a wide variety of talent. The sorting of research focus among different geographic areas will result in an entrepreneurial and competitive market, where each state has an economic incentive to pursue their chosen type of research and where private companies will sort themselves geographically to parallel each

125. For example, the Empire State Stem Cell Board has awarded over \$16 million in funds targeted to iPS and other non-embryonic derivation approaches to stem cells. See *Stem Cell Research Award Grantees*, NEW YORK STATE DEPT OF HEALTH, http://www.nyhealth.gov/funding/targeted_and_generic_award_list.htm (last revised March 2009). In New York, twenty-one percent of research grants have gone to support hESC while in California fully seventy-five percent of research grants have supported hESC research. See Karmali, *supra* note 89, at Table 1.

state's specialization.¹²⁶ This self-selection process feeds on itself, and it is unlikely to reverse even if NIH funding continues.

Therefore, the current balkanized funding landscape is not the optimum approach towards advancing stem cell science. In particular, the current funding scheme is inferior to the alternative of using the NIH as a single source of funding for all types of stem cell research. However, now that several states have invested in the facilities and other infrastructure involved in setting up a funding mechanism separate from the NIH, it is doubtful that these states will walk away from that investment. It is too late to turn back the clock and attempt to re-centralize funding at the federal level.

In an attempt to avoid the recurrence of similar funding controversies in the future, some observers have suggested placing the decision of whether to federally fund different kinds of medical research exclusively in the hands of medical researchers, thereby isolating these decisions from political influence.¹²⁷ However, this approach has been criticized on the grounds that it fails to ensure democratic accountability and that it effectively abandons ethical principles.¹²⁸ In any event, it is manifestly unrealistic to assume that politicians at either level—state or federal—will relinquish their power to influence the determination of public health policy.

The recognition that politicians have primacy of place in the field of public bioethics is not the end of the matter, however. While it may be useful to underscore the fundamental role that our elected officials play in the determination of stem cell funding policy, this observation does not lead to the conclusion that these officials should be left with unbounded discretion. To the contrary, when fulfilling their responsibility to formulate funding policies for medical research, our elected representatives should be guided by two objective and neutral principles: 1) the federal government should be the preferred

126. See Noll, *supra* note 105, at 1169-70.

127. See Snead, *supra* note 1, at 1553-58.

128. *Id.* at 1604.

source for funding basic medical research and 2) funding decisions should not adopt one religious perspective over another.

*THE FEDERAL GOVERNMENT SHOULD BE THE PREFERRED SOURCE
OF FUNDING FOR BASIC MEDICAL RESEARCH*

The freedom of scientific inquiry was one of the key principles of the "American Enlightenment."¹²⁹ Basic intellectual themes advanced during the founding of our nation included the right of free speech, the connection between an educated citizenry and the possibility of self-government, and the opposition to the Stamp Act on the grounds that it acted as an economic barrier to the free circulation of ideas.¹³⁰ The Founders believed strongly in the value of "knowledge diffused generally" among the people.¹³¹ The belief that scientific inquiry was a force for the benefit for all mankind was popularly held, and found its embodiment in the persona of Benjamin Franklin.¹³² Any restrictions on scientific progress, whether imposed by governmental or clerical sources of authority, were resisted strenuously. It is significant that the limited universe of powers granted to the federal government under the Constitution included the power to create a system for issuing patents. The federal government created by the United States Constitution was vested with its power by a people who believed that public benefits flowed inevitably from creativity in the sciences and the useful arts.¹³³

Support for medical research is consistent with this traditional vision of the power of the federal government, despite objections that have been raised concerning federal regulation of the broader health care market. The question has

129. *Id.* at 1560-63.

130. See LEWIS HYDE, *COMMON AS AIR: REVOLUTION, ART, AND OWNERSHIP* 93-100 (2010).

131. See *id.* at 95 (quoting John Adams).

132. See *id.* at 112-34.

133. See GORDON S. WOOD, *THE RADICALISM OF THE AMERICAN REVOLUTION* 191-92 (1991).

arisen whether the federal government possesses the power under the Commerce Clause of the Constitution to mandate the purchase of private health insurance. Opponents of health care reform argue that the Commerce Clause should be read to circumscribe the power of the federal government to intervene in the private market for health care insurance, often citing the economist Friedrich Hayek in support of their views. However, Hayek's caution against government overreaching in private markets does not apply to the funding of basic research,¹³⁴ and Hayek himself was a strong supporter of free scientific inquiry.¹³⁵

Instead, the funding of stem cell research is best understood as a modern manifestation of the federal government's traditional use of general tax revenues to invest in industries that contribute to the national infrastructure and that therefore benefit the entire nation. Government support for new technologies in the transportation and communication industries

134. As explained by Hayek:

All modern governments have made provision for the indigent, unfortunate, and disabled and have concerned themselves with questions of health and the dissemination of knowledge. . . . There are common needs that can be satisfied only by collective action and which can be thus provided for without restricting individual liberty. . . . There is little reason why the government should not also play some role, or even take the initiative, in such areas as social insurance and education, or temporarily subsidize certain experimental developments.

FRIEDRICH A. HAYEK, *THE CONSTITUTION OF LIBERTY* 257-58 (1960) (emphasis added).

135. *Id.* at 404-05. Hayek wrote generally in support of scientific progress and against government interference in the free dissemination of knowledge:

Personally, I find that the most objectionable feature of the conservative attitude is its propensity to reject well-substantiated new knowledge because it dislikes some of the consequences which seem to follow from it. . . . I will not deny that scientists as much as others are given to fads and fashions and that we have much reason to be cautious in accepting the conclusions that they draw from their latest theories. But the reasons for our reluctance must themselves be rational and must be kept separate from our regret that the new theories upset our cherished beliefs. I can have little patience with those who oppose, for instance, the theory of evolution or what are called 'mechanistic' explanations of the phenomena of life simply because of certain moral consequences which at first seem to follow from these theories, and still less with those who regard it as irreverent or impious to ask certain questions at all.

Id.

has long been accepted as a means of promoting economic development. However, in the 21st century our nation's economic growth is not driven by industries that produce and ship tangible products. Instead, the fastest growing sectors of the American economy are tied to intellectual advances in areas such as biotechnology and telecommunications. The state of California promoted its bond offering to fund the creation of CIRM as a state investment in "intellectual capital."¹³⁶ In so doing, California officials drew a parallel between government investment in intellectual infrastructure in the sciences and the traditional government financial support of physical infrastructure such as roads and bridges.

The present universe of scientific knowledge is not static, and the federal government plays an important role in funding efforts to expand upon our current base of knowledge. The federal government has greater resources than state governments, it can generate greater economies of scale when allocating research dollars among recipients, and, when it serves as the primary source of research funding, the federal government can avoid needless duplication of research efforts.

The role of the federal government is critical because it is highly unlikely that the private market will fund the optimum amount of basic medical research from a societal perspective. Private industry is beholden to its shareholders, who demand a return on their investment. This profit motive risks the creation of "orphan diseases," instances where companies forego research that is unlikely to lead to profitable applications due to the small number of persons afflicted. Shareholders also possess a short investment horizon, which creates a disincentive for management to fund research where direct applications lie decades in the future.¹³⁷ The federal government does not

136. See *Treasurer Lockyer Urges Californians to Participate in First Stem Cell Bond Issue: \$250 Million Sale Makes State Leader in Embryonic Stem Cell Research*, CAL. INST. FOR REGIONAL MED. (Oct. 2, 2007), www.cirm.ca.gov/PressRelease_100207.

137. See Melissa Little et al., *Delivering on the Promise of Human Stem-Cell Research: What Are the Real Barriers?*, 7 EUR. MOLECULAR BIOLOGY ORG. REP. 1188, 1190-91 (2006) (listing as impediments to private investment in the field skepticism

operate within these constraints.

Without government funding, the pharmaceutical and biotechnology industries will only serve the interests of those with the most common afflictions, or the interests of those who can afford expensive drugs and therapies. Low-income populations, in particular, are vulnerable to being left out of a market-driven system of medical research. In such cases, the federal government should use its funding power to help ensure that vital research continues and that the benefits of such research are made available to all.

*FUNDING DECISIONS SHOULD NOT ADOPT ONE RELIGIOUS
PERSPECTIVE OVER ANOTHER*

Government policymakers must base their public health decisions on non-religious grounds. The federal government should not incorporate one particular religious point of view as part of the official rationale for deciding whether or not to fund medical research. To do so is to adopt one religious perspective over another. There are a variety of religious perspectives on the moral status of the embryo, and it would violate the Constitution for any branch of government to endorse one religious perspective on the issue over another.¹³⁸

A respect for religious pluralism is one of the basic tenets of

over “the likely success of stem-cell research,” the fear that consumers will associate the company with a controversial topic, uncertainty over intellectual property rights, a lack of experience with the FDA approval process in the context of stem cells and doubts that any marketable products will ultimately result from the science).

138. John Danforth, the former Republican Senator from Missouri and an ordained Episcopal priest, concluded as much:

What distinguishes the opposition to embryonic stem cell research and [therapeutic cloning] is that it is based solely on a religious belief that life begins before implantation in the uterus. This religious concept is in opposition to the convictions of other people of faith who do not share this definition of the beginning of life, and who believe that it is their own religious obligation to discover the cures for disease, to heal the sick, to relieve suffering, and to save lives.

Legislators considering banning such research should realize that they are being asked to establish one religious point of view and to oppose another.

DANFORTH, *supra* note 41, at 97.

our constitutional system. It is well understood that the First Amendment of the Constitution precludes the federal government from establishing an official religion.¹³⁹ However, there is also strong evidence that the original language that James Madison proposed for the First Amendment was intended to go further and disestablish official religions at the state level as well.¹⁴⁰ Significantly, the First Amendment was designed to protect freedom of conscience by preventing any one religious sect from receiving a preferential place under the law.¹⁴¹ In fact, the overall purpose of the First Amendment to the Constitution was to ensure that all religious faiths were treated in a non-preferential fashion by public officials.

One example of the Founders' concern over government acts that granted preferential treatment to one religious denomination over another is reflected in the early debate over the constitutionality of the executive branch issuing prayer day proclamations. While Presidents Washington and Adams had issued proclamations declaring a "national day of prayer," President Jefferson considered such proclamations unconstitutional under the First Amendment.¹⁴² James Madison agreed with Jefferson, explaining his opposition on the grounds that the public trust that is delegated to elected officials does not include the agency to decide questions of religious faith.¹⁴³

These basic principles continue to carry great weight today. Recent Supreme Court precedent has employed the doctrine of judicial review in order to police the separation of church and state. The Court has emphasized that under the Constitution all official government acts must have a rational basis beyond the government's desire to adopt a moral point of view. In order to

139. WILLS, *supra* note 8, at 226-29.

140. *Id.* at 229-32. The language of the First Amendment that was ultimately ratified did not directly speak to this point, and states would continue to support established religions with tax dollars until Massachusetts abandoned the practice in 1833. See also DANIEL WALKER HOWE, WHAT HATH GOD WROUGHT: THE TRANSFORMATION OF AMERICA, 1815-1848 164-65 (2007).

141. See WILLS, *supra* note 8, at 232-35.

142. *Id.* at 237.

143. *Id.* at 237-41.

establish rational grounds for passing legislation, for example, state legislators cannot rely solely on moral arguments that condemn sodomy.¹⁴⁴ The Supreme Court also struck down a popularly ratified amendment to the Colorado State Constitution on the grounds that it could only be defended as an expression of animus against homosexuals that was premised upon moral condemnation.¹⁴⁵ If, as expected, the Ninth Circuit rules that California's prohibition on same sex marriage violates the Constitution, it will be one consequence of the federal courts' refusal to sanction official government policies that rest solely on religious justifications.¹⁴⁶

It has been argued that the government's refusal to accord blastocysts donated for research the moral status of a "person" would itself be a choice that promotes a religious perspective. This argument mistakenly assumes that the federal government is being asked to choose between a religious perspective and a secular perspective, and that to choose secularism is the equivalent of choosing a religious point of view. As discussed above, the stem cell funding debate does not ask the government to make a binary choice between, on the one hand, advancing religion or advancing secularism on the other. Instead, the government is being asked to choose among a variety of different religious perspectives that view the beginning of personhood as occurring at different stages. For the government

144. See *Lawrence v. Texas*, 539 U.S. 558, 578 (2003) (Kennedy, J.) (holding that the Texas anti-sodomy statute "furthers no legitimate state interest which can justify its intrusion into the personal and private life of the individual"). In the same case, Justice O'Connor stated:

Moral disapproval of this group, like a bare desire to harm the group, is an interest that is insufficient to satisfy rational basis review under the Equal Protection Clause Indeed, we have never held that moral disapproval, without any other asserted state interest, is a sufficient rationale under the Equal Protection Clause to justify a law that discriminates among groups of persons.

Id. at 582 (O'Connor, J., concurring).

145. See *Romer v. Evans*, 517 U.S. 620, 634 (1996).

146. See *Perry v. Schwarzenegger*, 704 F. Supp. 2d 921, 1001 (N.D. Cal. 2010), *cert. denied*, 130 S. Ct. 2432 (stating that the "evidence shows conclusively that moral and religious views form the only basis for a belief that same-sex couples are different from opposite-sex couples").

to remain neutral among these choices is not the same as the government endorsing one perspective over another. Government decisions that impact the funding of medical research must be justifiable upon non-religious grounds.

CONCLUSION

Professor O. Carter Snead has argued persuasively that, in questions of public bioethics, publicly accountable elected officials should be called to make the hard policy decisions themselves rather than to delegate their decision-making authority to panels of scientific experts.¹⁴⁷ However, what is missing from Professor Snead's analysis is the recognition that these elected officials exercise a public trust. The defect in Professor Snead's approach to public bioethics is that it emphasizes the "bioethics" component of the term at the expense of the "public" component. When making policy decisions in the realm of public health, politicians must be able to justify their choices on the basis of objective and neutral principles.

The study of public bioethics is incomplete without a recognition that the federal government operates within a sphere of authority and under an obligation of pluralism that is separate from the spheres of religion and the market economy.¹⁴⁸ Within its proper sphere, the federal government has an affirmative responsibility to foster the pursuit of knowledge, and it lacks the capacity to adopt as its own one out of a competing multitude of religious viewpoints. The Madisonian separation of church and state is an integral part of the limited government created under the United States Constitution,¹⁴⁹ and maintaining that separation is an ethical good that our elected officials must

147. See Snead, *supra* note 1, at 1602.

148. See generally MICHAEL WALZER, SPHERES OF JUSTICE: A DEFENSE OF PLURALISM AND EQUALITY 243-48 (1983) (Walzer argues that a free society consists of separate spheres within which the state, the church, and corporations each dominate, and where the polity acts to maintain the separation of the spheres.).

149. See generally WILLS, *supra* note 8, at 175-249 (tracing the intellectual foundations of the separation of church and state under the Constitution).

weigh along with other ethical goods such as the protection of vulnerable populations and the promotion of justice.

The convergence of science, religion and politics in the determination of public health policy presents a recurring temptation for policymakers to adopt policies designed to curry favor with distinct religious denominations rather than policies based upon scientific and medical objectives. This danger is heightened when the ever-changing state of scientific knowledge allows elected officials to exploit uncertainties and conflicting data when expressing the rationale for their position.

The federal government's slow response to the AIDS crisis in the 1980s reflects one manifestation of this phenomenon. Today, a common refrain among scientists engaged in stem cell research is that the uncertain availability of federal funds for hESC research over the past decade has slowed progress towards translating basic science into cures, has deterred graduate students and other researchers from entering the entire field, and has jeopardized the United States' leadership position in stem cell research versus our global competitors.¹⁵⁰ If the stem cell funding controversy provides any lessons for the future, it is that the failure to follow objective and neutral principles when making decisions for the public good inevitably undermines the achievement of our society's objectives to extend lives and to reduce suffering.

150. See *Public Funding Impacts Progress of Human Embryonic Stem Cell Research*, SCIENCE DAILY (June 5, 2008), <http://www.sciencedaily.com/releases/2008/06/080604140945.htm>.