

NOTE

Federal Regulation of Embryonic Stem Cells: Can Government Do It? An Examination of Potential Regulation through the Eyes of California's Recent Legislation

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I. INTRODUCTION

In 1998, scientists at Johns Hopkins University and the University of Wisconsin independently discovered methods for extracting human embryonic stem cells from fetuses.¹ With this discovery, some members of the scientific community recognized a unique opportunity to advance the goal of finding treatments and cures for diseases and disorders such as Parkinson's, Alzheimer's, and cancer. Previously, this hope had seen little success. Scientists who are proponents of embryonic stem cell research acknowledge that the exceptional potential of these cells to divide, reproduce, and thrive in environments foreign to those from which they originate presents a promising source for therapeutic treatments. Opponents of embryonic stem cell research, both within and outside of the scientific community, believe that research on embryos is immoral and/or unnecessary because stem cells can be acquired from other sources in the human body.²

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1. Press Release, Johns Hopkins Med. Inst., Hopkins Research Team Cultures Long-Awaited Human Embryonic Stem Cells (Nov. 5, 1998), <http://www.hopkinsmedicine.org/press/1998/981105>; Terry Devitt, *Wisconsin Scientists Culture Elusive Embryonic Stem Cells* (Nov. 5, 1998), at <http://www.news.wisc.edu/story.php?id=3327>.

2. Symposium, *Cloning Californians? Report of the California Advisory Committee*

The debate surrounding stem cell research, particularly embryonic stem cell research, is one involving much acrimony, both at the research and practical stages. A comparison between an edict issued by the President and a law passed in California illustrates this debate. In 2001, President Bush declared that federal funding of stem cell research would be permitted, but severely limited.³ Specifically, he announced that federal funding of embryonic stem cell research would cease, but research conducted using non-embryonic stem cells still would be supported by federal funds. President Bush qualified this ban by permitting continued federal funding of embryonic stem cell research on an estimated sixty-four existing cell lines. The President did not, however, ban embryonic stem cell research altogether; he merely placed a prohibition on the use of public funds for such research (with the exception of the above-mentioned cell lines).⁴ So, as it stands, private funding of embryonic stem cell research still is permitted with restrictions.

Recognizing the enormous potential for critical medical breakthroughs via embryonic stem cell research, on September 22, 2002, California passed Senate Bill 253 authorizing research involving the derivation and use of human embryonic stem cells.⁵ The following day, California extended its standing ban on human reproductive cloning, but continued to allow human therapeutic (i.e., non-reproductive) cloning.⁶ The legislative action taken by California on September 23, 2002 demonstrates the state's commitment to regulate, but not prohibit experimentation in areas, such as stem cell research, that fall within the category of human non-reproductive cloning.

So far, there has been a generally positive response to California's law among proponents of the research and members of the scientific community. For example, incident to an anonymous \$12 million private donation, Stanford University announced that it

on Human Cloning, 53 HASTINGS L.J. 1143, 1193 (2002).

3. Press Release, White House Office of the Press Secretary, White House Fact Sheet: Embryonic Stem Cell Research (Aug. 9, 2001), available at <http://www.npaf.org/initiatives.php?p=85>.

4. *Id.*

5. S.B. 253, 2002 Leg., Reg. Sess. (Cal. 2002); see former CAL. HEALTH & SAFETY CODE §§ 12115-17 (West 2002), respectively renumbered and amended by CAL. HEALTH & SAFETY CODE §§ 125300, 125315, 125320 (West Supp. 2004).

6. S.B. 1230, 2002 Leg., Reg. Sess. (Cal. 2002); see CAL. HEALTH & SAFETY CODE §§ 24185-86 (West Supp. 2004); CAL. BUS. & PROF. CODE §§ 16004, 16105 (West Supp. 2003).

would create an institute dedicated to cancer research and stem cell biology.⁷ And, recently, a preeminent stem cell scientist from Harvard moved to San Diego to head an independent research center that will focus on stem cell experimentation.⁸

The California law stands in direct conflict with President Bush's edict limiting embryonic stem cell research. Because no federal legislation supercedes California's law, California's practice presently appears constitutional. It seems probable that given the amount of public opposition to stem cell research in general, and embryonic stem cell research in particular, Congress will take some action to clarify and codify the national position on this topic. One wonders, then, what the fate of California's law will be. An obvious inquiry involves whether the federal government has the power to regulate stem cells and/or the products thereof at all. In theory, Congress could attempt to justify the regulation of stem cells and related products pursuant to a number of constitutionally based powers. However, analysis of such possible sources of power reveals that none of them would prove sufficient to authorize federal regulation of stem cells.

I will begin by providing a synopsis of stem cell biology and the moral and ethical controversy enshrouding it. Once this groundwork is laid, I will describe the California law in greater detail and offer an historical overview of the position of the federal government in the area of stem cell research. Finally, I will undertake to demonstrate that Congress does not have the constitutional authority to regulate stem cells or the products of stem cell research under any of its enumerated powers.

II. AN OVERVIEW OF STEM CELL BIOLOGY

A. What is a stem cell and where is one found?

Stem cells are undifferentiated cells capable of indefinitely producing other like cells or dividing to produce function-specific cells within the body.⁹ There are three types of stem cells: totipotent, pluripotent, and multipotent. Totipotent stem cells are created at the

7. News Release, Stanford Univ. Med. Ctr., Stanford Launches Unique Cancer and Stem Cell Biology Institute (Dec. 10, 2002), <http://mednews.stanford.edu/stem-cell-institute.html>.

8. Carl T. Hall, *Harvard Researcher Mines Stem Cell Riches in West*, S.F. CHRON., Jan. 6, 2003, at A6.

9. Anne E. Bishop et al., *Embryonic Stem Cells*, 197 J. PATHOLOGY 424, 424 (2002).

time of fertilization and are present only during the first four days following conception, after which they become pluripotent cells.¹⁰ Totipotent stem cells have the unique capacity to develop into any cell type in the body and therefore can give rise to an adult organism.¹¹ In contrast, pluripotent stem cells can differentiate into many, but not all cell types and cannot create a new human being.¹² Generally speaking, it is the pluripotent stem cells that are used for medical experimentation.¹³ Multipotent stem cells are adult cells that typically are capable of producing only other cells of the same type.¹⁴

Stem cells can be harvested from a variety of human tissues including bone marrow, brain, muscle, umbilical cord blood, liver, and fetal and embryonic tissues.¹⁵ Embryonic stem cells are harvested from the inner cell mass of the embryonic blastocyst, an early cluster of cells that have undergone several divisions.¹⁶ Removing these stem cells from the blastocyst results in the death of the embryo from which they are derived. Pluripotent stem cells further specialize into multipotent stem cells, which are harvested directly from the tissues in which they are found. In contrast to embryonic stem cells which possess a unique plasticity, adult stem cells are more committed; that is, they usually only can develop into the cell species of the organ from which they originate.¹⁷ For instance, an adult stem cell derived from the liver generally gives rise only to other liver cells, whereas an embryonic stem cell from the liver can give rise to neurons, blood cells, or other cell types.

B. What is the function of a stem cell and why is it useful?

Stem cells have two primary functions: (1) self-renewal and (2)

10. Alo H. Konsen, *Are We Killing the Weak to Heal the Sick?: Federally Funded Embryonic Stem Cell Research*, 12 HEALTH MATRIX 507, 508 (2002).

11. David B. Resnik, *The Commercialization of Human Stem Cells: Ethical and Policy Issues*, 10 HEALTH CARE ANALYSIS 127, 128 (2002); Konsen, *supra* note 10, at 508.

12. Resnik, *supra* note 11, at 128.

13. Rhonda Lahiri & Mie Kingsley, *Stem Cell Basics*, <http://www.molbio.princeton.edu/courses/mb427/2001/projects/09/SObasics.htm> (last visited Jan. 20, 2003).

14. Carly Goldstein, Note, *Dipping Into Uncle Sam's Pocket's: Federal Funding of Stem Cell Research: Is It Legal?*, 11 B.U. PUB. INT. L.J. 229, 234 (2002).

15. E.D. Pellegrino, *Balancing Science, Ethics and Politics: Stem Cell Research, A Paradigm Case*, 18 J. CONTEMP. HEALTH L. & POL'Y 591, 593 (2002).

16. Bishop, *supra* note 9, at 425.

17. Goldstein, *supra* note 14, at 234.

division and differentiation.¹⁸ The importance of these functions cannot be underestimated. To survive, the human body needs stem cell populations to renew themselves on a continual basis. Similarly, to give rise to the specialized cells of each organ, stem cells divide and differentiate, thereby creating and sustaining the various tissues and organs of the body.

Because stem cells are capable of regeneration, scientists and the medical community see a distinct potential in these cells for use in experimentation and medical treatment. On a most basic level, stem cell research can lead to an increased understanding of the processes of cellular differentiation and human development.¹⁹ From the more advanced standpoint of medical science there is an even greater therapeutic benefit that could be harnessed from experimentation with stem cells. Currently, replacement of damaged tissues or organs is limited by factors such as immune rejection, short supply, and donor site morbidity.²⁰ The envisioned therapeutic benefits of stem cell research are impressive and include, among others, curing diseases and providing a low-rejection alternative to present organ transplant procedures.²¹ Specifically, scientists expect that stem cell research will one day lead to cures for diseases such as Alzheimer's, Parkinson's, diabetes, forms of heart disease, and cancer.²² Advances in stem cell biology could lead to more frequent and successful organ transplant operations because embryonic stem cells placed in a new environment in the body believe that they are in their native environment; consequently, after transplant they have the potential to avoid rejection of the donor organ.²³ Today, the focus of such therapeutic potential rests on the use of embryonic stem cells;

18. Interview by Salick Health Care Patient Resource Center with John Kemshead, Ph.D., Director, Clinical and Scientific Affairs, Nexell Therapeutics, *Stem Cell Transplantation: A New Option for Treating Cancer*, <http://www.salick.com/resource/features/stem.html> (last visited Jan. 20, 2003).

19. Ass'n of Am. Med. Coll., *Stem Cell Research*, <http://www.aamc.org/advocacy/library/research/res0002.htm> (last visited Jan. 6, 2003).

20. A. Vats et al., *Stem Cells: Sources and Applications*, 27 *CLINICAL OTOLARYNGOLOGY* 227, 227 (2002).

21. See *Cloning Californians?*, *supra* note 2, at 1157-58; Erin P. George, *The Stem Cell Debate: The Legal, Political and Ethical Issues Surrounding Federal Funding of Scientific Research on Human Embryos*, 12 *ALB. L.J. SCI. & TECH.* 747, 758 (2002) (citing Gabriel S. Gross, Comment, *Federally Funding Human Embryonic Stem Cell Research: An Administrative Analysis*, 2000 *WIS. L. REV.* 855, 856 (2000)); Goldstein, *supra* note 14, at 235.

22. *Cloning Californians?* *supra* note 2, at 1157-58; George, *supra* note 21, at 757.

23. Goldstein, *supra* note 14, at 235; Vats, *supra* note 20, at 227.

however, there are suggestions that adult stem cells also possess therapeutic potential.²⁴ California seeks to advance this sort of therapeutically oriented research by endorsing embryonic stem cell research.

III. DEBATE OVER STEM CELL RESEARCH

The principal concerns regarding stem cell research relate to issues of respect for life, potential exploitation of women, and a fear of abusing the technology used in this research. The most vocal opponents to stem cell research are religious groups and anti-abortion advocates; but there are many people who consider themselves liberal minded or are not religiously affiliated who find the notion of stem cell research unsettling. Americans are thus sharply divided on the issue,²⁵ and it seems probable that these moral considerations would be high on Congress' list of reasons advocating federal legislation in the area of stem cell research.

A. Respect for Life

The source for embryonic stem cells causes some people to be put off by the thought of embryonic stem cell research. As already noted, stem cells can come from embryonic or adult tissue.²⁶ The primary sources for embryonic stem cells are embryos that either have been discarded as the by-product of abortions or were created for *in vitro* fertilization, but never used.²⁷ For some opponents of this practice, the use of embryonic stem cells for research is inconsistent with the values of political liberalism because it amounts to

24. Soren Holm, *Going to the Roots of the Stem Cell Controversy*, 16(6) *BIOETHICS* 493, 495 (2002). For papers advocating the potential of embryonic stem cells, see, e.g., Vats, *supra* note 20, at 230; and, Martin F. Pera, *Human Pluripotent Stem Cells: A Progress Report*, 11(5) *CURRENT OPINION IN GENETICS. & DEV.* 595, 598 (2001). For papers advocating the potential of adult stem cells, see, e.g., Catherine M. Verfaillie et al., *Stem Cells: Hype and Reality*, in *HEMATOLOGY* 2002 369 (Am. Soc. of Hematology 2002); and, Christopher B. Ballas, *Adult Bone Marrow Stem Cells for Cell and Gene Therapies: Implications for Greater Use*, 38 *J. Cell Biochem Supp.* 20 (2002).

25. See *New Poll Shows Mixed Opinions on Stem Cell Research*, USA Today, Pro-life Infonet (Jul. 12, 2001) (stating statistics acquired from polling Americans in 2001 on their positions on stem cell research), available at <http://web.archive.org/web/20021208031140/prolifeinfo.org/stemcell003.html>.

26. Holm, *supra* note 24, at 494.

27. See Am. Ass'n for the Advancement of Sci. & The Inst. For Civil Soc'y, *Stem Cell Topic: Sources of Stem Cells and Guidelines for Use*, at <http://www.counterbalance.net/stemcell/sourc1-body.html> (last visited Feb. 15, 2003).

exploitation of a weak and helpless population of human individuals.²⁸ For others, the issue is purely religious: life begins at conception, thus any destruction of the embryo is a destruction of life.²⁹

The religious position on embryonic stem cell research is consistent with the pro-life advocates' view on abortion. This consistency is not merely coincidental. That is, certain opponents of embryonic stem cell research are concerned that conducting experiments on embryos discarded after abortions makes those who use the cells complicit in the abortion, and therefore complicit in the murder of a human being.³⁰ One opponent of embryonic stem cell research has gone so far as to imply that the evil deriving from the use of embryonic stem cells for medical experimentation is analogous to the practice of human experimentation conducted by Nazis in World War II Germany.³¹

The conflict between a concern for life and the use of embryonic stem cells for research cannot be resolved easily. It is rooted in extremely personal and emotionally charged religious, moral, ethical, and philosophical beliefs. The only apparent resolution to the debate is to concede that there exists fundamental opposition to embryonic stem cell research deriving from these beliefs, just as there exists stalwart support for such research based on a different interpretation of the same values.

B. Exploitation of Women

In addition to the moral and ethical concerns for the embryo and for protecting and respecting life, there exists a fear that the practice

28. See Marc Hedrick & Scott Klusendorf, *Life Takes Priority Over Research*, UCLA DAILY BRUIN, Sept. 24, 2001, available at <http://www.dailybruin.ucla.edu/db/articles.asp?Preview=True&ID=16238>.

29. See United States Catholic Bishops, *Cloning and Embryo Research* (stating the position of the United States Catholic Bishops who oppose stem cell research), at <http://www.usccb.org/prolife/issues/bioethic/factsheets.htm> (last visited Jan. 24, 2003). See Gustav Niebuhr, *Religions Ponder the Stem Cell Issue*, New York Times Online (Aug. 27, 2001) (suggesting that other religious denominations have not come down on one side or the other of the stem cell debate), available at <http://www.uua.org/news/010827.html>; see also Interview by CNN with Elizabeth Cohen, CNN Medical Correspondent, *Elizabeth Cohen: Ethics of Stem Cell Research* (Jul. 18, 2001), at <http://www.cnn.com/2001/HEALTH/07/17/cohen.otscl/>.

30. Bruce Murray, *The Law and Ethics of Stem Cell Research and Cloning: Embryonic Stem Cell Research Bumps into Anti-Abortion Argument* (Apr. 2, 2001), at http://www.facsnet.org/tools/sci_tech/biotek/ethics.php3.

31. Linda K. Bevington, *Stem Cell Research and "Therapeutic" Cloning: A Christian Analysis*, The Center for Bioethics and Human Dignity, at <http://www.cbhd.org/resources/stemcells/overview.htm> (last visited Jan. 25, 2003).

of embryonic stem cell research will lead to exploitation and coercion of women.³² The argument begins with the proposition that women are crucial to the survival and persistence of embryonic stem cell research because they provide the fundamental basis for such research – the egg.³³ The ensuing concern derives from the possibility that women will feel a certain pressure to continue to provide eggs in order to sustain the needs of scientists for these cells.³⁴ Furthermore, there is a fear that women are vulnerable to pressures to take part in fertility research and that their participation in these studies might in some cases be involuntary.³⁵

Regardless of the impetus driving a woman's decision to donate eggs for stem cell research, two things remain true, at least for the foreseeable future: (1) women will continue to have abortions and undergo *in vitro* fertilization; and (2) hundreds of aborted embryos and excess eggs from *in vitro* fertilization will be produced each year. Whether or not women who obtain abortions or undergo *in vitro* fertilization feel pressure to do something constructive with their embryos or eggs (e.g., donate them to research) is unclear. But, the suggestion that women are vulnerable to pressures to aid in research because it ultimately will be a benefit to them is paternalistic. When presented with the option of either throwing away an embryo or an egg or donating it, a woman should be allowed to make a decision without any interference from either camp. But, for those women who desire to turn over their excess embryos or eggs for use in scientific experimentation, the option should not be foreclosed based merely on a fear that some women are too weak or susceptible to coercion to make an independent decision. If a woman prefers to donate her healthy, valuable eggs to science rather than discard them, she should have this option.

There is an argument that permitting embryonic stem cell research will lead to an increased demand for embryos to support this line of experimentation, which will create a market for embryos in our country, and ultimately will contribute to and amplify the problem of exploitation of women who seek to earn money through embryo donation.³⁶ It must be acknowledged that just as in the case

32. *Cloning Californians?*, *supra* note 2, at 1197.

33. *Id.*

34. *Id.*

35. *Id.*

36. See Reginald Shareef, *Do We Want Another Breathtaking Scientific Achievement or More Convenience Killing?* (Sept. 11, 2000),

of organ transplants where there simply are not enough organs for all the people in need of organ replacement, there are not enough embryonic stem cell lines to furnish the needs of scientists participating in this research. So, a market for stem cells already exists. In a capitalistic society such as ours, once there is a demand (as there is for embryonic stem cells), market forces come into play to satisfy this need in whatever way possible (in this case through payment for embryo donation).

California's law (to be discussed in greater detail below) avoids the problem of commodification at the demand level by prohibiting the purchase or sale of embryonic and cadaveric fetal tissue.³⁷ This sort of regulation is important in order to avoid the creation of an open market for embryos. As will be discussed below, regulation of this sort belongs at the state level, not with the federal government. The California law at issue here prohibits the exchange of money for embryos by requiring the acquisition of embryos on a purely donative basis; thus, it is not susceptible to the criticism that women will be exploited by stem cell research by the seductive opportunity to earn money through the sale of their embryos.³⁸

C. Fear of Abuse of Technology

Fear that one day the technology used for therapeutic stem cell research will be abused derives from the fact that the procedure used in this research is almost identical to that used in reproductive cloning. Therapeutic cloning of embryonic stem cells involves removing the DNA-containing nucleus of an ovum, replacing it with the DNA from another human cell, allowing the stem cells to divide and multiply, and ultimately providing the cells with certain growth factors to induce the undifferentiated stem cells to form specialized cells that one day might be injected into a patient.³⁹ The primary difference between therapeutic cloning involving stem cells and reproductive cloning is that the cells used for therapeutic cloning are

<http://www.roanoke.com/columnists/shareef/091100.html>; Interview by John King, CNN Senior White House Correspondent, with Christopher Reeve, *Christopher Reeve on Politics and Stem Cell Research* (Jul. 30, 2001), at <http://archives.cnn.com/2001/ALLPOLITICS/07/29/reeve.cnn/>.

37. CAL. HEALTH & SAFETY CODE § 125320 (West Supp. 2004) (replacing former CAL. HEALTH & SAFETY CODE § 125117 (West 2002)).

38. *Id.*

39. *Therapeutic Cloning: How it's Done*, SCIENTIFIC AMERICAN.COM (Nov. 24, 2001), available at <http://www.sciam.com/article.cfm?articleID=00016CF7-CE54-1CF4-93F6809EC5880000>.

never implanted into a woman's womb; thus, while they seem to have the potential to become organs, embryonic stem cells used for therapeutic cloning never will become a human being.⁴⁰

IV. CALIFORNIA'S LEGISLATIVE ACTION

On September 22, 2002, the California Legislature enacted Senate Bill 253 pertaining to the state's position on stem cell research.⁴¹ In an historic move, Governor Gray Davis approved the Bill, permitting the derivation and use of all types of stem cells, including embryonic stem cells, for research purposes.⁴² The Bill first outlines the potential uses to which stem cells can be put in the biomedical field and recognizes that ethical and policy concerns arise in this area.⁴³ Next, section 125300 of the California Health and Safety Code states:

The policy of the State of California shall be as follows: (a) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source . . . shall be permitted (b) [Said research] shall be reviewed by an approved institutional review board.⁴⁴

In a seeming attempt to satisfy moral opponents, the Bill is careful to include the above provision, ensuring that any research conducted with embryonic stem cells will be monitored by a review board to make certain that researchers are complying with the stated guidelines.

Further, section 125315 of the California Health and Safety Code provides instructions for medical practitioners in fertility clinics who deal with surplus embryos. It provides:

(a) A physician and surgeon, or other health care provider

40. B.A. Robinson, *Therapeutic Cloning: How it is Done; Possible Benefits*, Ontario Consultants on Religious Tolerance (Aug. 17, 2000), at http://www.religioustolerance.org/clo_ther.htm.

41. The following day, California enacted what essentially is an extension of prior legislation pertaining to cloning. Senate Bill 1230 (like its predecessors mentioned in footnote 6) reaffirms California's prohibition on human reproductive cloning and extends the provisions indefinitely. For more detail, see *infra* Part IV.

42. S.B. 253, 2002 Leg., Reg. Sess. (Cal. 2002).

43. *Id.*

44. CAL. HEALTH & SAFETY CODE § 125300 (West Supp. 2004) (replacing former CAL. HEALTH & SAFETY CODE § 125115 (West 2002)).

delivering fertility treatment shall provide his or her patient with timely, relevant, and appropriate information to allow the individual to make an informed and voluntary choice regarding the disposition of any human embryos remaining following fertility treatment (b) Any individual to whom information is provided pursuant to subdivision (a) shall be presented with the option of storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research.⁴⁵

The final clause of section 125315 specifies that any individual who opts to donate unused embryos to research must provide written consent before the embryos can be used by scientists.⁴⁶ Together, the clauses of section 125315 quell critics' fears pertaining to coercion or forced donation by women. The law requires medical practitioners to present clear options to women who then are able to make a free election regarding what to do with their embryos. As an additional safeguard, women who choose to donate their embryos are required to provide written consent. In the event that a woman orally commits to donation, she retains the option of reneging by not signing the consent form. In this way, the Bill attempts to ensure that consent is voluntary and not coerced.

The final section of the Bill states, "[a] person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter."⁴⁷ Because this law prohibits the exchange of money for transactions involving embryos, the fear that a market in embryos will be created is allayed. Although a steady and substantial supply of embryos is required to sustain the demand of stem cell researchers, the embryos that are made available to researchers through California's law from voluntary donations will satisfy this need, at least for the time being. Significantly, the text of the present law does not allocate particular funds for stem cell research. But, according to the Associate Vice Provost for Research in the University of California Office of the President, state funds in the amount of \$25 million are available for this research through various programs.⁴⁸

45. CAL. HEALTH & SAFETY CODE § 125315 (West Supp. 2004) (replacing former CAL. HEALTH & SAFETY CODE § 125116 (West 2002)).

46. *Id.*

47. CAL. HEALTH & SAFETY CODE § 125320 (West Supp. 2004) (replacing former CAL. HEALTH & SAFETY CODE § 125117 (West 2002)).

48. Laura DeFrancesco, *California Endorses Stem Cell Research* (Sept. 15, 2002), at <http://www.biomedcentral.com/news/20020925/05/>.

The day after California adopted its new policy on stem cell research, California re-enacted a related bill pertaining to cloning.⁴⁹ This Bill indefinitely extends California's prohibition on human reproductive cloning, while continuing to permit therapeutic (i.e., non-reproductive) cloning.⁵⁰ Specifically, to distinguish between reproductive and therapeutic cloning, Senate Bill 1230 defines "cloning" as "the practice of creating or attempting to create a human being by . . . [nuclear transfer] . . . for the purpose of, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being."⁵¹ Because therapeutic cloning is not aimed at creating a human being and no implantation occurs, it is not prohibited under this Bill. Thus, when considered together with the specifications for embryonic stem cell research under Senate Bill 253, explicitly allowing only therapeutic cloning puts to rest the concern that California's new law will generate or contribute to an abuse of technology.

V. HISTORY OF FEDERAL LEGISLATION IN THE AREA OF STEM CELL RESEARCH

Until the early 1990s, human embryo research faced much executive opposition.⁵² During their terms, both President Reagan and the first President Bush supported a ban on federal funding of human embryonic research.⁵³ The situation changed in 1993, however, when, during his first week in office, President Clinton issued a memorandum lifting an almost twenty year ban on federal funding of fetal tissue research.⁵⁴ President Clinton stated that the moratorium on fetal tissue research "ha[d] significantly hampered the development of possible treatments for individuals afflicted with serious diseases and disorders," and so he immediately lifted the ban.⁵⁵ Following President Clinton's bold move in support of scientific progress, the National Institutes of Health (NIH) issued a set of temporary guidelines governing the use of federal funds for

49. S.B. 1230, 2002 Leg., Reg. Sess. (Cal. 2002).

50. *Id.*

51. *Id.*

52. Goldstein, *supra* note 14, at 237; *see also* Kosen, *supra* note 10, at 510.

53. Goldstein, *supra* note 14, at 237.

54. Memorandum from President Clinton to the Secretary of Health and Human Services (Jan. 22, 1993), *available at* <http://www.grants.nih.gov/grants/guide/notice-files/not93-091.html>.

55. *Id.*

fetal tissue for research.⁵⁶

Despite President Clinton's executive effort to advance scientific research, Congress was not prepared to make a similar endorsement of federally funded fetal tissue research.⁵⁷ In 1995, through the so-called "Dickey Amendment" (named for Republican Representative Jay Dickey), Congress placed a ban on appropriating federal funds for fetal tissue research by the NIH.⁵⁸ The amendment, which continues to appear in even the most recent NIH appropriations bills, reads as follows:

Sec 510. (a) None of the funds made available in this Act may be used for—(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). (b) For purposes of this section, the term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.⁵⁹

The first embryonic stem cell lines, isolated in 1998, brought the embryonic stem cell/human embryo research debate to the forefront.⁶⁰ One year later, the Department of Health and Human Services (DHHS), of which the NIH is one principal branch, declared that the Dickey Amendment ban did not prohibit embryonic stem cell research "because human pluripotent stem cells are not embryos."⁶¹

56. See NIH Interim Guidelines for the Support and Conduct of Therapeutic Human Fetal Tissue Transplantation Research (Jan. 22, 1993), available at <http://www.grants.nih.gov/grants/guide/notice-files/not93-091.html>.

57. Am. Ass'n for the Advancement of Sci., *AAAS Policy Brief: Stem Cell Research* (Aug. 14, 2002), at <http://www.aaas.org/spp/cstc/issues/stemcells.htm>.

58. *Id.*

59. Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act of 2002, Pub. L. 107-116, 115 Stat. 2177.

60. See Press Release, Johns Hopkins Med. Inst., *supra* note 1.

61. Statement of Harold H. Varmus, M.D., Director, National Institutes of Health, Before the Senate Appropriations Committee on Labor, Health and Human Services, Education and Related Agencies (Jan. 26, 1999), at <http://stemcells.nih.gov/policy/statements/statement.asp>. The reasoning of the DHHS was as follows:

The statute that bans the use of Federal funds for embryo research defines

Following this declaration, the NIH issued a new set of guidelines in August 2000.⁶² A key stipulation in the NIH guidelines was that federal funds could not be used for the *derivation* of embryonic stem cells from human embryos.⁶³ Specifically, the guidelines state that studies conducted with federal funds are permissible only if “the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment.”⁶⁴ Therefore, even after the NIH established this more permissive policy on embryonic stem cell research, the derivation of embryonic stem cell lines still had to be accomplished through private funding.

The election of President George W. Bush troubled proponents of embryonic stem cell research: Would the conservative President-elect overturn the NIH guidelines and ban all embryonic stem cell research?⁶⁵ During his campaign, Candidate Bush stated, “I oppose federal funding for stem cell research that involves destroying living human embryos.”⁶⁶ Although it took him a few months before making a public statement regarding the current administration’s policy on stem cell research, President Bush announced his policy on August 9, 2001.⁶⁷ In his televised address to the Nation, the President outlined the moral dilemma at the root of the stem cell controversy.⁶⁸ He went on to declare, perhaps to the surprise of some Americans, that he would support federal funding of research using the approximately sixty existing embryonic stem cell lines.⁶⁹ The

embryo as an organism derived by fertilization and other means. The statute does not, however, define organism. Therefore, the legal opinion relied on the broadly accepted science-based definition of organism: an individual constituted to carry out all life functions. By this definition—and as you heard from all the witnesses that responded to that question at your hearing on this matter on December 2, 1999—pluripotent stem cells are not and cannot develop into organisms. Therefore, human pluripotent stem cells are not embryos and are not covered by this prohibition on Federal funding. In addition, the legal opinion states that DHHS funds can be used for research using human pluripotent stem cells that were derived from fetal tissue if the existing laws and regulations governing fetal tissue research are obeyed.

62. National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000).

63. *Id.* at 51,979.

64. *Id.*

65. See Am. Ass’n for the Advancement of Sci., *supra* note 57.

66. *Id.*

67. George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001), at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>.

68. *Id.*

69. *Id.*

President also stated that federal funds in the amount of \$250 million would be allocated to research on adult stem cells in 2001.⁷⁰ Furthermore, President Bush announced that, pursuant to his new policy, he would create a council composed of leading scholars in various disciplines “to monitor stem cell research, to recommend appropriate guidelines and regulations, and to consider all of the medical and ethical ramifications of biomedical innovation.”⁷¹ As was the case with the NIH guidelines of 2000, the President’s decree one year later appeared to allow private funding for the creation of new embryonic stem cell lines and research thereon. To date, Congress has not taken any legislative action to prohibit embryonic stem cell research or further restrict the President’s position.

VI. DOES CONGRESS HAVE THE POWER TO REGULATE EMBRYONIC STEM CELLS?

In light of the heated debate surrounding embryonic stem cells, the conservative nature of the current administration, Court, and the Republican-dominated Congress, one wonders whether the federal government will seek to regulate further in the area of embryonic stem cell research. Will Congress seek to undo state legislation like California’s permissive law on embryonic stem cell research? In theory, Congress could attempt to justify federal regulation of stem cell research based on a number of its constitutionally granted powers, including the commerce, spending, or taxing powers. But, as demonstrated below, these traditional constitutional powers will not suffice to validate any attempt by Congress to take the power of such regulation out of the hands of the states.

A. Commerce Clause

1. Commerce Clause Background

Article I, section 8 of the United States Constitution grants to Congress the power to “regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.”⁷² One of the Court’s earliest Commerce Clause analyses appeared in *Gibbons v. Ogden* in which Chief Justice Marshall dissected the language of the

70. *Id.*

71. George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001), at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>.

72. U.S. CONST. art. I, § 8, cl. 3.

Clause to uncover the scope of Congress' commerce power.⁷³ In this opinion, Marshall provided what became a fundamental definition of "commerce" as follows: "Commerce, undoubtedly, is traffic, but it is something more – it is intercourse. It describes the commercial intercourse between nations, and parts of nations, in all its branches, and is regulated by prescribing rules for carrying on that intercourse."⁷⁴ Similarly, he developed the concepts of "among the several states" and Congress' "power to regulate."⁷⁵ In the years following this decision, the Court repeatedly exhibited an unwillingness to validate uses of the Commerce Clause that seemed to interfere with state power.⁷⁶

In 1937, however, the Court's position with respect to the Commerce Clause shifted. The Court moved away from its formalistic, rule-oriented approach to Commerce Clause questions, and adopted a more functional, case-specific method of analysis.⁷⁷ For example, in *NLRB v. Jones & Laughlin Steel Corp.*, the Court employed a novel balancing approach in analyzing Commerce Clause issues in which it considered case-specific facts in making its determinations, rather than adhering to hard and fast rules as it had done in the past.⁷⁸ This functional approach can be seen repeatedly in Supreme Court jurisprudence between 1937 and 1995.⁷⁹

73. 22 U.S. (9 Wheat.) 1 (1824).

74. *Id.* at 189-90.

75. *Id.* at 194-96.

76. *See, e.g.,* *Champion v. Ames*, 188 U.S. 321 (1903) (holding that lottery tickets are subject to traffic and are therefore instruments of commerce to be regulated under the Commerce Clause); *Hammer v. Dagenhart*, 247 U.S. 251 (1918) (holding that Congress cannot regulate the products of child labor under the Commerce Clause); *Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935) (holding that applying federal wage and hour laws to intrastate businesses violated Congress' power under the Commerce Clause).

77. *See* Coby S. Nixon, *Human Cloning and the Commerce Power: In Light of United States v. Lopez Congress Can – But Should Not – Regulate Human Cloning*, 37 GA. L. REV. 295, 308 (2002).

78. 301 U.S. 1 (1937).

79. For cases during the years 1937-1995 utilizing the functional approach to Commerce Clause analysis, see cases such as *United States v. Darby*, 312 U.S. 100 (1941) (holding that Congress could regulate an activity carried on intrastate if it had a substantial effect on interstate commerce); *Wickard v. Filburn*, 317 U.S. 111 (1942) (using the broad impact of aggregated individual effects on interstate commerce to sustain regulation); and, *Hodel v. Va. Surface Mining & Reclamation Ass'n*, 452 U.S. 264 (1981) (holding that the commerce power is broad enough to regulate intrastate activities that have environmental effects beyond state borders). In the context of civil rights, see cases such as *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241 (1964) (holding that hotels, motels, etc. discriminating on the basis of race have an effect on interstate

The Court took a step backwards in 1995 by reverting to its pre-1937 formalistic approach to Commerce Clause jurisprudence to invalidate the Gun-Free School Zones Act of 1990.⁸⁰ For the first time in nearly sixty years, the Court invalidated a federal regulation on the ground that Congress had exceeded its commerce power.⁸¹ Under the Act, it was a federal offense “for any individual knowingly to possess a firearm at a place that the individual knows, or has reasonable cause to believe, is a school zone.”⁸²

In supporting its decision to invalidate the Act, the Court enumerated three areas in which Congress could regulate pursuant to its power under the Commerce Clause: (1) the use of the channels of interstate commerce, (2) the instrumentalities of interstate commerce, and (3) those activities “having a substantial relation to interstate commerce.”⁸³ The Court then stated that if the Gun-Free School Zones Act could be sustained, it would have to be under the third category, as it clearly did not fall within the first two areas.⁸⁴ Following this determination, the Court created a framework within which it conducted its analysis of the Act under the third category.⁸⁵

The Court reiterated what had become a pattern in Commerce Clause jurisprudence by stating, “[w]here economic activity substantially affects interstate commerce, legislation regulating that activity will be sustained.”⁸⁶ Looking at the Gun-Free School Zones Act, the Court held that the Act was unrelated to any sort of economic activity.⁸⁷ With regard to what constitutes an “economic activity,” the Court said that one of two criteria must be satisfied to justify regulation under the commerce power: Either (1) the statute must deal with commerce or an economic enterprise or, (2) it must be “an essential part of a larger regulation of economic activity.”⁸⁸ As can be seen in the Court’s above statement, it is not enough that an activity is characterized as “economic;” it must also “substantially

commerce sufficient to justify regulation); and, *Katzenbach v. McClung*, 379 U.S. 294 (1964) (validating use of the Commerce Clause to federal desegregation regulations relating to restaurants).

80. *United States v. Lopez*, 514 U.S. 549 (1995).

81. *Id.*

82. *Id.* at 551.

83. *Id.* at 558-59.

84. *Id.* at 559.

85. *Lopez*, 514 U.S. at 559-64.

86. *Id.* at 560.

87. *Id.* at 561.

88. *Id.*

affect[] interstate commerce.”⁸⁹

The second element required by the Court under its analysis was a “jurisdictional element which would ensure, through case-by-case inquiry, that the [offense at issue] affects interstate commerce.”⁹⁰ In *Lopez*, the Court said that no such jurisdictional nexus existed in the Gun-Free School Zones Act because the statute lacked the necessary element that “might limit its reach to a discrete set of firearm possessions that additionally [had] an explicit connection with or effect on interstate commerce.”⁹¹

Finally, the Court mentioned that congressional findings, although not necessary, can be useful to support the proffered relationship between the offense cited in the statute and its impact on interstate commerce.⁹² The evidence put forth by the Government concerning the correlation between guns in school zones and interstate commerce ultimately did not persuade the Court.⁹³ In eventually invalidating the Gun-Free School Zones Act, the Court found that in order to sustain the Government’s arguments, it would have to “pile inference upon inference in a manner that would bid fair to convert congressional authority under the Commerce Clause to a general police power of the sort retained by the States,” a step which the Court was unwilling to take.⁹⁴

Just five years after *Lopez*, the Court again invalidated an act of Congress premised on its commerce power.⁹⁵ The statute at issue in *United States v. Morrison* involved a civil remedy for victims of gender-based violent crimes under the Violence Against Women Act of 1994.⁹⁶ As in *Lopez*, the Court here conducted its Commerce Clause analysis by examining whether this Act fit within the third category listed in *Lopez*; that is, whether violence against women had a substantial effect on interstate commerce.⁹⁷

The Court in *Morrison* found some similarities between the Violence Against Women Act and the Gun-Free School Zones Act at

89. *Id.* at 560.

90. *Lopez*, 514 U.S. at 561.

91. *Id.* at 562.

92. *Id.* at 562-63.

93. *Id.* at 562-65.

94. *Id.* at 567.

95. *See United States v. Morrison*, 529 U.S. 598 (2000).

96. *Id.* at 601-02.

97. *Id.* at 609.

issue in *Lopez*.⁹⁸ As in *Lopez*, the Court here held that “[these crimes] are not, in any sense of the phrase, economic activity.”⁹⁹ Additionally, the Court held that Congress failed to provide any jurisdictional connection between violence against women and interstate commerce, as required to show a substantial effect on interstate commerce.¹⁰⁰

In contrast to *Lopez* in which the Court faced a lack of supporting congressional findings, in *Morrison* the Court stated that the Government presented a number of compelling findings to support a connection between gender-based violence and interstate commerce.¹⁰¹ The Court noted, however, that despite the Government’s showing, “the existence of congressional findings is not sufficient, by itself, to sustain the constitutionality of Commerce Clause legislation.”¹⁰² Because the prevention of violent crime falls within the powers traditionally reserved to the State, the Court refused to sustain this Act on the ground that the statute effectively would allow Congress to “use the Commerce Clause to completely obliterate the Constitution’s distinction between national and local authority”¹⁰³

2. *Commerce Clause Applied to Embryonic Stem Cell Regulation and its Effect on California’s Law*

In light of the three categories listed in *Lopez*, it is fair to conclude that stem cells do not fall within either category one or category two as the cells are not channels or instrumentalities of interstate commerce. Therefore, in order to justify federal regulation of embryonic stem cells under the Commerce Clause, Congress would have to demonstrate that embryonic stem cells (or embryonic stem cell research) have a substantial impact on interstate commerce.¹⁰⁴ Even under this classification, however, an attempt by Congress to regulate embryonic stem cells on this basis of its commerce power would be in vain.

A threshold requirement for exercising the commerce power is stated plainly in the text of the Constitution: The power must be

98. *Id.* at 613.

99. *Id.*

100. *Morrison*, 529 U.S. at 613.

101. *Id.* at 614.

102. *Id.* at 614.

103. *Id.* at 615.

104. *See Lopez*, 514 U.S. at 558-59.

wielded to regulate “commerce.”¹⁰⁵ Furthermore, Supreme Court precedent has interpreted this requirement by stating that an act that seeks to regulate an economic activity that has a substantial effect on interstate commerce is within the scope of the commerce power.¹⁰⁶ Therefore, in order for the government to regulate embryonic stem cells, it must show that these cells fall within the scope of its regulatory power under the Commerce Clause—a showing that cannot be made successfully.

The concepts of “commerce” and “economic activity” naturally bring to mind goods that are engaged in or are products of intercourse or commercial traffic. One cannot help but equate “commerce” with the commercial exchange or sale of goods. Likewise, if no money is exchanged in a transaction, one generally does not consider the exchange an “economic activity” or “commerce.” Recall that the Court in *Lopez* stated that to be classified as economic, an activity must be economic in nature or its regulation must be part of a larger regulatory scheme.¹⁰⁷ Examples of practices that have been treated as economic activities in the past include personal consumption of homegrown wheat, discriminatory practices in restaurants and motels, and extortionate credit transactions.¹⁰⁸ All of these examples clearly possess an “economic” or “commercial” nature, as each involves an activity that relates to a larger, related market, the regulation of which is justifiable.

Embryonic stem cells themselves are not economic in nature. Arguably, the cells constitute commerce because they are associated with highly lucrative research positions and large sums of money are donated or used for investment in stem cell research projects. But, this argument does not satisfy the *Lopez* requirement that the activity be economic in nature or a part of a larger regulation of an economic activity. Embryonic stem cells are the biological byproducts of fertilization, not common commercial items. As demonstrated in *Lopez*, the current Court is reluctant to expand the meaning of “economic activity” beyond the traditional sphere of “things commercial” as the term “commercial” is commonly used. If the

105. See U.S. CONST. art I, § 8, cl. 3.

106. See, e.g., *NLRB v. Jones & Laughlin*, 301 U.S. 1 (1937); *United States v. Darby*, 312 U.S. 100 (1941); *United States v. Lopez*, 514 U.S. 549 (1995).

107. See *Lopez*, 514 U.S. at 559-64.

108. See, respectively, *Wickard v. Filburn*, 317 U.S. 111 (1942); *Heart of Atlanta Motel, Inc. v. United States*, 379 U.S. 241 (1964); *Katzenbach v. McClung*, 379 U.S. 294 (1964); and, *Perez v. United States*, 402 U.S. 146 (1971).

potential fallout related to guns in school zones did not constitute a basis for regulation of an economic activity, the Court likely would show a similar reluctance to characterize embryonic stem cells as “commerce” or as associated with an economic activity. Similarly, even when presented with persuasive factual findings indicating that violence against women affects interstate commerce, the Court was unwilling to endorse use of the commerce power in this area. There is no clear link between embryonic stem cells and interstate commerce. In order to classify embryonic stem cells as economic, Congress would be forced to “pile inference upon inference” – a practice for which the Court already has shown its distaste.¹⁰⁹ Therefore, Congress should not be able to exercise its commerce power to regulate intrastate collection and use of embryonic stem cells.

Therefore, the question is: “What aspects of embryonic stem cells, or stem cell research more generally, cross state lines and consequently impact interstate commerce?” One could assert that scientists, embryo donors (cell donors), and financial donors who support stem cell research might cross borders to enter states that are research friendly (such as California), thus creating an effect on interstate commerce. While each of these prospects is possible (as evidenced by the recent movement of funds and scientists to California), the question remains as to whether or not they create a *substantial* impact on interstate commerce.

In *Lopez*, the Court refused to accept the alleged connection between guns in school zones and interstate commerce, which the Government advanced in support of its use of the commerce power.¹¹⁰ The Government’s first argument suggested that possession of a gun in a school zone may result in violent crime which would have a negative effect on the national economy because it is costly and because people are less likely to travel to areas that they perceive to be dangerous.¹¹¹ Second, the Government asserted that the presence of guns in school zones would have an adverse impact on the learning environment which would lead to less productive citizens and a disparate impact on the economic well being of the nation.¹¹² Just as in *Lopez*, where the Court concluded that the connection between guns in school zones and interstate commerce was too tenuous to sustain an act of federal legislation, it is a stretch to propose that

109. See *Lopez*, 514 U.S. at 567.

110. See *Lopez*, 514 U.S. at 563-66.

111. *Id.* at 563-64.

112. *Id.* at 564.

embryonic stem cells have more than an incidental effect on interstate commerce, if they have any perceptible impact at all.

The California law at issue here would serve as an exemplary state regulation that would be indefatigable against congressional attempts to regulate embryonic stem cells under the commerce power. California's law essentially eliminated any Commerce Clause issue by prohibiting the exchange of embryos for monetary consideration.¹¹³ The donation of embryos and the extraction of cells there from do not constitute economic activities. Furthermore, because no sales of such embryos or cells can be made, there will not be any resultant interstate transactions. Finally, whether or not people move to California either as donors, researchers, or supporters of the research, any such individual movement would have a negligible effect on interstate commerce. The California law thus appears protected from any potential future exercise of the commerce power to regulate stem cells or invalidate state laws pertaining thereto.

It should be noted, however, that Congress likely would be able to regulate the movement of products of embryonic stem cell research and the sale of embryonic stem cells or embryos pursuant to its commerce power. As compared to the extraction and use of embryonic stem cells within a state for research purposes, any action that moves the byproducts of stem cell research across state borders creates a much greater case for congressional regulation pursuant to the commerce power. To wit, various research groups hold patents for procedures used in conducting this research and may license other laboratories (including those in other states) to use their protocols for a price.¹¹⁴ And, part of the argument advanced above, suggesting that embryonic stem cells are not themselves within the scope of the Commerce Clause, rested on the determination that the cells do not qualify as commercial goods because no money is exchanged for them. Any sale of embryonic stem cells or embryos would be a commercial transaction, an economic activity. Therefore, if these sales were interstate, the cells or embryos likely would become subject to federal control in the event that Congress opted to exercise its commerce power over their sale.

Despite the federal government's ability to use its commerce power to regulate interstate movement of the products of embryonic

113. See CAL HEALTH & SAFETY CODE § 125320 (West Supp. 2004) (replacing former CAL. HEALTH & SAFETY CODE § 125117 (West 2002)).

114. Nixon, *supra* note 77, at 314.

stem cell research or the sale of embryonic stem cells and embryos, Congress should leave such regulating to the States. Generally, embryonic stem cell research involves various areas that traditionally have been under local (not federal) control. For instance, if Congress sought to regulate or ban these elements of embryonic stem cell research, it might run the risk of impinging on a state's general right to regulate health care, local crime, or local moral standards, which are not enumerated areas of federal control.¹¹⁵ Thus, Congressional use of the commerce power to regulate embryonic stem cell research products or the sale of the cells and embryos would risk "obliterat[ing] the Constitution's distinction between national and local authority" and should provide a logical deterrent to such regulation.¹¹⁶

B. The Taxing and Spending Powers

Congress' power to spend and tax comes from Article I, Section 8 which recites the power as follows: "The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States."¹¹⁷ The spending and taxing powers are potent regulatory devices Congress can use to place a given area under federal control, especially when it appears that Congress cannot exert such control under its commerce power.¹¹⁸

1. Historical Uses and Tests for the Taxing and Spending Powers

Generally speaking, federal taxation acts are presumed valid.¹¹⁹ Such acts are permissible even when their primary motive is to obtain revenue, although they have the "incidental motive" of discouraging particular practices by "making their continuance onerous."¹²⁰ But, when the penalizing feature of a tax exceeds the revenue-generating feature, such an act cannot be sustained under the taxing power.¹²¹

115. See *Engle v. Isaac*, 456 U.S. 107, 128 (1992); Lori B. Andrews, *Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643, 669 (1998); Nixon, *supra* note 77, at 318-20.

116. *Morrison*, 529 U.S. at 615.

117. U.S. CONST. art. I, § 8, cl. 1.

118. See, e.g., *United States v. Butler*, 297 U.S. 1 (1936); *Steward Mach. Co. v. Davis*, 301 U.S. 548, 590 (1937); *South Dakota v. Dole*, 483 U.S. 203, 207 (1987).

119. See *Child Labor Tax Case*, 259 U.S. 20, 37-38 (1922).

120. *Id.* at 38.

121. *Id.*

For instance, an excise tax of 10% placed on the net profits of each employer of child labor was deemed a penalty and was struck down on the ground that it aimed at eradicating the use of child labor and, therefore, could not be classified as an appropriate act of taxation.¹²²

Both the taxing and spending powers require that any funds collected or used pursuant to this clause be applied not only for the payment of debts and the provision of a common defense, but also for the “general Welfare of the United States”¹²³ In the context of the spending power, certain limitations are imposed in addition to the general welfare requirement of the constitutional text.¹²⁴ The applicable additional limitations for this discussion include the requirement that states be aware of the consequences of conditional funding and that the condition imposed by the federal government be related to the expenditure.¹²⁵ Furthermore, the Court stated that, “in some circumstances the financial inducement offered by Congress [to induce state compliance with a spending measure] might be so coercive as to pass the point at which ‘pressure turns into compulsion.’”¹²⁶

Pursuant to the spending power, the Court validated a federal law directing the Secretary of Transportation to withhold 5% of federal highway funds to states permitting the purchase or possession of alcohol by persons under 21 years of age.¹²⁷ Here, the Court determined that the 5% cut in federal funding was not a coercive measure, and was consistent with the government’s goal of increasing highway safety.¹²⁸

2. *The Taxing and Spending Powers as Applied to Embryonic Stem Cells*

If Congress wanted to exercise its taxing power to regulate embryonic stem cells or stem cell research for the purpose of essentially abolishing permissive state laws, one approach would be to impose heavy taxes on all aspects of the research. Congress could begin by taxing the facilities that provide women with the choice to donate their embryos to research. It could continue by taxing the use of embryonic stem cells in research, and complete the cycle by taxing

122. *Id.* at 37.

123. *See* U.S. CONST. art. I, § 8, cl. 1.

124. *South Dakota v. Dole*, 483 U.S. 203, 207 (1987).

125. *Id.*

126. *Id.* at 211, (quoting *Steward Mach. Co. v. Davis*, 301 U.S. 548, 590 (1937)).

127. *See Dole*, 483 U.S. at 212.

128. *See Dole*, 483 U.S. at 211.

any byproduct of embryonic stem cell research. Each of these moves could, in theory, be justified based on a desire to promote high standards of public health, appropriate guidelines for safe scientific research, or proper monitoring of biotechnological advances, which would all fall under the broad category of “general welfare.”

It is likely, however, that this kind of heavy taxation of stem cell research would raise suspicion regarding Congress’ motive in implementing these tax schemes. Such measures would effectively tax the promising industry of embryonic stem cell research to death, rendering it an area that few, if any, scientists would pursue. It seems clear that such measures amount to a penalty for participating in embryonic stem cell research, rather than a permissible exercise of the taxing power. The goal of these measures would be to eliminate the moral issue created by embryonic stem cell research by wiping out the industry altogether. However, this sort of exercise of the taxing power cannot be supported under the Constitution or Supreme Court precedent because, as Leo Martinez noted, “when taxes become prohibitive, and take on moral overtones . . . the Court will not allow such taxes to be imposed.”¹²⁹

If Congress’ power to tax embryonic stem cells could not be upheld, Congress conceivably could attempt to regulate embryonic stem cell research under its spending power. As such, one likely move would be to condition Medicare or other health benefits provided by the federal government on a state promise to prohibit embryonic stem cell research. Considering the limitations on the spending power enumerated in *South Dakota v. Dole*, as long as a state had full knowledge of the consequences of participation or non-participation in the federal spending plan, a case could be made that the condition imposed bore a relation to the expenditure at issue. That is, the government could assert that embryonic stem cell research, from the donation of embryos to the point at which any therapeutic use could be made of the products of the research, is a medical concern that will affect health care and have a consequential impact on federal budgetary matters.

The real problem with this scheme is that it provides states with an elusive “choice” – ban embryonic stem cell research or attempt to operate medical facilities without federal Medicare funding. States rely heavily on federal Medicare and other health benefits. Without this federal support, public hospitals and medical centers would cease

129. Leo P. Martinez, *Taxes, Morals, and Legitimacy*, 1994 BYU L. REV. 521, 564 (1994) (referring to *Dep’t of Revenue of Mt. v. Kurth Ranch*, 511 U.S. 767, 779 (1994)).

to exist and, likely, many private medical institutions would be forced to close their doors as well, creating a public health crisis of epic proportions. Obviously, when presented with this “choice,” states would have no alternative but to forego embryonic stem cell research in order to save medical care facilities. A measure such as this hypothetical one would present the exact sort of coercion mentioned in *Steward Machine* in which efforts to induce state compliance pass the point of mere pressure and become compulsion.¹³⁰ Furthermore, it would create an interference with a state’s autonomy to make policy decisions representative of the interests of its citizens. Such an action would amount to the type of “commandeering” Justice O’Connor so stridently opposed in *New York v. United States* because it would impermissibly interfere with the “Constitution’s division of authority between federal and state governments.”¹³¹ Thus, any conditional attachment like the one supposed herein would be an impermissible basis for congressional exercise of its spending power to regulate embryonic stem cell research.

C. Due Process: An Additional Defense to Federal Attempts to Regulate Embryonic Stem Cells and Stem Cell Research

The language of the Due Process Clause, which guarantees that no person will be “deprived of life, liberty, or property, without due process of law,” obviates the need to first identify the interest at issue when undertaking due process analysis.¹³² For purposes of this examination, only the issue of whether or not a liberty interest exists in embryonic stem cells will be considered, (although there is an argument to be made respecting a property interest as well).

Precedent teaches that if a liberty interest is “fundamental,” strict judicial scrutiny is the applicable standard of review, whereas a “non-fundamental” interest must only survive “rational basis” scrutiny.¹³³ In determining whether a particular interest is “fundamental,” the Court often looks to the traditions of the United States to see which interests have been recognized as “fundamental”

130. See *Steward Mach. Co.*, 301 U.S. at 590.

131. 505 U.S. 144, 175 (1992).

132. See U.S. CONST. amend. V, XIV.

133. See, e.g., *Williamson v. Lee Optical*, 348 U.S. 483 (1955); *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Roe v. Wade*, 410 U.S. 113 (1973); *Moore v. City of East Cleveland*, 431 U.S. 494 (1977); *Washington v. Glucksburg*, 521 U.S. 702 (1997).

throughout history.¹³⁴ One example of an interest that the Court repeatedly recognizes as fundamental is that of personal autonomy.¹³⁵ Although the specific slant on the issue changes over time, the Court stands firm in its protection of the right to personal autonomy against government intrusion.

In theory, the federal government could attempt to ban embryonic stem cell research by prohibiting embryo donation for use in such research. If the government opted for this course of action, however, a due process argument could be used to counter Congress' assertion of power. Specifically, one would assert that decisions pertaining to embryonic stem cells are fundamental interests because they implicate a woman's right to make a personal decision, a right of personal autonomy similar to the right as recognized in cases such as *Roe*, *Loving*, and *Griswold*. Any decisions pertaining to embryo donation thus would be protected from federal interference unless the government could show a compelling interest in regulation. But, the possible federal interests mentioned above (i.e., public health, appropriate guidelines for safe scientific research, and proper monitoring of biotechnological advances) would not meet the government's burden of showing a *compelling* interest.

One potential criticism that could result from characterizing decisions pertaining to embryonic stem cells as fundamental is that there is no history or tradition in our nation to support this classification. One could argue that, because of the dynamic nature of biological sciences and biotechnology, a hard and fast adherence only to traditionally recognized interests, interests that were identifiable long before the organization of our nation (e.g., marriage, childbearing, family life), would be short-sighted. Instead, traditionally recognized fundamental rights involving personal autonomy should be extended to accommodate new, but related interests that result from scientific progress. John A. Robertson echoed this point in his analysis of personal autonomy as it pertains to posthumous reproduction.¹³⁶ He noted that "the paradigm of personal autonomy must be refined and modulated if it is to deal

134. See, e.g., *Bowers v. Hardwick*, 478 U.S. 186 (1986); *Michael H. v. Gerald D.*, 491 U.S. 110 (1989); *Washington v. Glucksburg*, 521 U.S. 702 (1997).

135. See, e.g., *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Carey v. Population Servs. Int'l*, 431 U.S. 678 (1977); *Roe v. Wade*, 410 U.S. 113 (1973); *Loving v. Virginia*, 388 U.S. 1 (1967).

136. John A. Robertson, *Posthumous Reproduction*, 69 IND. L.J. 1027, 1028 (1994).

effectively with new biomedical technologies.”¹³⁷ With this enlightened approach, one can see that a woman’s decision to donate, discard, or save her excess embryos is protected from government intrusion under the Due Process Clause.

Alternatively, Congress could attempt to regulate embryonic stem cell research or the products thereof by controlling or prohibiting the research, thus precluding the possibility of creating any therapeutic products. In this instance, the research techniques and methods and the byproducts of the research would be considered “non-fundamental” interests. As already noted, where a non-fundamental interest is concerned, the applicable level of scrutiny is “rational basis,” a much less rigorous standard for the government to meet. Although it appears that under this lesser standard of scrutiny, an act of Congress to proscribe embryonic stem cell research might be within Congress’ authority, one must remember that such an exercise of congressional power still requires a constitutional basis. As can be seen from the analysis in the preceding sections, however, no such justification can be found in the Constitution.

VII. CONCLUSION: HOW WILL CALIFORNIA’S LAW FARE?

Does Congress have the power to regulate embryonic stem cells or proscribe any research on such cells? The above analysis suggests that Congress has no such authority under its commerce, taxing, or spending power. Furthermore, any attempt by Congress to regulate in this area would implicate principles of federalism and due process, thus creating additional obstacles to federal regulation. In light of the issues raised herein, it seems fair to assert that if Congress wants to attack the area of embryonic stem cell research, it will face an uphill and, ultimately, losing battle.

The issue of embryonic stem cell research raises a myriad of problems – moral, ethical, and political. California’s recent law cuts through all of these dilemmas by presenting a policy that is not only logically sound from the standpoint of scientific and medical progress, but one that carefully and cogently addresses and accounts for each concern related to embryonic stem cell research. The law avoids any possibility of coerced or involuntary participation. It expressly prohibits the exchange of embryos for monetary consideration to avoid the creation of an “embryo market;” and, it accomplishes these

137. Robertson, *supra* note 136, at 1028.

goals while promoting valuable experimentation in an area that promises significant potential for therapeutic innovation.

This paper does not advocate totally unregulated embryonic stem cell research. Such research holds the potential for abuse if not responsibly undertaken. This does not mean, however, that embryonic stem cell research should be prohibited subject to the whims of conservative opponents in Congress. California has taken the proper step by endorsing embryonic stem cell research, while maintaining guidelines to oversee it, and other states should be advised to follow California's lead by enacting legislation that promotes this valuable area of research, while ensuring that points of ethical concern are addressed.

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