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REGULATION OF STEM CELL RESEARCH: A RECOMMENDATION THAT THE UNITED STATES ADOPT THE AUSTRALIAN APPROACH

Bryn E. Floyd

Abstract: Research using embryonic stem cells may lead to great medical advances because of their ability to differentiate into nearly any type of human tissue. Currently, the United States regulates embryonic stem cell research by limiting the stem cell lines that can be studied using federal money or by scientists working at federally-funded institutions. The states are left to regulate privately funded research, if they choose. This creates a situation in which federally-funded research is severely limited, while private funds may be used to conduct ethically problematic research.

In contrast, the Australian Parliament has passed legislation regulating embryonic stem cell research and limiting the sources of new stem cell lines to embryos originally created for infertility treatments but beyond the needs of the person or couple being treated. The Australian laws outline the informed consent procedure required before excess embryos can be donated and set up a regulatory framework to ensure that stem cell research is conducted ethically.

The United States should follow Australia's lead and pass legislation that would allow federally-funded researchers to derive new embryonic stem cell lines from excess embryos left over after infertility treatments. This system reaches a compromise between those who oppose stem cell research and those who believe it should be fully supported because of the enormous potential for new medical treatments. Passing legislation similar to Australia's will allow the United States to explore the potential medical benefits of stem cell research, while avoiding the ethical dilemmas that arise when researchers are allowed to create cloned embryos for the sole purpose of deriving new stem cell lines.

I. INTRODUCTION

When researchers derived the first embryonic stem cells in November 1998, the public and most of the scientific community were caught off guard.¹ The announcement that human stem cells could be isolated offered great promise for scientific advances, but also gave rise to serious controversy over the ethics of creating human embryos solely for research purposes and then destroying them to obtain stem cells.² Ethicists, researchers, religious scholars, legislators, and the general public have

¹ THE HUMAN EMBRYONIC STEM CELL DEBATE: SCIENCE, ETHICS, AND PUBLIC POLICY xv (Suzanne Holland et al. eds., 2001) [hereinafter THE HUMAN EMBRYONIC STEM CELL DEBATE].

² *Id.* The debate runs along a continuum from those who believe disease treatments that may result from stem cell research justify the creation of embryos for the purpose of using them to derive stem cells to those who believe no medical benefits could possibly justify the destruction of an embryo to obtain stem cells, even if that embryo will otherwise be discarded.

joined in the debate.³ Deeply held beliefs and scientific uncertainties make resolution of the controversy difficult, though not impossible.⁴

Meanwhile, millions of patients in the United States and worldwide suffer from diseases that might one day be remedied by treatments resulting from stem cell research.⁵ In order to maximize the availability of potential treatments, however, stem cell researchers must have access to genetically diverse stem cell lines⁶ and adequate funding sources.

Yet the United States' current legislative scheme fails to address these needs. In the United States, federally-funded stem cell research is limited to using the few stem cell lines that were derived, prior to August 9, 2001, from excess embryos intended for use in in vitro fertilization.⁷ Because the federal government⁸ is a major source of medical research funding, this approach severely inhibits stem cell research in the United States,⁹ and prevents full realization of the benefits of stem cell research.¹⁰ Furthermore, the genetic diversity of these stem cell lines is extremely limited.¹¹ The federal government, however, does not place restrictions on the sources from which stem cells can be derived using private funds.¹² That is left to the states.

³ For examples of different perspectives on the debate see *id*; NATIONAL BIOETHICS ADVISORY COMM'N, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH: COMMISSIONED PAPERS II (2000); CENTER FOR BIOETHICS AND HUMAN DIGNITY, ON HUMAN EMBRYOS AND STEM CELL RESEARCH: AN APPEAL FOR ETHICALLY RESPONSIBLE SCIENCE AND PUBLIC POLICY (1999), at http://www.cbhd.org/resources/stemcells/position_statement.htm (last visited June 6, 2003).

⁴ George J. Annas, et al., *Stem Cell Politics, Ethics and Medical Progress*, 5 NATURE MED. 1339 (1999).

⁵ Daniel Perry, *Patients Voices: The Powerful Sound in the Stem Cell Debate*, 287 SCIENCE 1423 (2000). Perry cites data from the Patient's Coalition for Urgent Research showing 128.4 million patients in the United States suffering from diseases that may be helped by stem cell research. *Id.* These include cardiovascular diseases, autoimmune diseases, diabetes, osteoporosis, cancer, Alzheimer's disease, Parkinson's disease, severe burns, spinal cord injuries, and birth defects. *Id.*

⁶ Sheryl Gay Stolberg, *The President's Decision: The Research; U.S. Acts Quickly to Put Stem Cell Policy in Effect*, N.Y. TIMES, Aug. 11, 2001, at A1. To create effective medical treatments, researchers will need stem cell lines that match the genetic diversity of the population. *Id.*

⁷ President 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> (last visited Nov. 6, 2003) [hereinafter *Remarks by the President*].

⁸ As used in this comment, the term "federal government" will mean the United States federal government.

⁹ Over the last fifty years the United States has invested far more resources in basic research than all other nations combined. Jon D. Miller, *The Future of Research; In a Squeeze; Science Advisory Boards Get Loaded with Anti-Science*, NEWSDAY, Feb. 23, 2003, at A24.

¹⁰ Stem cell research has the potential to lead to treatments that will restore failing organs and repair injuries to the central nervous system. Thomas B. Okarma, *Human Embryonic Stem Cells: A Primer on the Technology and Its Medical Applications*, in THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 1, at 3.

¹¹ Kristen Philipkoski, *Bush: Too Far or Not Far Enough?*, WIRED NEWS, Aug. 10, 2001, at <http://www.wired.com/news/politics/0,1283,45992,00.html> (last visited Nov. 6, 2003).

¹² In recent years, Congress has attempted to pass legislation that would directly regulate cloning and stem cell research in the United States whether funded by public or private money, but none of the

In contrast to the American scheme, Australia's stem cell legislation provides a more logical system that addresses ethical concerns and is more likely to lead to greater medical benefits. In December 2002, the Australian Parliament passed two laws, the Research Involving Human Embryos Act ("RIHEA") and the Prohibition of Human Cloning Act ("PHCA").¹³ These acts were intended to prevent human cloning and to support research involving stem cells derived from embryos that were originally created to assist an infertile couple in becoming pregnant but were not needed by the couple.¹⁴ These laws seek to reach a compromise between the interests of patients who may benefit from stem cell research and those who oppose stem cell research on moral grounds.¹⁵ The RIHEA allows stem cell researchers in Australia to derive new stem cell lines using government funding, while the PHCA limits more ethically problematic sources of stem cells, including human embryos created solely for the purpose of deriving new cell lines.¹⁶

As a compromise to those who have a moral disagreement with embryonic stem cell research, the United States should follow Australia's lead and enact legislation to allow stem cell researchers to derive new and diverse stem cell lines using federal funding, but limit the sources of those new cell lines to embryos created, but no longer needed, for assisted reproductive technology. This approach would increase the likelihood that disease treatments will be commercially available sooner, while minimizing the moral dilemma that arises when researchers create embryos for the sole purpose of deriving stem cell lines.

Part II of this Comment explains the variety of stem cell sources. Part III explores the controversies surrounding stem cell research and discusses the benefits that may result from studying embryonic stem cells. Parts IV and V explain the current approaches toward regulating stem cell research in the United States and in Australia, respectively. Part VI argues that the

proposed bills have passed. Examples include: Human Cloning Ban and Stem Cell Research Protection Act of 2002, S. 1893, 107th Cong. (2002); Stem Cell Research Act of 2001, H.R. 2059, 107th Cong. (2001); Stem Cell Research Act of 2000, S. 2015, 106th Cong. (2000). Bills currently under consideration include the Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. (2003), and the Cloning Prohibition Act of 2003, H.R. 801, 108th Cong. (2003).

¹³ Darren Gray, *Senate Backs Use of Human Embryos in Stem Cell Research*, THE AGE, Dec. 6, 2002, 2002 WL 103071091; Sandra O'Malley, *Stem Cell Laws Pass Through Parliament with Little Fanfare*, AUSTRALIAN AP GEN. NEWS, Dec. 11, 2002, 2002 WL 103858390.

¹⁴ Research Involving Human Embryos Act No. 145, 2002 (Austl.); Prohibition of Human Cloning Act, No. 144, 2002 (Austl.).

¹⁵ *Australia to Allow Use of Human Embryos for Stem Cell Research*, TRANSPLANT NEWS, Apr. 28, 2002, LEXIS, News Group File.

¹⁶ Research Involving Human Embryos Act No. 145, 2002 (Austl.). Prohibition of Human Cloning Act, No. 144, 2002 (Austl.).

Australian approach is superior to the United States' because it creates a middle ground, allowing for a more diverse supply of stem cell lines than that permitted under federally-funded research in the United States, while providing greater safeguards against unethical sources of stem cell lines. Finally, Part VII recommends that the United States adopt federal legislation similar to Australia's.

II. EMBRYOS CREATED FOR IN VITRO FERTILIZATION ARE THE MOST FEASIBLE SOURCE OF STEM CELLS

Stem cells¹⁷ come from a variety of sources.¹⁸ Embryonic stem cells are obtained from human embryos at a very early stage of development.¹⁹ They may be derived from embryos that were created through in vitro fertilization ("IVF")²⁰ or through a cloning technique known as somatic cell nuclear transfer ("SCNT").²¹ Embryonic germ cells²² are derived from embryos at a later stage of development.²³ Multipotent stem cells are found in mature tissue.²⁴ Another source of stem cells is the somatic cells of a fully-formed organism.²⁵ Of these different sources, excess IVF embryos are the preferred source of stem cells for medical research. This is true for two reasons. First, they have the ability to develop into all types of human tissues. Second, they do not present the added ethical dilemmas that arise

¹⁷ Stem cells are cells that can renew themselves in the undifferentiated state as well as give rise to multiple types of differentiated tissue. Okarma, *supra* note 10, at 4. Various types of stem cells have differing abilities to give rise to specialized descendant cells. AUDREY R. CHAPMAN ET AL., AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE AND INSTITUTE FOR CIVIL SOCIETY, STEM CELL RESEARCH AND APPLICATIONS MONITORING THE FRONTIERS OF BIOMEDICAL RESEARCH 1 (1999), available at <http://www.aaas.org/spp/sfirl/projects/stem/report.pdf> (last visited Nov. 6, 2003). Cells that have the ability to develop into a complete, functioning organism are said to be totipotent. *Id.* Pluripotent stem cells are those that can differentiate into nearly any type of tissue but have lost the ability to develop into a complete organism. *Id.* Multipotent stem cells have already differentiated to a certain degree and can only give rise to a limited number of tissue types. *Id.*

¹⁸ CHAPMAN ET AL., *supra* note 17, at 1.

¹⁹ *Id.*

²⁰ NIH, *Stem Cell Basics* (2000), at <http://stemcells.nih.gov/infoCenter/stemCellBasics.pdf> (last visited Nov. 6, 2003) [hereinafter *Stem Cell Basics*]. In vitro fertilization is a process by which a woman's eggs are extracted and then fertilized outside of her body in a laboratory setting. *Id.*

²¹ CLONES AND CLONES: FACTS AND FANTASIES ABOUT HUMAN CLONING 31 (Martha C. Nussbaum & Cass R. Sunstein eds., 1998). SCNT is also known as "nuclear transplantation cloning." *Id.*

²² Human embryonic germ cells are derived from cells in the fetus that would ordinarily develop into eggs or sperm. NIH, *Stem Cells: Scientific Progress and Future Research Directions* 13 (2001), at <http://stemcells.nih.gov/stemcell/pdfs/chapter3.pdf> (last visited Dec. 19, 2003).

²³ CHAPMAN ET AL., *supra* note 17, at 1.

²⁴ *Id.*

²⁵ *Stem Cell Basics*, *supra* note 20.

when stem cells are derived from aborted fetuses or from embryos that were created specifically for the purpose of starting a new stem cell line.

A. Human Embryonic Stem Cells Created Through In Vitro Fertilization

The embryonic stem cells used in research are derived from in vitro fertilization.²⁶ At fertilization, a sperm cell and an egg cell come together to form a single cell that has the potential to develop into a complete organism.²⁷ The stem cells found in an early embryo are more versatile than stem cells found in a completely developed human being.²⁸ In the earliest stages of development as the fertilized egg divides and creates new cells, each of these cells is totipotent, meaning each has the potential to form any type of human tissue and to become a complete human being.²⁹

After four or five days of development, the embryo is a hollow ball of cells called a blastocyst.³⁰ By this stage, some of the cells have begun to lose their unlimited differentiation potential.³¹ The outer layer of cells, known as the trophoctoderm, is committed to forming placental tissues.³² Embryonic stem cells are obtained by destroying the trophoctoderm, and thus the cell, and removing the inner mass of about thirty cells from the blastocyst.³³

These cells are then cultured in a laboratory.³⁴ As the initial mass of cells divides and creates new cells, the cells are placed into new culture dishes.³⁵ After six months of this culturing process, the original cell mass can result in millions of pluripotent stem cells.³⁶

²⁶ *Id.*

²⁷ *Id.*

²⁸ NATIONAL BIOETHICS ADVISORY COMMISSION, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH: REPORT AND RECOMMENDATIONS I, 7 (1999) [hereinafter NBAC REPORT AND RECOMMENDATIONS].

²⁹ THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 1, at xvii.

³⁰ STEM CELLS: A PRIMER, *supra* note 20.

³¹ NBAC REPORT AND RECOMMENDATIONS, *supra* note 28, at 9.

³² *Id.*

³³ *Stem Cell Basics*, *supra* note 20.

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

B. *Human Embryonic Germ Cells are an Undesirable Source of Stem Cells*

A less desirable source of stem cells is the gonadal ridge³⁷ of early fetal tissue.³⁸ Experiments on embryonic germ cells have been limited and it is believed that their differentiation capabilities will be more limited than those of embryonic stem cells because they are further along in development³⁹—a fact that could limit their potential use in treatments. Because embryonic germ cells are derived from an aborted fetus,⁴⁰ they present an added ethical dilemma.

C. *Adult Stem Cells Are Also an Undesirable Source of Stem Cells*

Undifferentiated cells found in developed tissue, known as adult or somatic stem cells,⁴¹ are another undesirable source of stem cells. These adult stem cells replenish cells lost naturally by the organism.⁴² For example, they replace the lining of the gut, generate new skin, and produce many different types of blood cells.⁴³ However, because adult stem cells are already partially differentiated they are therefore only multipotent.⁴⁴ As a result, their potential usefulness for medical research is also limited. Moreover, because scientists do not currently know how many kinds of adult stem cells exist,⁴⁵ they are unlikely to serve as a satisfactory replacement for embryonic stem cells.⁴⁶

³⁷ The gonadal ridge is a specific structure in an embryo, which, if allowed to develop fully, would become the testes or ovaries of a mature human organism. NIH, *Stem Cells: Scientific Progress and Future Directions* (2001) at ES-2, at <http://stemcells.nih.gov/stemcell/pdfs/fullrptstem.pdf> (last visited Nov. 14, 2003).

³⁸ THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 1, at xvii.

³⁹ CHAPMAN ET AL., *supra* note 17, at 3. Embryonic germ cells are derived from fetuses aborted after five to nine weeks of development. *Id.*

⁴⁰ THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 1, at xvii.

⁴¹ *Stem Cell Basics*, *supra* note 20.

⁴² *Id.*

⁴³ NBAC REPORT AND RECOMMENDATIONS, *supra* note 28.

⁴⁴ *Id.*

⁴⁵ *Stem Cell Basics*, *supra* note 20.

⁴⁶ CHAPMAN ET AL., *supra* note 17, at 3.

D. *Stem Cells Created by Somatic Cell Nuclear Transfer Present Ethical Dilemmas*

A fourth source of stem cells is the Somatic Cell Nuclear Transfer (“SCNT”) technique, also known as nuclear transplantation cloning.⁴⁷ In this technique, the nucleus is removed from an egg and is replaced with the nucleus of a somatic cell.⁴⁸ The resulting cell contains a full set of chromosomes identical to that of the individual who donated the somatic cell.⁴⁹ This is the method that was used to create Dolly, the cloned sheep.⁵⁰ Using SCNT to create stem cells adds another layer to the controversy surrounding stem cell research because it involves human cloning. Although, the intent of stem cell researchers is merely to derive stem cells, use of SCNT is likely to lead to public concerns that researchers will take the next step and attempt to create a fully-formed human clone.

In addition to the ethical problems presented by using a cloning technique, SCNT is technically more difficult than creating an embryo through IVF.⁵¹ Furthermore, like IVF, SCNT is limited by the number of human eggs that are available for the procedure.⁵² For these reasons, it is unlikely that many researchers will use this process if stem cells are available from other, more convenient sources.

Therefore, of all the potential sources of stem cells, the most practical option is to use IVF embryos that were originally created to help an infertile couple, but that the couple no longer needs.⁵³ Stem cells derived from excess IVF embryos have the capability of developing into any type of human tissue, and, while destroying an IVF embryo to create a new stem cell line is controversial, it presents less of an ethical dilemma than deriving cell lines from aborted fetuses or cloned embryos.

⁴⁷ CLONES AND CLONES: FACTS AND FANTASIES ABOUT HUMAN CLONING, *supra* note 21.

⁴⁸ *Id.* Somatic cells are the cells that make up most of the body and contain two sets of chromosomes, one set from each parent. *Id.* In contrast, eggs and sperm cells, which contain only a single set of chromosomes, are called germ cells. *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.* In 1997, a scientist in Edinburgh, Scotland announced that he had cloned a sheep by replacing the nucleus of a sheep’s egg with DNA from an adult sheep. Gina Kolata, *With Cloning of a Sheep, the Ethical Ground Shifts*, N.Y. TIMES, Feb. 24, 1997, at A1. According to her creator, the sheep, born in July 1996, was named Dolly because her DNA came from a mammary gland cell “and we couldn’t think of a more impressive pair of glands than Dolly Parton’s.” Ian Dow, *Ewe Beauty; Country Star*, DAILY REC., Feb. 26, 1997, at 21. After developing a progressive lung disease, Dolly was put to sleep at the age of six—approximately half of her life expectancy. Emma Ross, *It’s Goodbye to Dolly, Hello Questions: Cloned Sheep Put to Death Due to Lung Disease*, CHI. TRIB., Feb. 15, 2003, at 4.

⁵¹ Erik Parens, *On the Ethics and Politics of Embryonic Stem Cell Research*, in THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 1, at 46.

⁵² Parens, *supra* note 51, at 46.

⁵³ THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 1, at xvii-xviii.

III. THE POTENTIAL FOR LIFESAVING MEDICAL ADVANCES OUTWEIGHS ETHICAL CONCERNS OVER EMBRYONIC STEM CELL RESEARCH

Embryonic stem cell research is highly controversial because human embryos must be destroyed in order to obtain stem cells.⁵⁴ This raises concerns among those who believe life begins at conception and that, therefore, an embryo is a human being.⁵⁵ These individuals and groups are staunchly opposed to any kind of research on human embryos. On the other end of the spectrum are those who support embryonic stem cell research because, they argue, the ends—the enormous promise of medical advances—justify the means. While deeply-held religious beliefs contribute to the disagreement at either end of the spectrum, many Americans beliefs are somewhere in the middle. Ultimately, however, the promise that embryonic stem cell research may provide the best hope for discovering disease treatments and cures outweighs these concerns.

A. *The Ethics of Embryonic Stem Cell Research—Religious Beliefs Affect Opinions About When Life Begins*

The major source of controversy surrounding embryonic stem cell research is the unresolved question of what moral status should be accorded to embryonic stem cells and to the embryos from which they are derived.⁵⁶ One difficulty in reaching agreement on this issue stems from the disagreement about when human life begins.⁵⁷ U.S. President George W. Bush wrestled with this issue in 2001 when deciding whether to allow federal funding for embryonic stem cell research.⁵⁸

Beliefs in this area are often influenced by religion, and opinions diverge not only between faiths, but also within faiths. Within the Catholic tradition, for example, the case can be made both for and against embryonic stem cell research.⁵⁹ One point of view is that human embryos should be given the same level of protection in research as human beings.⁶⁰ Some

⁵⁴ *Id.* at xix.

⁵⁵ *Id.* at xviii-xix.

⁵⁶ *Id.* at xix.

⁵⁷ John A. Balint, M.D., F.R.C.P., *Ethical Issues in Stem Cell Research*, 65 ALB. L. REV. 729, 734 (2002).

⁵⁸ *Remarks by the President*, *supra* note 7 (“As I thought through this issue, I kept returning to two fundamental questions: First, are these frozen embryos human life . . . ?”).

⁵⁹ Margaret A. Farley, *Roman Catholic Views on Research Involving Human Embryonic Stem Cells*, in *THE HUMAN EMBRYONIC STEM CELL DEBATE*, *supra* note 1, at 115.

⁶⁰ *Id.*

Catholics, however, believe that an embryo at the earliest stages of development does not yet have the “settled inherent potential to become a human being” and need not be given the same kind of protections as a person.⁶¹ This viewpoint is supported by embryologic studies that show conception is a process that takes place in stages, not an instantaneous event.⁶²

Other religions have a less ambivalent view on the use of embryonic stem cells for medical research. For example, under Jewish law, an embryo does not attain the moral status of a human being until forty days after implantation in the uterus.⁶³ Because the embryos used to derive embryonic stem cells are never implanted in a woman’s uterus, they have no legal status under Jewish law.⁶⁴ The Muslim faith does not confer the legal and moral status of a human being on a fetus until even later—at the end of the fourth month of pregnancy.⁶⁵

B. *Disagreement Over the Natural Potential of Excess IVF Embryos Contributes to the Controversy*

Setting aside religion, another focus of the debate over embryonic stem cell research is on the natural potential for life, rather than the point at which life begins.⁶⁶ Embryonic stem cells, once derived from an embryo, no longer have the natural potential to become a fully formed human.⁶⁷ Without the outer layers of the embryo, the stem cells have lost the capacity to create some of the structures necessary for continued development.⁶⁸ Some argue, therefore, that stem cells have the same moral status and should be treated like any other type of human tissue, but not like a completely formed person.⁶⁹

The embryos from which stem cells may be derived, however, are accorded a greater moral status under this natural potentiality analysis.⁷⁰ As

⁶¹ *Id.* at 115-16.

⁶² *Id.* at 115.

⁶³ Elliot N. Dorff, *Stem Cell Research – A Jewish Perspective*, in THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 1, at 91.

⁶⁴ *Id.*

⁶⁵ COMMITTEE ON THE BIOLOGICAL AND BIOMEDICAL APPLICATIONS OF STEM CELL RESEARCH, ET AL., *STEM CELLS AND THE FUTURE OF REGENERATIVE MEDICINE* 44 (2002), available at <http://www.nap.edu/openbook/0309076307/html/index.html> (last visited Nov. 6, 2003).

⁶⁶ Gene Outka, *The Ethics of Human Stem Cell Research*, 12 KENNEDY INST. ETHICS J. 175, 188 (2002).

⁶⁷ CHAPMAN ET AL., *supra* note 17, at 12.

⁶⁸ *Id.* at 3.

⁶⁹ *Id.* at 12.

⁷⁰ Outka, *supra* note 66.

with all issues surrounding embryonic stem cell research, there are different points of view on the potential of embryos to become human beings. Some focus on the embryo's potential to become an entire human being, while others focus on the fact that, while that capacity exists, the embryo has not actually achieved that state⁷¹—it is not a fully formed human being having the same rights and owed the same ethical obligations as a person.

The nature of the IVF process is such that a large number of embryos are created to achieve a single pregnancy, which makes excess IVF embryos an excellent source of stem cells. Embryos created to help couples conceive have the natural potential to become human beings. But this potential can only be reached if the embryo is implanted in a woman's uterus and allowed to develop. For many embryos created through IVF, however, this potentiality will never be reached.⁷² IVF generally involves giving a woman hormones to stimulate superovulation.⁷³ This process may result in the harvesting of ten or more eggs, all of which are usually fertilized to increase the potential that a suitable embryo will be created.⁷⁴ This process typically results in a number of excess embryos that can be frozen for later use.⁷⁵ Excess embryos may be donated to research, destroyed, donated to other couples, or kept frozen if a couple chooses not to use them for future implantation.⁷⁶ Of these four options, only embryos donated to other infertile couples could result in a person. The natural potential for human life among excess embryos created for IVF is present in these embryos, but it is highly improbable that it will ever be realized. Beliefs about an embryo's natural potential and about religion must be balanced with the potential for stem cell research to lead to disease treatments and cures.

C. *Embryonic Stem Cell Research May Lead to New Treatments and Cures for Many Serious Diseases*

Stem cells are important to medical science because of their regenerative potential and multipotency.⁷⁷ But the pluripotency of embryonic stem cells makes them particularly important because it gives

⁷¹ *Id.*

⁷² John A. Robertson, *Precommitment Strategies for Disposition of Frozen Embryos*, 50 EMORY L. J. 989, 991 (2001).

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ CHAPMAN ET AL., *supra* note 17, at 14.

⁷⁷ THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 1, at xviii.

them the ability to develop into nearly any type of cell found in the human body.⁷⁸

The potential benefits of embryonic stem cell research are numerous. Embryonic stem cells may be used to study the way genetic material in a fertilized egg can create an entire organism.⁷⁹ These cells can also be used to identify drugs and substances in the environment that cause fetal abnormalities during a pregnancy.⁸⁰ Drug toxicity testing could be conducted using tissues created from embryonic stem cells.⁸¹ This would allow for direct testing of the effects of new pharmaceuticals on human tissues before exposing human beings to the drugs in clinical trials.⁸²

A major hope for embryonic stem cells is their potential use as a source for clinical applications in the treatment of neurological diseases.⁸³ Disorders such as Parkinson's, Alzheimer's, and Lou Gehrig's disease occur when certain types of nerve cells die.⁸⁴ A mature human body cannot replace damaged nerve cells, but embryonic stem cell research may lead to the ability to create new nerve tissue.⁸⁵

Embryonic stem cell research may also lead to a cure for Type 1 Diabetes, the restoration of immune function in people with primary immunodeficiency disease, and treatments for people with bone and cartilage diseases and cancer.⁸⁶ Such dramatic possibilities illustrate why stem cell research must be funded and supported—to maximize the potential medical benefits they may provide.

IV. THE CURRENT U.S. APPROACHES TO REGULATING EMBRYONIC STEM CELL RESEARCH FAIL TO ADEQUATELY ADDRESS ETHICAL CONCERNS OR MAXIMIZE POTENTIAL MEDICAL BENEFITS

The U.S. Congress has yet to directly regulate stem cell research through legislation, leaving the individual states free to impose their own regulations on research. The U. S. regulates embryonic stem cell research at the federal level by limiting federal funding for certain types of stem cell

⁷⁸ *Id.* at xvii.

⁷⁹ Okarma, *supra* note 10, at 6.

⁸⁰ *Id.* Currently this type of screening is done using animal models, which can only approximate what will happen to humans. For obvious reasons, it would be unethical to conduct research in this area on pregnant women.

⁸¹ *Id.* at 7.

⁸² *Id.*

⁸³ *Id.* at 9.

⁸⁴ CHAPMAN ET AL., *supra* note 17, at 5.

⁸⁵ *Id.* at 1.

⁸⁶ *Id.* at 5-6.

research. Because federal grants are the main source of medical research funding in the U. S., this approach has the practical effect of placing severe limitations on stem cell researchers.⁸⁷ Stem cell researchers who obtain private funds, however, are only limited by the laws of the state in which they work.⁸⁸

The federal approach has allowed the states to take various approaches to regulating stem cell research. In 2002, California's legislature chose the most liberal approach by adopting an act that indicated its intent to promote stem cell research by specifically allowing research involving the derivation and use of stem cells from any source.⁸⁹

A. *The Federal Approach Results in Too Few Stem Cell Sources for Researchers*

The combination of a Congressional ban on federally-funded research that creates new stem cell lines, President Bush's decision to severely restrict the number of stem cell lines federally-funded researchers can work with, and Congress' failure to directly regulate stem cell research creates a situation in which researchers using federal funds or working at federally-funded institutions are limited to using the handful of stem cell lines that were in existence when President Bush made his decision.

In 1995, Congress banned federal funding for human embryo research by attaching a rider to the Omnibus Consolidated and Emergency Supplemental Appropriations Act ("OCESAA"), the appropriations bill that funds the Department of Health and Human Services ("DHHS"). In January 1999, the General Counsel for DHHS issued an opinion stating that, while derivation of embryonic stem cells is prohibited by the OCESAA rider, research on stem cells that have already been derived is not.⁹⁰ Later that year, the National Bioethics Advisory Commission ("NBAC") issued an executive summary on ethical issues in human stem cell research.⁹¹ Among

⁸⁷ This year, the NIH expects to spend US\$ 27.3 billion on medical research. Luke Timmerman, *Ban Hangs Over Decisions on Embryos*, CHI. TRIB., Apr. 9, 2003, at 3B.

⁸⁸ For example, California recently enacted a state law specifically permitting research on stem cells derived from any source. CALIFORNIA HEALTH & SAFETY CODE §§ 125115-125117 (2002).

⁸⁹ S.B. 253, 2001-02 Gen. Assem., Reg. Sess. (Cal. 2001) (enacted).

⁹⁰ Memorandum from Harriet S. Rabb, General Counsel, DHHS, to Harold Varmus, M.D., Director, NIH, on Federal Funding for Research Involving Human Pluripotent Stem Cells (Jan. 15, 1999), reprinted in LORI B. ANDREWS, ET AL., GENETICS: ETHICS, LAW, AND POLICY 138 (2002) [hereinafter *Rabb Memorandum*].

⁹¹ NATIONAL BIOETHICS ADVISORY COMMISSION, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH: EXECUTIVE SUMMARY (1999) [hereinafter NBAC EXECUTIVE SUMMARY]. NBAC was established by President Clinton to provide advice and make recommendations about the appropriateness of "governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to

other conclusions, the NBAC summary recommended that the federal government fund the derivation of stem cells from excess IVF embryos, as well as research on these stem cells.⁹² NBAC also recommended that federal money not be used to fund the derivation or use of stem cells from human embryos that were created using SCNT,⁹³ and that DHHS establish a National Stem Cell Oversight and Review Panel to ensure that federally-funded research in embryonic stem cells conforms to NBAC's ethical principles and recommendations.⁹⁴

Then, in August 2000, the National Institutes of Health ("NIH"), an agency under DHHS, published its own guidelines on stem cell research.⁹⁵ Constrained by the rider on the OCESAA, these guidelines prohibited the use of federal funds for derivation of new stem cell lines, but allowed researchers to use federal grants to study new stem cell lines that were derived, using private funding sources, from excess IVF embryos.⁹⁶ These events all took place during the Clinton Administration.

The following year, faced with recommendations and guidelines on embryonic stem cell research with which he did not agree, President Bush formed a new federal policy.⁹⁷ This new policy limits federally-funded stem cell research to stem cell lines that were derived prior to August 9, 2001, the date the president announced this new policy to the public.⁹⁸ Congress has attempted to formulate its own stem cell research policy through legislation, but has yet to successfully pass a bill through both the House and the Senate.⁹⁹

bioethical issues arising from research on human biology. Exec. Order No. 12,975, 60 Fed. Reg. 52,063 (Oct. 5, 1995).

⁹² NBAC EXECUTIVE SUMMARY, *supra* note 91, at 3.

⁹³ *Id.* at 5.

⁹⁴ *Id.* at 7.

⁹⁵ NIH Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000), *corrected at* 65 Fed. Reg. 69,951 (Nov. 21, 2000), *withdrawn at* 66 Fed. Reg. 57,107 (Nov. 14, 2001).

⁹⁶ *Id.* § II(A)(2).

⁹⁷ *Remarks by the President, supra* note 7.

⁹⁸ *Id.*

⁹⁹ Examples of Congressional attempts to legislate stem cell research that were never passed into law include: Human Cloning Ban and Stem Cell Research Protection Act of 2001, S. 1893, 107th Cong. (2002); Stem Cell Research Act of 2001, H.R. 2059, 107th Cong. (2001); Stem Cell Research Act of 2000, S. 2015, 106th Cong. (2000).

1. *The Omnibus Consolidated and Emergency Supplemental Appropriations Act*

An amendment to the OCESAA bans the use of appropriated federal funds for research involving the creation of human embryos and for 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.”¹⁰⁰ The amendment was first passed in 1995 and has been passed without change every year since then.¹⁰¹

In response to a request from the NIH Director for a legal opinion about whether federal funds could be used to support embryonic stem cell research, the General Counsel for DHHS determined that, under the OCESAA, federal funds cannot be used to create stem cell lines.¹⁰² This is because removal of the inner cell mass destroys the embryo.¹⁰³ However, while federal funds cannot be used to create new stem cell lines, the General Counsel opined that embryonic stem cells themselves are not human embryos and, therefore, federally-funded research on existing cell lines and privately derived cell lines is not prohibited by the OCESAA rider.¹⁰⁴

2. *National Institutes of Health Guidelines on Stem Cell Research*

Following the DHHS General Counsel’s determination that the OCESAA rider does not prohibit federally-funded researchers from working on new stem cell lines that were derived without the use of federal funds, NIH published guidelines for NIH-funded researchers because no specific and comprehensive rules regarding federally-funded stem cell research existed.¹⁰⁵

Under the guidelines, NIH funds could be used to conduct research on pluripotent stem cells derived from human embryos, but only if the embryos used to obtain the cells “were created for the purposes of fertility treatment

¹⁰⁰ Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105-277, 112 Stat. 2681 (1999).

¹⁰¹ Pub. L. No. 104-208, § 512, 110 Stat. 3009 (1995); Pub. L. No. 104-99, § 128, 110 Stat. 26 (1996); Pub. L. No. 105-78, § 513, 111 Stat. 1467 (1997); Pub. L. No. 105-277, § 511, 112 Stat. 2681 (1998); Pub. L. No. 106-113, § 510; 113 Stat. 1501 (1999); Pub. L. No. 106-554, § 510; 114 Stat. 2763 (2000); Pub. L. No. 107-116, § 510, 115 Stat. 2177 (2001).

¹⁰² *Rabb Memorandum, supra* note 90.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ NIH Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000), *corrected at* 65 Fed. Reg. 69,951 (Nov. 21, 2000), *withdrawn at* 66 Fed. Reg. 57,107 (Nov. 14, 2001).

and were in excess of the clinical need of the individuals seeking such treatment.”¹⁰⁶ This portion of the NIH guidelines complied with the determination of the General Counsel that the OCESAA allows the use of federal funds for research on pluripotent stem cells, but not for creating new stem cell lines by destroying embryos.

The NIH guidelines laid out standards on financial and other incentives for stem cell donors.¹⁰⁷ To ensure that the donation was completely voluntary, the individuals who donated the embryos should have received “no inducements, monetary or otherwise.”¹⁰⁸ Furthermore, the fertility clinics and laboratories involved in the creation of the embryos must have had “specific written policies and practices” in place to ensure such inducements were not offered.¹⁰⁹

NIH also called for a division between the decision to create the embryos and the decision to donate the excess embryos for research.¹¹⁰ To ensure that potential embryo donors made the decision to donate without pressure from a researcher who wished to derive the pluripotent stem cells, NIH stated that the researcher interested in the stem cells must not also have been the treating physician.¹¹¹

The NIH guidelines also detailed the elements of informed consent that must have been obtained from the embryo donors.¹¹² These elements were designed to ensure that the donors understood all aspects of their decision, including that the pluripotent stem cells might be used for human transplantation research,¹¹³ that the cell lines might be kept for many years,¹¹⁴ and that the donated embryos would not survive the pluripotent stem cell derivation process.¹¹⁵

The guidelines also specifically listed areas of research on pluripotent stem cells that were ineligible for NIH funding.¹¹⁶ These areas included

¹⁰⁶ *Id.* § II(A)(2).

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* § II(A)(2)(a).

¹⁰⁹ *Id.*

¹¹⁰ *Id.* § II(A)(2)(b).

¹¹¹ NIH Guidelines for Research Using Human Pluripotent Stem Cells § II(A)(2)(b), 65 Fed. Reg. 51,976 (Aug. 25, 2000), *corrected at* 65 Fed. Reg. 69,951 (Nov. 21, 2000), *withdrawn at* 66 Fed. Reg. 57,107 (Nov. 14, 2001).

¹¹² *Id.* § II(A)(2)(e).

¹¹³ *Id.* § II(A)(2)(e)(i).

¹¹⁴ *Id.* § II(A)(2)(e)(iv).

¹¹⁵ *Id.* § II(A)(2)(e)(vii).

¹¹⁶ *Id.* § III.

derivation of stem cells from human embryos,¹¹⁷ research using cells derived from sources other than excess embryos resulting from fertility treatment,¹¹⁸ creation of pluripotent stem cells through SCNT,¹¹⁹ and human cloning.¹²⁰

3. *President Bush's Guidelines on Stem Cell Research*

Dissatisfied with the Clinton Administration's recommendations and guidelines on embryonic stem cell research, President Bush released his own criteria for federal funding of embryonic stem cell research.¹²¹ In a televised address to the nation, President Bush spoke of the "widespread disagreement" among experts and private citizens alike over whether frozen embryos are a form of human life and whether, if they are going to be destroyed anyway, they should instead be used for research.¹²² Referring to embryonic stem cell research as being "at the leading edge of a series of moral hazards" that could lead to human cloning, President Bush announced his conclusion that federal funds could be used for embryonic stem cell research, but only on pre-existing stem cell lines that had been created through private research.¹²³

The president's announcement limited federally-funded research on embryonic stem cells to an estimated sixty stem cell lines in existence "where the life and death decision [had] already been made."¹²⁴ He also declared his intention to name a president's council charged with monitoring stem cell research, recommending additional guidelines, and considering the bioethical ramifications of stem cell research and other biomedical advances.¹²⁵

Because the president's announcement superseded NIH's guidelines, NIH withdrew the portion of the guidelines pertaining to human embryonic stem cell research.¹²⁶

Ultimately, the president's announcement that about sixty available stem cell lines met his criteria turned out to be an overestimate.¹²⁷ As of

¹¹⁷ NIH Guidelines for Research Using Human Pluripotent Stem Cells § III(A), 65 Fed. Reg. 51,976 (Aug. 25, 2000), *corrected at* 65 Fed. Reg. 69,951 (Nov. 21, 2000), *withdrawn at* 66 Fed. Reg. 57,107 (Nov. 14, 2001).

¹¹⁸ *Id.* § III(C).

¹¹⁹ *Id.* § III(E).

¹²⁰ *Id.* § III(G).

¹²¹ *Remarks by the President, supra* note 7.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells Derived from Human Embryos, 66 Fed. Reg. 57,107 (Nov. 14, 2001).

November 6, 2003, more than two years after the president's announcement, the NIH website indicated that only twelve stem cell lines meet the announced criteria and are currently available.¹²⁸

4. *Current Bills in Congress*

Congress is considering whether to regulate stem cell research in the United States, including privately-funded research, by banning human cloning, thus prohibiting derivation of new stem cell lines through SCNT.¹²⁹ For example, the Human Cloning Prohibition Act of 2003 ("HCPA"), would ban all forms of human cloning in the United States.¹³⁰ The bill defines human cloning as "human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) that is genetically virtually identical to an existing or previously existing human organism."¹³¹ If passed, the HCPA would impact stem cell research by making it a crime to create or attempt to create embryos through SCNT, to use SCNT embryos to derive stem cells, and to do any research on stem cells derived from SCNT embryos.¹³² This would apply to all researchers "in or affecting interstate commerce," not just those whose research is supported by federal funds.¹³³ The HCPA was passed by the House of Representatives on February 27, 2003 and awaits Senate action.¹³⁴

A competing bill, also introduced in the House of Representatives would ban human cloning for reproductive purposes only.¹³⁵ It would still allow SCNT to be performed, provided there is no attempt to initiate a pregnancy using the clone.¹³⁶ This would affirmatively allow research on cloned cells, but would not alter the ban on federal funding, thus allowing

¹²⁷ NIH, *Human Embryonic Stem Cell Registry*, at <http://stemcells.nih.gov/registry> (last visited Nov. 6, 2003).

¹²⁸ *Id.* This website lists eighteen cell lines that meet the President's criteria, but six of them are not currently available for shipping. *Id.* A second website lists several other stem cell lines that meet the President's criteria but are not yet available for shipping. NIH, *Human Embryonic Stem Cell Registry – Cell Lines Not Yet Available for Shipping*, at <http://stemcells.nih.gov/registry/unavailable.asp> (last visited Nov. 6, 2003).

¹²⁹ H.R. 534, 108th Cong. (2003).

¹³⁰ *Id.*

¹³¹ *Id.* § 301(1).

¹³² *Id.* § 302(a).

¹³³ *Id.*

¹³⁴ Congressional Research Service, *Bill Summary for H.R. 534*, <http://thomas.loc.gov/cgi-bin/bdquery/z?d108:HR00534:@@D&summ2=2&> (last visited Dec. 19, 2003).

¹³⁵ H.R. 801, 108th Cong. (2003).

¹³⁶ *Id.*

privately-funded scientists to use SCNT to derive stem cells. It would raise ethical concerns, however, because it would allow embryos to be cloned and destroyed anywhere in the United States for the sole purpose of obtaining stem cells. Similar bills have been introduced in the Senate.¹³⁷

The federal government's approach to stem cell research has consisted of funding restrictions, shifting administrative guidelines on research, and failed attempts to pass legislation that would regulate stem cell research directly. The lack of coherent federal legislation directly addressing stem cell research has allowed the states to fill the void with their own laws. The states have taken different approaches, with California passing the most liberal legislation.¹³⁸

B. California's Approach to Regulating Embryonic Stem Cell Research Fails to Properly Address Ethical Concerns

Stem cell researchers who are funded entirely by private monies and who do not work at federally-funded institutions are regulated only by state law. In California, embryonic stem cell research is regulated by a law that was passed by the California General Assembly after it found, among other things, that the state's "public policy on stem cell research must be carefully crafted to ensure that researchers have the tools necessary to fulfill the promise of stem cell research."¹³⁹ On September 22, 2002, California Governor Gray Davis signed Senate Bill 253, the nation's most relaxed stem cell legislation, into law.¹⁴⁰ The California law declares the state's policy "that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including SCNT, shall be permitted and that full consideration of the ethical and medical implications of this research be given."¹⁴¹

California's current law requires fertility treatment providers to present their patients with the information necessary to decide how to dispose of any excess embryos remaining after the fertility treatment is completed.¹⁴² The law further mandates that the patient "shall be presented with the option of storing any unused embryos, donating them to another

¹³⁷ S. 245, 108th Cong. (2003); S. 303, 108th Cong. (2003).

¹³⁸ The recently passed legislation has been codified as CALIFORNIA HEALTH & SAFETY CODE §§ 125115-125117 (2002).

¹³⁹ S.B. 253, 2001-02 Gen. Assem., Reg. Sess. (Cal. 2001) (enacted).

¹⁴⁰ Mark Martin, *Davis OKs Stem Cell Research / California is First State to Encourage Studies*, S.F. CHRON., Sep. 23, 2002, at A1.

¹⁴¹ CAL. HEALTH & SAFETY CODE § 125115(a) (2002).

¹⁴² CAL. HEALTH & SAFETY CODE § 125116(a) (2002).

individual, discarding the embryos, or donating the remaining embryos for research.”¹⁴³ The statute also requires written consent from individuals who choose to donate excess embryos for research.¹⁴⁴ The second recently-enacted law outlines the full range of options that infertility clinics must provide to patients and their partners regarding the disposition of human embryos.¹⁴⁵ It also calls for the creation of an anonymous embryo registry to provide researchers with better access to embryos that may be used for research purposes.¹⁴⁶

Although the law does not appropriate any state funds for research on embryonic stem cells and cannot alter the criteria for federally-funded research, it may have the benefit of encouraging private funding for embryonic stem cell research in California.¹⁴⁷ The law may also have the added effect of keeping California researchers from moving to countries that are more hospitable to stem cell research, and it may attract new researchers to the state.¹⁴⁸

In 2003, California enacted two more laws regarding stem cell research.¹⁴⁹ Both of these laws become effective January 1, 2004.¹⁵⁰ The first of these new laws directs the California State Department of Health Services to establish a Human Stem Cell Research Advisory Committee, which will be charged with developing guidelines for stem cell research in California.¹⁵¹ The committee is to consist of seven scientists, two medical ethicists, two members with backgrounds in legal issues relevant to stem cell research, and two members with religious affiliations.¹⁵² The guidelines must be in place by January 1, 2005.¹⁵³

While the federal government takes a conservative approach to stem cell research by limiting federally-funded stem cell researchers to experiments on only sixteen different stem cell lines, California has chosen

¹⁴³ *Id.* § 125116(b). Beginning in 2004, fertility providers will be required to provide their patient and the patient’s partner with a specified list of options for disposition of excess embryos in a range of situations. S.B. 771 (Cal. 2003). Failure to provide these options will be considered “unprofessional conduct.” S.B. 771 (Cal. 2003).

¹⁴⁴ CAL. HEALTH & SAFETY CODE § 125116(c). California prohibits the sale of embryonic tissue to ensure that donation of embryos for research is voluntary. *Id.* § 125117.

¹⁴⁵ S.B. 771, 2003-04 Gen. Assem., Reg. Sess. (Cal. 2003) (enacted).

¹⁴⁶ *Id.*

¹⁴⁷ Martin, *supra* note 140.

¹⁴⁸ Jennifer Coleman, *California Approves Research on Stem Cells*, CHI. TRIB., Sept. 23, 2002, at 7.

¹⁴⁹ Carl Ingram, *Gun, Stem Cell Bills Signed; Gov. Davis Approves Measures to Make Semiautomatic Pistols Safer and Advance Research on Serious Diseases*, L.A. TIMES, Sep. 25, 2003, § 2, at 1.

¹⁵⁰ S.B. 771, 2002-03 Gen. Assem., Reg. Sess. (Cal. 2003) (enacted); S.B. 322, 2003-04 Gen. Assem., Reg. Sess. (Cal. 2003) (enacted).

¹⁵¹ S.B. 322, 2002-03 Gen. Assem., Reg. Sess. (Cal. 2003) (enacted).

¹⁵² *Id.*

¹⁵³ *Id.*

an extremely liberal policy that encourages privately funded researchers to create as many new stem cell lines as possible, limited only by the availability of raw materials. California's law allows researchers to use excess IVF embryos to create new stem cell lines but does not require the consent of all parties who had a stake in the creation of the embryos.¹⁵⁴ Furthermore, California law allows researchers to create and destroy human embryos solely for the purpose of deriving new stem cell lines.

V. THE TWO-TIERED AUSTRALIAN APPROACH

The Australian government has adopted an embryonic stem cell policy that takes the middle ground between the conservative policy of the U.S. federal government and the liberal approach of the State of California. The Australian policy allows researchers access to a greater diversity of stem cell lines than the U.S. federal policy, yet more closely regulates the sources from which new stem cell lines may be derived than the California law. In this way, Australia recognizes the important medical benefits that may result from stem cell research, while remaining sensitive to the ethical dilemmas presented by deriving new stem cell lines.

Australian legislation regulating stem cell research and cloning grew out of a June 8, 2001 decision by the Council of Australian Governments ("COAG") to set a goal of achieving nationally consistent legislation banning human cloning.¹⁵⁵ Although COAG's decisions are not binding on

¹⁵⁴ California's original stem cell research laws required fertility providers to give the appropriate information regarding disposition of excess embryos only to the "patient." CAL. HEALTH & SAFETY CODE §125116(a). Beginning in 2004, fertility providers must provide this information to the patient, as well as "the male and female partner." S.B. 771, 2003-04 Gen. Assem., Reg. Sess. (Cal. 2003) (enacted). This appears to ensure that both members of any couple seeking fertility treatment, regardless of the couple's sexual orientation, receive information about how they may dispose of any excess embryos. However, once a decision to donate excess embryos has been made, the law requires the fertility provider to obtain written consent only from "any individual who elects to donate embryos." *Id.* Thus, it is not clear that both members of a couple must provide informed consent prior to donation of excess embryos for research purposes. Furthermore, in a case where embryos are created using a donated egg or donated sperm cells, there is no requirement that the egg or sperm donor be provided with information regarding the possible disposition of any excess embryos created with his or her gametes.

¹⁵⁵ COMMUNITY AFFAIRS LEGISLATION COMMITTEE OF THE AUSTRALIAN SENATE, PROVISIONS OF THE RESEARCH INVOLVING EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2002, 6 (2002). The Council of Australian Governments was established in 1992 by the Prime Minister of Australia, the Premiers of the Australian States, and the Chief Ministers of the Australian Territories. The Council of Australian Governments (COAG), *Framework*, at www.dpmc.gov.au/docs/Coag_framework.cfm (last visited Oct. 8, 2003). COAG exists to "initiate, develop and monitor the implementation of policy reforms which are of national significance and which require cooperative action by Australian governments." *Id.*

the Commonwealth of Australia or its states and territories, its decisions represent the consensus reached by the member governments.¹⁵⁶

In a meeting on April 5, 2002 COAG agreed that research should only be allowed on existing embryos that had originally been created as part of infertility treatments and would otherwise be destroyed.¹⁵⁷ COAG further agreed that a strict regulatory regime should be put into place to ensure that embryo donors gave informed consent and could restrict the types of research to be performed on the embryos they donated.¹⁵⁸

As a result of the COAG decision, on June 27, 2002 the Research Involving Embryos and Prohibition of Human Cloning bill was introduced in Australia's House of Representatives.¹⁵⁹ Public comment was invited from a variety of groups and individuals including researchers, consumer and health care groups, and ethicists.¹⁶⁰ Following six days of spirited debate at the end of August, 2002, the bill was split into two separate bills, the Research Involving Embryos bill, which regulates activities involving the use of human embryos originally created for IVF,¹⁶¹ and the Prohibition of Human Cloning bill, which bans the cloning of humans.¹⁶² Both bills were passed by the Australian House of Representatives without amendment.¹⁶³

Following passage in the House, the Research Involving Embryos bill and the Prohibition of Human Cloning bill were then introduced into the Australian Senate in September 2002.¹⁶⁴ Due to the controversial nature of these bills, the political parties permitted Senators to vote their conscience rather than requiring them to vote along party lines.¹⁶⁵ Following over forty

¹⁵⁶ COMMUNITY AFFAIRS LEGISLATION COMMITTEE OF THE AUSTRALIAN SENATE, *supra* note 155, at 7.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.* at 6-7.

¹⁵⁹ *Id.* at 1.

¹⁶⁰ *Id.*

¹⁶¹ Research Involving Human Embryos Act, 2002, part 1, div. 3 (Austl.).

¹⁶² COMMUNITY AFFAIRS LEGISLATION COMMITTEE OF THE AUSTRALIAN SENATE, *supra* note 155, at 2.

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Australia Approves Stem Cell Research*, THE STATE, Dec. 5, 2002, available at <http://www.thestate.com/mld/thestate/4667412.htm?template=contentModules/printstory.jsp> (last visited Nov. 6, 2003). In the Australian Parliament votes are generally determined along party lines. But conscience votes (also called free votes) occur when parties have made no particular decision as to how their members should vote, usually because the parties have no particular policy on that issue or because the matter is controversial and the parties feel their members should be able to vote their conscience. ODGERS' AUSTRALIAN SENATE PRACTICE, 10TH ED. 249 (Harry Evans ed., 2001), available at <http://www.aph.gov.au/senate/pubs/Html/pdf/Chapter11.pdf> (last visited Nov. 6, 2003); HOUSE OF REPRESENTATIVES PRACTICE, 4TH ED. 277-8 (I.C. Harris ed., 2001), available at <http://www.aph.gov.au/house/pubs/PRACTICE/4Ch08.pdf> (last visited Nov. 6, 2003).

hours of debate over eleven weeks, both bills were passed in December 2002.¹⁶⁶ They became the Research Involving Human Embryos Act (“RIHEA”) and the Prohibition of Human Cloning Act (“PHCA”), respectively.¹⁶⁷

Together, RIHEA and PHCA provide researchers in Australia with a vast source of new stem cell lines that may now be derived, with the consent of the appropriate parties, from embryos that were originally created to help infertile couples conceive a child. This method of regulation gives researchers the power to create diverse stem cell lines, thus increasing the likelihood of great medical advances, while avoiding the ethical dilemma that arises when an embryo is created and destroyed for the purpose of obtaining stem cells. RIHEA ensures that stem cells are only obtained from embryos originally created for assisted reproduction after full, informed consent is given by the parties who contributed genetic material to the embryos with the intention of conceiving a child.¹⁶⁸

A. The Australian Prohibition of Human Cloning Act Prohibits the Cloning of Human Embryos as a Source of Stem Cells for Research

PHCA effectively prohibits the creation of human embryos for any reason other than to achieve a pregnancy in a human female and by any method other than fertilization of an egg by a sperm.¹⁶⁹ Under PHCA, it is a crime to intentionally create a human embryo clone, to implant a human embryo clone in a human or animal, and to import or export a human embryo clone.¹⁷⁰ These crimes are punishable by up to fifteen years in prison.¹⁷¹ PHCA provides a legislative answer to the ethical debate over whether it is acceptable to create embryos solely for research purposes by prohibiting the practice altogether. This position is reinforced by RIHEA, which outlines acceptable sources for embryonic stem cells.¹⁷²

¹⁶⁶ Darren Gray, *Senate Backs Use of Human Embryos in Stem Cell Research*, THE AGE, Dec. 6, 2002, 2002 WL 103071091; Sandra O'Malley, *Stem Cell Laws Pass Through Parliament with Little Fanfare*, AUSTRALIAN AP GEN. NEWS, Dec. 11, 2002, 2002 WL 103858390.

¹⁶⁷ Research Involving Human Embryos Act No. 145, 2002 (Austl.). Prohibition of Human Cloning Act, No. 144, 2002 (Austl.).

¹⁶⁸ Research Involving Human Embryos Act, 2002, part 2, div. 1, § 9; part 2, div. 4, § 21(3)(a) (Austl.).

¹⁶⁹ Prohibition of Human Cloning Act, 2002, part 1, § 8(1) (Austl.).

¹⁷⁰ *Id.* part 2, div. 1, §§ 9-11.

¹⁷¹ *Id.*

¹⁷² Research Involving Human Embryos Act, 2002, part 2, div. 4, § 21; part 2, div. 1, § 9 (Austl.).

B. The Australian Research Involving Human Embryos Act Strictly Regulates Embryonic Stem Cell Research

RIHEA addresses ethical concerns about the use of human embryos for scientific research by regulating research involving embryos created by assisted reproductive technology.¹⁷³ RIHEA permits research on human embryos originally created for use in fertility treatment but determined to be in excess of the needs of the couple undergoing treatment.¹⁷⁴ An embryo is considered to be “excess” if the woman and her spouse have given written consent for the embryo to be used for purposes other than fertility treatment and they have made a written determination that the embryo is in excess of their needs.¹⁷⁵ RIHEA defines a human embryo as “a live embryo that has a human genome or an altered human genome and that has been developing for less than eight weeks since the appearance of two pro-nuclei or the initiation of its development by other means.”¹⁷⁶ In calculating the time of development, any time during which development is suspended, such as when the embryo is frozen, is disregarded.¹⁷⁷ RIHEA further restricts research that may result in damage to or destruction of the embryo to embryos created prior to April 5, 2002, the date of the COAG meeting that lead to this legislation.¹⁷⁸

RIHEA also establishes a committee to determine which researchers may use excess embryos and to ensure that their research complies with its requirements.¹⁷⁹ The Embryo Research Licensing Committee of the National Health and Medical Research Council consists of nine members with various and specified backgrounds.¹⁸⁰ These members include people with expertise in research ethics, stem cell research, assisted reproductive technology, law, and embryology.¹⁸¹ The licensing committee accepts applications from researchers hoping to use excess embryos originally created for fertility treatment.¹⁸²

¹⁷³ *Id.* part 1, § 3 (Austl.).

¹⁷⁴ *Id.* part 2, div. 4, § 21; part 2, div. 1, § 9(1) (Austl.).

¹⁷⁵ *Id.* part 2, div. 1, § 9(2).

¹⁷⁶ *Id.* part 1, § 7(1).

¹⁷⁷ *Id.* § 7(2).

¹⁷⁸ Research Involving Human Embryos Act, 2002, part 2, div. 4, § 21(3)(b); part 2, div. 4, § 24(1)(c); part 2, div. 4, § 24(3) (Austl.). This restriction, however, is only in force until either April 5, 2005, or an earlier date, if it is declared by the Council of Australian Governments by notice in the *Gazette*. *Id.* part 5, div. 1, § 46.

¹⁷⁹ *Id.* part 2, div. 3, § 13(1).

¹⁸⁰ *Id.* § 16(1).

¹⁸¹ *Id.*

¹⁸² *Id.* part 2, div. 4, § 20.

Once the licensing committee is satisfied that the researcher is in compliance with RIHEA, it will then issue a license to perform research on excess embryos.¹⁸³ To meet the criteria established by RIHEA, the researcher must have procedures in place to ensure that embryo donors have properly consented to the embryo's use in medical research and that the research complies with any restrictions on that consent.¹⁸⁴ If the research will result in damage to or destruction of the embryo, such as when stem cells are extracted, the embryos must have been created before April 5, 2002.¹⁸⁵ Finally, a Human Research Ethics Committee ("HREC") must have assessed and approved the research in compliance with the National Health and Medical Research Council's Statement on Ethical Conduct in Research Involving Humans.¹⁸⁶

In addition to assessing researcher compliance with these three requirements, the licensing committee must consider other factors, including the minimum number of embryos likely to be needed to carry out the research and the likelihood that the research will result in a significant advance in knowledge, or an improvement in treatments that could not otherwise be achieved.¹⁸⁷ The licensing committee must also consider the HREC's assessment of the project.¹⁸⁸

Once the licensing committee has assessed and approved an application, it must issue the license to the applicant and provide copies of the license to the HREC that assessed the project and the relevant state body in the state where the research is to take place.¹⁸⁹ The license then remains in effect until the date specified, unless the researcher surrenders it or the licensing committee suspends or revokes it earlier.¹⁹⁰ In issuing a license, the committee may place limitations on who can use the embryos and on the number of embryos that can be used.¹⁹¹ The licensing committee can also impose reporting and monitoring requirements.¹⁹² The conditions of existing licenses may be changed by the licensing committee on its own volition or at the request of the application holder.¹⁹³

¹⁸³ *Id.* § 21(3).

¹⁸⁴ Research Involving Human Embryos Act, 2002, part 2, div. 4, § 21(3)(a) (Austl.).

¹⁸⁵ *Id.* § 21(3)(b).

¹⁸⁶ *Id.* § 21(3)(c).

¹⁸⁷ *Id.* § 21(4).

¹⁸⁸ *Id.* § 21(4).

¹⁸⁹ *Id.* § 22.

¹⁹⁰ Research Involving Human Embryos Act, 2002, part 2, div. 4, § 23 (Austl.)

¹⁹¹ *Id.* § 24(5).

¹⁹² *Id.* § 24(5).

¹⁹³ *Id.* § 25.

The licensing committee must also create and maintain a public database containing information on each license granted.¹⁹⁴ This database must include the name of each license holder, a summary of the uses authorized by the license, any conditions placed on the license, the number of embryos the license holder is authorized to use, the date the license was issued, and the length of time the license is in effect.¹⁹⁵

RIHEA includes a provision requiring an independent review of the its operation, which is to be conducted two years after its passage.¹⁹⁶ The review must be undertaken concurrently with a review of PHCA.¹⁹⁷ The review will report on developments in technology related to infertility treatments, the potential clinical applications of developments in medical and scientific research, community standards, and whether a national stem cell bank should be established.¹⁹⁸ If the reviewers findings warrant amendments to RIHEA, their report must recommend appropriate revisions.¹⁹⁹

VI. COMPARISON OF RIHEA AND PHCA TO THE U.S. FEDERAL AND CALIFORNIA APPROACHES

The regulations of Australia, the United States federal government, and the State of California illustrate three different approaches to the regulation of stem cell research. The federal government has chosen to regulate stem cell research indirectly, by restricting the research that can be performed with federal funds. This means that states like California can allow researchers to create embryos for the sole purpose obtaining stem cells, so long as they do not either directly or indirectly receive federal research dollars. Australia, on the other hand, has passed legislation to directly regulate stem cell research. This legislation presents a more satisfying compromise than that reached in the United States because it provides researchers with the opportunity to create diverse stem cell lines to advance medical research, while ensuring that these new stem cell lines come only from excess embryos.

¹⁹⁴ *Id.* § 29.

¹⁹⁵ *Id.* § 29(1).

¹⁹⁶ Research Involving Human Embryos Act, 2002, part 5, div. 2, § 47(1) (Austl.).

¹⁹⁷ *Id.* § 47(2).

¹⁹⁸ *Id.* § 47(4).

¹⁹⁹ *Id.* § 47(5).

A. *By Permitting the Derivation of New Stem Cell Lines from Excess IVF Embryos, the Australian Approach Provides More Sources of Embryonic Stem Cells Than the U. S. Federal Government*

The Australian legislation will likely lead to more diversity in stem cell lines by allowing researchers to derive new lines from excess IVF embryos. It also avoids the thornier ethical dilemma that would result from allowing researchers to create and destroy human embryos solely to obtain new stem cell lines.

In comparison, the United States federal government regulates research on embryonic stem cells indirectly by restricting embryonic stem cell research conducted with federal funds to that using materials from cell lines that were created prior to August 9, 2001 “(1) with the informed consent of the donors; (2) from excess embryos created solely for reproductive purposes; and (3) without any financial inducements to the donors.”²⁰⁰ The federal government does not regulate the sources of stem cells used by privately-funded researchers. In contrast, Australia allows researchers to derive new embryonic stem cell lines from donated excess embryos originally created for fertility treatment purposes prior to April 5, 2002.²⁰¹ Finally, California has the most relaxed policy of the three, which permits research on stem cells derived from any source including embryos, fetal tissue, and cloned adult stem cells.²⁰²

The federal government’s approach best accommodates those who believe life begins at conception. By allowing federal funding for only those cell lines created prior to his announcement, President Bush limited federal funding to research on embryonic stem cell lines “where the life and death decision has already been made.”²⁰³ In contrast, the California law permitting research on stem cells from any source caters strongly to those who believe the scientific ends outweigh the means.

The Australian approach establishes a reasonable compromise between the competing viewpoints. It allows for the creation of new embryonic stem cell lines while limiting the sources of those lines to excess embryos created for the purpose of fertility treatment.²⁰⁴ Assuming, *arguendo*, that these frozen embryos are a form of life, the “life or death decision” has already been made. By definition, the “excess” embryos will

²⁰⁰ *Fact Sheet on Embryonic Stem Cell Research*, Aug. 9, 2001, available at <http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html> (last visited Nov. 6, 2003).

²⁰¹ Research Involving Human Embryos Act, 2002 (Austl.).

²⁰² CAL. HEALTH & SAFETY CODE § 125115(a) (2002).

²⁰³ *Remarks by the President*, *supra* note 7.

²⁰⁴ Research Involving Human Embryos Act, 2002 (Austl.).

not be implanted in the woman undergoing fertility treatment. The couple that has sought out fertility treatment is not precluded from donating the excess embryos to other infertile couples. But for couples who do not wish to do this, the only other options are disposal of the embryo or indefinite storage, neither of which result in a human life.

B. The Australian Legislative Scheme Also Provides Stronger Donor Consent Procedures

Under the Bush Administration's policy, federally-funded research on embryonic stem cells can only be performed on cell lines that were derived from embryos that were donated with the informed consent of the donors.²⁰⁵ NIH is charged with examining the stem cell lines in existence at the time this policy was announced and determining which lines satisfy President Bush's criteria.²⁰⁶ Until Congress passes legislation in this area, the United States has no nationally-consistent safeguard to ensure embryos used in privately-funded research were obtained under appropriate informed consent procedures. This is left open to regulation by the states.

California's new law supporting stem cell research includes measures designed to ensure that informed consent is received from those donating embryos for research²⁰⁷ but these measures do not extend as far as some ethicists recommend.²⁰⁸ California prohibits the purchase or sale of embryos for research purposes.²⁰⁹ This protects potential "donors" from coercive financial pressures. But California's statute does nothing to ensure that fertility providers do not, for example, create even more excess embryos than required for fertility treatment, in an attempt to guarantee that there will be excess embryos at the end of treatment.

A second problem with the California statute is that it does not require the informed consent of all appropriate parties. Currently, California requires a fertility treatment provider to give the appropriate information to "his or her patient" so that "the individual" can make an informed decision regarding what should be done with excess embryos after the fertility treatment is completed.²¹⁰ Beginning in 2004, California's law will expand to require that information on the methods of disposition of excess embryos

²⁰⁵ *Fact Sheet on Embryonic Stem Cell Research*, *supra* note 200.

²⁰⁶ *Id.*

²⁰⁷ CAL. HEALTH & SAFETY CODE §125116 (2002).

²⁰⁸ *Donating Spare Embryos for Embryonic Stem-Cell Research*, 78 FERTILITY AND STERILITY 957 (2002).

²⁰⁹ CAL. HEALTH & SAFETY CODE §125117(a) (2002).

²¹⁰ *Id.* § 125116(a).

be provided to both members of any couple seeking fertility treatment.²¹¹ The statute, however, does not clearly require both members of the couple to provide informed consent prior to donating embryos for research purposes.²¹² In a situation where two people have made a decision to create embryos through IVF, both should have a say in disposal of any excess embryos. Furthermore, California law contains no provision ensuring that individuals who donate eggs or sperm to infertile couples have the opportunity to weigh in on the decision about how to dispose of excess embryos, nor does the statute guarantee that they will be provided with information regarding the potential that excess embryos created with their gametes will be donated for research.

In contrast to the California approach, Australia provides more extensive procedures to ensure that the appropriate informed consent is received before an embryo is used for research purposes. PCHA guards against coercion in the decision to donate embryos by prohibiting their purchase and sale.²¹³ Violation of this provision carries a penalty of up to ten years in prison.²¹⁴

RIHEA also contains stronger safeguards to ensure that informed consent is obtained from embryo donors. A license to use excess embryos is subject to the condition that “each responsible person in relation to the excess ART embryo must have given proper consent to that use.”²¹⁵ It defines “responsible person” as each person who provided genetic material for the embryo, the woman in whom the embryo would have been implanted, and the spouses of any of these people at the time the embryo was created.²¹⁶ In many situations, the only responsible people who must give consent will be the couple for whom the embryo was created in the course of fertility treatment. But Australia recognizes that, in some cases, unrelated egg or sperm donors may have been necessary to the creation of the embryo and that these people may have decided against donating their germ cells if they had known one or more of the resulting embryos might be used for research.²¹⁷ Furthermore, by defining “spouse” broadly, Australia

²¹¹ S.B. 771, 2003-04 Gen. Assem., Reg. Sess. (Cal. 2003) (enacted).

²¹² The statute requires “any individual who elects to donate embryos” to provide written informed consent. *Id.*

²¹³ Prohibition of Human Cloning Act, 2002, part 2, div. 2, § 23 (Austl.).

²¹⁴ *Id.*

²¹⁵ Research Involving Human Embryos Act, 2002, part 2, div. 4, § 24 (Austl.). ART is an abbreviation for Assisted Reproductive Technology.

²¹⁶ *Id.* div. 1, § 8.

²¹⁷ Samantha Maiden, *Stem Cell Consent; Up to 70,000 Embryos Available*, ADVERTISER, Dec. 6, 2002, at 9. The article quotes Australian Senator Kay Patterson as saying, “I think we shouldn’t forget the donors of excess embryos from IVF . . . they will have the right to exercise their conscience as to whether

ensures that unmarried partners who are living together “on a bona fide domestic basis”²¹⁸ have a voice in the decision-making process. As these people likely took an active role in deciding to participate in fertility treatment, fairness requires that they have the opportunity to participate in deciding how to dispose of any excess embryos.

VII. RECOMMENDATION: THE UNITED STATES SHOULD ADOPT LEGISLATION MODELED ON AUSTRALIA’S

Of the federal, California, and Australian policies toward embryonic stem cell research, the Australian model has achieved the best balance between competing sides in the embryonic stem cell debate. Australia opens up the possibility for the creation of new stem cell lines, which will give researchers an opportunity to work with more genetically diverse material. It limits the new sources of these stem cell lines to excess IVF embryos and ensures that such embryos will only be donated to research with the consent of all parties who played a part in the decision to create the embryos. Finally, it prohibits the creation of embryos solely for the purpose of deriving stem cells from them.

In comparison, the current policy in the United States simultaneously offends the interests of those who support embryonic stem cell research and those who oppose it. A large amount of biomedical research in the United States is funded by federal money, yet researchers who use this money to support embryonic stem cell research are restricted to the limited genetic diversity of the few stem cell lines in existence on August 9, 2001. Researchers who obtain private funds, however, are subject only to the limitations imposed on them by the states. In California this means researchers are given *carte blanche* to derive stem cells from any source, including using SCNT to create embryos.

The United States should adopt legislation similar to RIHEA and PCHA in Australia. This would allow for nationally consistent regulation of embryonic stem cell research and would reach a compromise between those who support such research and those who oppose it.

they will donate their embryos . . . ,” and notes that in cases where an infertile couple creates embryos using an egg and sperm donated by two other couples, six people would have to consent in order for the excess embryos to be used for research purposes. *Id.*

²¹⁸ Research Involving Human Embryos Act, 2002, part 1, § 7 (Austl.).

VIII. CONCLUSION

Embryonic stem cell research is a controversial and divisive topic. Divergent beliefs about the natural potential of embryos and about the moral status that should be accorded to them are affected by strongly-held religious beliefs, as well as secular opinions. Equally strong beliefs about the effort that should be put into finding new treatments and cures for diseases add to the debate. Because beliefs are so intense, it is unlikely that the controversy over stem cell research will be completely resolved. The current approach in the United States, however, is unsatisfactory because it severely restricts research by limiting the projects that can be undertaken with federal funds, while allowing states to endorse research that creates embryos for the purpose of using—and destroying—they in research. In contrast, Australia's approach presents a more satisfactory compromise by allowing researchers to derive new stem cell lines from embryos created for in vitro fertilization that would otherwise have been discarded.