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Breaking Barriers, Pushing Promise: American's Need for an Embryonic Stem Cell Regulatory Scheme

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BREAKING BARRIERS, PUSHING PROMISE: AMERICA'S NEED FOR AN EMBRYONIC STEM CELL REGULATORY SCHEME

INTRODUCTION

For years, "[b]iomedical researchers have . . . known that their favorite lab critters, mice, have both 'adult' and embryonic stem cells."[1] In 1998, however, stem cell research was extended to human beings, "in the process touching off a massive ethical and political debate."[2] Specifically, biologist Dr. James Thomson, a researcher at the University of Wisconsin-Madison, and his team published a paper in *Science* revealing that they had isolated the very first human embryonic stem cell line.[3] For some, this was a major medical breakthrough, as human embryonic stem cell research was expected to have extremely promising health benefits.[4] For others, this was the destruction of human life,[5] as "the only

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1. CHRIS MOONEY, THE REPUBLICAN WAR ON SCIENCE 186 (2006).

2. *Id.*

3. James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145, 1145–47 (1998), *available at* http://www.sciencemag.org/cgi/reprint/282/5391/1145.pdf. *See also* NAT'L ACADEMIES, UNDERSTANDING STEM CELLS: AN OVERVIEW OF THE SCIENCE AND ISSUES FROM THE NATIONAL ACADEMIES 2 (2006), *available at* http://dels.nas.edu/dels/rpt_briefs/Understanding_Stem_Cells.pdf (In 1998, "a team of scientists from the University of Wisconsin-Madison became the first group to isolate human embryonic stem cells and keep them alive in the laboratory. The team knew that they had in fact isolated stem cells because the cells could remain unspecialized for long periods of time, yet maintained the ability to transform into a variety of specialized cell types, including nerve, gut, muscle, bone, and cartilage cells.").

4. *See, e.g.*, Nicholas Wade, *Scientists Cultivate Cells at Root of Human Life*, N.Y. TIMES, Nov. 6, 1998.

5. *See id.* (quoting Dr. Lori Andrews as saying that "[a]ny time you take a[n embryonic] cell off a blastocyst, that cell could be used itself to create a human being, so some groups in our society believe in making it transplantable you have derailed it into becoming a kidney or some other tissue"). It is to be noted that

> [a]long the wide spectrum of debate, there are those for whom embryonic stem cell research is acceptable as long as embryos are used with the consent of the egg and/or sperm donors . . . ; there are those who believe it is acceptable as long as it is done with embryos that would be destroyed anyway; and there are those for whom destroying even these 'extra' embryos is abhorrent, and creating embryos for research or therapy all the more so.

James Trefil, *Brave New World: Everything You Wanted to Know About Stem Cells, Cloning, and Genetic Engineering but Were Afraid to Ask*, *in* CRITICAL PERSPECTIVES ON STEM CELL RESEARCH 108, 119 (Brian Belval ed., 2006). *See also* MARSHA GARRISON & CARL E. SCHNEIDER, THE LAW OF BIOETHICS: INDIVIDUAL AUTONOMY AND SOCIAL REGULATION 841 (2003) (remarking that some argue that "because preeembryos have the

way to get such . . . cells was to pluck them from a human embryo several days after fertilization, destroying the embryo in the process."[6] Currently, over a decade later, new methods of embryonic stem cell retrieval allow for embryo preservation, which may quell much of the ethical debate, and it is commonly understood that embryonic stem cell research holds the key to medical advancement and the possibility of curing "complex and debilitating diseases and injuries."[7]

Despite the fact that embryonic stem cells are regarded as the holy grail of medicine, there is still no American federal regulatory scheme in place to deal with such research.[8] During his administration, President George W. Bush twice vetoed legislation that would support, promote, and fund embryonic stem cell research,[9] and consequently, individual

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capacity to become human beings . . . preeembryos are already human lives and thus cannot ethically be destroyed to benefit others").

6. Gina Kolata, *Scientists Bypass Need for Embryo to Get Stem Cells*, N.Y. TIMES, Nov. 21, 2007.

7. David Baltimore et al., Int'l Soc'y for Stem Cell Research Document, Stem Cell Science Leaders Say Nation Must Pursue All Avenues of Stem Cell Research 1 (Sept. 16, 2008), *available at* http://www.isscr.org/documents/ScienceStatementSept162008.pdf (also referring to embryonic stem cells as the "gold standard").

8. *See* Kristen Hicks, Note, *Embryonic Stem Cell Research and the Theory of Medical Self-Defense*, 21 HARV. J.L. & TECH. 547, 549 (2008) ("[C]urrently no federal law supports or bans embryonic stem cell research."). *See also* Maneesha Deckha, *The Gendered Politics of Embryonic Stem Cell Research in the USA and Canada: An American Overlap and Canadian Disconnect*, 16 MED. L. REV. 52, 71 (2008) ("The American debate at the federal level about the ethics of [embryonic stem cell research] is a product of multiple voices with competing values. . . . Yet, competing concerns that other countries with more liberal regimes will exceed American technological prowess in [embryonic stem cell research] and impair private enterprise, also explain why [President George W. Bush's 2001] federal ban for [embryonic stem cell research] on non-pre-existing stem cell lines only affects public funds. The overall American federal position is reasonably viewed as a conservative position on [embryonic stem cell research] that matches the conservative national position on abortion that is corroding the rights secured in [*Roe v. Wade*]."). It is to be noted, however, that the federal position on embryonic stem cell research is changing under the Barack Obama administration. For more information on the steps that have been taken by President Obama regarding embryonic stem cell research, see *infra* note 9.

9. In August 2001, President Bush announced that because embryonic stem cell research "offers both great promise and great peril," his administration would limit federal funding for such research to [sixty] pre-existing stem-cell lines. George W. Bush, President, U.S., Remarks on Stem Cell Research (Aug. 9, 2001), *available at* http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html. For a thorough understanding of the implications of George W. Bush's 2001 decision, see MOONEY, *supra* note 1, at 188–89 ("George W. Bush's 2001 decision so dramatically constricted the potential of research by limiting federal funding to embryonic stem cell lines already in existence as of August 9, 2001. At least for scientists in need of federal funding, the Bush policy ei-

states have chosen not to wait.[10] Several states have not only legalized embryonic stem cell research, but also authorized millions in funding and

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ther entirely blocks or substantially impairs [them from doing so,] . . . not to mention stifl[es] more basic research aimed at understanding the properties of human embryonic stem cells in the first place. . . . [The Bush-approved lines were limited in number, but] hardly represent[ed] the genetic diversity of America, much less the world. . . . Rather, they contain[ed] the genes of affluent, mostly white Americans with fertility problems" who had sought out IVF, and thus, because not used for implantation, may also "have been flawed or undesirable to begin with."). Despite Bush's 2001 announcement, research plowed forward. *See* Roland Jones, *After California, More States Eye Stem Cell Research*, MSNBC.COM, Feb. 9, 2005, http://www.msnbc.msn.com/id/6847933 (discussing how some states have donated millions to the embryonic stem cell research effort). In July 2006, Bush "issued the first veto of his . . . administration[,] . . . rejecting Congress's bid to lift funding restrictions on human embryonic stem cell research." Charles Babington, *Stem Cell Bill Gets Bush's First Veto*, WASH. POST, July 20, 2006, at A04. And similarly, in June 2007, he vetoed the Stem Cell Research Enhancement Act of 2007, which "would have allowed the use of federal funds to support embryonic stem cell research," remarking that "[d]estroying human life in the hopes of saving human life is not ethical—and it is not the only option before us." Maura Reynolds, *Bush Vetoes Embryonic Stem Cell Funding*, L.A. TIMES, June 21, 2007, at A12 (discussing Bush's veto of the Stem Cell Research Enhancement Act of 2007).

Since President Barack Obama's induction as the 44th President of the United States, the federal position on embryonic stem cells has been changing. President Obama is a supporter of the effort and has recently issued an executive order reversing George W. Bush's 2001 directive limiting stem cell research. Exec. Order., Removing Barriers to Responsible Scientific Research Involving Human Stem Cells (Mar. 9, 2009), *available at* http://www.whitehouse.gov/the_press_office/Removing-Barriers-to-Responsible-Scientific-Research-Involving-Human-Stem-Cells/. *See also* Sheryl Gay Stolberg, *Obama Lifts Bush's Strict Limits on Stem Cell Research*, N.Y. TIMES, Mar. 10, 2009 (explaining President Obama's executive order and quoting him as saying that "the majority of Americans 'have come to a consensus that we should pursue this research; that the potential is great, and with proper guidelines and strict oversight the perils can be avoided'"). President Obama has not, however, addressed "the thorniest question in the debate: whether taxpayer dollars should be used to experiment on embryos themselves"; he intends to "leave it to Congress to determine whether the long-standing legislative ban on federal financing for human embryo experiments should also be overturned." Sheryl Gay Stolberg, *Obama Is Leaving Some Stem Cell Issues to Congress*, N.Y. TIMES, Mar. 8, 2009. *See also* Maggie Fox, *Stem Cell Bill Research Supporters Offer Senate Bill*, REUTERS, Feb. 26, 2009 (noting how the Stem Cell Research Enhancement Act of 2007, vetoed by Bush, has been reintroduced by Senators Tom Harkin and Arlen Specter). Thus, as it stands on March 11, 2009, President Obama's new executive order will open the door for change, but federal funding has not been approved, nor has an embryonic stem cell regulatory scheme been established.

10. *See, e.g.*, Richard Guerra, *States Take the Initiative to Regulate and Resolve the Stem Cell Debate*, 7 FLA. COASTAL L. REV. 35, 39 (2005) ("In the absence of federal regulation on the issue, states have been busy developing their own legislation regulating research, funding and possible liabilities associated with stem cell research and human embryonic cloning."). George W. Bush's decision to decline to fund the embryonic stem

developed institutes to administer state stem cell research programs.[11] California, for example, passed Proposition 71 in November of 2004,[12] which

> provided $3 billion in funding for [all kinds of] stem cell research at California universities and research institutions . . . and called for the establishment of a new state agency [the California Institute for Regenerative Medicine] to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.[13]

However, there are also states that specifically prohibit most or all forms of embryonic stem cell research, like Arkansas, Louisiana, North Dakota, and South Dakota.[14] Other states, like Iowa, permit embryonic stem cell research but do not fund the effort.[15] States like North Carolina and West Virginia have no law on the subject.[16] And some states are

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cell research effort has also spurred a bit of a "brain drain," as some researchers have opted to move to other countries, such as "Britain, Singapore and China, where the governments [a]re more receptive to their work." Alice Park, *The Quest Resumes*, TIME, Feb. 9, 2009, at 41. *See also Embryonic Stem Cells: Can I Serve You Now?*, ECONOMIST, Jan. 31, 2009, at 85 (noting that with a federal regulatory scheme supporting embryonic stem cell research, "American academics will no longer have to watch enviously from the sidelines as their colleagues in Australia, Britain, China, the Czech Republic, Israel, Singapore and South Korea push ahead").

11. These states include California, Connecticut, Illinois, Maryland, Massachusetts, New Jersey, New York, and Wisconsin. *See* Christine Vestal, *Stem Cells: States Divide*, STATELINE.ORG, June 21, 2007, http://www.stateline.org/live/details/story?contentId=218416 (last visited Jan. 11. 2009); National Conference of States Legislatures, State Embryonic and Fetal Research Laws, http://www.ncsl.org/programs/health/Genetics/embfet.htm (last visited Jan. 11, 2009). Most recently, Michigan voted in favor of Proposal 2 in November of 2008, legalizing embryonic stem cell research so long as the embryos used for such research would otherwise be discarded, and allowing for government funding. *See* Jeff Karoub, *Michigan Voters Approve Stem Cell Research Measure*, CHI. TRIB., Nov. 5, 2008.

12. *California Gives Go-Ahead to Stem-Cell Research*, MSNBC.COM, Nov. 3, 2004, http://www.msnbc.msn.com/id/6384390/ [hereinafter *California Gives Go-Ahead*].

13. California Institute for Regenerative Medicine, http://www.cirm.ca.gov/ [hereinafter CIRM] (last visited Nov. 3, 2008).

14. National Conference of States Legislatures, *supra* note 11. *See also* Guerra, *supra* note 10, at 41–42 (noting that South Dakota law, like Arkansas law, "has the effect of banning any and all forms of embryonic stem cell research regardless of the possible therapeutic applications that the research was designed to explore").

15. Iowa's Stem Cell Research Enhancement Act, passed in 2007, repealed a prior ban on embryonic stem cell research and ensured the research's legality. *See* Vestal, *supra* note 11; Press Release, Office of Governor Chet Culver, Gov. Culver Provides Facts on Stem Cell Research (Feb. 14, 2007).

16. National Conference of States Legislatures, *supra* note 11.

deadlocked on the issue, like Florida.[17] Clearly, "a void of nationally cohesive regulation on the issue [of embryonic stem cell research] remains,"[18] and this lack of uniformity among states will cause only some states to prosper economically and medically, with others lagging behind.[19] It will also be difficult for researchers to engage in interstate collaboration.[20] Most importantly, however, this wide range of embryonic stem cell research policy and regulation makes the United States look polarized and in disarray, with the more "blue" states surging ahead with research and the more "red" states sticking to a conservative approach, likely due to religious influence.[21]

It is necessary for the United States to construct a federal framework of rules and guidelines to govern the use of embryos for research purposes, particularly since American society is one that aspires towards both gov-

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17. In Florida, two initiatives regarding embryonic stem cell research began circulating in 2005—one requiring state support of embryonic stem cell research and the other prohibiting it. In 2007, the Florida Supreme Court was asked to review these bills because of their opposition to each other, and it approved both to be placed on the 2008 ballot. *See Advisory Opinion to the Attorney General Re: Funding of Embryonic Stem Cell Research*, Nos. SC06-2183 & SC06-2261 (May 31, 2007), *available at* http://www.floridasupremecourt.org/decisions/2007/SC06-2183.pdf; Deanna Poole, *Stem Cells Debated Around Tallahassee*, PALM BEACH POST, Apr. 17, 2007, http://www.palmbeachpost.com/business/content/state/epaper/2007/04/17/a13a_xgr_stemcell_0417.html. The two competing proposals failed to make the 2008 ballot, with both initiatives still pending. Tim Martin, *Michigan Voters to Decide Stem Cell Research Measure,* ASSOCIATED PRESS, Oct. 4, 2008 ("In Florida, two competing stem cell proposals failed to make the ballot this year. One proposal would have banned state funding of embryonic stem cell research, while the other would have required the state to provide $20 million a year for such research.").

18. Guerra, *supra* note 10, at 39.

19. *See, e.g.*, *id*. at 39–43. For example, Arkansas and South Dakota, which both, in essence, prohibit embryonic stem cell research and development, ranked in 2002 in the bottom third of states

> for the total amount that [their] universities expended on research and development; . . . for the amount received from the National Institute of Health in support of its research institutions; . . . in the amount of higher education degrees awarded in the biological sciences; [and] . . . in the amount of biological scientists that compromise the[ir] workforce.

Id. at 41–43 (internal citations omitted). Both states' employment in the national research and development market was 0.1% in 2002. *Id*.

20. Joe Palca, *States Take Lead in Funding Stem-Cell Research*, NPR.ORG, Mar. 30, 2007, http://www.npr.org/templates/story/story.php?storyId=9244363.

21. *See* Deckha, *supra* note 8, at 71 (noting that the embryonic stem cell research ethical debate "has occurred in the shadow of a political and legal landscape that is indelibly marked by religious influences and polarized views on abortion and the beginning of human life in particular").

ernment monitoring and a green light for research. Countries like the United Kingdom[22] have thorough regulation for embryonic stem cell research, and even Germany, which has been notoriously "conservative about genetic research,"[23] has passed the Stem Cell Act of 2008, which allows for the importation of "human embryonic stem cell lines that were extracted before May 1, 2007."[24] In order for the United States to stay at the forefront of medical research, be able to develop new drugs to cure disease, and be able to pioneer new technologies to aid in the transplantation of organs and tissue, our nation needs to dispel ambiguities and unite our country's states with thorough regulation that supports and funds embryonic stem cell research.

This Note will explore the progress of embryonic stem cell research in the United States and will argue for thorough federal regulation on the subject. Specifically, it will look to the regulatory models in the United Kingdom and in the state of California for guidance, as well as the Bush-vetoed Stem Cell Research Enhancement Act of 2007, and will discuss what the best approach is and in which direction the United States ought to move. This Note proceeds in four parts. Part I examines why embryonic stem cells are so vital to medical research, as well as how they can help our generation and future generations. Part II addresses the traditional ethical arguments against embryonic stem cell research, looking to the pro-life commentary, which argues that it is immoral to use embryonic stem cells for medical experimentation. Part II then explains why the medical benefits of embryonic stem cell research trump the moral concerns, particularly in light of new techniques of embryonic stem cell extraction. Part III examines the regulatory models of the United Kingdom and California, as well as the Stem Cell Research Enhancement Act of 2007. Finally, Part IV notes where the three aforementioned models

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22. For the regulation in the United Kingdom, see Human Fertilisation and Embryology (Research Purposes) Regulations, No. 188 (2001) (U.K.), *available at* http://www.opsi.gov.uk/SI/si2001/20010188.htm [hereinafter 2001 Regulations] (last visited Nov. 3, 2008); Human Fertilisation and Embryology Act, ch. 37 (1990) (U.K.), *available at* http://www.opsi.gov.uk/Acts/acts1990/pdf/ukpga_19900037_en.pdf [hereinafter 1990 Act]. *See also* Select Committee on Stem Cell Research Report, Feb. 13, 2002, *available at* http://www.parliament.thestationeryoffice.co.uk/pa/Id200102/Idselect/Idstem/83/8302.htm.There is also a pending bill in the United Kingdom termed the Human Fertilisation and Embryology Bill [HL] 2007–2008. Human Fertilisation and Embryology Bill [HL] (2007–2008) (U.K.), *available at* http://www.publiccations.parliament.uk/pa/cm200708/cmbills/120/2008120.pdf.

23. *German Lawmakers Loosen Limits on Stem Cell Research*, SPIEGEL ONLINE, Apr. 11, 2008, http://www.spiegel.de/international/germany/0,1518,546867,00.html.

24. Dorothee Bürkle, Discussion, Goethe-Institut (Aug. 2008) (Jonathan Uhlaner trans.), http://www.goethe.de/wis/fut/thm/deb/en3610292.htm.

agree and divide, and proposes what an American embryonic stem cell regulatory model should look like and why.

I. EMBRYONIC STEM CELL RESEARCH AS HOPE FOR THE FUTURE

A. Stem Cells: A Background

A stem cell is a single cell that has the capacity to both replicate itself ("self-renew") and differentiate into many different cell types ("specialize").[25] Stem cells are like "blank microchip[s] that can ultimately be programmed to perform particular tasks"—under certain conditions, they will begin to distinguish themselves and turn into specialized cells that carry out a specific function for the body.[26] There are three different types of stem cells, embryonic stem cells, fetal stem cells, and adult stem cells.[27]

Five days after a sperm fertilizes an egg, a blastocyst is born—a five-day-old embryo.[28] The blastocyst "contains all the material necessary for the development of a complete human being," but at five days, is "a mostly hollow sphere of cells that is [incredibly] small[]."[29] Inside the interior of the blastocyst is the "inner cell mass, which is composed of [thirty to thirty-four] cells that are referred to by scientists as pluripotent because they can differentiate into all of the cell types of the body"; these inner cell mass cells, when removed, are laced "in a culture dish with a nutrient-rich liquid where they give rise to embryonic stem cells."[30]

Fetal stem cells, on the other hand, are derived from fetal tissues and are also termed "embryonic germ cells."[31] Fetal stem cells "come from the primordial germ cells of a [five to ten] week-old embryo/foetus."[32]

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25. Deckha, *supra* note 8, at 55–56; NAT'L ACADEMIES, *supra* note 3, at 3.

26. INT'L SOC'Y FOR STEM CELL RESEARCH, STEM CELL FACTS: THE NEXT FRONTIER? (2008), *available at* http://www.isscr.org/public/ISSCR08_PubEdBroch.pdf.

27. Deckha, *supra* note 8, at 55–56.

28. NAT'L ACADEMIES, *supra* note 3, at 4.

29. *Id.*

30. *Id.* at 4–5. *See also* Deckha, *supra* note 8, at 56 ("Embryonic stem cells are extracted from the inner cell mass of the 4–5 day old embryo, called the blastocyst, which consists of 50–150 cells. Embryonic stem cells are pluripotent; they can develop into almost all cell types of the foetus and the adult body."). Yet while embryonic stem cells are pluripotent, they are not totipotent—that is, "they cannot develop into placental cells." *Id.*

31. Deckha, *supra* note 8, at 56. An embryo becomes a "fetus" at eight weeks. Stages of Development: Normal Pregnancy: Merck Manual Home Edition, http://www.merck.com/mmhe/sec22/ch257/ch257c.html (last visited Jan. 11, 2009).

32. Deckha, *supra* note 8, at 56.

They, too, are pluripotent, but have different properties, live for less time, and "have a more limited range of potential specialization."[33]

Lastly, adult stem cells are stem cells obtainable from adult tissues.[34] While they "retain the ability to renew themselves for the lifetime of the organism,"[35] they are "not found in all tissues."[36] It is currently being debated whether adult stem cells can, like embryonic stem cells, undergo transdifferentiation—that is, give rise to a cell of a different tissue type.[37] Moreover, adult stem cells cannot multiply at the rate of embryonic stem cells[38] and are "difficult to identify, isolate, maintain, and grow in the laboratory."[39]

B. Why Scientists Are Particularly Interested in Embryonic Stem Cells

Embryonic stem cells are the most versatile type of stem cell because "they have the potential to produce every [single] cell type in the human body."[40] Their ability to self-renew quickly is also very beneficial, as "just a few embryonic stem cells can build a large bank of stem cells to be used in experiments."[41] Accordingly, scientists believe that human embryonic stem cells have "great scientific, technological and therapeutic potential."[42] Namely, embryonic stem cells "could generate specia-

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33. *Id. See also* University of Edinburgh: Social and Political Studies, What is Stem Cell Research?, http://www.talkingstemcells.ed.ac.uk/index.php?action=ShowAll&id=12 (last visited Nov. 3, 2008) ("The advantages of foetal stem cells are that they are easy to collect and they have a lower rejection rate compared to bone marrow transplants. Because of targeted collections, they also offer a greater chance of transplant matches for ethnic minorities . . . . [However, t]he risk of transmitting illness through foetal stem cells . . . raises new problems that scientists and clinicians have to address. Since this research is new and experimental, it is still unclear what the specific risks are or how to resolve them.").

34. Deckha, *supra* note 8, at 56; NAT'L ACADEMIES, *supra* note 3, at 8.

35. Deckha, *supra* note 8, at 56.

36. NAT'L ACADEMIES, *supra* note 3, at 8.

37. Suzanne Kadereit, *The Plasticity of Stem Cell Plasticity*, ISSCR.ORG, Apr. 2004, at 1, *available at* http://www.isscr.org/scientists/TOM/printversions_archive/TOM_Apr_04.pdf.

38. Deckha, *supra* note 8, at 56.

39. NAT'L ACADEMIES, *supra* note 3, at 8.

40. *Id.* at 5.

41. *Id.* However, "undifferentiated stem cells [cannot] be used directly for tissue transplants because they can cause a type of tumor called a teratoma. To be used for therapies, embryonic stem cells would first need to be differentiated into specialized cell types." *Id.*

42. Natasha Hammond & Soren Holm, *Resolving the "Egg Supply Problem" in Human Embryonic Stem Cell Derivation Through Technical Means—A Legal and Ethical Analysis*, 27 MED. & L. 167, 167 (2008).

lized tissue for transplantation"[43] and could be used "to treat currently untreatable diseases such as Parkinson's Disease, diabetes, traumatic spinal cord injury, and heart disease."[44]

Yet, many believe that "anything that can be done with embryonic stem cells can be accomplished with adult stem cells,"[45] and that the plasticity of stem cells—that is, their ability to differentiate into a variety of cell types—is equivalent to that of embryonic stem cells. Much research indicates that "adult stem cells continue to ignore the dogma of developmental biology, [for example] . . . blood cells switching to lung cells."[46] Other studies, such as a highly regarded study conducted by Irving Weissman of Stanford University and Amy Wagers of Harvard University, indicate that plasticity "may not be a biological principle but rather an experimental peculiarity."[47] Specifically, Weissman and Wagers' study noted both technical problems and cell fusion, "resulting in cells that masquerade as 'transdifferentiated' cells."[48] Weissman and Wagers also "combed through the [existing] literature" and concluded "that reports of adult stem plasticity may be due to other reasons than cells switching their fates."[49] As the plasticity of adult stem cells is controversial, it is clear that for the moment embryonic stem cells have greater therapeutic power. Thus, research must be conducted on embryonic stem cells in order to break ground on medical therapies and procedures.

Lawrence S. B. Goldstein, a professor at the University of California-San Diego and the Director of the UC San Diego Stem Cell Program,[50] explained in a 2004 speech at Rice University why researchers are interested in embryonic stem cell research. Goldstein stated that "because of their unique attributes, embryonic stem cells could help us bypass four current 'bottlenecks' in the development of medical therapies."[51] His theory is as follows:

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43. MOONEY, *supra* note 1, at 187.

44. Yi-Chen Su & Albert Wai-Kit Chan, *Mary Doe's Destiny: How the United States Has Banned Human Embryonic Stem Cell Research in the Absence of a Direct Prohibition*, 14 RICH. J.L. & TECH. 12, ¶ 11 (2008), http://law.richmond.edu/jolt/v14i4/article12.pdf.

45. CHRISTOPHER THOMAS SCOTT, STEM CELL NOW 89 (2006).

46. *Id.* at 90 (reports by the Karolinska Institute in Sweden).

47. *Id.* at 91. For the study itself, see Amy Wagers et al., *Little Evidence for Developmental Plasticity of Adult Hematopoietic Stem Cells*, 297 SCIENCE 2256, 2256–59 (2002).

48. Kadereit, *supra* note 37, at 1.

49. SCOTT, *supra* note 45, at 91, 93.

50. *See* News Release, Debra Kain, UC San Diego Appoints Larry Goldstein Director of Stem Cell Research Program, Sept. 22, 2006, *available at* http://ucsdnews.ucsd.edu/newsrel/health/goldstein06_a.asp.

51. MOONEY, *supra* note 1, at 187.

> First, there [are not] enough sources of tissues for transplantation to meet medical needs at present, but we might grow vast amounts of tissues from embryonic stem cells. Second, drugs are extremely expensive to bring to market because of the cost of human trials and because animal trials can often lead scientists down the wrong road, but drug discovery might proceed much more efficiently if we could test drugs in human stem cell preparations. Third, we currently lack a complete understanding of the mechanisms by which many diseases develop, but research on stem cells bearing the generic signature for various diseases would allow for greater understanding of how these conditions emerge (which, in turn, could suggest new possibilities for treatment). And finally, we see enormous variations among individuals when it comes to their responses to various drugs and other therapies, but certain kinds of stem cells would eventually lead to therapies specially tailored to individual patients.[52]

Goldstein's explanation clearly demonstrates that stem cell research is "not a one trick pony," but rather, a "broad enabling technology" that could help us in many different areas of medicine.[53]

II. DEFEATING THE ETHICAL CONCERNS

A. The Traditional Argument: The Moral Status of the Embryo

> *"In the field of regenerative medicine, embryonic stem cell research holds far-reaching promise in alleviating and preventing an array of debilitating diseases and conditions. Yet the biggest ethical stumbling block continues to be conflicting beliefs about the moral status of the human embryo."*[54]

As the traditional method of removal for embryonic stem cells destroys the blastocyst, many have argued that this involves the "intentional[] creati[on of] a blastocyst that will never develop into a human being," and, accordingly, that it is immoral to use them for medical experimentation.[55] Much of the traditional argument has religious influence, particu-

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52. *Id.* at 187–88 (discussing Goldstein's speech at the *Stem Cells: Saving Lives or Crossing Lines—Human Embryonic Stem Cell Policy* forum at Rice University in 2004). *See also* Stem Cells: Saving Lives or Crossing Lines—Program Day 1, http://www.ruf.rice.edu/~neal/stemcell/program1.html (last visited Nov. 4, 2008) (demonstrating that Dr. Goldstein delivered this speech).

53. MOONEY, *supra* note 1, at 188.

54. Michael Brannigan, *Fixations on the Moral Status of the Embryo*, *in* BIOMEDICAL ETHICS REVIEWS: STEM CELL RESEARCH 41, 41–57 (James H. Humber & Robert F. Almeder eds., 2004).

55. NAT'L ACADEMIES, *supra* note 3, at 6.

larly that of the Roman Catholic Church, which "has declared its formal opposition to [embryonic stem cell research] despite the prospective medically beneficial potential, urging . . . lawmakers and scientists to promote the use of methods that would not entail resorting to embryos for stem cell research."[56] The Church believes that "life and personhood begins at conception and that [pre]embryos are sacred forms of life because they are human beings who deserve the respect and protection that being human affords."[57] Persons of the Eastern Orthodox Christian, Islamic, and Protestant faiths have also expressed their opposition to embryonic stem cell research, often utilizing a "sanctity of life" argument.[58]

Pro-life advocates have also had a "prominent voice shaping [embryonic] stem cell discourse," particularly in spurring opposition to it.[59] The religious and anti-abortion views are very similar: both follow the idea that "human life is sacred and personhood begins at conception."[60] However, since abortion law and politics is such a dense topic, I have chosen to limit Part II(a) of this Note to a synopsis of the traditional argument against embryonic stem cell research, and would merely like to note that some courts have viewed pre-embryos as humans in wrongful death actions and have "increase[d] the scope and nature of the interest that states can recogni[z]e in fetuses when regulating abortion,"[61] which not only puts *Roe v. Wade* in "precarious standing" but also demonstrates the impact of pro-life philosophy on American decision making.[62]

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56. Deckha, *supra* note 8, at 62.

57. *Id.* at 63.

58. *Id. But see* Margaret A. Farley, *Roman Catholic Views on Research Involving Human Embryonic Stem Cells*, *in* THE HUMAN EMBRYONIC STEM CELL DEBATE (Suzanne Holland, Karen Lebacqz & Laurie Zoloth eds., 2001) (noting that while some Roman Catholics disagree with embryonic stem cell research, there is also "a case for human embryo stem cell research . . . within the Roman Catholic tradition," since "[g]rowing numbers of Catholic moral theologians, for example, do not consider the human embryo in its earliest stages (before development of the primitive streak or implantation) to constitute an individualized human entity with the settled inherent potential to become a human being."). However, there is "widespread Jewish support for stem-cell research . . . [partly because of] the high regard that 'the Jewish vision places on life and on healing . . . and on the good of medicine.'" *The Moral Status of the Embryo*, HARV. MAG., May–June 2007, at 66–67, *available at* http://harvardmag.com/pdf/2007/05-pdfs/0507-66.pdf. *See also* Elliot N. Dorff, *Stem Cell Research—A Jewish Perspective*, *in* THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* (explaining why the Jewish tradition may allow for embryonic stem cell research).

59. Deckha, *supra* note 8, at 64.

60. *Id.* at 65.

61. *Id.*

62. *Id.* at 65–67.

Opponents of embryonic stem cell research believe that the blastocyst possesses a moral status,[63] and because "we tend to think of moral status as simply being synonymous with the ownership of moral rights . . . moral status equals having moral rights."[64] Thus, for the person who believes blastocysts should have moral status, since "there is no more fundamental moral right than the right to exist . . . [and] the moral right to exist is fundamental . . . [t]he moral right to exist is therefore a foundational right."[65] Some scholars have argued that there should be more flexibility with regard to the moral status of the blastocyst,[66] but staunch pro-life advocates see the blastocyst's moral status as static.[67]

B. The Benefits of Embryonic Stem Cell Research Trump the Moral Argument

Legal, medical, and sociological scholars alike have stated that embryonic stem cells "have the potential to provide a limitless source of specific cell types for transplantation,"[68] organ creation, tissue regeneration, nerve repair, and so on, which could aid in alleviating the "debilitating conditions"[69] of so many persons around the globe. Michael Brannigan has argued that "[b]ecause the benefits of embryonic stem cell research clearly outweigh the burdens, the moral status of [persons who

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63. *See, e.g.*, ROBERT P. GEORGE & CHRISTOPHER TOLLEFSEN, EMBRYO: A DEFENSE OF HUMAN LIFE 202–03 (2008) (arguing that pre-embryos are human beings, that "any scientific research conducted on embryonic humans, and destructive of their life or health, is wrong, immoral, unjust," and that "[n]o scientist, or any other agent, should ever willingly engage in activities that would deliberately threaten the life or health of human beings at any stage of development or in any condition").

64. Brannigan, *supra* note 54, at 45.

65. *Id.* Brannigan constructs his "equation" as follows: "moral status equals possessing moral rights equal possessing the right to exist." *Id.* Accordingly, for a person fixated on the moral status of the blastocyst, establishing that the blastocyst does indeed have such a status leads to the necessary conclusion that the blastocyst "has an absolute right to an existence." *Id.*

66. *See, e.g.*, *id.* at 54. *See also* Brent Waters, *Does the Embryo Have a Moral Status?*, *in* GOD AND THE EMBRYO: RELIGIOUS VOICES ON STEM CELLS AND CLONING 64–76 (Brent Waters & Ronald Cole-Turner eds., 2003) (Although a Christian who finds himself ambivalent towards embryonic stem cell research, Waters does find there to be many problems with assigning a "moral status" to the embryo, and suggests viewing the embryo as a "neighbor," rather than an "abstract object[] to which . . . [there] must [be] assign[ed] a value or moral status.").

67. *See, e.g.*, GEORGE & TOLLEFSEN, *supra* note 63, at 22 ("We argue in this book that embryonic human beings deserve full moral respect.").

68. James A. Thomson, *Human Embryonic Stem Cells*, *in* THE HUMAN EMBRYONIC STEM CELL DEBATE, *supra* note 58, at 22.

69. Brannigan, *supra* note 54, at 52.

suffer from debilitating diseases and conditions] clearly ha[ve] priority over the moral status of the early embryo."[70] Brannigan joins philosopher Mary Anne Warren in arguing for a sliding-scale approach to moral status.[71] While I will not go to the same extent as Brannigan to say that the moral status of diseased persons trumps the moral status of the blastocyst, under a cost-benefit analysis, this nation should fully support embryonic stem cell research by implementing a federal regulatory scheme so that "other countries will no[t] . . . outpace the United States in embryological science."[72]

With the benefits being so great—the capacity to understand disease, the potential to save so many peoples' lives, and the ability to remain at the forefront of medical research and development—it is difficult for the moral argument to trump the need for this kind of medical research. Utilitarian ethicists would agree that the ultimate beneficence of this science justifies the cost,[73] particularly because adult stem cell research is not an alternative that would rationalize abandoning the great promise of embryonic stem cell research. Furthermore, embryonic stem cell research still shows respect to the embryo, just "respect of a different kind": as argued by Heather Johnson Kukla, "by allowing spare embryos to be used in stem cell research to enhance the lives of people who otherwise would continue to suffer," the embryo becomes "a powerful symbol of human life [and] . . . more respected and valued . . . than when it is simply discarded."[74]

Another argument in favor of embryonic stem cell research is that the blastocysts used in such research are doomed for destruction anyway, and serve no other purpose. Embryonic stem cells traditionally come from blastocysts created at fertility clinics, and "[b]ecause not all the fertilized eggs are implanted [in the woman's womb], a large bank of 'excess' blastocysts [remains with many blastocysts] that are currently

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70. *Id.*

71. *Id.* at 41–57.

72. *Id.* at 55.

73. *See, e.g.*, Marianne Means, Editorial, *Undeveloped Human Tissue Can Help Save the Living*, SEATTLE POST-INTELLIGENCER, Sept. 28, 2000, at B4 ("The political struggle over abortion intrudes once again on an issue crucial to the health of millions of Americans, pitting reverence for undeveloped, unborn human tissue against potential advances in medical treatment for living men, women and children. . . . Where should the compassion lie? With inanimate, non-breathing embryonic stem cells or disabled and sick friends and family members needing medical help? No contest, I say. Save the living.").

74. *See, e.g.*, Heather Johnson Kukla, Note, *Embryonic Stem Cell Research: An Ethical Justification*, 90 GEO. L.J. 503, 531 (2002).

stored in freezers around the country."[75] These in-vitro fertilization ("IVF") leftovers, if not used for a future pregnancy, donated to another couple, or used for research, are discarded,[76] so they might as well provide researchers with the opportunity to "learn[] about early human developmental processes that they otherwise can[not] access, modeling disease and establishing strategies that could ultimately lead to therapies to replace or restore damaged tissues."[77]

C. Reducing Controversy: Blastomere Biopsy

In order to reduce controversy, scientists have strived to find other methods for producing embryonic stem cells that do not damage the embryo.[78] Most recently, a new technique known as blastomere biopsy has come about, which relies on the pre-implantation genetic diagnosis ("PGD") procedure.[79] Blastomere biopsy is "performed on a two-day-old embryo, after the fertilized egg has divided into eight cells, known as blastomeres."[80] When a woman is undergoing IVF at a fertility clinic, "the embryo is available outside the woman" and "one of these blasto-

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75. NAT'L ACADEMIES, *supra* note 3, at 5. *See also* Deckha, *supra* note 8, at 57–58; INT'L SOC'Y FOR STEM CELL RESEARCH, *supra* note 26, at 3.

76. *What to Do with Leftover Embryos in Fertility Clinics?*, SCIENCEDAILY.COM, Sept. 25, 2008, http://www.sciencedaily.com/releases/2008/09/080924162942.htm.

77. INT'L SOC'Y FOR STEM CELL RESEARCH, *supra* note 26, at 4.

78. This Note will discuss the blastomere biopsy procedure, but there is another potential source of embryonic stem cells: somatic cell nuclear transfer ("SCNT"). SCNT is a process by which "an egg has its original nucleus including its genetic material removed and replaced with that of a donor cell[, the 'somatic cell']. The egg is then coaxed into developing as if it had been fertilized, dividing to the blastocyst stage from which embryonic stem cells can be derived." INT'L SOC'Y FOR STEM CELL RESEARCH, *supra* note 26, at 4. *See also* Deckha, *supra* note 8, at 58 ("SCNT refers to the cloning method whereby the nucleus of a donor cell . . . itself is implanted into an egg from which the nucleus has been removed. The egg is then electrically charged to simulate fertilization."). SCNT involves no sperm and "[c]loning occurs because the receiving enucleated egg starts to grow as an embryo, but carries the identical genetic makeup of the donor somatic cell, that has not been mixed or adulterated with genetic information from a second person through sperm." Deckha, *supra* note 8, at 58. As SCNT is a cloning procedure, it is extremely controversial. *See id.* Furthermore, "[the] method has been shown to work for certain animals such as mice but has proven extremely difficult in humans." INT'L SOC'Y FOR STEM CELL RESEARCH, *supra* note 26, at 4.

79. PGD "is a marriage of IVF and prenatal diagnosis" and "involves two stages: IVF/embryo biopsy and genetic testing" in order to detect genetic defects in embryos created via IVF. JOYCE C. HARPER, JOY D.A. DELHANTY & ALAN H. HANDYSIDE, PREIMPLANTATION GENETIC DIAGNOSIS 3 (2001).

80. Nicholas Wade, *Stem Cell News Could Intensify Political Debate*, N.Y. TIMES, Aug. 24, 2006 (noting critics' objections to the blastomere biopsy procedure).

meres can be removed for diagnostic tests, like for Down syndrome."[81] If there are no abnormalities found when that single blastomere is tested, then the embryo, now with seven cells, can "be implanted into a mother's womb,"[82] and the extracted blastomere can be used for research. This procedure differs from the traditional method of embryonic stem cell retrieval in that it derives the cells at an earlier stage of development, and instead of destroying the embryo, leaves the embryo intact.[83]

The pioneer of this procedure, Dr. Robert Lanza, has stated that extracting the blastomere (that is, the embryonic cell) is unlikely to pose any additional risk to the embryo,[84] other than the risks inherent in PGD, and that the procedure itself "does not itself harm or destroy embryos," making it morally acceptable.[85] That is not to say that blastomere biopsy is perfect and without controversy. Ethical questions still abound, as it is uncertain whether the procedure will always be safe for the resulting fetus and child,[86] and there is still a risk that embryos may be harmed or destroyed.[87] PGD currently has an embryo survival rate of eighty percent,[88] and while Dr. Lanza "s[eeks] to piggyback on [PGD's] safety

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81. *Id.*

82. Dan Vergano, *Embryos Spared in Stem Cell Creation*, USA TODAY, Aug. 23, 2006, *available at* http://www.usatoday.com/tech/science/discoveries/2006-08-23-stem-cell-breakthrough_x.htm.

83. Karen Kaplan, *Stem Cell Advance Spares Embryos*, L.A. TIMES, Aug. 24, 2006, at A1; Helen Pearson, *Early Embryos Can Yield Stem Cell . . . And Survive*, 442 NATURE 858, Aug. 24, 2006.

84. I. Klimanskaya et al., *Human Embryonic Stem Cell Lines Derived from Single Blastomeres*, 444 NATURE 481, 481 Nov. 23, 2006, *abstract available at* http://www.nature.com/nature/journal/v444/n7118/abs/nature05142.html (last visited Jan.11, 2009); Wade, *supra* note 80, ¶ 15. *See also* Editorial, *A Way Out? Scientists Might Now Be Able to Harvest Stem Cells Without Harming Embryos*, WASH. POST, Aug. 28, 2006, at A14 [hereinafter Editorial] (discussing blastomere biopsy, why it could defeat the moral argument, and why federal regulation and funding for embryonic stem cell research should be possible).

85. Ethics Advisory Board for Advanced Cell Technology, Inc., *Human Embryonic Stem Cell Lines Derived from Single Blastomeres*, http://www.advancedcell.com/recent-news-item/ethics-advisory-board-for-advanced-cell-technology-inc-human-embryonic-stem-cell-lines-derived-from-single-blastomeres [hereinafter ACT] (last visited Nov. 4, 2008).

86. Cynthia S. Marietta, Comment, *Embryonic Stem Cell Research Debate Indirectly Focuses Spotlight on Safety of Pre-implantation Genetic Diagnosis*, HEALTH L. PERSPS., June 11, 2008, at 3, *available at* http://www.law.uh.edu/healthlaw/perspectives/2008/(CM)%20pgd.pdf; Pearson, *supra* note 83, at 858.

87. Marietta, *supra* note 86, at 3.

88. Brandon Keim, *Embryonic Stem Cells Created Without Harming Embryo, for Real This Time*, WIRED, Jan. 10, 2008, at 2, *available at* http://www.wired.com/medtech/stemcells/news/2008/01/blastocyst_biopsy.

record,"[89] such may seem too low for staunch pro-life advocates.[90] But if Lanza's predictions for the safety of blastomere bioscopy are indeed correct, this may reduce the controversy that surrounds embryonic stem cells.

Currently, "there [is] no evidence that a single blastomere [removed during the blastomere biopsy procedure] could develop into a person."[91] If it were proven that a single blastomere could never become a human being, then there is no pro-life, religious argument for challengers to rely on. In sum, assuming the blastomere biopsy procedure is thoroughly vetted and everything articulated by its pioneers is "demonstrated to be viable,"[92] there leaves no "rational reason[, or moral one, for that matter,] to oppose this [method of extraction and embryonic stem cell] research."[93]

D. Embryonic Stem Cell Near Equivalents

Researchers have also been busy creating embryonic stem cell near equivalents. Harvard University researchers have created induced pluripotent stem cells ("iPS cells")—that is, they have induced "adult stem cells into an embryonic-like state without forming tumors," which "are one of the efficacy problems, along with immune system rejection issues, that plague embryonic stem cells."[94] However, the success of iPS cells has only been demonstrated in mice.[95] Scientists have also recently re-

89. Kaplan, *supra* note 83, ¶ 17. There is little comprehensive data about PGD's accuracy and the effects it has on children. *See, e.g.*, Susannah Baruch et al., *Genetic Testing of Embryos: A Critical Need for Data*, 11 REPROD. BIOMED. ONLINE (No.6) 667, 667–70 (2005) (commenting on the lack of PGD data and conducting a survey regarding the practices and beliefs of IVF clinic directors with respect to PGD).

90. *See* Wade, *supra* note 80 (noting critics' objections to the blastomere biopsy procedure).

91. *Id.* ¶ 29.

92. Editorial, *supra* note 84, ¶ 5.

93. Wade, *supra* note 80, ¶ 7.

94. Steven Ertelt, *Ethical Embryonic Stem Cell Research Alternative Crosses Another Hurdle*, LIFENEWS.COM, Sept. 26, 2008, at 1, http://www.lifenews.com/bio2588.html. The study, conducted by Matthias Stadtfeld, Masaki Nagaya, Jochen Utikal, Gordon Weir, and Konrad Hochedlinger, was published in *Science*. Matthias Stadtfeld et al., *Induced Pluripotent Stem Cells Generated Without Viral Integration*, 322 SCIENCE 945 (2008), *abstract available at* http://www.sciencemag.org/cgi/content/abstract/sci;322/5903/945?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=konrad+hochedlinger&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT (last visited Nov. 3, 2008). *See also* Stem Cell Briefing for ISSCR M. William Lensch, Breakthroughs in Stem Cell Biology: Human iPS Cells, Feb. 27, 2008, *available at* http://www.isscr.org/public/briefings/breakthrough.html.

95. Ertelt, *supra* note 94, at 1. *See also* Park, *supra* note 10, at 43 ("iPS cells have yet to prove that they are a safe and suitable substitute for the diseased cells they might even-

ported being able to "turn[] human skin cells into what appear to be embryonic stem cells without having to make or destroy an embryo,"[96] but these near equivalents "might not be medically ready for years and they might never be as powerful as [embryonic stem cells]."[97] Thus, "[u]ntil those [skin] cells [or iPS cells] are ready, . . . research on embryonic stem cells is still required."[98]

III. REGULATORY MODELS—THE CALIFORNIAN, THE ENGLISH, AND THE PROPOSED U.S. FEDERAL

Knowing that embryonic stem cell research is the key to medical advancement, and assuming that embryonic stem cell research opponents have been painted into a corner, it is clear that the United States needs federal regulation for embryonic stem cell research. Thus, the question is not whether the nation needs it, but rather, what provisions it should include. For guidance, this Note will examine two regulatory models—that of the state of California, the U.S. state most recognized for its embryonic stem cell research regulation and funding, and that of the United Kingdom, a nation that has had embryological science law in place for decades. This Note will then look at the proposed Stem Cell Research Enhancement Act of 2007, which was vetoed by President George W. Bush.

A. California's Proposition 71

On November 2, 2004, California passed Proposition 71, "a controversial bond measure that devote[d] $3 billion to human embryonic stem cell experiments and comprise[d] the biggest-ever state-supported scientific research program in the country."[99] Proposition 71 established the California Institute for Regenerative Medicine ("CIRM") and its Inde-

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tually replace in a patient," or that they are "as stable and as versatile as embryonic stem cells.").

96. Kolata, *supra* note 6. *See also* J. R. Minkel, *Human Stem Cell Breakthrough: No Embryos Required*, SCI. AM., Nov. 20, 2007, *available at* http://www.sciam.com/article.cfm?id=human-stem-cells-no-embryo ("Two groups of researchers report today that washing human skin cells in similar cocktails of four genes enabled them to reprogram the cells to resemble those harvested from embryos.").

97. Keim, *supra* note 88, at 2.

98. *Id.* at 2. *See also* Baltimore et al., *supra* note 7, at 2 ("[T]he recent success in reprogramming adult human cells into cells that closely resemble [embryonic stem] cells would not have occurred without the last decade of human [embryonic stem] cell research. . . . [I]t will likely be several years before we know whether the resulting iPS cells differ in clinically significant ways from human [embryonic stem] cells . . . [and thus] vital research on human [embryonic stem] cells must continue to move forward.").

99. *California Gives Go-Ahead*, *supra* note 12, ¶ 1.

pendent Citizen's Oversight Committee ("ICOC") in order to centralize the funding for California's stem cell research projects, to dole out research grants to state universities and research laboratories, and to "support and advance stem cell research and regenerative medicine under the highest ethical and medical standards."[100] Immediately thereafter, however, groups opposed to embryonic stem cell research, abortion, and taxes challenged the program set forth in Proposition 71,[101] arguing "that the program . . . violate[d] laws concerning state spending, the structure of ballot initiatives [and] rules regarding conflicts of interest."[102] Although the state did not issue any of its $3 billion in bonds "[b]ecause of the uncertainty over the litigation,"[103] an appeals court held in their favor in February of 2007, which Robert Klein, CIRM's chairman, "hailed . . . as 'one huge step for California.'"[104] CIRM has since allocated over $635 million in grants all over the state, mostly to University of California schools and to private research institutes, notably the Salk Institute for Biological Studies.[105]

Proposition 71, now codified in the California Constitution at Article XXXV, provides a right to conduct embryonic stem cell research—to be precise, it "established a right to conduct stem cell research . . . [on] adult stem cells, cord blood stem cells, pluripotent stem cells, and/or progenitor cells."[106] Under Proposition 71, pluripotent cells are those that are "capable of self-renewal, [and also] have broad potential to differentiate into multiple adult cell types,"[107] a definition which encompasses embryonic stem cells.[108] Proposition 71 clearly notes the sources that could be used to obtain embryonic stem cells, namely IVF and SCNT,[109] but also indicates that human reproductive cloning would be neither tolerated nor funded.[110]

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100. CIRM, *supra* note 13. *See also* California Proposition 71 (codified as California Constitution Art. XXXV), *available at* http://www.cirm.ca.gov/pdf/prop71.pdf [hereinafter Proposition 71].

101. Cal. Family Bioethics Council v. Cal. Inst. for Regenerative Med., 147 Cal. App. 4th 1319 (Cal. Ct. App. 2007).

102. Andrew Pollack, *California Stem Cell Research Is Upheld by Appeals Court,* N.Y. TIMES, Feb. 26, 2007.

103. *Id.* ¶ 4.

104. *Id.* ¶ 5.

105. CIRM: Approved CIRM Grants as of January 2008, http://www.cirm.ca.gov/info/grants.asp (last visited Jan. 23, 2009).

106. Proposition 71, *supra* note 100, § 5.

107. *Id.*

108. *See supra* Part I.A.

109. Proposition 71, *supra* note 100, art. XXXV, § 5.

110. *Id.* art. XXXV, § 3.

Proposition 71 also amended the California Health and Safety Code, notably adding the California Stem Cell Research and Cures Bond Act,[111] the California Stem Cell Research and Cures Bond Act of 2004,[112] and Definitions.[113] Proposition 71 amended the Health and Safety Code to include public meeting laws for the CIRM's ICOC;[114] a provision that disallows an ICOC disinterested member to "use his or her official position to influence a decision to approve or award a grant, loan, or contract to his or her employer," thus omitting the possibility for conflicts of interests;[115] a prohibition on compensation to research donors or participants in the stem cell research process, but an allowance for the reimbursement of expenses;[116] a time limit for when embryonic stem cells can be extracted from blastocysts, that is, no more than eight to twelve days after cell division commences;[117] and competitive bidding for government-funded grants.[118] It is very important to note that Proposition 71 also has a provision that requires the CIRM to create standards for obtaining all research donors' informed consent.[119] Now, CIRM's informed consent standards are as follows:

> Because human embryonic stem cell research is controversial, prospective donors need to be informed as completely as possible about possible research uses of embryos, gametes, and tissue that they might donate. If donors have stated restrictions on the future uses of donated materials, CIRM-funded researchers must respect these. Because it is difficult to foresee all future uses, however, researchers are free to utilize only materials whose donors have consented to all future research uses that are approved by scientific and ethical review bodies. This . . . strikes a balance between respecting the informed preferences of donors and maximizing the scientific benefit from research funding.[120]

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111. California Health and Safety Code, §§ 125290.10–125290.70, *available at* http://law.justia.com/california/codes/hsc/125290.10–125290.70.html [hereinafter CSCR&C] (last visited Nov. 5, 2008).

112. California Health and Safety Code, §§ 125291.10–125291.85, *available at* http://law.justia.com/california/codes/hsc/125291.10-125291.85.html [hereinafter CSCR&C 2004] (last visited Nov. 5, 2008).

113. California Health and Safety Code, § 125292.10, *available at* http://law.justia.com/california/codes/hsc/125292.10.html [hereinafter Definitions] (last visited Nov. 5, 2008).

114. CSCR&C, *supra* note 111, § 125290.30(d).

115. *Id.* § 125290.30(g)(1)(A).

116. *Id.* § 125290.35(b)(3).

117. *Id.* § 125290.35(b)(6).

118. *Id*. § 125290.30(f).

119. CSCR&C, *supra* note 111, § 125290.35(b)(1).

120. Geoffrey P. Lomax, Zach W. Hall & Bernard Lo, *Responsible Oversight of Human Stem Cell Research: The California Institute for Regenerative Medicine's Medical*

B. The United Kingdom's Fertilisation and Embryology Act, Regulations, and Pending Bill

The United Kingdom's Fertilisation and Embryology Act of 1990 ("1990 Act") established a national Human Fertilisation and Embryology Authority ("Authority") to grant licenses to researchers.[121] In order to obtain a license for research under the 1990 Act, two criteria must be satisfied: first, an application must demonstrate that the activity is "for the purpose of . . . (a) promoting advances in the treatment of infertility, (b) increasing knowledge about the causes of congenital disease, (c) increasing knowledge about the causes of miscarriages, (d) developing more effective techniques of contraception, or (e) developing [abnormality detection] methods for . . . embryos" pre-implantation, and second, it must demonstrate that the activity is "necessary or desirable" to achieve one of the specified purposes.[122]

Because the 1990 Act does not clearly permit stem cell research, in 2001, Parliament specified that a license may be issued by the Authority for the purposes of "(a) increasing knowledge about the development of embryos[,] (b) increasing knowledge about serious disease, or (c) enabling any such knowledge to be applied in developing treatments for serious disease."[123] This can be viewed as an explicit endorsement of embryonic stem cell research by the British government, and the Authority soon began to grant licenses for such research.[124]

The pending 2007–2008 Human Fertilisation and Embryology Bill hopes to supplement the 1990 Act in order for it to remain appropriate for the twenty-first century.[125] The bill aims to ensure that "all human embryos outside the body—whatever the process used in their creation—are subject to regulation" and that "the scope of legitimate embryo research activities, subject to controls," is extended.[126] The bill will also

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and Ethical Standards, 4 PLOS MED. 803, 804 (Issue No. 5) (2007), *available at* http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1858709&blobtype=pdf.

121. *See* 1990 Act, *supra* note 22, § 5.

122. *Id.* sched. 2, ¶ 3.

123. 2001 Regulations, *supra* note 22, ¶ 2(2)(a)–(c).

124. *See, e.g.*, Emma Young, *Human Embryonic Stem Cell Research Begins in U.K.*, NEWSCIENTIST.COM, Mar. 1, 2002, http://www.newscientist.com/article/dn1992-human-embryonic-stem-cell-research-begins-in-uk.html (noting the commencement of embryonic stem cell research due to the Authority's issuance of appropriate licenses).

125. Impact Assessment on the Human Fertilisation and Embryology Bill, http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Regulatoryimpactassessment/DH_080209, at 1 [hereinafter Impact Assessment] (last visited Nov. 5, 2008).

126. Department of Health—News Distribution Services, http://nds.coi.gov.uk/environment/fullDetail.asp?ReleaseID=329426&NewsAreaID=2&NavigatedFromDepartment=True (last visited Jan. 11, 2009).

provide regulation for "'inter-species' embryos created from a combination of human and animal genetic material for research" and will alter the "restrictions on the use of data collected by the [Authority] to make it easier to do follow-up research."[127] Members of Parliament have backed this bill, particularly in its support for the creation of hybrid embryos, which have been referred to as "saviour siblings" because of their ability to aid in the treatment of debilitating diseases.[128]

C. The Vetoed U.S. Stem Cell Research Enhancement Act of 2007

The Stem Cell Research Enhancement Act of 2007 ("2007 Act") aimed "[t]o amend the Public Health Service Act to provide for human embryonic stem cell research."[129] The 2007 Act explicitly supported human embryonic stem cell research and noted that the Secretary would conduct such research, meaning that embryonic stem cell research would be federally funded.[130] The 2007 Act also included the creation of guidelines and would have mandated that the Secretary comply with some reporting requirements.[131] Most importantly, however, the 2007 Act provided for three ethical obligations to be met in order for human embryonic stem cells to be used for research purposes.[132] These three requirements were as follows:

> 1) The stem cells were derived from human embryos that have been donated from in vitro fertilization clinics, were created for the purposes of fertility treatment, and were in excess of the clinical need of the individuals seeking such treatment.
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> 2) Prior to the consideration of embryo donation and through consultation with the individuals seeking fertility treatment, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded.

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127. *Id.*

128. *MPs Back Hybrid Embryo Research,* BBCNEWS.COM, May 19, 2008, http://news.bbc.co.uk/2/hi/uk_news/politics/7407589.stm. *See also Green Light for Hybrid Research*, BBCNEWS.COM, Jan. 17, 2008, http://news.bbc.co.uk/2/hi/health/7193820.stm.

129. Stem Cell Research Enhancement Act of 2007, S.5, 110th Cong. (1st Sess. 2007), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:s5enr.txt.pdf.

130. *Id*. § 2 (amending the Public Health Service Act to include 42 U.S.C. § 498D). Hereinafter in this Note, when provisions of the 2007 Act are referred to, they refer to what would have been 42 U.S.C. § 498D(a)–(d) had the statute been enacted.

131. *Id.* § 498D(c)–(d).

132. *Id.* § 498D(b)(1)–(3).

> 3) The individuals seeking fertility treatment donated the embryos with written informed consent and without receiving any financial or other inducements to make the donation.[133]

President George W. Bush vetoed the 2007 Act, after it passed in the House and Senate, on June 20, 2007.[134]

IV. WHAT KIND OF FEDERAL REGULATION WOULD BE OPTIMAL?

A. The Six Elements

I have isolated six important issues stemming from an analysis of the aforementioned regulatory models, as well as the Massachusetts regulatory model,[135] which is quite thorough, like California's. These issues are, in no order of importance, (1) a centralized agency, (2) the right to research, (3) the sources of the human embryonic stem cells, (4) a prohibition on compensation, (5) informed consent, and (6) federal licensing.

First, the Californian and British regulatory models have both established a centralized agency to make grants and loans to researchers, and to monitor and report all stem cell activities.[136] Yet, a centralized agency is not only useful to dole out funds and report where money is going. A centralized agency could also encourage cooperation, advocate for a common cause, allow for effective monitoring, and could ensure that different sorts of projects are pursued in a way that avoids too much overlap. Furthermore, a centralized agency could ensure that funds are spread across the nation, and could also push for adherence to certain ethical standards, as well as medical ones. The vetoed 2007 Act, however, did not contain a provision to establish such an agency. An American federal regulatory agency could be extremely beneficial to an embryonic stem cell regulatory scheme, particularly as there has been no prior federal law on the subject and there is great variance among the states' laws.[137]

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133. *Id.*

134. Reynolds, *supra* note 9.

135. Massachusetts has a stem cell research regulatory model, despite Governor Mitt Romney's veto, as the state legislature overturned it. *See Lawmakers Override Veto of Stem Cell Bill*, L.A. TIMES, June 1, 2005, at A10. For the text of the Massachusetts statute, see An Act Promoting Stem Cell Research, S.2032 (Mass. 2005), *available at* http://www.mass.gov/legis/bills/senate/st02/st02032.htm [hereinafter Massachusetts Act] (last visited Nov. 5, 2008).

136. *See supra* Part III.A–B.

137. *See supra* Intro.

Second, California's Proposition 71 explicitly establishes a constitutional right to conduct stem cell research.[138] While federal legislators may not want to form an absolute right to research,[139] one could make the argument that "[i]f the First Amendment serves to protect free trade in the dissemination of ideas and information, it must also protect the necessary preconditions of speech, such as the production of ideas and information through research."[140] Indeed, the government could argue for the establishment of a federal right to embryonic stem cell research because "society must foster bio-scientific inquiry and innovation,"[141] especially in a context such as this, where so many lives could be saved. While this argument may satisfy a constitutional rational basis analysis,[142] it is unlikely that the government would establish the constitutional right to embryonic stem cell research in its first law on the subject.

Third, Proposition 71 and the vetoed 2007 Act specifically describe where embryonic stem cells for research purposes could be obtained. California's Proposition 71 notes IVF and SCNT as both acceptable sources for embryos.[143] In the first of its three ethical requirements for embryonic stem cell research, the vetoed 2007 Act also states that fertility clinics are an appropriate source for embryos.[144] However, the vetoed 2007 Act does not indicate a position on SCNT, nor does it mention it, likely because it involves cloning and is therefore controversial.[145] In a federal regulatory scheme for embryonic stem cell research, IVF should be designated as the primary source for embryos, and if SCNT is ever

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138. *See* Steve Keane, Note, *The Case Against Blanket First Amendment Protection of Scientific Research: Articulating a More Limited Scope of Protection*, 59 STAN. L. REV. 505, 506 (2006) (noting that, in addition to the $3 billion in state funding, California's right to "unfettered" research has resulted in many stem cell researchers relocating to the state).

139. *Id.* at 507 ("[I]n its 1997 report, the National Bioethics Advisory Commission claimed that 'society recognizes that the freedom of scientific inquiry is not an absolute right and scientists are expected to conduct their research according to widely held ethical principles.'").

140. *Id.* at 506 n.5 (quoting John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1217–18 (1978)).

141. *Id.* at 189.

142. Under minimal rationality review, the Supreme Court determines whether there is a rational relationship to a legitimate government end, and deference is usually given to means-ends relationships—any conceivably rational basis suffices. *E.g.*, New Orleans v. Dukes, 427 U.S. 297, 303 (1976) (noting that states may make "rational distinctions . . . with substantially less than mathematical exactitude").

143. Proposition 71, *supra* note 100, § 4 (now Article XXXV of the Constitution, § 5).

144. Stem Cell Research Enhancement Act of 2007, *supra* note 129, § 498D(b)(1).

145. *See supra* note 78 (discussing SCNT and the controversy that surrounds it).

proven to be extremely successful beyond mice, it too could be added as an appropriate source.

Fourth, California and the vetoed U.S. federal bill both articulate a prohibition on compensating embryo donors.[146] The United Kingdom's law, as it currently reads, does not have such a prohibition, but this could be relevant to the pending 2007–2008 bill. This prohibition is not, however, uncommon: for example, Massachusetts' embryonic stem cell regulatory scheme provides that "[n]o person shall knowingly purchase or sell any pre-implantation embryo for human embryonic stem cell research for valuable consideration," adding that "reasonable payments associated with storage, quality control, preservation, processing or transportation of such pre-implantation embryos" are to be excluded from the definition of "consideration."[147] The prohibitory language in the Massachusetts law does not differ much from California's, which only allows reimbursements to be paid.[148] The vetoed 2007 bill articulates that nothing ought to induce one to make the embryo donation,[149] but its reasoning is entirely the same as both states' provisions: the donation should not be coerced or executed out of self-interest. Rather, the donation should be voluntary and incentive-free.

Fifth, Proposition 71 and the vetoed 2007 bill (in the third of its three ethical requirements) equally stress the need for informed consent when receiving a donated embryo.[150] The vetoed 2007 bill states that informed consent must be given in written form;[151] Proposition 71 does not specify the method by which informed consent is to be given.[152] Either way, this might be one of the most important inclusions in a regulatory scheme for embryonic stem cell research. Given that individuals may "suffer a dignitary harm by being deprived of their 'autonomous right to chose'" if they are not "adequately equipped with information pertinent to their decision about whether or not to participate in [embryo donation]," the informed consent procedure is critical to the donor as well as to the embryonic stem cell donation process.[153] This is likely why Massachusetts has pro-

146. Stem Cell Research Enhancement Act of 2007, *supra* note 129, § 498D(b)(3); CSCR&C, *supra* note 111, § 125290.35(b)(3).

147. Massachusetts Act, *supra* note 135, § 3(b)(ii).

148. CSCR&C, *supra* note 111, § 125290.35(b)(3).

149. Stem Cell Research Enhancement Act of 2007, *supra* note 129, 42 U.S.C § 498D(b)(3).

150. *Id.*; CSCR&C, *supra* note 111, § 125290.35(b)(1).

151. Stem Cell Research Enhancement Act of 2007, *supra* note 129, 42 U.S.C § 498D(b)(3).

152. CSCR&C, *supra* note 111, § 125290.35(b)(1).

153. Natalie Ram, *Tiered Consent and the Tyranny of Choice*, 48 JURIMETRICS J. 253, 256 (2008).

vided a lengthy definition of what qualifies as informed consent, articulating the physician's expansive duties, the need for an informational pamphlet to be provided to the patient, and the need for an informed consent form to be fully filled out by both the patient and the physician.[154] Accordingly, it is imperative that a thorough informed consent provision be included in a federal embryonic stem cell research regulatory scheme.

Lastly, the United Kingdom's 1990 Act established an agency with all federal licensing authority, but has requirements that must be met in order to obtain a license for research.[155] Particularly after the addition of the 2001 Regulations, the United Kingdom's structure for giving out licenses seems especially organized, seeing as everyone's embryonic stem cell activity is authorized and monitored by the government.[156] Such a licensing structure for embryonic stem cell research could prove beneficial in the United States, as it would create order and cohesion in a system that is in disarray. While there are certainly benefits to implementing such licensing, there are certainly some complications that could arise, notably the typical time delays in dealing with government agencies and standards that could prohibit certain kinds of researchers from engaging in very promising research. Moreover, some research projects have been ongoing for years, and may have multiple phases to them, so it may prove difficult to decide at what point it is necessary for the researchers to apply for a license. While this qualm could be easily rectified by excusing ongoing projects from applying for a license for their current phase, and requiring them to apply for a license for the next phase, issues could still come about if their application for a license is denied. That is, any potential benefit gained from the research could be unrealized. More comprehensive research must be conducted to determine if federal licensing is indeed a beneficial structure for the United States and whether or not it will abate the controversies that surround embryonic stem cell research. Chances are, however, that most researchers would find a federal licensing system to be unfeasible in the United States, as it would be too costly to implement and administer.

B. What an American Federal Regulatory Scheme Should Look Like

As previously mentioned, a federal regulatory scheme for embryonic stem cell research should prohibit compensation for donors, and if SCNT is proved successful beyond mice, SCNT should be deemed an appropriate source for embryos. Furthermore, if research does reveal that federal

154. *See* Massachusetts Act, *supra* note 135, § 5(b)(1)–(2).
155. 1990 Act, *supra* note 22, sched. 2, ¶ 3.
156. 2001 Regulations, *supra* note 22, ¶ 2(2)(a)–(c).

licensing would be beneficial to the United States, then such a system should also be implemented via a federal licensing authority, such as in the United Kingdom.

The United States should establish a new federal agency under the U.S. Department of Health and Human Services to deal with regenerative medicine and stem cell research. This agency would be empowered, like the Human Fertilisation and Embryology Authority in the United Kingdom and CIRM in California, to delegate federal funds to researchers who meet objective criteria of an application process. It would also be responsible for federal licensing, if such a system were deemed appropriate for the United States. This new agency would not only fund, monitor, and report all stem cell projects, but also affirmatively endorse embryonic stem cell research as medicine's key to the future. This agency would expressly focus on the need for embryonic stem cell research for medical advancement. While another federal agency in the U.S. Department of Health funds research opportunities—the Agency for Healthcare Research and Quality ("AHRQ")—the research this agency funds and supports is broad and focuses more on improving the quality and safety of the current healthcare system than on understanding and developing treatments for incurable diseases and degenerative conditions.[157] Specifically, the AHRQ's mission is "to improve the quality, safety, efficiency, and effectiveness of health care for all Americans."[158] The mission of a regenerative medicine and stem cell research agency would be "to endorse, support and fund regenerative medicine and stem cell research projects in order to develop new therapies and treatments for untreatable disease and to aid with tissue and organ transplantation."

A new federal regulatory scheme should not only establish a new federal agency, but also explicitly include a thorough informed consent provision. However, while informed consent is critical for patient autonomy, patients should not be inundated with information that merely confuses them, as this will not lead to better decision making, which is the goal of the informed consent doctrine.[159] Furthermore, providing informed consent necessitates an extraordinary expenditure of time, resources, and funds. Thus, in deciding what *kind* of informed consent to provide to embryo donors in a U.S. federal regulatory scheme, it is important to take into account both the need for patient autonomy as well as the con-

157. *See* AHRQ Portfolios of Research, http://www.ahrq.gov/fund/portfolio.htm (last visited Jan. 12, 2009) (noting what the Agency does fund and support).

158. AHRQ—Director's Welcome, http://www.ahrq.gov/fund/dirwelcome.htm (last visited Dec. 2, 2008).

159. Professor Marsha Garrison, Lecture at Brooklyn Law School (Aug. 21, 2008) (notes on file with author).

straints. I propose that a patient give both oral and written consent and that a physician engage in dialogue that firmly discloses to the patient that her embryos will be used for research, as well as the benefits and risks of choosing to donate embryos for research purposes. An explanation of where, how, and why embryonic stem cell research is conducted is not mandatory, although a very brief one could be encouraged; elaborate videos, pamphlets, and pictorial displays are excessive. Since embryo donation for research purposes is not a life-or-death, patient-determinative medical process, and each donated embryo will undergo the same procedure in order to be utilized for research, each patient can be told the exact same information by a physician. Accordingly, physicians can adhere to a reasonable physician informed consent standard: he or she should disclose all information that would usually be disclosed to an embryo donor.[160]

Information that should be disclosed to all embryo donors, both in the written consent form and by the physician, should be the following: (1) that an agreement to donate does not necessarily mean that the embryos will be used for research purposes, but that they could be, and if not used, or if stem cells cannot be obtained from them, they will be discarded; (2) that any embryonic stem cell line derived from the embryo will be anonymized;[161] (3) that an embryonic stem cell line can be maintained for years, can be transferred among facilities, and can be used for various different projects; (4) that a failure to donate will not adversely affect the potential donor's medical care;[162] (5) that donors will not receive any direct financial or personal benefit from donating, but that donation will benefit research to better the social aggregate; (6) that a risk of donation is that this embryo will not be able to be used for fertility purposes; and (7) that there is a psychological risk of "anxiety or regret."[163] Donors should also be told that they can withdraw their consent

160. For comparative purposes, see Massachusetts Act, *supra* note 135, § 5(b).

161. Canada, for example, has necessitated in its informed consent guide for stem cell research that donors be told that "the cell line(s) will be anonymized (i.e., that no personal identifiers of those who donated embryos from which ES cell lines were derived for research will be provided to stem cell investigators), except if the research involves autologous donation." CANADIAN INST. OF HEALTH RESEARCH, UPDATED GUIDELINES FOR HUMAN PLURIPOTENT STEM CELL RESEARCH 8.3.3., June 28, 2006, *available at* www.irsc.ca/e/31488.html.

162. *See* Robert Streiffer, *Informed Consent and Federal Funding for Stem Cell Research*, 38 HASTINGS CENTER REP. 140, 141 (2008) (discussing a 1997 statement from the American Society of Reproductive Medicine, which noted the need for informed consent with embryo donation).

163. ISSCR Sample Research Consent Form, http://www.biology.iupui.edu/biocourses/Biol540/pdf/CFembryos.doc (last visited Dec. 4, 2008).

up until the stem cells are obtained from the embryos. When procedures like blastomere biopsy become commonplace, the language used to disclose the above information would be different. For example, "embryo donation" would become "embryonic stem cell donation." Moreover, the need to explain to the donor that the donated embryos cannot be used for fertility purposes would be eliminated.

CONCLUSION

It is critical for the United States to develop a federal regulatory scheme for embryonic stem cell research. The range of embryonic stem cell research policy and regulation across the fifty states is much too wide for a topic so vital to our country's medical future and, accordingly, the United States should endorse, support, regulate, and fund the embryonic stem cell research effort on a federal level. As the principal objection to embryonic stem cell research, which was also President Bush's objection, can be overcome with new technology such as blastomere biopsy, it is time for the United States to follow many other Westernized countries and develop thorough regulation on the subject. Optimal regulation for embryonic stem cell research would articulate the establishment of a centralized federal agency to administer and fund such research, the kind of informed consent to be provided to embryo donors, the need for incentive-free embryo donation, the appropriate sources for embryos, the fact that such research will be awarded federal funds, and the federal government's active endorsement of the embryonic stem cell research effort. Embryonic stem cells hold medicine's key to the future—now all we need is a federal regulatory scheme in place to deal with such research.

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