STEM CELL RESEARCH AND THE CLONING WARS

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In the 1976 novel *The Boys from Brazil*,[1] the infamous Nazi concentration camp doctor, Josef Mengele, who disappeared after World War II, never to be found, has created ninety-four clones of Adolph Hitler. The children, sent to live with German families around the globe, are being raised in circumstances that Mengele has chosen to mimic Hitler's upbringing. Now that the clones have reached the age at which Hitler's father died, Mengele sets out to have each of the ninety-four stepfathers murdered. The stoic Mengele thinks nothing of the bloodshed, of course. It is just one more necessary step in his plan to breed a new "Fuehrer" who will lead a reconstructed "Fourth Reich." In the movie version, an icy Gregory Peck portrays Mengele, while Laurence Olivier plays the Nazi hunter, a character based loosely on Simon Wiesenthal, who successfully foils the plot.[2]

There would seem to be a great distance between a man called "the Angel of Death" bent on recreating history's most evil man and academic scientists trying to create new kinds of disease treatments that will not set off immune system reactions in patients. The scientific distance, however, is not so great. The consequence of this similarity, unfortunately, is the potential enactment of legislation that could severely undermine the medical potential of stem cell research, which offers hope for finding cures for debilitating diseases and injuries. This article explains how a revolutionary biomedical technology became entangled in the cloning wars and why Congress should not permit it to become a casualty.

Part I explains the scientific basis for the unfortunate rhetorical linkage between cloning human beings and potentially revolutionary medical research.

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1. *See* IRA LEVIN, THE BOYS FROM BRAZIL (1976).
2. BOYS FROM BRAZIL (Incorporated Television Company 1978).

Part II describes the state-level legislation that prohibits both and the congressional bill that would do the same. Part III describes and responds to the policy arguments for enacting a cloning ban that would extend to the use of cloning technology in stem cell research rather than stop at prohibiting cloning for reproductive purposes. This Part concludes that, although there are plausible arguments for the broader ban, the fears that they seek to address are not sufficient to justify the costs to medical research. Part IV evaluates three sets of constitutional problems raised by a broad congressional cloning ban: the breadth of federal regulatory power under the Commerce Clause, individual rights to reproductive liberty, and individual rights to pursue medical treatment. This Part concludes that none of these concerns would likely be sufficient for federal courts to strike down a cloning ban as unconstitutional, but that they are sufficiently serious to provide an independent basis for Congress to reject the ban.

I. STEM CELL RESEARCH AND CLONING

A. THE POTENTIAL OF STEM CELL RESEARCH

Each human cell contains forty-six chromosomes, half inherited from the mother and half from the father, that together contain the person's entire genome—that is, every one of his or her genes. According to the findings of the Human Genome Project, the genome of each human consists of about 25,000 genes.[3] Different types of cells have different characteristics and different functions: skin cells, blood cells, bone cells, and brain cells, for example. In order to be able to serve such different functions, different genes are activated, or "expressed," in different types of cells, while the remaining genes in any particular type of cell lie dormant. Through "gene expression," the cell creates particular proteins that, working together with proteins created by other cells, build and maintain the organism and enable it to function.[4]

When a specialized cell is created, its function is decided and is fixed. In the lingo of cell biology, such a specialized cell is "fully differentiated." The genes that are expressed will remain expressed, while the others will lie

3. Sources do not agree on the exact number of genes in the human genome, and even the Human Genome Project itself publishes a variety of figures. *See* NAT'L HUMAN GENOME RESEARCH INST., NAT'L INSTS. OF HEALTH, A BRIEF GUIDE TO GENOMICS (2006), *available at* http://www.genome.gov/18016863; *see also* NAT'L HUMAN GENOME RESEARCH INST., NAT'L INSTS. OF HEALTH, AN OVERVIEW OF THE HUMAN GENOME PROJECT (2007), *available at* http://www.genome.gov/12011238. Most sources, however, talk about there being around 25,000 to 30,000 genes.

4. For a concise description, see CHRISTOPHER THOMAS SCOTT, STEM CELL NOW: FROM THE EXPERIMENT THAT SHOOK THE WORLD TO THE NEW POLITICS OF LIFE 15-22 (2006).

dormant. A stem cell, in contrast, is one that is not fully differentiated. It can divide into two identical copies of itself, but it also can divide into one copy of itself and one different, more specialized cell, with a different gene expression pattern.[5]

The least differentiated of stem cells, embryonic stem cells (ESCs), are found in very early stage embryos, called blastocysts.[6] ESCs have the potential to develop into all of the types of tissues found in the human body.[7] More differentiated stem cells, often collectively called adult stem cells (ASCs), are found in fetuses and persons.[8] ASCs can develop into one or more kinds of specialized cells, usually within the same tissue type—for example, hematopoietic stem cells have the ability to develop into nine types of blood cells[9]—but lack the flexibility of ESCs.[10] Most scientists believe that ESCs have greater scientific potential because they are easier to harvest, are more stable, and can replicate for longer periods of time than ASCs,[11] and because many types of specialized cells cannot be developed from any known ASCs.[12] ESC research is far more controversial, however, and is mostly ineligible for federal research funding at this time[13] because the destruction of the blastocyst is a necessary side effect of harvesting ESCs, given technology currently in use.[14]

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5. *See* Darwin J. Prockop, *Embryonic Stem Cells Versus Adult Stem Cells: Some Seemingly Simple Questions*, *in* ESSENTIALS OF STEM CELL BIOLOGY at xxiii (Robert Lanza et al. eds., 2006) (identifying the ability to produce differentiated descendants as the "textbook definition" of a stem cell); *see also* PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 111-12 (2004), *available at* http://www.bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf [hereinafter PCB MONITORING].

6. PCB MONITORING, *supra* note 5, at 126.

7. Douglas A. Melton & Chad Cowen, *"Stemness": Definitions, Criteria, and Standards*, *in* ESSENTIALS OF STEM CELL BIOLOGY, *supra* note 5, at xxv, xxvi.

8. PCB MONITORING, *supra* note 5, at 113-14.

9. SCOTT, *supra* note 4, at 67.

10. Prockop, *supra* note 5, at xxiiii; PCB MONITORING *supra* note 5, at 8, 10.

11. PCB MONITORING, *supra* note 5, at 115.

12. *See, e.g.*, Yuval Dor & Douglas A. Melton, *Pancreatic Stem Cells*, *in* ESSENTIALS OF STEM CELL BIOLOGY, *supra* note 5, at 245, 250-51 (noting that pancreatic beta cells, necessary to treat Type 1 diabetes, appear to be maintained in the adult body by self-duplication rather than stem cell differentiation).

13. *See generally* Russell Korobkin, *Embryonic Histrionics: A Critical Evaluation of the Bush Stem Cell Funding Policy and the Congressional Alternative*, 47 JURIMETRICS J. 1 (2006).

14. PCB MONITORING, *supra* note 5, at 8. Recently published research demonstrated the possibility of creating ESC lines by extracting and culturing single cells from eight to ten cell embryos in a way that does not destroy the embryos themselves. Irina Klimanskaya et al., Letter, *Human Embryonic Stem Cell Lines Derived from Single Blastomeres*, 444 NATURE 481 (2006). If further developed and used to create ESC lines, this technique has the potential to reduce the controversy surrounding ESC research, although the initial response

Stem cell research potentially could lead to cures for a wide range of diseases with a genetic component (and also treatments for injuries that damage or destroy cell populations, such as paralysis) in three different ways. First, by studying the ways that stem cells differentiate and create specialized cells, researchers hope to better understand the causes and development of a range of diseases that result from abnormal cell division or differentiation or from cell injury or death.[15] Second, if scientists can prompt stem cells to differentiate and develop in ways that mimic the progression of diseases, researchers can test the efficacy and toxicity of pharmaceuticals and other medical treatments on the stem cells.[16]

Third, and most significant, is the potential of stem cells to directly cure diseases and repair injuries. In theory, stem cells, prompted to differentiate into healthy specialized cells, can be used to replace diseased or dead cells. In other words, medical science can harness the body's natural healing powers to cure disease rather than relying on blunt, external force that fights against the body's biology, such as surgery, chemicals, or radiation. One approach is to inject stem cells into the diseased or damaged area of the body and allow them to regenerate healthy cells inside the body.[17] Another is to prompt stem cells to actually grow replacement cells or tissues outside of the diseased body and then surgically replace the diseased tissues with the specially constructed replacements.[18] For example, heart cells destroyed by a heart attack could be grown with stem cells and used to patch the organ.

B. THE ROLE OF SOMATIC CELL NUCLEAR TRANSFER (SCNT) IN STEM CELL RESEARCH

If and when researchers learn how to use stem cells therapeutically to replace or repair dead or damaged cells, they likely will still face the problem of the patient's body rejecting the presence of foreign cells.[19] This has always

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to the new technology among ESC opponents has been cool. *See, e.g.*, Nicholas Wade, *In New Method for Stem Cells, Viable Embryos*, N.Y. TIMES, Aug. 24, 2006, at A1; Rick Weiss, *Stem Cells Made with No Harm to Embryos*, WASH. POST, Aug. 24, 2006, at A3.

15. PCB MONITORING, *supra* note 5, at 3, 130.

16. PCB MONITORING, *supra* note 5, at 129.

17. *See, e.g.*, PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY 65-66 (2002) [hereinafter PCB CLONING] (describing how this might be done to treat Parkinson's disease).

18. *See, e.g.*, John C. Fletcher, *Deliberating Incrementally on Human Pluripotent Stem Cell Research*, *in* NATIONAL BIOETHICS ADVISORY COMMISSION, ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH VOL. II E6, E6-E7 (2000); National Institutes of Health, *Stem Cell Basics*, http://stemcells.nih.gov/staticresources/info/basics/StemCellBasics.pdf (last visited Jan. 28, 2007).

19. *See* PCB MONITORING, *supra* note 5, at 133 (discussing the likelihood of immune rejection problems in allogenic transplants using ESC derived cells), 140 (concluding that

been a problem in the context of bone marrow and organ transplants, skin grafts, and the like that attempt to place tissue from one individual into the body of another individual. Proteins on the surfaces of donor cells called human leukocyte antigens (HLA) alert the immune system of the recipient to the presence of foreign cells.[20] Because foreign cells could be harmful viruses or bacteria, the immune system of the host responds by attacking (and killing) the cells of the donor.[21] The donor tissue can also sense that the cells of the host are foreign to it, and attack those cells. This side effect of transplants is known as "graft versus host" disease.[22]

In modern practice, physicians attempt to match transplant donors and recipients with similar HLA profiles, which reduces the rejection problem but does not solve it entirely.[23] Recipients of organ transplants also must take immunosuppressive drugs, which produce side effects.[24] If stem cell treatments could be developed using only cells that match those of the patient however, the tissues will be a perfect HLA match, and the problem of rejection could be avoided without the need for high doses of dangerous drugs.

Scientists hope to one day create individualized, rejection-proof stem cell therapies through a process called somatic cell nuclear transfer (SCNT). The process requires one human egg cell and one adult "somatic" cell, which could theoretically originate from any part of a donor's body. The nucleus of the egg cell is removed and replaced with the nucleus of the somatic cell, resulting in an egg that is genetically virtually identical to the somatic cell donor.[25] The trick, at this point, is to stimulate the egg in a way that convinces the genes in the transplanted nucleus to express as if the cell were a zygote rather than an adult cell. If this feat is accomplished, the egg will begin the long process of cell division that could lead eventually to the birth of an organism.[26] After several days, scientists would harvest ESCs from the developing embryo exactly as they would harvest ESCs from an embryo created through the normal process of fertilizing an egg cell with a sperm cell, and use those ESCs

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the "transplant rejection problem remains a major obstacle . . .").

20. *See, e.g.*, *Principles of Transplantation*, MERCK MEDICAL MANUALS: ONLINE MEDICAL LIBRARY, http://www.merck.com/mmhe/sec16/ch187/ch187b.html (last visited Oct. 25, 2006).

21. *See* ANN B. PARSON, THE PROTEUS EFFECT 63-64 (2004); PCB CLONING, *supra* note 17, at 66.

22. PCB MONITORING, *supra* note 5, at 132.

23. *See, e.g.*, Medline Plus, National Institutes of Health, Transplant Rejection, http://www.nlm.nih.gov/medlineplus/ency/article/000815.htm (last visited Oct. 25, 2006).

24. *Id.*

25. PCB MONITORING, *supra* note 5, at 128; PCB CLONING, *supra* note 17, at 65.

26. *See generally* PCB CLONING, *supra* note 17, at 59-60 (describing the steps in the SCNT process).

to develop therapeutically useful cells.[27] But because these cells would be virtually identical to those of the donor, the problem of immune system rejection should, in theory, be solved.[28]

In 2004, South Korean scientist Woo Suk Hwang announced that he had used the SCNT process to create a human ESC line.[29] The following year, he claimed to have improved his laboratory's efficiency and created eleven lines.[30] Months later, however, rumors began to circulate that Hwang's data and photographs, published in *Science* magazine, might have been forged.[31] Ultimately, South Korean investigators determined that Hwang's claims were a complete hoax.[32] With the Hwang claims debunked, the creation of human ESC lines using SCNT remains a future possibility rather than a present reality. Most scientists in the field, however, continue to believe that the feat will be accomplished, and probably sooner rather than later. The reason for the optimism is "Dolly," the Scottish lamb.

C. THE DUAL USES OF SCNT

In 1996, Ian Wilmut and his research team at the Roslin Institute in Scotland, with the assistance, of course, of a mature female sheep that supplied the necessary womb, gave birth to the first mammal created through the use of SCNT. Specifically, Wilmut inserted a cell from the mammary tissue of a six-year-old sheep into an enucleated sheep ovum and using electrical impulses stimulated the resulting cell to divide as if it were a newly fertilized zygote.[33]

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27. PCB CLONING, *supra* note 17, at 65-66.

28. *See, e.g.*, R.L. Gardner, *Present Perspective and Future Challenges*, *in* ESSENTIALS OF STEM CELL BIOLOGY, *supra* note 5, at 1, 8 ("[T]herapeutic cloning has been widely advocated as a way of tailoring grafts to individual patients, thereby circumventing the problem of graft rejection."). It should be noted that, although SCNT could solve the problem of tissue rejection, it could create a different problem. If the donor's disease is caused by an inherited genetic mutation, attempts to replace dead or malfunctioning cells with stem cells derived from the same genome might simply replicate the problem. This concern might be dealt with, however, by using new technology to repair gene defects in human embryonic stem cells (hESCs) before using them to create the cell line that will be used for treatment. This process has been demonstrated successfully in mice. *See* W.M. Ridout et al., *Correction of a Genetic Defect by Nuclear Transplantation and Combined Cell and Gene Therapy*, 109 CELL 17 (2002).

29. *See* Gina Kolata, *Cloning Creates Human Embryos*, N.Y. TIMES, Feb. 12, 2004, at A1.

30. *See* Gina Kolata*, Koreans Report Ease in Cloning for Stem Cells*, N.Y. TIMES, May 20, 2005, at A6.

31. Woo Suk Hwang, *Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst*, 303 SCIENCE 1565, 1669 (2004).

32. *See* Nicholas Wade & Choe Sang-Hun, *Human Cloning Was All Faked, Koreans Report,* N.Y. TIMES, Jan. 10, 2006, at A1.

33. *See* Gina Kolata, *Scientist Reports First Cloning Ever of Adult Mammal*, N.Y.

When Dolly's birth was announced, it was taken quite seriously across the globe as a cautionary tale. By suggesting that the technology might one day be available to create a cloned human being, the announcement gave rise to an immediate and virtually unanimous chorus of opposition to human cloning, in the United States as well as abroad. Bills were immediately introduced in the House and Senate (although not enacted) that would prohibit human cloning.[34] President Clinton issued a Presidential Directive prohibiting the use of federal funds for the cloning of humans, and he instructed his National Bioethics Advisory Commission to produce a report on the ethical implications of human cloning.[35] Several months later, that commission called for a prohibition on the creation of human clones.[36]

Ten years later, publicly expressed views on reproductive cloning remain overwhelmingly negative. A few iconoclasts and provocateurs write essays extolling the virtues of human cloning, but virtually all bioethicists, scientists, and elected officials to speak on the issue of reproductive cloning oppose the practice, and most favor a strict legal prohibition on any attempts. This includes the entire membership of the President's Council on Bioethics, which unanimously recommended in a 2002 report that reproductive cloning be banned.[37]

The arguments for prohibition follow three lines of reasoning. The first consists of ethical objections to engineering human life in a way that does not involve fertilization and the combination of the DNA of two donor gametes.[38] The second consists of concerns for the psychological and physical safety of the cloned individual. Most attempts to clone mammals have failed to result in live births, and the "successful" efforts typically result in animals that suffer significant genetic disorders in comparison to the same type of animals created

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TIMES (Late Edition (East Coast)), Feb. 23, 1997, at A1. A decade earlier, the Danish veterinarian Steen Willadsen produced a live-born sheep after fusing the nucleus of a sheep embryonic stem cell (rather than a somatic cell) with a sheep's egg. *See* SCOTT, *supra* note 4, at 45.

34. S. 368, 105th Cong. § 1 (1997) (introduced on Feb. 27, 1997 by Senator Bond); Human Cloning Prohibition Act, H.R. 923, 105th Cong. § 1 (1997) (introduced on Mar. 5, 1997 by Representative Ehlers); Human Cloning Research Prohibition Act, H.R. 922, 105th Cong. § 1 (1997) (introduced on Mar. 5, 1997 by Representative Ehlers).

35. Memorandum on the Prohibition on Federal Funding for Cloning of Human Beings, 1 PUB. PAPERS 233, 281 (Mar. 4, 1997) [hereinafter Clinton Directive]. Letter to National Bioethics Advisory Commission Chair Harold Shapiro on Cloning Technology Issues, 1 PUB. PAPERS 196, 237 (Feb. 24, 1997).

36. NATI'L BIOETHICS ADVISORY COMM'N, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS (1997).

37. PCB CLONING, *supra* note 17, at 205-27. The Council split on the question of whether therapeutic cloning should also be prohibited. *Id.*

38. *See, e.g.*, R. Alta Charo, *Cloning: Ethics and Public Policy*, 27 HOFSTRA L. REV. 503, 504-05 (1999) (reporting anti-cloning arguments presented to the National Bioethics Advisory Commission).

through fertilization.[39] Dolly herself suffered from a range of abnormalities and died prematurely. There is no good reason to think that human clones would not suffer from the same range of problems.[40] Opponents of reproductive cloning also argue that clones would lack the individuality that humans should enjoy,[41] might view the course of their life as preordained by that of their donor,[42] and might suffer other unknown psychological harms caused by knowing that their DNA is an exact replica of their donor's DNA.[43] The third set of concerns, although the most muted, have to do with possible physical consequences for the human species. The exact reproduction of genes from one generation to the next will reduce the genetic variation of the human race, which could, in theory, create problems for the survival of the species over the long term.[44] The SCNT technology scientists hope to use to create rejection-proof stem cell therapies is precisely the same (sans womb) as the technology used to create Dolly, who was a clone of an adult sheep. The only difference in protocol is that stem cell researchers wish to harvest ESCs from embryos created through SCNT rather than incubate the embryo and create a live birth. Thus, SCNT technology in the context of biomedical research is often referred to as "therapeutic cloning," "biomedical cloning," or "research cloning"—terms that reveal its close connection to, while also demarking its distinction from, "reproductive cloning."

Scientists who hope to use an adult cell and an ovum to create an embryo with the same genotype as the adult cell often wince when the term "cloning" is used to describe their endeavor, even when modified by a word like "therapeutic." In fact, largely as a public relations matter, many informally boycott the term "therapeutic cloning" altogether as misleading. The problem is that the scientific link between therapeutic and reproductive cloning is real, and one consequence is that some policy arguments in support of prohibiting the

39. *See, e.g.*, PCB CLONING, *supra* note 17, at 80 ("[S]erious though nonfatal abnormalities in cloned animals have also been observed, including substantially increased birth-size, liver and brain defects, and lung, kidney, and cardiovascular problems."); SCOTT, *supra* note 4, at 46-49; Zhongde Wang et al., *Nuclear Cloning and Epigenic Reprogramming*, *in* ESSENTIALS OF STEM CELL BIOLOGY, *supra* note 5, at 93, 93 (describing developmental abnormalities observed in cloned animals)..

40. *See* PCB CLONING, *supra* note 17, at 89 ("Cloning experiments in other mammals strongly suggest that cloning-to-produce-children is, at least for now, far too risky to attempt.").

41. *See id.* at 102 ("Cloning-to-produce-children could create serious problems of identity and individuality.").

42. *See id.* at 103-04 ("A cloned child . . . is at risk of living out a life overshadowed in important ways by the life of the 'original'—general appearance being only the most obvious.").

43. *See, e.g.*, Charo, *supra* note 38, at 506.

44. *See* Leon Eisenberg, *The Outcome as Cause: Predestination and Human Cloning*, 1 J. MED. PHIL. 318 (1976).

latter present a plausible case for banning the former as well. It is, therefore, unlikely that the use of SCNT in stem cell research can be fully divorced from the broader cloning wars and, in fact, it should not be.

II. CLONING LEGISLATION

Given the vivid fears that the specter of reproductive cloning raises, it is unsurprising that a number of states have enacted comprehensive cloning bans that are insensitive to the purpose for which a cloned embryo is created. To date, at least six states—Arkansas,[45] Indiana,[46] Iowa,[47] Michigan,[48] North Dakota,[49] and South Dakota[50]—have enacted statutes that prohibit all human cloning, for therapeutic as well as reproductive purposes, within their borders. Some of these statutes make engaging in the prohibited activities a felony,[51] while others punish transgressions only with civil fines.[52] Most of these statutes prohibit not only creating a cloned human embryo but also receiving a cloned embryo.[53] These statutes might preclude any research on stem cells derived from any cloned embryo, but they might alternatively be interpreted to permit scientists to conduct research on stem cell lines that were derived from cloned embryos out of state and then imported as cell lines. Other states, most notably those that actively support hESC research, explicitly support the practice of SCNT for therapeutic purposes,[54] and the statutes of these states are clear to distinguish (and prohibit) reproductive cloning.[55]

At the federal level, there is a congressional ban on federal funding of cloning, even if done for therapeutic rather than reproductive purposes.

45. ARK. CODE ANN. § 20-16-1002 (West 2005).

46. IND. CODE §§ 16-18-2-56.5, 16-21-3-4, 25-22.5-8-5, 35-46-5-2, 35-46-5-3 (2005); IND. CODE ANN. § 16-34.5-1-2 (West 2006).

47. IOWA CODE ANN. §§ 707B.2, 707B.4 (West 2005).

48. MICH. COMP. LAWS ANN. §§ 333.16274, 333.16275 (West 2005).

49. N.D. CENT. CODE § 12.1-39-02 (2005).

50. S.D. CODIFIED LAWS §§ 34-14-26 to 34-14-28 (2005).

51. ARK. CODE ANN. § 20-16-1002 (2006) (class C felony); IND. CODE § 35-46-5-2 (2006) (class D felony); IOWA CODE ANN. § 707B.4 (2005) (class C felony); N.D. CENT. CODE § 12.1-39-02 (2006) (class C felony); S.D. CODIFIED LAWS §§ 34-14-27 (2006) (class 6 felony).

52. MICH. COMP. LAWS ANN. § 333.16275 (2006) ($10,000,000 fine); VA. CODE ANN. § 32.1-162.22 (2006) ($50,000 fine for each cloning incident).

53. *E.g.*, ARK. CODE ANN. § 20-16-1002 (West 2005).

54. CAL. HEALTH & SAFETY CODE § 125300 (West 2005); MASS. GEN. LAWS ch. 111L, § 1 (2005); N.J. STAT. ANN. § 26:2Z-2 (West 2005); R.I. GEN. LAWS § 23-16.4-2 (2005); VA. CODE ANN. § 32.1-162.22 (West 2005).

55. CAL. HEALTH & SAFETY CODE § 24185 (West 2005); MASS. GEN. LAWS ch. 111L, § 8 (2005); N.J. STAT. ANN. § 2C:11A-1 (West 2005); R.I. GEN. LAWS § 23-16.4-1 (2005); VA. CODE ANN. § 32.1-162.22 (West 2005).

Congress's annual renewal of the Dickey Amendment prohibits the use of federal funds for the creation of human embryos[56]—exactly the result of cloning, whatever its purpose. But there is also significant support in Congress for imposing a regulatory prohibition on cloning for any purpose. The House of Representatives has twice passed a bill called the Human Cloning Prohibition Act,[57] which would outlaw the production of cloned embryos whether their intended use is reproduction or therapeutic research, and it has done so by quite comfortable majorities: just over 100 votes in 2001, and just under 100 votes in 2003.[58] If enacted, the Act would subject violators to a criminal penalty of up to ten years of imprisonment, and if the violator profited from the act, not less than one million dollars in civil penalties.[59] The bill has faltered in the Senate so far, although sponsors continue to reintroduce it in both houses of Congress,[60] and President Bush called for its enactment in his 2006 State of the Union Address.[61]

Congressional opponents of the complete ban, without any visible exceptions, support bills that would prohibit cloning for reproductive purposes but allow the use of SCNT technology for stem cell research. While overwhelming opposition to reproductive cloning would seem to suggest that a reproductive cloning ban would pass easily, these bills have been stymied by proponents of a comprehensive prohibition who hold the reproductive cloning ban hostage to their insistence that therapeutic cloning also be outlawed.[62] Somewhat surprisingly, then, other than the Dickey Amendment, which concerns only federal funding, there is no federal law of any kind on the subject of cloning.

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56. *See, e.g.*, Consolidated Appropriations Act of 2005, Pub. L. No. 108-447, § 509, 118 Stat. 2809, 3163-64 (2004). The limitation of the Dickey Amendment's language to "research purposes" might suggest that a federal agency could legally fund a human cloning project with a goal of developing cloned embryos for implantation. In 1997, President Clinton issued a directive barring the federal funding of any cloning research. *See* Clinton Directive, *supra* note 35. This directive was integrated into the 2000 Research Guidelines for Research on Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000), *corrected by* 65 Fed. Reg. 69,951 (Nov. 21, 2000), *withdrawn by* 66 Fed. Reg. 57,107 (Nov. 14, 2001).

57. Human Cloning Prohibition Act of 2003, H.R. 534, 108th Cong. (2003); Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. (2001).

58. The vote in 2003 was 241 to 155; the vote in 2001 was 265 to 162. *See* Jeffrey Brainard, *After Heated Debate, U.S. House Votes Again to Ban Cloning*, CHRON. HIGHER EDUC. (Wash., D.C.), Mar. 14, 2003, at A24.

59. *See* Human Cloning Prohibition Act of 2005, H.R. 1357, 109th Cong. (2005).

60. *Id.*; Human Cloning Prohibition Act of 2005, S. 658, 109th Cong. (2005).

61. Address Before a Joint Session of the Congress on the State of the Union, 42 WEEKLY COMP. PRES. DOC. 141, 151 (Feb. 6, 2006).

62. *See* Alexander Morgan Capron, *Placing a Moratorium on Research Cloning to Ensure Effective Control Over Reproductive Cloning*, 53 HASTINGS L.J. 1057, 1064 (2002) (describing the "stalemate" in Congress over cloning legislation).

III. POLICY ARGUMENTS AGAINST THERAPEUTIC CLONING

The medical argument for pursuing therapeutic cloning technology is compelling for the reasons laid out above. To be sure, there are some serious obstacles to overcome, both technical and industrial, before cloning-based stem cell treatments becoming a reality. The inability, to date, of scientists to perfect the cloning technique with a human somatic cell is only one of the problems. A second is that SCNT does not produce a pure clone because cells in the new embryo retain small bits of mitochondrial DNA from the egg donor.[63] Thus, it is possible that problems of immune system rejection will not be solved by SCNT.[64] A third problem is that the cost of truly individualized treatments that would require technicians to create a cloned embryo from a patient's cell, extract the embryonic stem cells, and create a new cell line might be prohibitive, at least in the short run. Notwithstanding these obstacles, however, the potential for therapeutic benefits are so substantial that few if any critics of therapeutic cloning base their opposition on an argument that the scientific potential is not worth the financial costs.

Against the potential of therapeutic cloning, opponents advance at least three types of arguments as to why the law should ban research in this field.

A. OPPOSITION TO ALL EMBRYONIC STEM CELL RESEARCH

Arguments in the first category mirror arguments made against any type of hESC research, whether or not cloning technology is involved.

First, at least given presently available technology, therapeutic cloning ultimately requires the destruction of embryos for the stem cells to be collected and used. For people who believe destroying early-stage embryos is immoral, it logically follows that therapeutic cloning is also improper.

Second, therapeutic cloning by definition entails the creation of an embryo for research purposes, in addition to its destruction. Most people who believe it is improper to create embryos for purposes other than reproduction—whether or not they find embryo destruction for research problematic—will also oppose therapeutic cloning, although some bioethicists believe creating a cloned embryo for research is less troubling than creating one through fertilization because the former lacks a unique genome.[65]

Because my intention here is to focus on the issue of therapeutic cloning

63. Although most of a cell's DNA resides in its nucleus, a small bit of mitochondrial DNA resides outside the nucleus. In the SCNT process, the egg retains its original mitochondrial DNA, and resulting ESCs will retain the mitochondrial DNA that comes from the egg rather than the somatic cell. *See* PCB CLONING, *supra* note 17, at 58-59.

64. PCB MONITORING, *supra* note 5, at 132-33.

65. *See, e.g.*, Paul R. McHugh, *Zygote and "Clonote"—The Ethical Use of Embryonic Stem Cells*, 351 NEW. ENG. J. MED. 209, 210 (2004).

rather than the broader issues involved with hESC research generally, I will not evaluate the merits of these arguments.[66] However, it is important to point out that there is one important way in which this set of arguments, when made against therapeutic cloning, takes a different form than when it is employed in the context of hESC research more generally. Opponents of all hESC research have focused, at least at the federal level, on preventing government funding. Although some individual Americans undoubtedly would support either a prohibition of any research that destroys embryos or a prohibition against creating embryos for research purposes, there is relatively little popular support for such a proposal, at least as far as popular support can be judged by the position of members of the legislative or executive branches of the federal government. In the context of therapeutic cloning, however, the battleground issue is *complete prohibition*, not merely federal funding. Because of this difference, the debate over cloning raises a series of constitutional issues that are usually not present in the hESC research debate. These issues are addressed below.

B. CLONING IS UNNATURAL

The second category of arguments in opposition to therapeutic cloning is distinct from general opposition to hESC research. Arguments in this category emphasize the "unnaturalness" of creating an embryo with the genes of a single parent. They are routinely offered as criticisms of reproductive cloning, but sometimes used to criticize therapeutic cloning as well: creating embryos through SCNT is either morally unacceptable in principle or problematic as an indication of mankind's willingness to engineer human life, which shows moral hubris.[67]

What are essentially moral intuitions can be a signal of deeper wisdom, as Leon Kass, the former chair of the President's Bioethics Commission, has written.[68] But the problem with relying on them is that they are just as often an indication of unfamiliarity and prejudice. It was only a half-century ago that most Americans thought interracial marriage was unnatural and immoral. When the Supreme Court struck down a Virginia antimiscegenation statute as unconstitutional in 1967, sixteen states still had such laws on their books, and fourteen others had repealed their laws only within the previous fifteen years.[69] Today, it is the fact that people once believed such laws were appropriate that

66. For such an evaluation, see Korobkin, *supra* note 13.

67. *See* PCB CLONING, *supra* note 17, at 161-63 (stating the moral hazards of the "complete instrumentalization of nascent human life").

68. Leon R. Kass, *The Wisdom of Repugnance*, *in* THE ETHICS OF HUMAN CLONING 3, 18 (Leon R. Kass & James Q. Wilson eds., 1998).

69. *See* Loving v. Virginia, 388 U.S. 1, 6 n.5 (1967).

seems immoral. When in vitro fertilization (IVF) technology debuted, it was criticized as an immoral interference with the natural process of procreation[70]; today it causes little controversy at all.

C. THE SLIPPERY SLOPE TO REPRODUCTIVE CLONING

The strongest argument against therapeutic cloning relies on the claim of a slippery slope between therapeutic and research cloning: permitting SCNT for therapeutic purposes either increases the likelihood of, or will inevitably lead to, reproductive cloning.[71] Assuming that reproductive cloning is undesirable, a slippery slope that leads from therapeutic to reproductive cloning could potentially justify a prohibition on the former, even if therapeutic cloning itself is not ethically problematic.

Slippery slope arguments take the following form: "Even if *A* is unobjectionable in itself, permitting *A* is ill-advised because it will increase the likelihood of *B*, which is objectionable."[72] The implied causal mechanisms embedded in slippery slope claims are varied, however, and when fleshed out often undermine either the premise that *A* is itself unobjectionable or the premise that *B* is itself objectionable. For example, a common variety of slippery slope argument is that if society permits *A*, which appears similar to *B*, people will become used to *A*, and this, in turn, will reduce their revulsion toward *B*.[73] A version of this claim sometimes surfaces in arguments against therapeutic cloning in the following guise: creating blastocysts for research today could lead us to create fetuses for research tomorrow and babies for research the following day.[74] The flaw in this line of argumentation is that, if exposure to *A* will reduce revulsion to *B*, perhaps *B* is not so bad after all. On the other hand, if *B* really is that terrible and *A* is not terrible at all, exposure to *A* should not cause rational people to decide that *B* is acceptable.

There is a slippery slope argument against therapeutic cloning, however, that is significantly more powerful because it rests not on fear that *A*'s acceptance will change public morality, but on the fact that *A*'s acceptance will tangibly interfere with the practical ability of society to police *B*. If SCNT were illegal, it would be difficult, although probably not impossible, for a renegade scientist to create a cloned embryo without being discovered by colleagues and

70. *See, e.g.*, PARSON, *supra* note 21, at 125.

71. *See* Capron, *supra* note 62, at 1061-62 (claiming that therapeutic cloning "would greatly increase the risk of reproductive cloning, just the way the availability of guns greatly increases the risk of homicide").

72. *Cf.* Eugene Volokh, *The Mechanisms of the Slippery Slope*, 116 HARV. L. REV. 1026, 1030 (2003) (defining a "slippery slope").

73. Volokh calls this an "attitude-altering slippery slope." *Id.* at 1077-1105.

74. *See, e.g.*, PCB CLONING, *supra* note 17, at 163-64 (arguing that therapeutic cloning will "open the door to additional (and to some of us, far greater) moral hazards").

reported. If SCNT is legal for therapeutic purposes and becomes widespread, however, the act of creating a cloned embryo would not raise any eyebrows. With the widespread use of IVF, implanting an embryo in a woman's uterus is already commonplace, and this part of the procedure is relatively low-tech and simple. A rogue scientist bent on reproductive cloning could relatively easily take a cloned embryo created as a routine part of one process (SCNT) and use it for another routine process (IVF).[75]

In theory, the slippery slope claim is quite powerful, and it would seem, at a minimum, to force a careful balancing of the potential benefits that therapeutic cloning might help scientists to develop against the potential costs of reproductive cloning. There are two reasons, however, that this argument is much less powerful than it first appears. The first is that there is a substantial obstacle to the slide down the slippery slope; the second is that prohibiting therapeutic cloning will not keep us off that slope in the first place.

Fortunately for stem cell research, the biological facts are more complicated than the slippery slope theory implicitly assumes, and the risk of rogue scientists creating illicit babies with legally-cloned embryos is considerably less likely than one might otherwise fear. As it turns out, creating a cloned baby is considerably more complicated than inserting a cloned embryo into a female's uterus.

The nucleus of the somatic cell used to create the cloned embryo must be reprogrammed in a way that returns it to its embryonic state before it can successfully develop into a fetus and lead to a live birth. This is extremely difficult, because, during the process by which a sperm cell fertilizes an egg cell, a chemical process important for proper embryonic development occurs, one to which the sperm and egg genomes react differently. In the SCNT process, however, there is no separate sperm and egg genome—just the single genome of the donor cell. In order to program the nucleus of that cell correctly, scientists would have to first divide its genome into its two original donor genomes, an ability beyond scientists current capabilities.[76] According to an important article by Massachusettes Institute of Technology biologist Rudolph Jaenish, one of the field's leaders, this step is not required in order for a cloned embryo to create usable embryonic stem cells.[77] The upshot of this is that the slippery slope concern, while it could become significant in the future, is currently based more on science fiction than science fact.

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75. *See* PCB CLONING, *supra* note 17, at 165 ("[I]f we accept even limited uses of cloning-for-biomedical research, we significantly increase the likelihood of cloning-to-produce-children. The technique will gradually be perfected and the cloned embryos will become available, and those who would be interested in producing cloned children will find it much easier to do so.").

76. *See* Rudolf Jaenisch, *Human Cloning—The Science and Ethics of Nuclear Transplantation*, 351 NEW. ENG. J. MED. 2787 (2004).

77. *Id.* at 2789-90.

If and when technology advances to the point at which it becomes trivial to program cloned embryos to develop into babies, a less restrictive alternative to prohibiting SCNT for research purposes would be to regulate SCNT research by requiring that it include a step that would make the reproductive use of cloned embryos impossible. Such technology appears to be on the horizon. Jaenish and his team recently created cloned mouse embryos that were unable to implant into a mouse uterus because the scientists deactivated a gene in the donor cell that facilitates implantation.[78] After harvesting stem cells from the embryos, the scientists reactivated the gene in those cells and then used them to create normal ESC lines.[79]

This technique, dubbed "altered nuclear transfer" (ANT), was created in an attempt to moot some moral concerns about SCNT. Because an ANT embryo cannot implant, so the argument goes, creating one does not create a potential life, and destroying one to extract embryonic stem cells does not destroy a potential life. Whether ANT or a process like it would win over those opponents of hESC research who object to the creation or destruction of embryos seems quite doubtful. Surely, it is mere semantics to say that an embryo that is altered so that it cannot implant in a womb is not actually an embryo. This point was not lost on the U.S. Conference of Catholic Bishops, a representative of which said that ANT is just as morally objectionable as SCNT.[80] On the other hand, pragmatists who support SCNT for research purposes but fear it could make it easier for rogue scientists to create human clones should find the concept behind ANT useful in suggesting that therapeutic cloning need not make reproductive cloning unavoidable.

Whatever the likelihood that widespread therapeutic cloning will lead to reproductive cloning, prohibiting the former in this country alone would do little to forestall the latter, even if the goal is only to prevent reproductive cloning in the United States. When the technological obstacles to therapeutic cloning in humans are overcome, other nations on the cutting edge of stem cell research will embrace it. When that happens, a rogue scientist could steal a cloned embryo from a laboratory in one of those nations and hop an international flight to the United States almost as easily as one might take a cloned embryo from a stem cell research laboratory in this country and drive it across town to an IVF clinic.

Staying off the slippery slope would require that all the leading nations in

78. *See* Alexander Meissner & Rudolf Jaenisch, *Generation of Nuclear Transfer-Derived Pluripotent ES Cells from Cloned Cdx2-deficient Blastocysts*, 439 NATURE 212 (2006).

79. After harvesting stem cells from the embryos and creating cell lines, the scientists reactivated the gene and demonstrated that the resulting cells could differentiate appropriately. Irving L. Weissman, *Politic Stem Cells*, 439 NATURE 145, 146 (2006).

80. *See* Wade, *supra* note 14, at A16 (citing Richard N. Doerflinger, Dep. Dir. of the Secretariat for Pro-life Activities, U. S. Conference of Catholic Bishops).

scientific research band together to prevent SCNT. The prospects for such a coordinated action are virtually nil. A United States-supported attempt in the United Nations General Assembly to pass a resolution prohibiting cloning for any purpose, including research, recently failed miserably.[81] Substantial support for therapeutic cloning in that body led to the enactment instead of a generally-worded anti-cloning resolution, with instructions that each nation should interpret how broadly the ban ought to extend.[82]

In sum, both banning therapeutic and reproductive cloning would do little more in terms of preventing reproductive cloning than would a ban on reproductive cloning alone.

IV. CONSTITUTIONAL CONCERNS

The debate over the rules that should govern hESC research, at least at the national level, generally concern public funding. How these issues are eventually resolved will be determined, entirely, by the political process.

Because the issue of prohibition is central to the public debate over cloning, constitutional concerns that call into question the ability and the desirability of Congress to legislate in this area are also implicated here. Before cloning can be prohibited, its opponents must not only succeed in the political crucible of the Congress but also navigate the choppy waters of judicial review. For the reasons explained below, none of these constitutional concerns raised by a cloning ban are likely to prove significant enough to trump the political process, given the relevant jurisprudential views of the Supreme Court's current membership. However, a congressional cloning ban would undermine the constitutional principles of limited federal power and individual liberty rights. These consequences of a ban provide an independent justification for opposing its enactment.

A. FEDERALISM AND THE COMMERCE CLAUSE

Under our federal system, the national government lacks general regulatory authority: Congress's ability to enact legislation is limited to the powers granted to it by the Constitution. Between 1937 and 1995, this fact was little more than vaguely interesting trivia for policy wonks. The Supreme Court interpreted the Constitution's Commerce Clause—the grant of power "to regulate Commerce with foreign Nations, and among the several States"[83]—so expansively that the Court found no act of Congress that exceeded its authority.

81. Warren Hoge, *U.S. Drops Effort for Treaty Banning Cloning*, N.Y. TIMES (Late Edition (East Coast)), Nov. 20, 2004, at A3.

82. G.A. Res. 59/280, ¶¶ a-c, U.N. DOC A/RES/59/280 (Mar. 23, 2005).

83. U.S. CONST. art. I, § 8.

The landmark 1995 decision of *United States v. Lopez*,[84] however, reinvigorated the Commerce Clause and placed some limits on federal power.

Lopez, a high school senior in San Antonio, brought a concealed handgun to school.[85] Although this constituted a crime under Texas law, Lopez was charged with and convicted of violating a federal statute that prohibited possession of a firearm in a school zone. The federal court of appeals reversed his conviction, and the Supreme Court upheld the reversal, on the grounds that the federal law exceeded Congress's power under the Commerce Clause.[86] The Court concluded that the statute regulated a purely local activity, the effect of which on interstate commerce was too attenuated to justify federal regulation.[87] Five years later, the Court reaffirmed *Lopez* in *United States v. Morrison*,[88] in which a rape victim sued her assailants under the federal Violence Against Women Act. Asserting that the Commerce Clause draws a line "between what is truly national and what is truly local," the High Court held that Morrison's "remedy must be provided by the Commonwealth of Virginia, and not by the United States."[89]

In 2005, however, the Supreme Court's decision in *Gonzales v. Raich*[90] called into doubt whether *Lopez* and *Morrison* heralded a significant contraction of congressional power. *Raich* concerned the federal Controlled Substances Act (CSA), which, among other things, makes the production and possession of marijuana a federal crime.[91] Under the authority of the CSA, which the government claimed was permissible under the Commerce Clause, federal drug agents seized and destroyed six of plaintiff Diane Monson's marijuana plants following a three-hour standoff.[92] The *Raich* plaintiffs, including Monson, were Californians permitted by that state's "Compassionate Use Act" to use marijuana for medicinal purposes with a doctor's prescription.[93] They contended that their marijuana use existed within the boundaries of a traditional state concern (the practice of medicine), had no substantial effect on interstate commerce, and was therefore beyond the realm of federal regulation.[94] Justices Kennedy and Scalia, part of five-Justice majorities in *Lopez* and *Morrison*, joined the four dissenters in those cases—

84. 514 U.S. 549 (1995).
85. *Id.* at 551.
86. *Id.* at 566-568.
87. *Id.* at 561.
88. 529 U.S. 598 (2000).
89. *Id.* at 617-18 (citation omitted), 627.
90. 545 U.S. 1 (2005).
91. 21 U.S.C. §§ 801-841 (2006).
92. *Raich*, 545 U.S. at 7.
93. *Id.* at 5-6.
94. *Id.* at 7-8.

Justices Stevens, Breyer, Souter, and Ginsburg—to uphold Congress's power.[95]

The *Raich* opinion relies heavily on an analogy between intrastate production and use of marijuana and the intrastate production and use of wheat in the New Deal-era case of *Wickard v. Filburn*.[96] *Wickard* concerned a federal regulation designed to boost wheat prices during the Great Depression that limited the number of acres Filburn was permitted to cultivate with that crop.[97] Filburn argued that the federal government had no authority to regulate his production of wheat for his private use, because this was an intrastate activity with no effect on interstate commerce.[98] Ruling for the government, the Supreme Court found federal regulation was proper because Filburn's production of wheat for personal use, when aggregated with similar production of other farmers, would affect interstate commerce.[99]

In *Raich*, the High Court applied the *Wickard* aggregation principle to Diane Monson's marijuana, holding that, in the aggregate, intrastate marijuana production and possession could substantially affect interstate commerce by seeping into a market that, here, the government was legitimately trying to prevent altogether.[100] In finding *Wickard* the most appropriate precedent rather than *Lopez* and *Morrison*, the Court also drew a line between "non-economic" activity at issue in the latter cases that Congress cannot regulate under the Commerce Clause and "economic" activity at issue in the former case that subjects even intrastate activity to the aggregation principle.[101] By defining the class of economic activities extremely broadly to include any production, distribution, or consumption of commodities[102]—a definition strongly criticized by the dissent[103]—the Court determined intrastate production and consumption of marijuana was economic in nature and subject to the same analysis that governed *Wickard*.[104]

As a predictive matter, the *Raich* reasoning strongly suggests that the Supreme Court would uphold a cloning ban against a federalism challenge. As a point of departure, Congress clearly possesses the authority to prohibit the interstate transmission of cloned embryos. The question is whether Congress also has the power to prohibit the intrastate creation of cloned embryos. Under *Raich*, creating an embryo would presumably be considered an "economic" activity because it entails the production of a commodity, even if the

95. *Id.* at 1.
96. *Id.* at 17-22.
97. 317 U.S. 111 (1942).
98. *Id.* at 119.
99. *Id.* at 124.
100. *Raich*, 545 U.S. at 19.
101. *Id.* at 26.
102. *Id.*
103. *Id.* at 48-52 (O'Connor, J., dissenting), 58-60 (Thomas, J., dissenting).
104. *Id.* at 29.

production is for a non-commercial purpose such as basic scientific research. Employing the aggregation principle, the *Raich* reasoning suggests the conclusion that cloned embryos produced within states could seep into the interstate market and thus, in the aggregate, substantially affect interstate commerce, even though—as is the case for marijuana—there is no legal interstate market. Therefore, the government's power to prohibit interstate commerce in cloned embryos gives it the power to prohibit the intrastate production of cloned embryos by way of the "substantial effects" test and the aggregation principle.

There are paths of reasoning that the Supreme Court justices could take that would lead them to strike down a cloning prohibition on Commerce Clause grounds, but it is unlikely that they will. The Court could determine that cloned embryos are not "commodities," and therefore not subject to analysis under *Raich*, because, unlike the case with marijuana, there is no market—legal or illegal—for cloned embryos. The problem with this analysis is that the lack of a market results from technological limitations, specifically the fact that no one has yet created a cloned human embryo, rather than the character of cloned embryos. One can easily foresee a day in which there will be either a legal or black market for cloned embryos.

Alternatively, the Court could narrow its conclusion that the production of any commodity is within the realm of "economic" activity that the Commerce Clause permits Congress to regulate under the "substantial effects" test. Arguably, therapeutic cloning conducted by academic scientists seeking to improve our understanding of the body's regenerative potential, as opposed to the same activity conducted by corporate scientists in the hopes of developing a commercial product, is non-commercial in nature, like the operation of schools at issue in *Lopez*. This analysis seems unlikely, however, because it would require the Court to directly overrule a significant part of its *Raich* analysis.

Notwithstanding the prediction that a cloning prohibition would survive Commerce Clause review by the courts, such a ban would undermine important federalism values. This consequence constitutes an independent argument against congressional action, above and beyond beliefs about the potential benefits of therapeutic cloning specifically and the value of scientific research more generally. The jurisprudential principle central to the *Lopez* and *Morrison* decisions was that federal legislation should not encroach on areas of "traditional state concern."[105] Proposals to prohibit cloning are primarily motivated by the perceived moral impropriety of the technology. Although there is no readily agreed upon definition of what precisely comprises the category of traditional state concerns, we believe moral regulation falls within it.

105. United States v. Morrison, 529 U.S. 598, 611-19 (2000); United States v. Lopez, 514 U.S. 549, 564-68 (1995).

In some instances, laws driven by moral or ethical concerns bear directly on interstate commerce. In such cases, federal regulation is appropriate under the Commerce Clause regardless of Congress's primary motivation, as exemplified by the facts of one of the Supreme Court's most famous Commerce Clause opinions. In *Heart of Atlanta Motel v. United States*,[106] the Court properly found that the Commerce Clause provides Congress with the power to ban racial discrimination in motels because such discrimination impedes interstate travel, even if the regulation was motivated primarily by Congress's desire to redress a moral wrong.[107]

In contrast, the Human Cloning Prohibition Act of 2005[108] lacks a significant, even if secondary, commercial justification. The bill's goal is not to regulate interstate commerce in cloned embryos by preventing it, nor is the bill even useful for that purpose. Instead, the bill's proponents wish to prevent the intrastate conduct of an activity that they perceive to be ethically improper and that has only the most tangential relationship to interstate commerce concerns. That relationship is sufficient to satisfy the expansive view of the Commerce Clause that the Supreme Court adhered to for most of the twentieth century and then returned to in *Raich*. But a principled division between federal and state regulatory power ought to place judgments about the ethics of human cloning in the states' bailiwick, along with the regulation of schools at issue in *Lopez* and the regulation of violence at issue in *Morrison*.

B. RIGHTS TO PURSUE MEDICAL TREATMENT

A legitimate challenge to cloning prohibitions also could be raised under the 14th Amendment's Due Process Clause[109] by persons suffering from maladies that might be cured one day as the result of therapeutic cloning technology.

More than fifteen years ago, the Supreme Court recognized that individuals have a liberty interest under the Due Process Clause to refuse medical treatment.[110] In the wake of the publicity over the Terri Schiavo case, in which the husband and parents of a woman in a persistent vegetative state battled over whether Terri should be kept alive by artificial methods, a good deal of popular attention has been paid recently to this constitutional principle.[111] Rarely, however, does the government attempt to interfere with the ability of

106. 379 U.S. 241 (1964).

107. *Id.* at 261-62.

108. H.R. 1357, 109th Cong. (2005).

109. U.S. CONST. amend. XIV, § 1 ("[N]or shall any State deprive any person of life, liberty, or property, without due process of law . . . .").

110. Cruzan v. Dir. Mo. Dep't of Health, 497 U.S. 261 (1990).

111. Schiavo ex rel. Schindler v. Schiavo, 353 F. Supp. 2d 1161 (M.D. Fla. 2005).

individuals to obtain medical treatments for their maladies, and when it does the usual reason is to protect that individual from harm that could be caused by unsafe or ineffective remedies. Consequently, the constitutional principle of protecting individual liberty from unwarranted government interference is rarely discussed in the context of access to medical treatments. The liberty principle is implicated in this context too, however, and therefore by government attempts to prohibit medical research, such as therapeutic cloning, that could lead to the development of new treatments.

What is commonly remembered from the landmark decision of *Roe v. Wade*[112] is the Court's pronouncement that the right to privacy prevents states from proscribing abortion during the first two trimesters of pregnancy, but that countervailing interests permit state prohibitions during the final trimester.[113] In describing that the balance of interests shifts in the third trimester justifying state prohibitions, however, the Court noted, almost in passing, that prohibitions—even at this point—are not permissible when abortion "is necessary to preserve the life or health of the mother."[114] Although *Roe* is perhaps the most controversial Supreme Court decision of our time, the majority found common ground with Justice Rehnquist's dissent on this point.[115] The implication of this reasoning is that a pregnant woman has a constitutionally cognizable right to pursue medical treatment (in this case, an abortion) when her health is in jeopardy. If this were not the case, it would make little sense that the Court precluded state interference with abortion when a woman's health is at stake, even at the point of the pregnancy at which the Court explicitly recognized the state has a countervailing interest in protecting fetal life.[116]

Nineteen years after *Roe*, a plurality of the Supreme Court, writing in *Planned Parenthood v. Casey*,[117] replaced *Roe*'s trimester framework with the less rigid "undue burden" test for determining the constitutionality of state laws that interfere with the exercise of abortion rights.[118] Yet the *Casey* Court maintained that abortion prohibitions are flatly unconstitutional, even after fetal viability, if abortion is necessary to protect not just the life of the mother, but the health of the mother as well.[119] In 2000, the Court applied this dicta

112. 410 U.S. 113 (1973).

113. *Id.* at 164-65.

114. *Id.* at 163-64.

115. *Id.* at 173 (Rehnquist, J., dissenting) (observing there would be "little doubt" that the Texas anti-abortion statute at issue would be unconstitutional if it were to prohibit abortion even when the mother's life was in danger).

116. *See* Eugene Volokh, *Right to Medical Care: Roe & Casey*, 120 HARV. L. REV. at pt. 2 (forthcoming Apr. 2007).

117. 505 U.S. 833 (1992).

118. *Id.* at 876.

119. *Id.* at 878.

explicitly in *Stenberg v. Carhart*,[120] finding Nebraska's "partial-birth abortion" ban unconstitutional because it did not contain an exception to the prohibition when necessary to preserve the health of the mother.[121]

If the government cannot interfere, under any circumstances, with a woman's attempt to obtain an abortion when doing so is necessary to protect her health, it arguably follows that the government may only interfere with medical research designed to lead to treatments and cures for disease, including therapeutic cloning, when doing so serves a compelling government interest, the standard required in constitutional law for interference with a fundamental right.

To be sure, the analogy between abortion jurisprudence and therapeutic cloning requires inferential reasoning on several points. The most obvious difference between the circumstances is that the abortion cases preclude the government from interfering with a woman's ability to preserve her health by removing something (the fetus) from her body, whereas a government ban on medical research would only impede an individual from seeking an external treatment to introduce into the body. On close analysis, however, this internal-external distinction collapses. In both cases, a condition internal to the body—be it pregnancy or a malady such as Parkinson's disease or diabetes—threatens an individual's health, and the issue is whether the government may prohibit the individual from using the assistance of others to intervene in that internal condition to restore health. In either case, the individual requires the assistance of one or more third parties to preserve health, be it a physician or scientific researchers, and in either case the right claimed is not an affirmative right to have the government provide an abortion or fund medical research, but merely the negative right to be free of government interference in the pursuit of treatment.

Another difference between the two contexts is that, when pregnancy threatens a woman's health, abortion is a known "cure" for the problem with immediate results, at least in many cases, whereas therapeutic cloning and stem cell research more generally only offer the vague potential of leading to cures in the distant future. But whether patients have a fundamental right not to have the government impede their search for cures should not depend upon the likelihood of a cure being available. Indeed the Supreme Court made this point in *Stenberg*, determining that the constitutionality of Nebraska's partial-birth abortion ban did not depend on how likely it was that the banned procedure would be more conducive to preserving a patient's health than alternative procedures. In that case, despite substantial disagreement in the record over whether the banned procedure had any positive health benefit, the Court found it sufficient that a "significant body of medical opinion believes a procedure

120. 530 U.S. 914 (2000).

121. *Id.* at 937-38.

may bring with it greater safety for some patients."[122] Analogously, there is widespread belief within the scientific and medical communities that patients suffering from a range of diseases might one day be cured or alleviated by innovations arising from stem cell research, although such an outcome is far from certain and there are many doubters.

A recent decision of the D.C. Circuit Court of Appeals in *Abigail Alliance v. Von Eschenbach*[123] provides legal support for this argument. In that case, the court held that terminally ill patients have a fundamental right not to be prevented by the Food and Drug Administration (FDA) from using potentially life-saving drugs that have passed that agency's Phase I trials—meaning they have been judged safe enough in small-scale clinical trials to proceed to larger-scale clinical trials—but have not been approved by the agency for general use.[124] The decision did not require the FDA to approve the drugs at issue for use by the terminally ill because the agency may yet be able to provide a compelling interest sufficient to override the fundamental right.[125] But it did articulate a presumption against government interference with patients' attempts to seek medical treatment, at least under certain conditions.[126]

As a practical matter, it seems unlikely that the U.S. Supreme Court would either uphold the D.C. Circuit ruling in *Abigail Alliance*[127] or determine that the Due Process Clause provides patients with a right to seek therapeutic cloning. The majority of justices currently serving on the U.S. Supreme Court have, in previous opinions, articulated a relatively narrow view of the substantive due process doctrine. Under this prevailing perspective, the only rights protected by the Due Process Clause that are not explicitly enumerated in the Constitution are those specific rights that have traditionally been recognized as such in Anglo-American law. In *Washington v. Glucksberg*,[128] for example, the Court refused to recognize physician-assisted suicide as a fundamental right under the Due Process Clause, leaving legislatures to prohibit the practice if they see fit.[129] The Court majority relied mainly on the observation that the practice of assisted suicide—and, indeed, suicide in general—enjoyed no historical tradition of support in the United States, or support in Great Britain prior to the American Revolution.[130] More generally, the Court stated that constitutional rights cannot be "simply deduced from abstract concepts of

122. *Id.* at 937.
123. 445 F.3d 470 (D.C. Cir. 2006).
124. *Id.* at 486.
125. *Id.*
126. *Id.*
127. The D.C. Circuit is currently considering a petition for en banc review of the case.
128. 521 U.S. 702 (1997).
129. *Id.* at 735.
130. *Id.* at 710-12.

personal autonomy."[131]

The *Abigail Alliance* Court appears to have attempted to innoculate itself against the current Supreme Court's negative view of unenumerated rights by claiming that there is a "long-standing tradition in our Nation that would protect individual access to potentially life-saving medication."[132] The factual support for this claim provided in the *Abigail Alliance* opinion is thin, however, and, in any case, the Justices would be unlikely to agree to consider therapeutic cloning at that level of generality. There is no question that a history-based Due Process Clause jurisprudence that defines claims of rights as specifically as possible bodes ill for therapeutic cloning, a technology with no history and thus no history of support in Anglo-American law.

The *Abigail Alliance* decision highlights, however, that congressional interference with the ability to seek medical treatment outside the politically-charged context of abortion does raise constitutional concerns. The principle of constitutional liberty would be compromised more, in fact, by a cloning ban than by the FDA's refusal to permit the terminally ill access to unapproved drugs. The reason is that, under the Food, Drug and Cosmetics Act, the FDA balances the benefits to patients of access to medications against the costs of access to those patients, including the possibility that the drugs will be unsafe or ineffective. A line of federal court cases dealing with challenges to FDA authority observe, quite reasonably, that any individual liberty interests to use particular pharmaceuticals is counterbalanced by the government's interest in protecting the public health.[133] In the case of a cloning ban, in contrast, Congress would not be seeking to impede the search for health-enhancing technologies because of the potential risks that therapeutic cloning would entail for its potential beneficiaries, but because of concerns totally unrelated to the health of the potential beneficiaries. Congress should erect an impediment in such circumstances only when the interests it seeks to protect are particularly compelling.

C. REPRODUCTIVE RIGHTS

Although this article concerns therapeutic cloning, a broad congressional ban on cloning would also prohibit reproductive cloning and, in so doing, implicate constitutional concerns that arise from clearly established liberty rights related to reproduction and child rearing.

In *Skinner v. Oklahoma*,[134] the Supreme Court recognized marriage and

131. *Id.* at 725.

132. Abigail Alliance v. Von Eschenbach, 445 F.3d 470, 479-83 (D.C. Cir. 2006) (footnotes omitted).

133. *See,* Rutherford v. United States, 616 F.2d 455, 457 (1980).

134. 316 U.S. 535, (1942).

procreation as "basic civil rights of man."[135] In *Griswold v. Connecticut*,[136] the Court found the Constitution protects the fundamental right of married couples to use contraceptives. It extended this protected zone of privacy to the use of contraceptives by unmarried couples in *Eisenstadt v. Baird*.[137] In *Roe v. Wade*,[138] the Court found a fundamental right of women to terminate a pregnancy in the first two trimesters, and it essentially reaffirmed this ruling nearly two decades later in *Casey*.[139] In related cases, the Court has invalidated legal bans on interracial marriage,[140] found a general fundamental right to marry,[141] and struck down various governmental attempts to interfere with parents' decisions concerning child rearing.[142] Recently, in *Lawrence v. Texas*,[143] the Supreme Court articulated a fundamental right of privacy in the realm of sexual behavior.

Even assuming that a majority of Supreme Court justices was willing to overcome its general hostility to unenumerated rights[144] and adopt a jurisprudential view that Constitutional interpretation should evolve alongside technological and social change,[145] there would remain a question as to how broadly the holdings in the Court's due process cases can be fairly interpreted. The Court's plurality opinion in *Casey*, jointly authored by Justices O'Connor, Kennedy, and Souter, refers to the Court's tradition of protecting individual freedom to make "intimate" decisions.[146] If *Casey* and the prior decisions on which it relies stand for a proposition this broad, protection of the right to use cloning technology seems appropriate as well. The decision to create a baby and the method of doing so seem just as "intimate" as the choices at issue in the Court's related landmark cases.[147] If the precedents are read somewhat more

135. *Id.* at 541.

136. 381 U.S. 479 (1965).

137. 405 U.S. 438 (1972).

138. 410 U.S. 113 (1973).

139. 505 U.S. 833 (1992).

140. Loving v. Virginia, 388 U.S. 1 (1967).

141. Zablocki v. Redhail, 434 U.S. 374 (1978).

142. Pierce v. Soc'y of Sisters, 268 U.S. 510 (1925); Meyer v. Nebraska, 262 U.S. 390 (1923).

143. 539 U.S. 558 (2003).

144. *See supra* text accompanying notes 128-131.

145. *See generally* William J. Brennan, Jr., *The Constitution of the United States: Contemporary Ratification*, *in* INTERPRETING THE CONSTITUTION: THE DEBATE OVER ORIGINAL INTENT 23 (Jack N. Rakove ed., 1990).

146. Planned Parenthood v. Casey, 505 U.S. 833, 851 (1992) ("These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment.").

147. *Cf.* John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439, 453-55 (arguing that "one could reasonably view" Supreme Court decisions as

narrowly as protecting freedom of choice in matters relating to sexuality, freedom from interference with reproductive capabilities, or even liberty necessary to ensure gender equality, it is less clear that their holdings are applicable to the issue of cloning. By definition, cloning is unrelated to sexual behavior because sexual intercourse cannot create a clone, and a ban on cloning would seem to burden men and women roughly equally.[148]

If the Supreme Court were to determine that its previous decisions supporting individual freedom of choice in the area of reproduction and familial relationships imply a fundamental right to make use of reproductive cloning technology, due process doctrine still would allow the government to prohibit cloning if it could demonstrate a compelling government interest in doing so.[149] Here the argument for cloning protection seems stronger. That is, if the pursuit of cloning technology were recognized as a fundamental right, the government would fail to prove an interest in interfering with that right sufficiently compelling to satisfy the requirements of constitutional doctrine.

The two strongest arguments in support of a compelling governmental interest in prohibition are conceptually quite different. One rests on the need to protect potential clones and the other on the need to protect everyone else in society.

As to the first, reproductive cloning of non-human mammals has, to date, not been particularly healthy for the clones. Dolly the sheep died prematurely.[150] Cloned mice are substantially more likely to suffer from birth defects and/or die prematurely than sexually reproduced mice.[151] Put simply, science has not yet been able to reproduce mammals through SCNT that are as healthy as those reproduced through more traditional methods. At least given present technology, human clones would likely suffer the same disadvantages. If so, a plausible argument that the fundamental rights of a would-be parent to reproduce asexually, even if recognized, might be outweighed by the government's interest in protecting the competing claims of the potential offspring to be created by methods that offer the best chance of good health and

supporting a right to reproductive cloning).

148. One could argue that a cloning ban differentially burdens women because only women could produce a clone without the contribution of biological material from another person. For a man to produce a clone, a donor egg would be needed.

149. *See generally* JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW § 11.4 (6th ed. 2000).

150. *See* Jim Giles & Jonathan Knight, *Dolly's Death Leaves Researchers Woolly on Clone Ageing Issue*, 421 NATURE 776 (2003) (reporting Dolly's death of a viral lung tumor at the age of six, and noting that, apart from her previously diagnosed arthritis, the autopsy revealed no other gross abnormalities).

151. Narumi Ogonuki et al., *Early Death of Mice Cloned from Somatic Cells*, 30 NATURE GEN. 253, 253 (2002) ("[T]he lifespan of mice cloned from somatic cells is significantly shorter than that of genotype- and sex-matched controls, most likely due to severe pneumonia and hepatic failure.").

longevity.[152]

If this argument is understood to be that the government has a compelling interest in insuring that children are born with the *maximum likelihood* of living a long and healthy life, it could have the perverse consequence of indicting reproduction through sexual intercourse. With current technology, a potential child arguably has the best possible chance of being born in good health with maximum expected longevity if he or she is conceived through an IVF process in which embryos are screened for genetic diseases and only healthy embryos are implanted in the mother's uterus. If the government has a compelling interest in maximizing the expected health and lifespan of children that justifies its interference with reproductive choice, it seems to follow that the government could ban sexual reproduction that does not use a process of screening either gametes or embryos. It seems safe to predict that the Supreme Court would not adopt a position that would suggest Congress may ban sexual reproduction.

A more moderate version of the anti-cloning position would be that the government has a compelling interest in protecting potential children from *substantial risks* of being born with serious health problems. This argument faces a conceptual and a practical problem. The fact that a child produced through cloning is more likely to suffer ill health than a child produced through sexual reproduction seems to be relevant only on the assumption that a potential parent who wishes to create a cloned offspring would in fact resort to sexual reproduction if cloning is prohibited. There is little doubt this would be the case for some would-be parents. It is probably not true of all would-be parents. Potential parents interested in cloning who cannot sexually reproduce—single people, homosexual couples, or heterosexual couples in which one member is infertile—might choose not to reproduce if the only legal option is to engage a sperm or egg donor and create a child with one-half of its DNA contributed by an outside party.

Even assuming for the purposes of argument that a substantial risk of a child being born with a significant health impairment is worse than the child not being born at all, as a practical matter, this risk is likely to decline over time. The government might have a compelling interest in protecting clones from being born today, but if cloning efforts in other countries reduce these risks in time, that interest would likely cease to be compelling.

The second, and very different, argument for a compelling government interest in prohibiting cloning focuses on the potential negative externalities that too much cloning could conceivably create. Presumably, humans reproduce sexually because sexual reproduction arose in our vertebrate

152. *See* NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 36, at 63. ("Virtually all people agree that the current risks of physical harm to children associated with somatic cell nuclear transplantation cloning justify a prohibition at this time on such experimentation.").

ancestors. Through the evolutionary process, by shuffling DNA each generation creates constant changes in the genetic makeup of the human species, which helps to keep us one step ahead of bacterial and viral agents that seek to invade and destroy us by learning how to evade or overcome our antibodies.[153] No individual clone creates a risk to the continued viability of the human species, but a world in which cloning becomes a common method of reproduction could conceivably create such risks. Prohibiting cloning entirely, it might be argued, is the only non-discriminatory method of protecting against such future risks.[154] This argument has a compelling logic to it, but cloning would have to be so widespread for the species to be endangered that it is unlikely this would ever become a practical concern.

Other arguments in favor of a ban on reproductive cloning are relevant from a policy perspective but seem far from being sufficiently compelling to outweigh a fundamental right to cloning, if such a right were ever recognized.

Many people feel an intuitive negative reaction to the idea of cloning.[155] But one person's disgust, even with government support, should not override another's fundamental right. A large number of people are morally opposed to abortion and many are offended by various specimens of constitutionally protected speech. Yet in neither case are such popular sentiments dispositive.

Others fear that parents would attempt to engineer their children by selecting a child's DNA donor (whether it be one of the parents or a third party) in order to maximize his or her physical or intellectual capabilities.[156] Although perhaps different in degree from what is possible using sexual reproduction, it is hard to argue that this is different in kind from what some parents already do. Nothing prevents people from choosing their spouses on the basis of their genetic endowments, or from choosing a gamete donor on such a basis. With sexual reproduction, of course, it is no sure thing that any offspring will inherit his or her parents' desirable endowments. It is similarly less than a sure thing with clones, for genes interact with the environment, and the environmental influences on a donor and a clone will always be different.

Still other cloning opponents argue that clones would be psychologically harmed by being denied a unique identity.[157] This argument seems not only

153. *See generally* MATT RIDLEY, THE RED QUEEN: SEX AND THE EVOLUTION OF HUMAN NATURE (1994).

154. *But see* Cass R. Sunstein, *Is There a Constitutional Right to Clone?*, 53 HASTINGS L.J. 987, 997 (2002) (rejecting this argument on the ground that it is implausible that cloning would become so popular as to endanger genetic diversity).

155. *See, e.g.*, Kass, *supra* note 68.

156. *See* PCB CLONING, *supra* note 17, at 104-05 ("[P]arents, with the help of science and technology, may determine in advance the genetic endowment of their children.").

157. *See id.* at 102 (arguing that "our genetic uniqueness is an important source of our sense of who we are and how we regard ourselves" and therefore "[c]loned children may experience concerns about their distinctive identity").

quite speculative but also likely to be false. There is no reason to believe that monozygotic twins suffer undue psychological harm from the fact that they share their DNA with their sibling.

Given the Supreme Court's reluctance to recognize new substantive due process rights, it is quite unlikely that the federal courts would recognize a fundamental right to pursue cloning technology on account of its relationship to reproduction. But this prediction about the outcome of hypothetical litigation, does not undermine the fact that a cloning ban would raise serious constitutional concerns because of its effect on reproductive and child rearing decisions, just as it would raise constitutional concerns because of its implications for the pursuit of medical treatment and its implications for federalism. This set of constitutional concerns, like the others discussed in the previous two Subparts, provides a powerful argument against a congressional ban on the use of cloning technology.

V. CONCLUSION

Attempts by the House of Representatives, with the support of the President, to enact a legislative ban on human cloning, whether for reproductive or therapeutic purposes, would have a significantly deleterious effect on the likelihood that stem cell research will eventually lead to revolutionary biomedical treatments for disease and injury. There is an undeniable scientific link between therapeutic cloning and reproductive cloning, but the connection does not justify a ban on the former, even assuming the latter to be undesirable. Neither intuitive moral concerns with using cloning technology to create embryos nor fears of a slippery slope justify the proposed ban. In addition, the proposed congressional prohibition would undermine principles of federalism and compromise individual rights to both medical and reproductive freedom. It is unlikely that the federal courts would find any of these concerns to be significant enough to declare the statute unconstitutional, but its infringement on these important principles provides an independent basis for Congress to reject the prohibition.