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"All truth passes through three stages. First, it is ridiculed. Second, it is violently opposed. Third, it is accepted as being self-evident."
Arthur Schopenhauer, 1788-1860

INTRODUCTION

The announcement by British scientists in 1997 that they had successfully cloned a sheep sparked an immediate reaction of shock and alarm. The legislative and executive branches of the federal government responded rapidly. President Clinton ordered the National Bioethics Advisory Commission (NBAC) to study the ethical implications of cloning human beings. Individual states began passing laws that prohibited human cloning, enforced through civil or criminal penalties.[1] A "crisis atmosphere" prevailed in Congress, where the Senate majority leader tried to move an anti-cloning bill directly to the Senate floor without hearings less than 48 hours after its presentation.[2] Several proposals for federal cloning legislation were introduced, but so far none have passed.[3]

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1. HUMAN CLONING: SCIENCE, ETHICS, AND PUBLIC POLICY 118 (Barbara MacKinnon ed., University of Illinois Press 2000).

2. *Id.*

3. Recent proposals for legislative action have included the following: Human Cloning Prohibition Act of 2002, S. 2439, 107th Cong. (2002); Human Cloning Prohibition Act of 2001, S. 1758, 107th Cong. (2001); Human Cloning Prohibition Act of 2001, S. 1899, 107th Cong. (2001) (passed by the House on July 31, 2001, but not taken up by the Senate). Each bill would have made it a crime to clone human beings, but differed significantly on other issues, such as cloning for biomedical research. To some extent, this flurry of legislative activity has continued to the present day at the state level. In 2003, sixty-nine cloning bills were introduced by state legislatures in twenty-eight different states (though only four were enacted). *See* National Conference of State Legislatures website, *available at*

The current political climate condemns reproductive cloning.[4] At present, the procedure cannot guarantee the viability of the clone and there is a fairly widespread moral consensus that it would be unacceptable to clone a human being even if it was safe.[5] Several states have prohibited human reproductive cloning, and some have also banned therapeutic cloning.[6] By contrast, other states have carved out exceptions that permit research using nuclear transplantation as long as the research will not result in a human being.[7] The question this Note asks, and attempts to answer, is one posed by the Senate Appropriations Committee in 2002: "must we

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http://www.ncsl.org.

4. *See* June Mary Zekan Makdisi, *The Slide from Human Embryonic Stem Cell Research to Reproductive Cloning: Ethical Decision-making and the Ban on Federal Funding*, 34 RUTGERS L.J. 463, 465 (2003).

5. Several bioethics commissions have reached this conclusion. For example, the National Bioethics Advisory Commission determined that "any attempt to clone human beings via somatic cell nuclear transfer techniques is uncertain in its prospects, is unacceptably dangerous to the fetus and, therefore, morally unacceptable." The National Bioethics Advisory Commission, Cloning Human Beings: Report and Recommendations (June 1997), *available at* http://www.bioethics.gov/reports/past_commissions/nbac_cloning.pdf (last visited Aug. 12, 2004). Even the American Association for the Advancement of Science endorses a ban on "efforts to implant a human cloned embryo for the purpose of reproduction" based on the risks identified in animal studies. Am. Ass'n for the Advancement of Science, Statement on Human Cloning (Apr. 10, 2002), *available at* http://www.aaas.org/news/releases/2002/Cloning.shtml (last visited Aug. 12, 2004).

6. In its report, the President's Council on Bioethics abandoned the ambiguity of the terms "reproductive cloning" and "therapeutic cloning," instead referring to "cloning-to-produce-children" and "cloning-for-biomedical-research," respectively. The President's Council on Bioethics, Human Cloning and Human Dignity: An Ethical Inquiry (July 2002) [hereinafter The President's Council on Bioethics], *available at* www.bioethics.gov/reports/cloningreport/index.html (last visited Aug. 12, 2004). Simply because the latter terms are unwieldy, this paper will continue to refer to reproductive cloning and therapeutic cloning throughout, despite the potential for some ambiguity.

7. The legislatures in Iowa, Michigan, North Dakota, and Arkansas have passed total bans on human cloning, both reproductive and therapeutic. *See* http://www.ncsl.org/programs/health/genetics/rt-shel.htm. By contrast, Rhode Island, California, Louisiana, and Virginia prohibit reproductive cloning but carve out an exception that allows therapeutic cloning to proceed. *Id.* Perhaps most importantly, some policymakers view therapeutic cloning as the first step on a slippery slope that will eventually lead to reproductive cloning. Additionally, some state statutes may implicitly prohibit nuclear transplantation techniques even though they may not explicitly mention cloning for biomedical research. South Dakota's law prohibiting the use or destruction of embryos for research purposes is an example, though it appears to be fairly unique. *See* S.D. CODIFIED LAWS § 34-14-16 (Michie 2004) ("No person may knowingly conduct nontherapeutic research that destroys a human embryo."); § 34-14-17 ("No person may knowingly conduct nontherapeutic research that subjects a human embryo to substantial risk of injury or death. No person may sell or transfer a human embryo with the knowledge that the embryo will be subjected to nontherapeutic research."). Cloning for biomedical research is considered "nontherapeutic research" because it is not "intended to help preserve the life and health of the particular embryo subjected to risk." § 34-14-19.

sacrifice medical research in the name of a total [cloning] ban?"[8]

Legislatures have addressed the issue of therapeutic cloning in a number of ways including regulation, voluntary moratoria, self-enforcement among the scientific community, and legislative bans. Many people believe that the process of therapeutic cloning, in which embryos are destroyed, is so unethical and the possible misuse of the resulting cloned embryos so threatening, that cloning for biomedical research should be criminalized. The central ethical issue is that embryos created through this method are discarded when they are no longer useful for research. Some also object that the embryos are created for the sole purpose of research and are never intended to develop into a person.[9] Others are concerned that if therapeutic cloning is permitted, than it is just a matter of time before human beings are cloned as well.[10]

It is worth noting that a criminal ban on the practice of cloning human embryos – regardless of whether a scientist intends to create a human being – is the most restrictive of all potential legislative policies, yet several states have already adopted this approach and Congress has considered enacting such laws.[11] Some states, however, have placed a criminal ban on reproductive cloning while allowing therapeutic cloning to proceed, albeit without public funding.[12] In theory, legislatures could not only permit therapeutic cloning to proceed without threat of criminal sanction, but also fund, and perhaps even encourage, the research.[13] Such a debate currently

8. *Human Cloning: Must We Sacrifice Medical Research in the Name of a Total Ban?: Hearing Before the Senate Comm. on the Judiciary*, 107th Cong. (Jan. 24 and Mar. 12, 2002), *available at* http://www.access.gpo.gov/congress/senate (last visited Aug. 10, 2004).

9. There are other ethical considerations in therapeutic cloning and stem cell research that are beyond the scope of this Note, most notably ensuring that the egg donors who provide the raw material for cloning do so only upon informed consent. *See* R.M. Green et al., *Overseeing Research on Therapeutic Cloning: A Private Ethics Board Responds to Its Critics*, HASTINGS CENTER REP. 27, 30 (May-June 2002). Even if therapeutic cloning is allowed to proceed legally, the scientific community must continue to ensure its ethical practice. *Id.* at 32.

10. *Id.* at 28.

11. On February 27, 2003, the House passed by an overwhelming vote of 241 to 155 the Human Cloning Prohibition Act of 2003 (S. 245), but it stalled in the Senate. If passed into legislation, this Act would have banned both types of cloning, and it also would make it a crime to "receive or import a cloned human embryo or any product derived from a cloned human embryo," punishable by ten years in prison and fines of $1 million. Wendy Lim, *Towards Developing a Natural Law Jurisprudence in the U.S. Patent System*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. 559, 612 (2003).

12. *See* National Conference of State Legislatures website, at http://www.ncsl.org/programs/health/Genetic/rt-shcl.htm (last visited Aug. 12, 2004).

13. In fact, this is precisely what the California legislature has done, though there appears to be virtually no chance of adopting this stance as federal policy, given Congress' reluctance to fund any embryo research. *See infra* notes 103-108.

rages over whether stem cell research should receive federal funding.[14] Interestingly, the debate in this context is not over whether stem cell research will be criminally banned, but whether it will receive public funding.

Determining the best public policy for this potential research requires tackling the ethical issues and practical drawbacks presented by therapeutic cloning. In order to provide a scientific background, Part I of this Note will briefly outline the processes by which nuclear transplantation and the subsequent derivation of stem cells occur in the laboratory. Part II will argue that because of the American tradition of scientific inquiry free from governmental prohibition, as a matter of policy, those who would criminalize this area of research bear the burden of showing why a criminal ban would benefit society. In order to weigh the costs and benefits of therapeutic cloning from a policy standpoint, Part III will examine the potential benefits of embryonic stem cells, particularly those derived from cloned embryos, while Part IV will examine some of the arguments put forth by those who would make therapeutic cloning a crime. Part V will discuss when it is proper to invoke the criminal law to enforce moral views, ultimately concluding that criminal sanctions are particularly ill-suited to therapeutic cloning. This Note concludes that, despite the ethical concerns legitimately raised in response to therapeutic cloning, legislatures should not criminalize the practice at this point. Finally, Part VI will offer less restrictive policy alternatives that could still provide necessary oversight of this controversial research.

I. THE SCIENCE OF NUCLEAR TRANSPLANTATION AND STEM CELLS

The scientific phrase for the process of embryo "cloning" is somatic cell nuclear transfer, or "nuclear transplantation" for short.[15] It is accomplished by transferring the DNA from a human adult cell nucleus into the cytoplasm of an oocyte (egg) whose own nucleus has been removed.[16] The fertilized egg is then induced by an electrical charge to begin dividing.[17] Nuclear transplantation is the initial step in deriving embryonic stem cells for eventual treatment of patients (therapeutic cloning), or in potentially

[14] President Bush announced his decision that federal funds may be used for research on stem cell lines that existed as of August 9, 2001. Press Release, The White House, Office of the Press Secretary, Remarks by the President on Stem Cell Research (Aug. 9, 2001) (*available at* http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html).

15. IAN WILMUT ET AL., THE SECOND CREATION: DOLLY AND THE AGE OF BIOLOGICAL CONTROL 56 (Farrar, Straus & Giroux 2000).

16. *Id.* at 56.

17. *Id.* at 134.

creating cloned people (reproductive cloning).[18] In therapeutic cloning, the resulting embryo is not implanted into a woman for gestation as in reproductive cloning.[19] Rather, the embryo is allowed to divide in a laboratory petri dish until it is made up of 100 to 150 cells, roughly the size of a pin point.[20] At this time, the five- to seven-day-old embryo, known as a blastocyst, does not yet contain any distinctive body tissues.[21] Blastocysts created through nuclear transplantation share the same genetic material as their parent.[22] If a cloned blastocyst were implanted into a woman, a cloned human being would result after gestation.[23] However, the main focus of scientific researchers conducting nuclear transplantation is not to create people, but rather to create a source of embryonic "stem cells."[24]

Stem cells are present in many tissues of the human body, and because they are constantly self-generating, they serve to repair or replace damaged cells within tissues.[25] In 1998, James Thomson from the University of Wisconsin successfully isolated pluripotent stem cells from the inner cell mass of human blastocysts.[26] In doing this, Thomson discovered how to maintain human embryonic stem cells indefinitely in a culture.[27] Pluripotent cells such as embryonic stem cells have the potential to develop into a variety of human tissues; they can give rise to almost any type of cell in the human body.[28]

To generate embryonic stem cells, blastocysts created through nuclear transplantation are tricked into thinking they are still at a stage where cell division is supposed to occur without differentiation.[29] This deception is carried out by placing the blastocyst in a petri dish overloaded with molecular signals that foster proliferation of millions of identical,

18. *Id.* at 112-13.

19. Press Release, University of California San Francisco, *UCSF Researchers Have Explored Various Strategies Seeking Stem Cells* (May 24, 2002) (*available at* http://pub.ucsf.edu/newsservices/releases/200307222).

20. *Id.*

21. *Id.*

22. *Id.* Technically, the newly cloned blastocyst is not a perfect genetic copy because some mitochondrial DNA that was present in the parent cell is not passed on to the clone.

23. *Id.*

24. WILMUT ET AL., *supra* note 15, at 233.

25. *Id.* at 233-34.

26. James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 282 SCIENCE 1145-47 (1998).

27. *Id.*

28. Stem cells of the blood and some other tissues are multipotent; they can give rise to different forms of white and red blood cells, but they cannot give rise to other types of cells, such as nerves or muscles. WILMUT ET AL., *supra* note 15, at 53.

29. LEE M. SILVER, REMAKING EDEN: HOW GENETIC ENGINEERING AND CLONING WILL TRANSFORM THE AMERICAN FAMILY 150 (Avon 1998).

undifferentiated cells.[30] By exposing this undifferentiated cell mass to growth factors, researchers then force the embryonic cells down specific pathways of differentiation into, for example, bone marrow or nerve cells.[31] Within a generation, scientists might discover which signals are needed to convert embryonic cells into every kind of tissue that exists in the human body.[32]

II. THE SOCIETAL VALUE OF SCIENTIFIC INQUIRY, AND THE BURDEN OF PROOF ON THOSE WHO WOULD RESTRICT IT

Scientists have not always been given free rein to conduct research. Until at least the Eighteenth Century, scientific research was often subject to severe restrictions by ecclesiastical and civil authorities: "[f]ear of reprisal by the church, the state, or the mob was a major reason for cloaking scientific activities in secrecy."[33] For the most part, scientific research in America has rejected this repressive attitude, with the government supporting and funding science.[34] The framers of the Constitution were themselves products of Eighteenth Century Enlightenment thinking, which venerated science.[35] Freedom to pursue knowledge is "an enduring American value, supported by scientists and non-scientists alike."[36] In keeping with this American tradition of free scientific inquiry, Congress has generally avoided banning any particular area of scientific research.

The Supreme Court recognized that historically, Americans have

30. *Id.*

31. *Id.*

32. *Id.* at 150-51.

33. HAROLD C. RELYEA, SILENCING SCIENCE: NATIONAL SECURITY CONTROLS AND SCIENTIFIC COMMUNICATION 9-10 (Ablex Corp. 1994). Of course, in some parts of the world, scientific (and non-scientific) expression is still repressed in a similar manner. Lessons learned from these experiences inform a petition letter signed by forty Nobel Laureates opposing restrictive cloning laws:

> By declaring scientifically valuable biomedical research illegal, Senator Brownback's legislation, if it becomes law, would have a chilling effect on all scientific research in the United States. Such legal restrictions on scientific investigation would also send a strong signal to the next generation of researchers that unfettered and responsible scientific investigation is not welcome in the United States.

Statement of Forty Nobel Laureates Regarding Cloning, The American Society for Cell Biology (Apr. 10, 2002) (*available at* http://www.ascb.org/publicpolicy/Nobelletter.html).

34. *See generally* Steven Goldberg, *The Constitutional Status of American Science*, 1979 U. ILL. L.F. 1, 1 (arguing that the Constitution contains an implied science clause that protects the publication of science-related information).

35. STEVEN GOLDBERG, CULTURE CLASH: LAW AND SCIENCE IN AMERICA 26 (New York Univ. Press 1994).

36. NAT'L BIOETHICS ADVISORY COMM'N (NBAC) REPORT, CLONING HUMAN BEINGS 77 (June 1997) [hereinafter CLONING HUMAN BEINGS].

protected and encouraged scientific inquiry because of the great social benefit in maintaining the sanctity of knowledge and the value of intellectual freedom.[37] Scientists have the responsibility of advancing knowledge, and are thus granted a great deal of freedom "in the expectation that knowledge beneficial to society will be yielded."[38] Because knowledge is most likely to be advanced through empirical tests,[39] the scientific researcher is expected to conduct experiments and press the frontier of our understanding of the natural world. It is "contradictory to lay that expectation upon [professional scientists and scholars] and then to prevent its accomplishment by deterring its fulfillment through rules that punish its exercise."[40] Thus, regulation of scientific inquiry is not to be taken lightly. "[F]reedom of inquiry is a value of the very deepest importance which, without most compelling reasons to the contrary, should not be abridged,"[41] and suppression of scientific inquiry is to be imposed only when vitally important societal interests would be negatively impacted.

Many commentators have argued that restrictions on scientific research are an unconstitutional infringement upon a fundamental right to free scientific inquiry derived from the First Amendment.[42] These arguments probably go too far in protecting scientific research itself, as opposed to

37. Branzburg v. Hayes, 408 U.S. 665, 705 (1972). Similarly, the Supreme Court stated in *Meyer v. Nebraska* that the right to liberty guaranteed by the Fourteenth Amendment encompassed freedom to "acquire useful knowledge . . . and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men." 262 U.S. 390, 399 (1923).

38. JOHN T. EDSALL, SCIENTIFIC FREEDOM AND RESPONSIBILITY 5 (Am. Ass'n for the Advancement of Science 1975).

39. Carl Cohen, *When May Research Be Stopped?*, *in* THE RECOMBINANT DNA DEBATE 321-22 (David A. Jackson & Stephen P. Stich eds., Prentice-Hall 1979).

40. William Van Alstyne, *The Specific Theory of Academic Freedom and General Issue of Civil Liberty*, *in* THE CONCEPT OF ACADEMIC FREEDOM 77-78 (E. Pincoffs ed., Univ. of Tex. Press 1975). *See also* John T. Edsall, *Scientific Freedom and Responsibility, Report of the AAAS Committee on Scientific Freedom and Responsibility,* 188 SCIENCE 687, 687-88 (May 16, 1975) ("Scientific freedom, like academic freedom, is an acquired right, generally accepted by society as necessary for the advancement of knowledge from which society may benefit.").

41. Alvin Zander, *The Discussion of Recombinant DNA at the University of Michigan*, *in* THE RECOMBINANT DNA DEBATE, *supra* note 39, at 12-13.

42. *See, e.g.*, Elizabeth Price Foley, *The Constitutional Implications of Human Cloning*, 42 ARIZ. L. REV. 647, 677-87 (2000) (arguing that banning human cloning would encroach on scientists' First Amendment "right of scientific inquiry"); Mathew B. Hsu, *Banning Human Cloning: An Acceptable Limit on Scientific Inquiry or an Unconstitutional Restriction of Symbolic Speech?*, 87 GEO. L.J. 2399, 2412-14 (1999) (arguing same); Richard Delgado & David R. Millen, *God, Galileo and Government: Toward Constitutional Protection for Scientific Inquiry*, 53 WASH. L. REV. 349 (1978) (arguing that scientific inquiry is protected expression).

protecting science-related publications.[43] Scientists do not have the unqualified freedom to pursue whatever inquiries they choose; research undertakings may be constitutionally restricted whenever the government has a rational basis for doing so.[44] The right of free inquiry must sometimes yield to conflicting rights or to the demands of conflicting moral principles.[45] Still, our society's commitment to the freedom of inquiry is such that, as a matter of policy rather than constitutional right, the burden of proof should rest upon those who would prohibit an area of research.

Most decisions about whether to proceed with a type of research are appropriately made by applying the utilitarian criterion of "the greatest good for the greatest number," in which the soundness of a policy is measured by comparing expected benefits to expected harms.[46] A reasonable formulation might be that research or its by-product should only be prohibited when it causes harm so great as to clearly outweigh the reasonably anticipated benefits.[47] Those who would ban therapeutic cloning because they believe it is unethical to destroy embryos must show not only that the harms outweigh expected benefits, but also that the harms so greatly outweigh potential benefits so as to enforce this moral view through criminal sanctions.[48] By this reasoning, if the benefits equaled harms, our society's commitment to scientific research would demand that

43. Regulation of scientific experiments to protect public health and safety or for other valid reasons is constitutional. After all, the First Amendment protects speech, not action. *See* GOLDBERG, *supra* note 35, at 86 ("biologists have no First Amendment right to perform experiments in their basement when those experiments endanger the safety of the neighbors or the environment. Properly drawn statutes, such as those relating to the use of plutonium, can and do limit scientific experimentation to protect public safety."). Thus, prohibiting therapeutic cloning is not a constitutional violation (provided there is a rational reason for the legislature to object to the research), but rather, as this Note will suggest, merely unwise policy.

44. Cohen, *supra* note 39, at 303. Even if scientific inquiry were determined to be a fundamental constitutional right, the government could regulate to protect against compelling harms. If the government can show that restrictions on cloning and cloning technology are sufficiently important to the general well-being of individuals or society, such restrictions would still be upheld as constitutional state action. *See* John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203, 1278 (1977); *See also* CLONING HUMAN BEINGS, *supra* note 36, at 77.

45. Stephen P. Stich, *The Recombinant DNA Debate: Some Philosophical Considerations*, *in* THE RECOMBINANT DNA DEBATE, *supra* note 39, at 186.

46. *See generally* JOHN STUART MILL, UTILITARIANISM (George Sher ed., 2d ed. 2001). We multiply the gravity of expected harms by the probability that they will occur, and weigh it, as on a balance scale, against the product of reasonably anticipated benefits multiplied by the likelihood of realizing those benefits (which may be referred to as expected utility). Utilitarianism demands that we adopt the policy with the highest expected utility. *See, e.g.*, Stich, *supra* note 45, at 194-95; Cohen, *supra* note 39, at 318.

47. Cohen, *supra* note 39, at 303.

48. *See* discussion *infra* Part VI.

cloning research be allowed to continue. However, as the next section will demonstrate, the scales are not balanced; anticipated benefits of therapeutic cloning far outweigh its harms. It is critical to understand the potential benefits of therapeutic cloning when combined with embryonic stem cell research. The awesome potential of this line of applied science argues strongly in favor of allowing cloning research to proceed.

Some commentators believe that because the destruction of human embryos implicates our deeply felt moral intuitions, the deontological theory, which focuses on the duty of right action instead of just consequences, is an appropriate framework for making decisions about therapeutic cloning.[49] A deontological approach, however, would short-circuit the discussion because therapeutic cloning cannot occur without the destruction of embryos, a practice considered immoral by a significant minority of Americans.[50] The advantage of this Note's utilitarian framework is that it invites a broader discourse about the best possible legislative policy on therapeutic cloning by requiring exploration and balancing of both harms and benefits.[51]

III. BENEFITS OF THERAPEUTIC CLONING

A. Why Stem Cells Should Continue to Be Developed from Embryos

A major argument against therapeutic cloning is that other alternatives exist for creating stem cells, and we need not resort to nuclear transplantation. Senator Brownback (R-Kan.) has voiced this argument: "recent scientific advances indicate that there are fruitful and morally unproblematic alternatives to [therapeutic cloning]. There is no need for this technology to ever be used with humans."[52] It is true that "adult" stem cells[53] can be obtained from the following sources in humans: tissues such

49. *See, e.g.*, Makdisi, *supra* note 4, at 465-66.

50. At the very least, the debate within the deontological framework would have to focus on whether the research process itself is immoral, a question that opens a veritable Pandora's box, contemplating the relative moral status of the human embryo.

51. It is concededly quite difficult to quantify the harms and benefits likely to result from therapeutic cloning. Harms are difficult to quantify because there is no ready formula for how society should weigh the destruction of embryos. Benefits of therapeutic cloning are perhaps even more difficult to quantify, because both their likelihood and the substance of any future health benefits are to some extent speculative.

52 Sen. Sam Brownback, *Bioethics: Human Cloning*, *at* http://brownback.senate.gov/LICloningText.htm (last visited Aug. 20, 2004).

53. A more accurate term for "adult stem cells" might be *multipotent adult progenitor cells*. ANN A. KIESSLING & SCOTT C. ANDERSON, HUMAN EMBRYONIC STEM CELLS, AN INTRODUCTION TO THE SCIENCE AND THERAPEUTIC POTENTIAL 142 (Jones and Bartlett Publishers 2003) [hereinafter HUMAN EMBRYONIC STEM CELLS].

as bone marrow, skin, or blood;[54] umbilical cord blood and placentas; and fetal tissues from aborted fetuses.[55] Stem cells derived from human embryos, however, have particularly desirable characteristics. Ian Wilmut, one of the scientists who cloned Dolly the Sheep, said, "[f[or human cloning at the cellular level to achieve its medical promise, it will become necessary to do research on very early embryos, created specifically for this purpose."[56]

Adult stem cells are generally thought to be less than ideal for research since they have already begun forming specific cells and are less elastic.[57] Furthermore, they have not been isolated for all cell and tissue types, are present only in minute quantities, are difficult to isolate and purify,[58] and may lose their potency over time because they do not always grow well in laboratory culture dishes.[59] Embryonic stem cells, by contrast, can proliferate indefinitely,[60] and their chromosomal composition remains stable throughout many cell cycles.[61] Embryonic stem cells work best because they produce large quantities of undifferentiated cells and are therefore pluripotent; that is, they have the potential to develop into any kind of cell in the human body except for the cells needed to develop a fetus.[62] In contrast, adult stem cells have restricted developmental potential.[63] Thus far, only pluripotent stem cells have been isolated from adult tissue; that is, cells capable of giving rise to some, but not all, cell types.[64]

For example, adult nerve cells have been transplanted in numerous

54. When stem cell lines are created from adult tissues, the cells' nuclei must be reprogrammed so that they become pluripotent. *Id.*

55. Because a fetus grows rapidly during the last six months of gestation, all of a fetus's tissues and organs, including the brain, contain stem cells. *Id.*

56. THE CLONING SOURCEBOOK 128 (Arlene Klotzko ed., Oxford Univ. Press 2001).

57. Nat'l. Inst. of Health, *NIH Backgrounder on Stem Cells* [hereinafter *NIH Stem Cell Backgrounder*], *at* www.nih.gov/news/backgrounders/stemcellbackgrounder.htm (last visited Aug. 12, 2004).

58. *Id.*

59. This is a significant drawback, because any effective cell or tissue replacement would require that transferred cells survive and continue to function normally for the lifetime of the patient. Ian Wilmut, *Human Cells from Cloned Embryos in Research and Therapy*, 5 CLONING AND STEM CELLS 163, 164 (2003).

60. *See generally* M.J. Evans & M.H. Kaufman, *Establishment in Culture of Pluripotential Cells from Mouse Embryos*, 292 NATURE 154 (1981).

61. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 145.

62. *NIH Stem Cell Backgrounder*, *supra* note 57.

63. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 145.

64. *NIH Stem Cell Backgrounder*, *supra* note 57. "Adult stem cells have not been found for all types of tissue, but discoveries in this area of research are increasing. For example, until recently it was thought that stem cells were not present in the adult nervous system, but in recent years such stem cells have been found in the brain." *Id.*

studies, but they have not formed functional connections with the host's brain.[65] Embryonic stem cells, by contrast, can be induced to differentiate into mature neurons, nerves remarkably similar to those in the human body and capable of transmitting electrical and chemical signals.[66] The journal *Nature* published a study in which neuronal stem cells derived from embryos were successfully implanted in rats. This study illustrates the principle that embryonic stem cells can integrate into a host and repair damaged nerve cells without causing tumors.[67] This breakthrough holds great promise for the treatment of neurologic conditions such as Parkinson's disease and spinal cord injury by creating healthy tissue for replacement.[68]

Recent studies indicate, however, that some adult stem cells may actually be able to contribute to tissues other than their tissue of origin,[69] and some researchers believe adult stem cells are actually preferable to embryonic stem cells because they are less likely to become cancerous. Additionally, adult stem cell differentiation is easier to manage than embryonic stem cell differentiation.[70] Certainly, further study of adult stem cells is needed.[71] Time will tell if pluripotent adult stem cells capable of contributing to a wide variety of tissues can be developed, or if they are perhaps superior to embryonic stem cells for therapeutic purposes. In the meantime, the scientific community need not decide which type of stem cell is superior; rather, research with both types should proceed simultaneously.[72]

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65. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 160.

66. *Id.*

67. *See* Jong-Hoon Kim et al., *Dopamine Neurons Derived from Embryonic Stem Cells Function in an Animal Model of Parkinson's Disease*, 418 NATURE 50, 50-56 (2002); *see also* HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 160-63 (discussing the Kim experiment).

68. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 163.

69. *See, e.g.*, C.M. Verfaillie et al., *Unexpected Potential of Adult Stem Cells*, 996 ANNALS N.Y. ACAD. SCI. 231 (2003); Daniel Q. Haney, *Marrow Cells Surprisingly Versatile, Study Finds*, THE MIAMI HERALD, May 4, 2001, at A20.

70. *Hearing on Stem Cell Research Before the Subcommittee on Labor, Health and Human Services, and Education Appropriations Committee*, 107th Cong. (July 18, 2001) (testimony of Richard Doerflinger on behalf of the Committee for Pro-Life Activities United States Conference of Catholic Bishops), *available at* 2001 WL 878936 (F.D.H.C.).

71. Donald Kennedy, *Stem Cells: Still Here, Still Waiting*, 300 SCIENCE 865, 865 (2003).

72. According to molecular neurobiologist Charles F. Stevens, "[i]t is absolutely vital to continue research using embryonic neural stem cells. It may be that, for reasons we don't yet understand, adult stem cells will never be useful in therapy and that we will always need embryonic cells. Or, it may be the other way around. We just don't know." HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 164; *see also NIH Stem Cell Backgrounder*, *supra* note 57 ("Given the enormous promise of stem cells [sic] therapies for so many devastating diseases, NIH believes that it is important to simultaneously pursue all lines of research and search for the very best sources of these cells.").

B. Why Stem Cells Should Continue to Be Developed From Cloned Embryos

Having demonstrated the superiority of embryonic stem cells, a question remains: must we resort to *cloning* in order to conduct embryonic stem cell research? Opponents of therapeutic cloning point to other sources of embryos for research, such as "surplus" embryos created at *in vitro* fertilization clinics.[73] Stem cell lines created from cloned embryos, however, offer key advantages. Nuclear transplantation is the fastest and most reliable way to reproduce genetically identical stem cells.[74] More importantly, stem cells derived from cloned embryos would be autologous, meaning they would be derived from the same individual who will receive the replacement therapy, which minimizes the likelihood of tissue rejection.[75] Cloned embryos also have an application beyond stem cells: through experiments with embryonic cells for which they already know the genetic composition, scientists can gain a better understanding of how inherited predispositions lead to a variety of cancers and neurological diseases.[76]

It is only through the use of cloned embryos that the awesome potential of "regenerative" medicine may be unlocked. Embryonic stem cells created through nuclear transplantation offer the possibility of a renewable source of replacement cells, tissues, or even fully formed organs for transplantation into humans to regenerate or replace damaged or diseased body parts.[77] Potential applications range from skin grafts for burn victims and bone marrow stem transplants for leukemia patients to nerve stem cell transplants for neurodegenerative diseases.[78] A recent survey published in *Science* predicted that therapies developed from stem cells will eventually be able to cure 125 million people in the United States.[79] According to the National Institutes of Health (NIH), "[t]here is almost no realm of medicine that might not be touched by this innovation."[80]

Eventually, stem cell lines created from cloned embryos could alleviate the current shortage of transplantable organs and eliminate tissue rejection based on genetic incompatibility.[81] Transplantable tissues and organs could

73. HUMAN EMBRYONIC STEM CELLS, supra note 53, at 144.

74. *Id.* at 153.

75. *Id.*

76. Statement of Forty Nobel Laureates Regarding Cloning, *supra* note 33.

77. HUMAN CLONING: SCIENCE, ETHICS, AND PUBLIC POLICY, *supra* note 1, at 156-57.

78. *Id.*

79. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at xiii.

80. *NIH Stem Cell Backgrounder*, *supra* note 57.

81. The newly created tissue would be cloned from a person's own cells. The tissue made from cloned cells would be virtually genetically identical to the patient's tissue, or at

be effective in curing or reversing many serious illnesses and injuries, including Parkinson's disease, juvenile diabetes, Huntington's disease, amyotrophic lateral sclerosis (ALS, or Lou Gehrig's disease), multiple sclerosis, and spinal cord injury.[82] Additionally, gene therapy could potentially cure genetic diseases by replacing "defective" genes whose nucleotides are not in the proper sequence with intact ones.[83] The genetic deficiencies would be corrected in culture: the embryonic stem cells derived from the patient through nuclear transplantation would then be reinfused into the patient, correcting the gene defect.[84] These genetically engineered stem cells could eventually cure genetic diseases such as cystic fibrosis, hemophilia, and some types of cancer.[85]

C. The Uncertainty of Achieving Health Benefits through Cloning Research

Critics of "therapeutic" cloning argue that the term itself is too optimistic; there is no guarantee that stem cells grown from cloned embryos will ever be used in the treatment of patients, or yield any results whatsoever. The President's Council on Bioethics emphasized that there are questions about the likelihood that this research will deliver its promised benefits.[86] Even proponents of therapeutic cloning concede that its potential benefits are somewhat hypothetical and will require long-term investment.[87]

The perceived uncertainty of eventual benefits, however, is exaggerated in light of the successes that have already been achieved. Scientists have created and implanted a cow kidney from stem cells that were produced by nuclear transfer.[88] After transplanting the kidney under the skin of the

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least similar enough at the level of the cell surface to evade immune surveillance. *NIH Stem Cell Backgrounder*, *supra* note 57.

82. The President's Council on Bioethics, *supra* note 6, at 117. On the topic of cloning for biomedical research, the Council is split into a majority opinion and a minority opinion. *Id.* at xxxv-xxxix. To reach its decision, the Council discussed the moral and public policy implications of cloning, both reproductive and therapeutic. *Id.* After significant discussion, the majority of the council recommended that there be a four-year moratorium on cloning for biomedical research (therapeutic cloning). *Id.* By contrast, the minority opinion recommended that cloning for biomedical research be allowed with regulation. *Id.*

83. Makdisi, *supra* note 4, at 467-68.

84. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 177.

85. *Id.* at 177-78. Therapeutic application of stem cells might be particularly effective against these genetic diseases because they have a well-known etiology and are thought to involve a single genetic defect. *Id.*

86. The President's Council on Bioethics, *supra* note 6, at 117.

87. Carol A. Tauer, *Responsibility and Regulation: Reproductive Technologies, Cloning, and Embryo Research*, *in* CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH 146 (Paul Lauritzen ed., Oxford Univ. Press 2001).

88. *See* R.P. Lanza et al., *Generation of Histocompatible Tissues Using Nuclear Transplantation*, 20 NATURE BIOTECHNOLOGY 689-96 (July 2002).

donor cow, researchers found that it performed some functions of a normal kidney, including the excretion of urine.[89] Most importantly, there was no indication of tissue rejection by the donor-host.[90] In 2002, researchers reported the first successful application of nuclear transplantation to produce stem cells that could be used for cell-based treatment in mammals.[91] The clinical potential of stem cells in general has been demonstrated in the treatment of diabetes and advanced kidney cancer, among other diseases.[92] In 2001, Israeli researchers were able to create insulin-secreting structures similar to pancreatic islet cells from human embryonic stem cells.[93] This discovery indicates that it may be possible in the future to derive cell replacement therapies from stem cells for the treatment of diabetes.[94] Currently, research has yet to solve some of the problems associated with insulin-producing structures derived from stem cells,[95] but this simply points to the need for more research in this area.

Scientists in cloning laboratories are continually learning about cellular function and gene expression, which may also have applications in other areas of medicine. A better understanding of cell development will allow us to understand and perhaps correct the genetic errors that cause serious medical conditions.[96] Notwithstanding the fact that the National Bioethics Advisory Commission (NBAC) has remarked on the "important scientific and biomedical advances"[97] cloning research has already provided.

89. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 175.

90. *Id.* Of course, the fact that the bioengineered tissue in the Lanza study was not rejected, *supra* note 87, demonstrates that rejection will not necessarily occur when the nuclear transfer approach is used, but does not prove that rejection will never occur. *See* Hugh Auchincloss & Joseph V. Bonventre, *Transplanting Cloned Cells into Therapeutic Promise*, 20 NATURE BIOTECHNOLOGY 665-66 (2002).

91. W.M. Rideout et al., *Correction of a Genetic Defect by Nuclear Transplantation and Combined Cell and Gene Therapy*, 109 CELL 17-27 (2002).

92. *NIH Stem Cell Backgrounder*, *supra* note 57.

93. Suheir Assady et al., *Insulin Production by Human Embryonic Stem Cells*, 50 DIABETES 1691, 1691-97 (2001).

94. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 172.

95. The procedure is at this time highly inefficient, yielding insulin-producing cells only once in every hundred attempts. Unfortunately, there appears to be an inverse relationship between the ability to proliferate and the ability to differentiate. The cells that grow well do not produce therapeutic levels of insulin, while those that produce insulin do not grow at a sufficiently rapid rate. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 171-72; *see* Bernat Soria et al., *Insulin-Secreting Cells Derived from Embryonic Stem Cells Normalize Glycemia in Streptozotocin-Induced Diabetic Mice*, 49 DIABETES 157, 157-62 (2000).

96. *NIH Stem Cell Backgrounder*, *supra* note 57.

97. Report of the Nat'l Bioethics Advisory Comm'n, CLONING HUMAN BEINGS. NBAC was established by President Clinton in October of 1995 to advise and make recommendations regarding bioethical issues and to "identify broad principles to govern the ethical conduct of research." Exec. Order No. 12,975, 60 Fed. Reg. 52,063 (Oct. 3, 1995).

Arguably, the chief reason there is a lack of convincing data on the use of embryonic stem cells to treat serious diseases is the current federal funding moratorium for these lines of inquiry. As a result, the development of embryonic stem cells has been limited to relatively few companies and laboratories in the private sector. Therefore, because for-profit entities understandably want to capitalize on their own research advances, the results of this research are not available to the scientific community at large.[98]

Regardless of the level of success already achieved in the cloning labs, uncertainty about future success alone does not justify a statutory ban on experimentation. The eventual results of all research are to some extent uncertain. The banning of scientific inquiry requires compelling reasons, and it is difficult to weigh the risks against the benefits until the extent of the potential benefits is better understood. Furthermore, it is likely that the technical difficulties currently experienced in developing stem cell lines from cloned embryos will be solved in the not-too-distant future.

The scientific community continually announces discoveries that turn conventional theories on their head. For example, the fairly recent breakthrough of nuclear reprogramming, in which scientists have directed fully differentiated cells back to a totipotent state, is a good example.[99] What seemed impossible yesterday may become commonplace in the near future. If therapeutic cloning is allowed to proceed, it is even possible that a new method of extraction may develop, whereby stem cells could be extracted without destroying the cloned embryos.[100] Such a technique would provide health benefits while at the same time assuaging critics who object to nuclear transplantation because of embryo destruction. Surely even those who stress that the potential of therapeutic cloning is speculative should avoid cutting off an area of emerging technology that could lead to revolutionary health benefits.[101] Perhaps this is why Congress has not yet

98. J.D. Rowley et al., *Harmful Moratorium on Stem Cell Research*, 297 SCIENCE 1957 (2002).

99. Alan Colman, *Turning Back the Development Clock*, 20 NATURE BIOTEHNOLOGY 348 (2002).

100. Currently, the inner cell mass of blastocysts, the developmental precursors to embryos, are used in isolating stem cell lines. Roughly five days post-fertilization, the blastomere becomes a blastocyst, which in turn becomes an embryo around Day 14. In the future, a technique may be developed allowing stem cells to be isolated directly from blastomeres, the cells that result immediately from the cleavage of an activated egg: a technique in which no embryo or blastocyst would be destroyed. HUMAN EMBRYONIC STEM CELLS, *supra* note 53, at 151. As the blastomeres divide (or, more accurately, cleave), their cell functions are thought to not yet be controlled by the genes of the newly created or fertilized embryo, but rather by the genome of the oocyte (egg). *Id.* at 65-66.

101. ANDREA L. BONNICKSEN, CRAFTING A CLONING POLICY: FROM DOLLY TO STEM CELLS 56 (Georgetown Univ. Press 2003).

passed a statutory ban.

IV. ADDRESSING THE ETHICAL ARGUMENTS AGAINST THERAPEUTIC CLONING

The potential benefits of cloning for biomedical research, and its potential application in tissue replacement therapies, justify the harms involved in the research. In other words, the opponents of therapeutic cloning have not met their burden of showing the harms of therapeutic cloning outweigh the sum of advantages likely to accrue from such research. It is important to separate the issues of therapeutic and reproductive cloning because they have differing rationales and present distinct ethical dilemmas. The birth of a genetically identical person is the primary objection to reproductive cloning, while the chief objection to therapeutic cloning is that the embryos are created solely for the purposes of research and then destroyed.[102]

The most fundamental argument against permitting therapeutic cloning is that it involves the deliberate production, use, and ultimate destruction of cloned human embryos.[103] Properly weighing harm to the embryo versus the benefit to society necessarily requires some determination of the moral status of the human embryo. The American public exhibits a wide range of opinions on this issue. In fact, even reaching consensus on an approach to analyzing the issue is difficult. One commentator has stated that to some extent, the debate over the morality of embryo research is at an impasse, asking, "[d]o those who defend embryo research have to show why it is morally justifiable, or do those who oppose it have to show why it is morally wrong?"[104]

While some believe that the preimplantation embryo is neither a human individual nor the sort of entity that demands significant protection, others hold that the preimplantation embryo is a human being, or may be a human being, and hence embryo research is *prima facie* prohibited.[105] For the latter group, the burden of proof is on the scientist, and any research must have a moral justification that overrides the *prima facie* prohibition.[106] At one extreme are those who say the embryo is equivalent to a human being.[107] Put another way, life is sacred from the moment that its biologic

102. The President's Council on Bioethics, *supra* note 6.

103. *Id.*

104. Tauer, *supra* note 87, at 145.

105. *Id.* at 151-52.

106. *Id.*

107. John T. Noonan, Jr., *An Almost Absolute Value in History*, *in* THE MORALITY OF ABORTION: LEGAL AND HISTORICAL PERSPECTIVES 57 (John T. Noonan, Jr. ed., 1970).

character is defined by receipt of its genetic material.[108] Therefore, embryos should be given the rights, protections, and respect that we give to all other human beings. This is the current position of the Catholic Church.[109] At the other extreme are those who say that the embryo is no different from any other clump of human cells and should not be treated in any special way; life is sacred only after birth.

This Note adopts a middle view between the two extremes: human embryos should be accorded respect because of their human *potential*. The embryo is not actual human life, but a potential human life.[110] As reproductive ethicist John Robertson wrote:

> The embryo deserves respect greater than that accorded to other human tissue, because of its potential to become a person and the symbolic meaning it carries for many people. Yet it should not be treated as a person, because it has not yet developed the features of personhood [such as neurological attributes] . . . and may never realize its biologic potential."[111]

If the embryo were to eventually develop into a fetus and be born, it would be endowed with a full panoply of rights that would trump application of a pure utilitarian framework.[112]

Apart from the more general question of whether embryo research is

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108. *Id.*

109. Tauer, supra note 87, at 145.

110. SILVER, supra note 29, at 48; *see also* Heather Johnson Kukla, *Embryonic Stem Cell Research: An Ethical Justification*, 90 GEO. L.J. 503, 520 (2002) ("Under the symbolic view, an embryo is not a holder of rights and interests because it is not yet a human person; however, as a developing form of human life, it is a powerful symbol of human life."); Nat'l Bioethics Advisory Comm'n, *Ethical Issues in Human Stem Cell Research* (1999), *available at* http://www.georgetown.edu/research/nrcbl/nbac/pubs.html ("[A]lthough the human embryo . . . deserve[s] respect as [a] form of human life, the scientific and clinical benefits of stem cell research should not be foregone."); Davis v. Davis, 842 S.W.2d 588, 596 (Tenn. 1992) (the human embryo is entitled to respect greater than that owed to human tissues because of if its "symbolic" value and its potential to develop into a human person, but the respect owed is less than that owed to "persons" because it lacks the features of a developed person and "may never reach its biological potential.").

111. SILVER, *supra* note 29, at 48. Harold Varmus, the director of NIH, commissioned the Human Embryo Research Panel (HERP) in 1994 to assess the types of embryo research that should and should not be acceptable for federal funding and to propose any warranted guidelines for research beyond those already in place (research with *in utero* fetuses and fetal tissue transplantation were already forbidden federal funding). HERP concluded that embryo research was ethically acceptable under carefully defined conditions and qualifications. In arriving at this conclusion, the panel determined that preimplantation embryos do not have the moral status of a full human subject and thus do not require all the protections due such a subject. Tauer, *supra* note 87, at 150.

112. Dan W. Brock, *Cloning Human Beings: An Assessment of the Ethical Issues Pro and Con*, *in* CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH, *supra* note 87, at 95.

permissible, is it permissible to bring human embryos into existence for purposes of research? This is a unique ethical dilemma presented by therapeutic cloning. Those who oppose therapeutic cloning for this reason flip on its head a traditional argument against reproductive cloning, namely that the cloned embryos should not result in a human being.[113] According to this view, the research is impermissible because it creates "human life that may not be intended to come to fruition."[114] Some oppose the creation of embryos for research purposes, although they do not object to the use of embryos that remain after infertility treatments.[115] The use of surplus embryos in research is defended by the argument that they were initially created for a procreative purpose for which they are no longer needed, and hence may now be used for another worthwhile purpose.[116] It may be argued that the ethical basis is found in:

> [T]he nature of the original intention (where procreation is regarded as a legitimate goal for In vitro fertilization (IVF), but research is not) or the necessity to choose the "lesser evil" (assuming that the existence of surplus embryos forces us to choose among undesirable options: discard, indefinite frozen storage, or research use).[117]

A related argument is that even if we allow research involving the byproducts of assisted reproduction ("spare" embryos), we should not allow the deliberate creation of embryos for research because doing so is not a legitimate goal for meddling in the procreative process.[118] According to this view, reproductive interventions are justified only insofar as they serve the goals of responsible human reproduction: the "bringing forth of new life in loving and nurturing relationship."[119] Fertilization not linked with reproduction is problematic because it stands outside of the goods and values that medically-assisted reproduction appropriately serves.[120] The risks to be weighed, therefore, involve the traditional balancing of moral anxieties over the treatment of embryos against the social importance of the research, as well as society's interest in the integrity of sexuality, reproduction, and parenthood.[121]

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113. Tauer, supra note 87, at 146.

114. *Id.*

115. *Id.* at 152

116. *Id.*

117. *Id.*

118. Maura A. Ryan, *Creating Embryos for Research: On Weighing Symbolic Costs*, *in* CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH, *supra* note 87, at 51.

119. *Id.*

120. *Id.*

121. Ryan, *supra* note 118, at 66; *see also* Carol A. Tauer, *Bringing Embryos into*

However, when contrasting the discretion IVF clinics have in embryo research with currently proposed legislative bans of therapeutic cloning, the preceding arguments against embryo research break down. In the United States, there is no comprehensive regulatory scheme for IVF or embryo research.[122] Today, embryo research is funded by private investment proceeds in the private sector. In addition, the more than four hundred fertility clinics throughout the country conduct extensive experimentation on reproductive technologies, usually involving human embryos, with little or no federal oversight.[123] The lack of federal funding has also led to a lack of regulation, resulting in private research not being regulated at the federal level.[124] Guidelines and ethical considerations have been developed by the fertility industry, but compliance is voluntary.[125]

It is inconsistent to allow IVF clinics to destroy embryos in pursuing assisted reproduction while at the same time banning research that does the same. Both procedures involve discarding embryos. If preimplantation embryos deserve protection, it should not matter that therapeutic cloning destroys them in research while IVF clinics destroy them in attempting reproduction. Assisted reproductive technologies are not only legal, but are barely regulated at all. Except for a clinical reporting requirement, there is no regulation at the federal level, and assisted reproductive technologies are barely regulated by the states. Given the disparity in our legislative response to the two activities, it appears that much of the opposition to therapeutic cloning may be based on the fear of potential human clones.

Currently, neither cloning nor embryo research may legally be funded by federal agencies such as the National Institutes of Health (NIH), the source of most federal research grants.[126] However, there are currently no federal

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Existence for Research Purposes, *in* CONTINGENT FUTURE PERSONS: ON THE ETHICS OF DECIDING WHO WILL LIVE, OR NOT, IN THE FUTURE 171-89 (Nick Fotion & Jan C. Heller eds., Kluwer Academic Pub. 1997). Professor Leon Kass, chairman of the President's Council on Bioethics, argues that IVF and other assisted reproductive technologies that place the "origin of human life literally in human hands" have led to "the continuing erosion of respect for the mystery of sexuality and human renewal." LEON R. KASS & JAMES Q. WILSON, THE ETHICS OF HUMAN CLONING 80 (AEI Press 1998). Kass argues that weakening human respect for the profundity of sexual union would lead to the replacement of procreation with manufacturing. *Id.* at 80-81.

122. Though with respect to embryo research, several states do have restrictive laws.

123. THE CLONING SOURCEBOOK, *supra* note 56, at 127; Tauer, *supra* note 87, at 148-49. The only federal oversight is a congressional reporting requirement for clinics. *See* Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (1992).

124. Tauer, *supra* note 87, at 148-49.

125. THE CLONING SOURCEBOOK, *supra* note 56, at 127. *See* Ethics Comm. of the Am. Fertility Soc'y, *Ethical Considerations of Assisted Reproductive Technologies*, 62 FERTILITY & STERILITY SUPP. 5 (1994).

126. Tauer, *supra* note 87, at 148-49.

prohibitions of either type of research when carried out in the private sector.[127] Researchers in the private sector are free to clone embryos through nuclear transplantation, except in the handful of states where this research is prohibited by statute.[128] Technically, there is no statute or directive that specifically prohibits federal funding of the cloning technique itself. However, since 1995, federal policy has prohibited funds for research in which human embryos are destroyed,[129] a limitation which almost all commentators agree would extend to embryos generated through nuclear transplantation.[130] Because cloning would be used to create embryos for further research, the limitation on such research serves as a *de facto* limitation on the funding of therapeutic cloning.

This limitation on funding is consistent with Congress's common practice of refusing to fund procedures or experiments that are morally controversial;[131] however, there is no similar tradition of *criminalizing* a type of scientific research simply because it is morally controversial. In 1979, within a year of the birth of the first IVF baby, the now-defunct Ethical Advisory Board of the Department of Health, Education and Welfare (HEW) (now the Department of Health & Human Services (HHS)) concluded that IVF research was ethical.[132] Nevertheless, HEW rejected federal funding for IVF research because the moral issues surrounding IVF made it too politically controversial.[133]

The debate over fetal tissue transplantation (research on tissue from aborted fetuses) has, like the debates regarding IVF research and stem cell research, properly focused on whether it should receive public funding, not whether conducting this research should be criminalized. Contrary to the

127. *Id.*

128. *See supra* note 3.

129. The Omnibus Consolidated and Emergency Supplemental Appropriations Act prohibits federal funding to create human embryos for research purposes or for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to" a greater than minimal risk of injury or death. Pub. L. No. 105-277, § 511(a), 112 Stat. 2681-386 (1998).

130. THE CLONING SOURCEBOOK, *supra* note 56, at 128. Congress has prohibited NIH from using federal funds to finance any research in which human embryos are harmed or destroyed outside the womb. This was done through the "Dickey-Wicker amendment" to the appropriations bills funding the National Institutes of Health, passed every year since 1995. *Id.*

131. *Cf.* Harris v. McRae, 448 U.S. 297, 314, 319 (1980) (stating that Congress may deny federal funding to abortions in passing moral judgment intended to influence citizens' behavior); Rust v. Sullivan, 500 U.S. 173 (1991) (recipients of federal family planning funds could be prohibited from engaging in abortion counseling).

132. Keith Alan Byers, *Infertility and In Vitro Fertilization: A Growing Need for Consumer-Oriented Regulation of the In Vitro Fertilization Industry*, 18 J. LEGAL MED. 265, 291 (1997).

133. *Id.*

recommendations of an NIH Advisory Committee, on March 22, 1988, the Assistant Secretary for HHS imposed a temporary moratorium on federal funding of research involving tissue from aborted fetuses.[134] On his second day of office in 1993, President Clinton issued an executive order lifting this ban on federal funding.[135] Current federal law and regulations allow federal funding of experimentation on human fetal tissue pending approval by a federally-sanctioned Institutional Review Board.[136]

In the United Kingdom, nationally funded therapeutic cloning exists because the country not only allows, but also funds, the creation of embryos for research purposes.[137] In the United States, by contrast, federal funding for this type of research is extremely unlikely, given the political opposition to public funding for any type of embryo research. The American political debate is limited by the fact that research involving the deliberate creation of embryos not destined to be implanted has never received federal funding.[138] One commentator has remarked that in the United States, therefore, "concerns about creating and destroying human embryos have superimposed the unresolved politics of embryo research onto the politics of cloning."[139] This situation does not appear to be amenable to change any time in the near future. Given the absence of a consensus on the morality of embryo research, prohibitions of public funding are reasonable because, as the Human Embryo Research Panel (HERP) stated in its report on embryo research, public policy is the "accommodation of diverse interests."[140]

A. The "Slippery Slope" to Human Reproductive Cloning

Another chief argument against permitting cloning research is that it could pave the way for the eventual cloning of a human child.[141] This is the

134. Office of Science Policy and Planning, Report to Congress, Theraputic Human Fetal Tissue Transplantation Research Activities Funded by the National Institutes of Health in FY 1998 (July 1999), *at* http://ospp.od.nih.gov/policy/fetal.asp (last visited Aug. 12, 2004).

135. Memorandum for the Secretary of HHS, Federal Funding of Fetal Tissue Transplantation Research, 58 Fed. Reg. 7457 (Jan. 22, 1993).

136. *See* 42 U.S.C. § 289 (2003); 45 C.F.R. § 46.101 (2003).

137. THE CLONING SOURCEBOOK, *supra* note 56, at 128-29.

138. At the state level, Missouri passed a law providing that "[n]o state funds shall be used for research with respect to the cloning of a human person." MO. ANN. STAT. § 1.217 (West 2002).

139. THE CLONING SOURCEBOOK, *supra* note 56, at 128-29.

140. Brian Stiltner, *Morality, Religion, and Public Bioethics: Shifting the Paradigm for the Public Discussion of Embryo Research and Human Cloning, in* CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH, *supra* note 87, at 182.

141. *See* President George W. Bush, Remarks by the President on Human Cloning Legislation (Apr. 10, 2002) (*available at* http://www.whitehouse.gov/news/releases/2002/04/20020410-4.html) (last visited Aug. 10, 2004).

classic "slippery slope" argument, the notion that it will be more difficult to prevent the cloning of human beings once embryos are already being cloned. The most effective way to prevent cloning of humans, the argument goes, is to stop the process at the initial act of cloning. President Bush has said, "we must prevent human cloning by stopping it before it starts."[142] Rep. David Weldon, one of the proponents of the Human Cloning Prohibition Act of 2003, said, "[t]hose who perform experimental research cloning will only make reproductive cloning easier, and increase the likelihood that even more rogue scientists will produce cloned babies."[143]

This argument is flawed, however. It seems unlikely that policymakers would use the fact that therapeutic cloning is permitted to justify the cloning of human beings, even though embryos produced for research are no different from cloned embryos that could be used to produce cloned children.[144] Scientific inquiry should not be blocked "simply upon the presentation by critics of a parade of imagined horribles" if these are in fact unlikely to occur.[145]

Here, the allegedly harmful future event is the eventual cloning of human beings. But would the existence of cloned embryos actually bring about the cloning of a human being? Certainly, the existence of a cloned embryo is a prerequisite for creating a cloned human being. But assuming a ban on reproductive cloning only, it is difficult to believe that someone who is determined to illegally clone a person would be any more deterred from the practice if it were also illegal to make the clone in the first place.

The argument fails to address why it would not be a sufficient deterrent to simply prohibit the implantation of a cloned embryo into a woman's uterus, as the United Kingdom has done. Moreover, when the increased probability of cloned human beings is proffered as a justification for banning therapeutic cloning, it is important to recognize that the probabilities involved are not whether humans will be cloned (which can be handled through a ban on reproductive cloning), but whether allowing therapeutic cloning *adds* to this probability. Ultimately, there is no real evidence to back up the claim that allowing the cloning of embryos will necessarily facilitate the birth of cloned humans. Rather, this claim seems to be an overreaction motivated by the fear of reproductive cloning.

There is reason to think that the "slippery slope" position is too alarmist

142. *Id.*

143. Statement of Rep. Dave Weldon (Jan. 8, 2003) (*available at* http://www.house.gov/stupak/press2003-2004/010803cloningban.html) (last visited May 19, 2005).

144. Tauer, *supra* note 87, at 146.

145. Cohen, *supra* note 39, at 213.

because even without a ban on therapeutic cloning, there are existing hurdles to the creation of cloned human beings. First, cloned embryos would not be lying around science labs all over the country. Nuclear transplantation is an extremely costly process, funded exclusively by private companies, with no prospect of federal funding in the near future. The profit motive alone provides sufficient incentive for those who create cloned embryos to keep them from falling into third parties' hands.[146]

Even if some embryos were stolen or illegally sold, a limited number of labs and organizations in the United States have the capacity to clone.[147] Despite the absence of a federal ban, the American Society for Reproductive Medicine, the Biotechnology Industry Organization, and the Federation of American Societies of Experimental Biology have already agreed in principle to a voluntary moratorium on human cloning. These three groups represent virtually all scientists who currently have the capacity to clone.[148] Further, in the absence of any other federal regulation, the United States Food and Drug Administration (FDA) has asserted its authority to ensure that experimentation with nuclear transplantation to create a human child will not begin until the procedure is deemed safe enough.[149] In short, even if the cloning of embryos is permitted for limited purposes, it does not follow that banning reproductive cloning makes human cloning inevitable, or even much more likely.

V. INVOKING THE CRIMINAL SANCTION

To borrow from the classic work of Herbert L. Packer, criminalizing therapeutic cloning would violate several fundamental principles that serve

146. The cloned embryos are not likely to be sold, either, because federal law already prohibits the profit in interstate commerce from the sale of human embryos.

147. HUMAN CLONING: SCIENCE, ETHICS, AND PUBLIC POLICY, *supra* note 1, at 123.

148. *Id.* Severe complications are often associated with mammalian reproductive cloning. Cloned embryos often exhibit developmental abnormalities. Moreover, only a tiny proportion (less than one percent) of cloned mammals make it to birth, and many of the offspring that are born suffer from various birth defects. A. Hadjantonakis & V.E. Papaioannou, *Can Mammalian Cloning Combined With Embryonic Stem Cell Technologies Be Used to Treat Human Diseases?*, 3 GENOME BIOLOGY 1023.1, 1023.1 (2002). These problems create a valid argument as to why reproductive cloning should be banned; however, they do not provide adequate justification for proscription of therapeutic cloning. The flaws apparent in the reproductive cloning process do not impede the use of nuclear transplantation for therapeutic applications. Rudolf Jaenisch et al., *Nuclear Cloning, Stem Cells, and Genomic Reprogramming*, 4 CLONING & STEM CELLS 389, 394 (2002). In fact, the danger and inefficiency of mammalian cloning at this point is evidence that even if cloning research is allowed to proceed in the private sector, scientists are not likely to attempt to clone human beings, at least for the foreseeable future.

149. Letter from Sharon Smith Holston, Dep. Comm'r for External Affairs, Food and Drug Admin., to Sen. Edward Kennedy (Feb. 10, 1998) (inserted in 144 Cong. Rec. S562 (daily ed., Feb. 10, 1998)).

to limit the usefulness of the criminal law.[150] First, conduct that is remote from the feared harm should not be criminalized. Opponents of therapeutic cloning raise the specter of reproductive cloning. If reproductive cloning is the harm feared, then prohibit *it*. Do not throw the baby out with the bath water by prohibiting therapeutic cloning, which is one step removed from the creation of identical humans, and thereby lose all the potential benefits of the research.[151] Instead of prohibiting the process of cloning itself, a less restrictive option is for the legislature to target the act of implanting a cloned embryo with the intent to create a human being. Great Britain's Human Reproductive Cloning Act of 2001 criminalized reproductive cloning by targeting the placement "in a woman of a human embryo which has been created otherwise than by fertilisation."[152] This way, reproductive cloning is still prohibited, but cloning for biomedical research can continue.

Next, only conduct that is viewed as immoral, without significant social dissent, should be criminalized.[153] This principle is designed to avoid the risks of imposition upon minorities and the specter of unenforceability.[154] There are many people who do not view therapeutic cloning as immoral, including most of the scientific community.[155]

Criminalization must also serve the goal of deterring crime.[156] Conduct to which people feel deeply committed should not be criminalized because they will not be adequately deterred.[157] The deterrent value of a criminal ban on scientific inquiry is questionable. Historically, scientists committed to pursuing knowledge and truth have not been deterred from their research even under threat of prosecution. Moreover, laws should not be enacted that cannot be enforced. There are serious monitoring and enforcement problems with a criminal proscription of cloning for research because cloning only occurs in laboratories, and enforcement of a therapeutic

150. *See generally* HERBERT L. PACKER, THE LIMITS OF THE CRIMINAL SANCTION (1968) (questioning what the criminal sanction is good for).

151. *See* Roger B. Dworkin, *Biocatastrophe and the Law: Legal Aspects of Recombinant DNA Research*, *in* THE RECOMBINANT DNA DEBATE, *supra* note 39, at 227 (arguing against the criminal prohibition of recombinant DNA research).

152. Human Reproductive Cloning Act 2001, c. 23 (Eng.), *available at* http://ww.legislation.hmso.gov.uk/acts/acts2001/20010023.htm (last visited Aug. 20, 2004).

153. PACKER, *supra* note 150, at 262.

154. Dworkin, *supra* note 151, at 227.

155. *See, e.g., Four of Five Oppose Human Cloning: U.S. Funding of Stem Cell Research Has More Acceptance, a Survey Reports*, GRAND RAPIDS PRESS, Apr. 14, 2002, at A6 (explaining that while most of the public opposes cloning, two-thirds of Americans do not oppose federal funding of stem cell research) (*available at* 2002 WL 11909813).

156. Deterrence has been defined as "the inhibiting effect that punishment, either actual or threatened, will have on the actions of those who are otherwise disposed to commit crimes." PACKER, *supra* note 148, at 39.

157. Dworkin, *supra* note 151, at 227.

cloning ban would require intrusions into private, often high-security, locations.[158]

Conduct should not be criminalized unless society seriously wants the law enforced and violators imprisoned.[159] It is not in society's best interest to imprison its top scientific minds if they are attempting to ameliorate human suffering.[160] Additionally, the enforcement of anti-cloning laws diverts scarce police, prosecutorial, and judicial resources away from serious crimes such as murder, robbery, and rape. Lastly, the criminal sanction is already overused in our society, and the costs of this overuse are enormous.[161]

There are several reasons why therapeutic cloning is particularly inappropriate for criminal prohibition. Because the nuclear transplantation technique already exists and is used around the world, prohibiting it here will serve only to deny Americans its benefits while failing to eliminate its practice elsewhere.[162] In addition, because legislatures are ill-equipped to obtain, understand, and react to current scientific information, modesty is the wisest legislative policy when it comes to science.[163] Even assuming the legislature has access to the most current scientific information, it is impossible for the drafters of legislation to keep up with the pace of technological change, particularly in the rapidly changing field of reproductive technologies. LeRoy Walters has referred to this as the "instant obsolescence" problem.[164] The National Bioethics Advisory Commission (NBAC) pointed out in its 1997 report that it is "notoriously

158. On the other hand, because the nuclear transplantation process is costly and requires specialized equipment and knowledge, this type of research is occurring in very few laboratories across the country, possibly indicating easier enforcement.

159. PACKER, *supra* note150, at 262.

160. Dworkin, *supra* note 151, at 227.

161. Dworkin, *supra* note 151, at 226; *see also* Task Force on the Federalization of Criminal Law, THE FEDERALIZATION OF CRIMINAL LAW 7 n.9 (Washington, DC: American Bar Association, 1998) (noting that more than a quarter of federal criminal laws enacted since the Civil War have been enacted since 1980); John C. Coffee, Jr., *Paradigms Lost: The Blurring of the Criminal and Civil Law Models—And What Can Be Done About It*, 101 YALE L.J. 1875, 1877 (1992) ("[C]riminal law should not be overused.").

162. Dworkin, *supra* note 151, at 226. On the other hand, there does seem to be a growing movement throughout Europe and other Western nations to ban both types of cloning. Germany and Norway prohibit embryo research and cloning, both reproductive and therapeutic. Even in the Netherlands, a country normally considered very liberal, the Parliament adopted a law to ban the cloning of human embryos. The Council of Europe, which includes not only the fifteen European Union member states but also more than forty countries including Russia and Turkey, adopted a convention on biomedicine that prohibits the creation of human embryos for research purposes.

163. Dworkin, *supra* note 151, at 228.

164. LeRoy Walters, *Ethics and New Reproductive Technologies: An International Review of Committee Statements*, HASTINGS CENTER REP., June 1987, at 3, 9.

difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science."[165] If the anti-cloning law is worded loosely, it may proscribe too much. On the other hand, a law tailored to one specific technique, such as nuclear transplantation, might not provide a framework for later innovations in reproductive and genetic technologies.[166]

An ambiguous definition of cloning could shut down a significant amount of otherwise uncontroversial research. For example, "anti-cloning laws could prohibit or stifle tremendous opportunities that derive from the application of cloning techniques to animal biotechnology" through selective breeding.[167] The NBAC cautions that any regulatory or legislative actions "should be carefully written so as not to interfere with other important areas of scientific research," such as the cloning of human DNA sequences or animals by nuclear transplantation.[168] To give one example of the dangers of ambiguity, Britain's Human Fertilization and Embryology Act of 1990 was intended to ban human reproductive cloning, but some think the Act contains loopholes that actually permit human cloning.[169] Although the legislation prohibits the transplant of nuclei into embryos, it may not explicitly forbid nuclear transplantation, which is the transfer of nuclei into eggs.[170] Laws can always be amended, but "revisiting a law is awkward and not always successful, which leaves legitimate activities in a state of legal limbo."[171]

Legislatures often struggle to understand innovative issues requiring profound scientific expertise. Legislatures must often hastily responded to public outcry. In drafting legislation in response to such issues, the resulting law may be incomplete and vague. Such statutes, therefore, may have the effect of inhibiting rather than encouraging the study of therapeutic cloning. For example, if a Virginia researcher is studying therapeutic cloning and discovers that the cloned embryo produces viable stem cells only after it is implanted in a woman's uterus for some time period and then removed, this form of scientific research would be prohibited in Virginia because such implantation could result in the birth of a human being.[172]

165. KASS & WILSON, *supra* note 121, at xvii.

166. BONNICKSEN, *supra* note 101, at 4.

167. *See* Heidi Forster & Emily Ramsey, *The Law Meets Reproductive Technology: The Prospect of Human Cloning*, *in* CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH, *supra* note 87, at 217.

168. *Id.*

169. *Id.* at 213.

170. *Id.*

171. HUMAN CLONING: SCIENCE, ETHICS, AND PUBLIC POLICY, *supra* note 1, at 120.

172. VA. CODE ANN. § 32.1-162.22 (Michie 2004).

Although the researcher's intent would not be the birth of a child, the relevant conduct could subject the individual to prosecution because the statute does not require intent.[173] Consequently, this would likely chill research that the legislature attempted to exempt under the statute.

California's law against reproductive cloning is one example of a cloning statute that is unintentionally overbroad. Under the law, "clone" means "the practice of creating or attempting to create a human being by transferring the nucleus from a human cell *from whatever source* into a human egg cell from which the nucleus has been removed for the purpose of [initiating a pregnancy]."[174] By including cells "from whatever source" within the ban, the law forbids more than adult cloning – it also bans embryo nuclear transplantation and fetal and adult cell nuclear transplantation, as well as egg cell nuclear transplantation, which is not cloning at all because no genome is replicated.[175] Perhaps in the end, a scientist would not be liable under the law if he or she did not intend to initiate a pregnancy, but the argument can be made that the potential liability would chill activity that the legislature did not intend to prohibit.

A. The Scientific Debate about Recombinant DNA as Historical Analog

In the early 1970s, molecular biologists discovered how to remove bits of genetic material (DNA) from various organisms and insert them into bacteria in such a way that the transferred DNA became part of the bacteria's genetic material.[176] The bacterial cells then duplicated and re-duplicated the transferred DNA as they grew.[177] This novel "recombinant DNA" methodology, which allowed researchers for the first time to isolate and produce large quantities of specific genes, provided a uniquely powerful tool for studying the mechanisms of genetics in organisms, especially in the genetically complex cells of higher organisms.[178] Recombinants make it possible to study much more effectively the mechanisms of inheritance and the regulation of gene function, questions which had interested biologists for decades.[179]

However, the new methodology also poses many potential dangers. Most importantly, it raises a small possibility that highly virulent infective agents could be released accidentally, leading to epidemic diseases of

173. *Id.*
174. CAL. HEALTH & SAFETY CODE § 24185 (West 2005) (emphasis added).
175. HUMAN CLONING: SCIENCE, ETHICS, AND PUBLIC POLICY, *supra* note 1, at 119.
176. THE RECOMBINANT DNA DEBATE, *supra* note 39, at 39.
177. *Id.* at 42.
178. *Id.* at 39.
179. Zander, *supra* note 41, at 11.

unknown proportions.[180] The hybrid organisms produced by recombinant DNA research are novel, laboratory-created organisms that may never have otherwise occurred in nature and may therefore be uniquely pathogenic to humans or other organisms.[181] Concern about these possible hazards sparked an international debate on whether and how recombinant DNA research should proceed.[182] Proponents of recombinant DNA research hailed its potential applications to the treatment of genetic disease, the manufacture of drugs, chemicals, and fuels, and the improvement of crop plants and crop yields, among other areas, while opponents criticized the research because of the potential hazards.[183]

There are many similarities between the debate over recombinant DNA and the current debate about cloning human embryos. First, both the perceived benefits of the research, and its potential pitfalls, are highly speculative.[184] Several philosophical and moral objections to recombinant DNA research surfaced in the 1970s, objections which could easily be raised today by opponents of therapeutic cloning.[185] Among these objections were the following: (1) some kinds of knowledge, for example nuclear fission, are dangerous and should not be sought by humankind; (2) "[t]he fact that a particular kind of research can be done does not automatically grant the right to do it"; and (3) in pursuing this research, we begin to tamper with the nature of life itself.[186]

Scientists themselves also recognized a more pressing issue: the small possibility that new organisms with unexpected and perhaps dangerous characteristics could be created in some types of recombinant DNA experiments.[187] Several of the scientists whose work led to the development of the cloning techniques wrote a letter to the scientific community calling for a self-imposed moratorium on some recombinant DNA research so that a careful risk assessment could be made.[188] The National Institutes of Health (NIH) prepared guidelines to ensure the safety of all research involving recombinant DNA molecules and the containment

180. A.M. Chakrabaty, *Recombinant DNA: Areas of Potential Applications*, *in* THE RECOMBINANT DNA DEBATE, *supra* note 39, at 56.

181. Science for the People, *Biological, Social, and Political Issues in Genetic Engineering*, in THE RECOMBINANT DNA DEBATE, *supra* note 39, at 104.

182. THE RECOMBINANT DNA DEBATE, *supra* note 39, at xiii.

183. Chakrabaty, *supra* note 180, at 56.

184. *Id.*

185. Zander, *supra* note 41, at 8-9.

186. *Id.* at 9.

187. David A. Jackson, *Principles and Applications of Recombinant DNA Methodology*, *in* THE RECOMBINANT DNA DEBATE, *supra* note 39, at 39.

188. *Id.* at 39-40; Paul Berg et al., *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE 303, 303 (1974).

of organisms within the laboratory.[189] Under the guidelines, the riskiest kinds of recombinant DNA research, experiments with high-risk pathogens (referred to in the guidelines as "major actions"), are prohibited unless approved through a restrictive process.[190]

Other recombinant DNA experiments are permitted, subject to certain safeguards. For example, the cloning of viruses known to cause cancer in animals is permitted under very restrictive conditions.[191] The safeguards require the use of specially designed physical containment facilities and organisms specifically engineered to have a diminished ability to survive outside the laboratory.[192] "Major actions" require approval by an Institutional Biosafety Committee (IBC) and the NIH Director, review by the Recombinant DNA Advisory Committee (RAC), and an opportunity for formal agency notice-and-comment rulemaking.[193]

The guidelines are flexible and anticipate continuous review; a dozen revisions since 1976 have taken into account new data and experience accumulated through recombinant DNA research.[194] Moreover, the guidelines provide an incentive for scientists to comply with them, rather than a sanction for noncompliance. As a condition of NIH funding, institutions must ensure that recombinant DNA research conducted at or sponsored by the institution, irrespective of the source of funding, complies with NIH Guidelines.[195] "This is not only an attractive symbolic stance for the law to take,"[196] but is also less expensive, since it requires a much less sophisticated enforcement apparatus.

VI. LESS RESTRICTIVE POLICY ALTERNATIVES

Instead of criminalizing therapeutic cloning, legislatures should opt for regulating therapeutic cloning. Although none of several alternative approaches is perfect, any of them would avoid the problems associated with the application of criminal sanctions to scientific research.

189. National Institutes of Health, NIH Guidelines for Research Involving Recombinant DNA Molecules {hereinafter NIH Guidelines], Apr., 2002, *available at* http://www4.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm (last visited Aug. 10, 2004).

190. *Id.*

191. Science for the People, *supra* note 181, at 101.

192. Dworkin, *supra* note 151, at 229-30.

193. NIH Guidelines, supra note 189.

194. *Id.*

195. Of course, the guidelines only control the behavior of those who need NIH funding. Biotechnology companies and laboratories that seek no federal funds are left completely unregulated. Science for the People, *supra* note 181, at 104.

196. Dworkin, *supra* note 151, at 230.

A. Active support for therapeutic cloning

The United Kingdom was the first nation to pass a law allowing limited human cloning for the purpose of creating stem cells from cloned human embryos, and is currently the only country in Europe that clearly supports therapeutic cloning.[197] While this is not a politically realistic goal in the United States at the federal level, states are free to support therapeutic cloning. California stands out as the innovator – for better or for worse – on this issue. It is the first state to pass a law that affirmatively protects and encourages embryonic stem cell research.[198]

California allows stem cell research in the hope that it will lead to breakthrough treatments for the millions of people who struggle with crippling and degenerative diseases.[199] The United States and California are leaders in biomedicine and biotechnology. Open and public research is vital to California's biotechnology industry, and also to discovering new treatments for diseases.[200] The California bill permits "the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation."[201] Any research that will use embryonic stem cells must be reviewed and approved by a state ethics committee.[202]

The California law encourages embryonic stem-cell research by offering state funding, matching funds from private biotechnology companies and, perhaps most importantly, creating an anxiety-free environment for researchers.[203] The statute also addresses alternative sources of embryos for research: fertility practitioners shall give their patients appropriate information to make voluntary decisions about their surplus embryos – storing them, donating them to other couples, discarding them, or donating them to research with written consent.[204] However, donors may not accept any remuneration, except "reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or

197. *After Vigorous Debate Great Britain Becomes First Nation to Legalize Cloning Stem Cells from Human Embryos*, TRANSPLANT NEWS, Jan. 31, 2001.

198. CAL. HEALTH & SAFETY CODE §§ 125300, 125320 (West 2004) (providing for the revocation of licenses issued to businesses for violations relating to human cloning, prohibits the purchase or sale of ovum, zygote, embryo, or fetus for the purpose of cloning human beings, and establishes civil penalties for violations).

199. CAL. HEALTH & SAFETY CODE § 125300.

200. Jessica J. Monachello, *The Cloning for Biomedical Research Debate: Do the Promises of Medical Advances Outweigh the Ethical Concerns?*, 10 TULSA J. COMP. & INT'L L. 591, 604 (2003).

201. *Id.*

202. CAL. HEALTH & SAFETY CODE § 125300.

203. CAL. HEALTH & SAFETY CODE § 125291.25.

204. CAL. HEALTH & SAFETY CODE § 125315.

implantation."[205] For now, the California bill allows scientists to pursue their research. If Congress were to pass a pre-emptive ban on therapeutic cloning, however, this laudable state experiment would be terminated.

B. The "aspirational" approach

Andrea Bonnicksen has proposed that even on the state level, legislatures should refrain from enacting cloning laws, and instead, should seek to encourage scientists to voluntarily comply with nationally developed aspirational standards.[206] Bonnicksen argues that instead of statutory bans, there should be guidelines for action that leave room for adjustment as new technologies emerge.[207] She urges legislatures to craft "a cloning policy" rather than draft "a cloning law."[208]

Bonnicksen made these arguments with an eye toward reproductive cloning, but the arguments are even more persuasive for therapeutic cloning. She suggests that regulatory policies can be better crafted over time than can punitive laws.[209] Cloning bans at either the state or federal level may give a false sense of security to those who oppose cloning and may remove some of the incentive to develop integrated, well-thought-out cloning policies.[210] Moreover, working rules will provide a more effective foundation for managing cloning developments than a targeted ban because they develop through the medical and research community's achievements, inquiry, and comment.[211]

Once again, our experience with assisted reproductive technologies, such as embryo freezing and gamete donation, provides a useful analogy that underscores the value in refraining from restrictive statutes. Critics have called for laws each time a novel reproductive technique is made available, but legislative restraint has allowed professional associations and academics to develop more comprehensive policies that address related issues, such as informed consent, parent-child relationships, and safety.[212] Doctor Wilmut

205. CAL. HEALTH & SAFETY CODE § 125320.

206. Andrea L. Bonnicksen, *Crafting Cloning Policies*, *in* HUMAN CLONING: SCIENCE, ETHICS, AND PUBLIC POLICY, *supra* note 1, at 123. In contrast to a law, which is a binding rule of conduct enacted by the government, aspirational documents present a framework for making decisions based on shared values and goals. Such an approach attempts to articulate a community consensus that guides behavior. The consensus that has developed in the United States seems to be that reproductive cloning should be prohibited, at least until it is safe, and federal funds should not be used for cloning and embryo research. *Id.* at 120-21.

207. Bonnicksen, *supra* note 1, at 123.

208. *Id.*

209. *Id.*

210. *Id.* at 128.

211. *Id.*

212. *See* ISLAT Working Group, *ART into Science: Regulation of Fertility Techniques*,

and his colleagues have observed that people "tend to object as a matter of course to any new, exotic technology that affects the human body."[213] The innate suspicion eventually levels out and sometimes technology "that once seemed outlandish, or even diabolical, is widely accepted as normal practice."[214]

C. Regulation

Another option for legislative consideration is the establishment of a regulatory apparatus to oversee therapeutic cloning and cloning research. This hypothetical commission or agency could also be given authority over new reproductive technologies, as well as other genetic technologies. Administrative agencies are designed to make optimal use of experts in technical areas and to use informal procedures to produce "flexible, easily changed, realistic controls."[215] A regulatory agency could be established at either the state or federal level. Great Britain's Human Fertilisation and Embryology Authority, which regulates the safety and efficiency of embryo research and assisted reproduction, is one model for a national regulatory body.[216] Susan Wolf suggests extending protection afforded to individuals engaged in testing in the private sphere and regulating reproductive technologies in conjunction with a central advisory body for novel issues.[217] Efforts by the President's Council on Bioethics and the National Bioethics Advisory Commission (NBAC) to examine embryo research and human cloning are at least an attempt to inject clinical and scientific expertise into the legislative process. The National Institutes of Health (NIH) Guidelines for recombinant DNA research are such an example.

However, in light of the American reluctance to oversee assisted reproductive technologies, Congress is unlikely to erect a regulatory framework. A potential middle ground would be to utilize an existing agency, such as the Food and Drug Administration (FDA), for oversight. The FDA has previously asserted that it has regulatory authority over cloning.[218] It has been argued, however that process-based oversight by the government would be disastrous because regulatory compliance raises costs

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281 SCIENCE 651-52 (July 31, 1998).

213. WILMUT ET AL., *supra* note 15, at 273.

214. *Id.* at 273-74.

215. Dworkin, *supra* note 151, at 229.

216. John A. Robertson, *Human Cloning: Public Policy When Cloning Is Safe and Effective, in* HUMAN CLONING: SCIENCE, ETHICS, AND PUBLIC POLICY, *supra* note 1, at 145.

217. Susan M. Wolf, *Ban Cloning? Why NBAC Is Wrong*, 27 HASTINGS CENTER REP. 12, 12 (Sept.-Oct. 1997) (arguing that even reproductive cloning warrants regulation instead of a ban).

218. BONNICKSEN, *supra* note 101, at 10.

and increases paperwork.[219] As states reserve jurisdiction over matters of health and family, perhaps they should step in and oversee therapeutic cloning. To the limited extent that assisted reproductive technologies are regulated at all, it is the states that already do so. As mentioned, California law provides for review by a state ethics committee of all proposed therapeutic cloning protocols.[220] The states also have an additional power available to enforce regulatory standards: states can revoke medical licenses.[221]

At the very least, if Congress is determined to outlaw both reproductive and therapeutic cloning, bans should include a sunset provision. In effect, this would be like an enforced three-year moratorium on therapeutic cloning. The NBAC endorsed a three to five year sunset provision so that Congress could reevaluate "whether the prohibition continues to be needed."[222] The President's Council on Bioethics also called for a moratorium rather than a statutory ban.[223] Such a solution would provide flexibility and allow Congress to revisit the issue as society's needs change over time. Legislation on the matter should also require that at some point prior to the expiration of the sunset period, an appropriate oversight body will valuate and report on the current status of nuclear transplantation technology and on its pertinent ethical and social issues at that time.[224]

CONCLUSION

Although ethical issues underlying therapeutic cloning, as well as arguments for and against its criminalization, are in fact quite distinct from the debate about banning reproductive cloning, it appears that some of the impetus behind the ban on therapeutic cloning is motivated by social revulsion to the concept of human genetic clones. Yet there is no solid evidence that allowing therapeutic cloning to proceed in the laboratory will usher in an era of human reproductive cloning.

Statutory bans of therapeutic cloning are bad policy because they eliminate the potentially revolutionary health benefits that are expected to

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219. Susanne L. Huttner, *Cloning and Public Policy: Biotechnology Lessons, in* HUMAN CLONING: SCIENCE, ETHICS, AND PUBLIC POLICY, *supra* note 1, at 157. The author argues that the USDA and EPA experience has shown that government restrictions on technique or process can discourage research and commercial investment by raising costs. *Id.*

220. CAL. HEALTH & SAFETY CODE § 125300.

221. Forster & Ramsey, *in* CLONING AND THE FUTURE OF HUMAN EMBRYO RESEARCH, *supra* note 87, at 211.

222. NAT'L BIOETHICS ADVISORY COMM'N REPORT, CLONING HUMAN BEINGS, *available at* http://65.205.1.226/cloning/cloning_report.html.

223. The President's Council on Bioethics, *supra* note 6.

224. NAT'L BIOETHICS ADVISORY COMM'N REPORT, CLONING HUMAN BEINGS, *supra* note 222.

emerge from cloning research, especially with stem cells. Viewed from a utilitarian perspective, these anticipated benefits outweigh the legitimate ethical concern of destroying cloned embryos to create stem cells. Restraints on scientific research are not preferred as a matter of policy, and must be compelling enough to warrant implementation.

Opponents of therapeutic cloning have not met their burden of showing that therapeutic cloning should be prohibited. Furthermore, the criminal law is particularly ill-suited to the issue of therapeutic cloning. Problems of enforcement, lack of deterrence, difficulties in crafting cloning laws, and proper scope all point to the need for legislative restraint regarding nuclear transplantation for biomedical research. Prior experiences with assisted reproductive technologies and the recombinant DNA debate in the 1970s demonstrate that restricting funding and issuing regulatory guidelines are more effective ways for the legislature to shape the development of novel scientific research.