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CLONING CALIFORNIANS? REPORT OF THE CALIFORNIA ADVISORY COMMITTEE ON HUMAN CLONING AND RECENT CLONING-RELATED LEGISLATION

María S. Quintero†

Although reports of Dolly (“the world’s most famous sheep”), Dr. Seed and Clonaid’s announcements of plans to clone humans, and more recently, the cloning of Cc the cat, have brought the issue of human cloning to the public consciousness, legislatures—both state and federal—are either silent or just beginning to grapple with the technical, legal, and moral issues raised by human cloning.¹ While in 1997 an executive order barred federal funding of cloning research, and various states have enacted legislation banning human cloning, both scholars and legislatures continue to debate the appropriate form of action.²

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1. See Robin McKie, *Scientists Clone Adult Sheep*, OBSERVER (London), Feb. 23, 1997, at A1 (reporting on the successfully cloned sheep, Dolly, by a team of researchers at the Roslin Institute in Scotland); *Despite Criticism, Scientist Avows Plan to Clone Humans*, BOSTON GLOBE, Jan. 12, 1998, at A3 (reporting on Dr. Seed’s announcement to open a human cloning clinic); Jan Cienski, *Human Cloning: ‘this will be done’: Scientists in race: Embryos to be Implanted Soon in Female Volunteers*, NAT’L POST, Aug. 8, 2001, at A3 (reporting on Clonaid’s intent to clone human beings); *Texas Researchers Clone A House Cat*, MIAMI HERALD, Feb. 15, 2002, at A24 (reporting on the December 22, 2001 birth of the cloned cat Cc, short for “Carbon copy,” by the company Genetic Savings & Clone); Nell Boyce & Katherine Hobson, *Pets of the Future*, U.S. NEWS & WORLD REP., Mar. 11, 2002 (cover story evaluating the moral and ethical issues involved in cloning pets).

2. On March 4, 1997 President Clinton issued an executive order barring federal funding of cloning research. See President’s remarks announcing the prohibition on federal funding for cloning on human beings and an exchange with reporters, 33 WEEKLY COMP. PRES. DOC. 278 (Mar. 4, 1997), available at 1997 WL 10084635; Memorandum on the Prohibition of Federal Funding for Cloning of Human Beings (Mar. 4, 1997), available at http://grants1.nih.gov/grants/policy/cloning_directive.htm. Prior to this order, President Clinton had requested a report from the National Bioethics Advisory Commission (NBAC) to evaluate and make recommendations concerning the use of cloning technology. The NBAC report was published on June 9, 1997, and recommended a prohibition of human cloning while calling for broad public dialogue on the issue. See NATIONAL BIOETHICS ADVISORY COMMISSION, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS

Forming part of that debate, on January 11, 2002, the California Advisory Committee on Human Cloning (the "Committee") published its report, *Cloning Californians? Report of the California Advisory Committee on Human Cloning* (the "Report"), which it submitted to the California Department of Health Services.³ This Case Note summarizes that Report and briefly reviews recent human cloning-related legislation at the state and federal levels. Because of its limited scope, this Note neither discusses nor draws conclusions as to whether various legislative responses to the prospect of human cloning are sound or valid, given the myriad of legal, political, moral, ethical, and scientific issues involved. Rather, recognizing that the regulation of human cloning is still in its infancy, this Note identifies what recent legislative action there has been on both the state and federal levels.

I. REPORT OF THE CALIFORNIA ADVISORY COMMITTEE ON HUMAN CLONING

In 1997, California became the first state to enact comprehensive legislation banning human cloning.⁴ The legislation placed a five-year moratorium on the cloning of an entire human being "in order to evaluate the profound medical, ethical, and social implications that such a possibility raises."⁵ To that end, the Legislature called upon the State Director of Health Services "to establish a panel of representatives from the fields of medicine, religion, biotechnology, genetics, law, bioethics, and the general public to evaluate those implications, review public policy, and advise the Legislature and the Governor in this area."⁶ On December 23, 1998, the Director of the Department of Health Services formally appointed twelve individuals

ADVISORY COMMISSION (June 1997), available at <http://bioethics.georgetown.edu/nbac/pubs/cloning1/cloning.pdf>. There has also been subsequent state and federal legislative action regarding human cloning. See discussion *infra* Part II and accompanying notes.

3. CAL. ADVISORY COMM. ON HUMAN CLONING, *CLONING CALIFORNIANS? REPORT OF THE CALIFORNIA ADVISORY COMMITTEE ON HUMAN CLONING* (Jan. 11, 2002) [hereinafter REPORT], available at <http://www.scu.edu/SCU/Centers/Ethics/publications/adbdreport.html>.

4. See CAL. BUS. & PROF. CODE §§ 16004, 16105, 2260.5 (2001) (providing for revocation of licenses issued to businesses for violations relating to human cloning and construing such violations as unprofessional conduct); CAL. HEALTH & SAFETY CODE §§ 24185, 24187, 24189 (2001) (establishing administrative penalties and prohibiting the cloning of human beings and the purchase or sale of ovum, zygote, embryo or fetus for the purpose of cloning human beings).

5. CAL. HEALTH & SAFETY CODE § 24185 (2001).

6. *Id.* The Genetic Disease Branch of the California Department of Health Services was charged with implementing the legislation.

to serve as members of the Committee.⁷ On May 8, 1999, the Committee held its first meeting and thereafter held a round of public hearings followed by a series of five closed meetings.⁸ As a result of those meetings, in its Report, the Committee made five main recommendations regarding human cloning.⁹

A. Recommendation One: California Should Prohibit Human Reproductive Cloning

California law already prohibits human reproductive cloning, but this moratorium is operative only until January 1, 2003.¹⁰ After reviewing the arguments for and against human reproductive cloning, the Committee ultimately concluded that another flat ban should issue, but with no expiration date. The Committee also noted, however, that a “subsequent Legislature and Governor could, of course, allow human reproductive cloning based on new information or changed views,” but that “the burden of going forward should fall to those who seek to convince the State to make such a change.”¹¹

The Report includes a review of a number of arguments for and against human reproductive cloning. The Committee suggests that the most compelling argument against human reproductive cloning is that of safety,¹² since direct evidence concerning the safety of human reproductive cloning is lacking, and “serious theoretical reasons”¹³ cause concern about the safety of reproductive cloning.

7. Committee members did not receive any funding for their work, save for reimbursement of some travel expenses. The twelve members, with their expertise in parenthesis, are as follows: Francine Coeytaux, MPH (Public); Theodore Friedman, MD (Genetics); David Gollaher, Ph.D. (Biotechnology); Henry T. Greely, JD (Law); Roger Hoag, MD (Medicine); Bernard Lo, MD (Ethics); Bert Lubin, MD (Medicine); Margaret R. McLean, M.Div., Ph.D (Religion); Francis C. Pizzulli, JD (Law); Radhika Rao, JD (Law); Larry Shapiro, M.D. (Medicine); and Tracy Trotter, MD (Medicine).

8. REPORT, *supra* note 3, § I(A), at 5.

9. Human reproductive cloning can be defined generally and will be used throughout this Note to mean the use in humans of somatic cell nuclear transfer to create a human fetus that is substantially genetically identical to a previously-born human being. In contrast, human non-reproductive cloning is defined as “the transfer of human cell nuclei into enucleated oocytes to produce human pre-embryos without implanting the pre-embryos to produce a human child.” *Id.* § III, at 38.

10. See CAL. BUS. & PROF. CODE §§ 16004, 16105, 2260.5 (2001) (operative until Jan. 1, 2003); CAL. HEALTH & SAFETY CODE §§ 24185, 24187, 24189 (2001) (operative until Jan. 1, 2003).

11. REPORT, *supra* note 3, § II(C), at 37.

12. See *id.* § II, at 17.

13. *Id.* § II(B)(1), at 23. Such reasons include “epigenetic changes in the donor cell’s DNA, which might not be reversed in the cloning process; problems with maternal and paternal

Beyond physical safety concerns, the Committee also cited arguments that psychological harm to individuals and harm to society could ensue should human reproductive cloning be allowed. Although proponents argue that such harms are speculative, a cloned child and the DNA donor may risk the feeling of the loss of uniqueness, while parents of cloned children may impose unfair expectations during their children's development.¹⁴ Furthermore, harms to society, including, but not limited to, a confusion of family and generation structures, genetic eugenics, and the creation of a DNA divide, also militate against permitting human reproductive cloning.¹⁵

In making its recommendation to prohibit human reproductive cloning, the Committee also addressed arguments that human reproductive cloning is impermissibly unnatural or inherently immoral, and also noted the political argument against human reproductive cloning.¹⁶ The Committee further examined the possible alternative to a complete ban on human reproductive cloning—to permit some human reproductive cloning and selectively regulate it—but concluded there were numerous pragmatic difficulties with such a policy option.¹⁷

B Recommendation Two: California Should Not Prohibit But Should Reasonably Regulate Human Non-Reproductive Cloning

While the Committee unanimously agreed that human reproductive cloning should be prohibited, it also unanimously agreed that human non-reproductive cloning, rather than being banned, should be reasonably regulated. The Committee found persuasive the arguments favoring human non-reproductive cloning, such as general benefits to human health and medicine—including the promise of preventing and alleviating human disease, disability and premature death—and using cloning technology as a source of human stem cells in order to avoid immune responses to transplanted tissue.¹⁸

imprinting of DNA in a clone; accumulated damage in the DNA of the donor somatic cell; telomere length; and problems with reprogramming of the donor cell's DNA." *Id.*

14. REPORT, *supra* note 3, § II(B)(2)(a)–(c), at 24–27.

15. *Id.* § II(B)(3)(a)–(c), at 27–29. Genetic eugenics refers to the possibility of the deliberate genetic selection of certain characteristics for a child. A "DNA divide" refers to a world of genetic have and have-nots, since the technology may be available only to the rich. *Id.*

16. REPORT, *supra* note 3, § II(B)(4), (6), at 31–32, 36–37.

17. *Id.* § II(B)(4)–(6), at 32–36.

18. *Id.* § III(A)(1)–(2), at 38–40.

The Committee also discussed arguments against non-reproductive cloning: (1) human non-reproductive cloning will lead to human reproductive cloning; (2) the creation and use of pre-embryos in research violates the pre-embryo's moral status as a person; (3) the need for donated human eggs will necessarily increase demand for such eggs; and, (4) access to the technology will be limited on the basis of wealth and hence violate the principle of distributive justice.¹⁹

Because the use of human non-reproductive cloning, which may prove essential to effective stem cell therapy, holds "enormous medical promise" in preventing and alleviating human disease and suffering, the Committee ultimately concluded that, although there are "appropriate concerns about this kind of research," such cloning should be permissible.²⁰ The Committee reasoned that the "moral scale weighing harms to a limited number of pre-embryos on one side against potentially hundreds of thousands of affected and clearly morally significant humans, on the other hand, can, it seems to us, justify the use of pre-embryos in this work. To ban such research would, to many of us, be itself unethical."²¹

The Committee also stated that human non-reproductive cloning research should be regulated both in the public and private spheres and such regulation should be designed to protect the interest of the individuals involved. In particular, the Committee stated that the regulation should (a) prohibit the use of pre-embryos after development of the primitive streak, since the appearance of the primitive streak may be an important indicator of the development of the moral status of the pre-embryo, (b) ensure that the persons providing cells for this purpose give informed consent, and (c) require that the research be permitted by an approved Institutional Review Board ("IRB").²²

C. Recommendations Three, Four, and Five: Implementation

While Recommendations One and Two provide substantive advice regarding the prohibition or regulation of human cloning,

19. *Id.* § III(B)(1)-(4), at 40-44.

20. *Id.* § III(C), at 44.

21. REPORT, *supra* note 3, § III(C), at 44.

22. *Id.* § III, at 38. Francis C. Pizzuli, an advisory committee member writing separately, goes further in specifying IRB review. He states that regulation should "(1) suggest the scope of an enforcement agency, particularly for non-federally funded entities that are not deterred by IRB disapproval and consequent loss of federal funding" and "(2) recommend directing the agency having jurisdiction over public and private research to promulgate regulations for the approved IRBs." *Id.* at 49 (separate statement of Francis C. Pizzulli).

Recommendations Three, Four, and Five suggest how California should implement a human cloning policy. The Committee's third recommendation—that federal and state regulation and action should be watched carefully—derives from the concern that should the federal government prohibit human reproductive cloning, this action may either preempt California legislation or make California legislation unnecessary.²³ The actions of other states, the Committee noted, should also be watched since such actions could provide helpful and useful experience to California's formation of a regulatory plan.

Recognizing that “[r]egulating a scientific field undergoing rapid change is difficult for a legislature,” the Committee made its fourth recommendation that the legislature should broadly define human cloning and delegate the duty of writing and revising specific definitions to a state agency.²⁴ The Committee gave the following example of such a definition:

Human reproductive cloning is defined as the creation of a human fetus that is substantially genetically identical to a previously-born human being. The use in humans of somatic cell nuclear transfer with a donor cell from an adult, as used in the creation of Dolly, is an example of such cloning. The Department of Health Services shall have the power to write and interpret regulations defining more precisely the procedures that consist human reproductive cloning for the purposes of this statute.²⁵

Following this call for regulatory flexibility, the Committee, also in its fifth recommendation, suggested that the legislature create an “on-going mechanism,” such as a panel of experts, to provide advice to the government on new and developing issues in biotechnology.²⁶

23. *Id.* § IV(A), at 45. Federal preemption presumes, of course, that the federal legislation is constitutionally valid. Whether a ban on human cloning is constitutional has been questioned by a number of scholars, who raise possible constitutional challenges based on the reach of the Commerce Clause, the right to privacy and the right to scientific inquiry, among others. *See, e.g.*, Lori Andrews, *Is There A Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643 (1998). *See also* REPORT, *supra* note 3, § II(A)(1), at 18–20 (discussing whether there is a fundamental right to reproduce and whether such a right might encompass human reproductive cloning).

24. REPORT, *supra* note 3, § IV(B), at 46.

25. *Id.* § IV(B), at 46–47.

26. *Id.* § IV(C), at 47–48. The issue of cloning by embryo-splitting particularly troubled the Committee, in which it may be possible to use such technology to have a “delayed-twin.” Stating that recommendation on this issue was not before it, the Committee suggested that further evaluation “by someone” should be considered. *Id.*

II. STATE AND FEDERAL CLONING-RELATED LEGISLATION

Since California became the first state to prohibit human cloning in 1997, only five states—Louisiana, Michigan, Missouri, Rhode Island, and Virginia—have either prohibited the cloning of human beings or limited the use of state funds for human cloning research.²⁷ Seventeen other states have proposed human cloning related legislation, but no bills have passed.²⁸

Specifically, Louisiana, Michigan, Rhode Island, and Virginia each prohibit human cloning, while Missouri limits the use of state funds for human cloning research.²⁹ These states also, with the exception of Missouri, provide specific exceptions for purposes of scientific research and cell-based therapies, and establish civil penalties for violations ranging from \$50,000 for each incident in Virginia to \$10 million, if the violator is a corporation, firm, clinic, laboratory or research facility, in Louisiana.³⁰ Michigan is currently the only state to impose criminal penalties, making a violation of its prohibition on human cloning a felony, punishable by imprisonment for not more than ten years, or a fine of not more than \$10 million, or both.³¹

However, in California, California Senate Bill 1557 would similarly impose criminal sanctions:

27. See LA. REV. STAT. ANN. 40 § 1299.36.6 (2002) (prohibiting human cloning, providing exceptions for scientific research and cell-based therapies and establishing civil penalties); MICH. STAT. ANN. §§ 333.26401-06 (2002) (prohibiting use of state funds for human cloning, providing exceptions for scientific research or cell-based therapies, and establishing civil penalties); 2002 MO. LAWS § 1.217 (limiting use of state funds for human cloning research); R.I. GEN. LAWS § 23-16.4-1 to 4-4 (2002) (prohibiting human cloning, providing exceptions for biomedical, microbiological, and agricultural research and establishing civil penalties for individuals, hospitals, and corporations); VA. CODE ANN. § 32.1-162.32.2 (2002) (prohibiting human cloning, providing exceptions for research purposes, and establishing civil penalties).

28. These states are Alabama, Arizona, Florida, Georgia, Illinois, Indiana, Kentucky, Maryland, Massachusetts, Minnesota, New York, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, and Wisconsin. Some states, such as New Jersey, have held committee meetings to discuss the implications of human cloning. Over 20 states also have laws banning or restricting research with human embryos, which might prohibit forms of non-reproductive cloning. See REPORT, *supra* note 3, § I(C)(2), at 15.

29. See *supra* note 27.

30. LA. REV. STAT. ANN. 40 § 1299.36.3 (2002); VA. CODE ANN. § 32.1-162.32.2 (2002).

31. MICH. COMP. LAWS § 750.430a (2002).

(a) If the defendant is a corporation, firm, clinic, hospital, laboratory, or research facility, by a fine of not more than one million dollars (\$1,000,000) or the applicable amount under subdivision (c), whichever is greater.

(b) If the defendant is an individual, by a fine of not more than the greater of two hundred fifty thousand dollars (\$250,000) or the applicable amount under subdivision (c).

(c) If any defendant derives pecuniary gain from a violation of this section, the defendant may be fined not more than an amount equal to the amount of the gross gain multiplied by two.³²

The bill would prohibit both human reproductive and therapeutic cloning, and eliminate the sunset date of California's current ban on human reproductive cloning.³³ Another bill, California Senate Bill 1230, would also extend the operation of the prohibition indefinitely, echoing the Committee's recommendation for a flat ban with no expiration date.³⁴ Unlike California Senate Bill 1557, however, the bill would only prohibit human reproductive cloning, and give power to the Department of Health Services to adopt, interpret, and revise the definition of "human reproductive cloning" in order to "more precisely defin[e] the procedures that constitute human reproductive cloning."³⁵ The legislation would also require the Department to establish an advisory committee, composed of specified representatives, "for purposes of advising the Legislature and the Governor on human cloning and other issues relating to human biotechnology."³⁶ Both bills are currently in the California Senate.³⁷

32. S.B. 1557, 2001-02 Reg. Sess. (Cal. 2002).

33. *Id.* The original bill extended the prohibition regarding human cloning to January 1, 2005.

34. S.B. 1230, 2001-02 Reg. Sess. (Cal. 2002). *See also* REPORT, *supra* note 3, § II(C), at 37.

35. S.B. 1230, 2001-02 Reg. Sess. (Cal. 2002). The original bill defined "human being" as a "living being with all the physical and mental qualities that make up a person." The bill as amended, however, omits this definition.

36. *Id.* As proposed, the advisory committee would be composed of at least seven members, appointed by the Director of Health Services, and would serve without compensation.

37. S.B. 1557 was referred, and S.B. 1230 re-referred, to the Committee on Health and Human Services on February 28, 2002, and February 19, 2002, respectively. More recently, on April 18, 2002, S.B. 1557 was re-referred to the Committee on Health and Human Services, with a hearing date set for April 24, 2002. S.B. 1230, as amended, passed the Committee on Health and Human Services on March 20, 2002, the Committee on the Judiciary on April 2, 2002, and on April 22, 2002, the Committee on Appropriations voted to pass the bill as amended.

No federal cloning-related legislation has passed, but ten bills have been introduced—seven in the House and three in the Senate—during the first session of the 107th Congress.³⁸ Similar to the California definition of human reproductive cloning, most of the bills generally define reproductive cloning as transferring the nucleus of a human somatic cell into an egg cell from which the nucleus has been removed or rendered inert for the purpose of initiating a pregnancy.³⁹ In contrast, human non-reproductive cloning, or therapeutic cloning, is generally defined as the use of such somatic cell nuclear transfer for the purpose of conducting research. Of these bills, five would prohibit only reproductive cloning, and five would prohibit both reproductive and therapeutic cloning.

Senator Dianne Feinstein introduced Senate Bill 1758 on December 3, 2001.⁴⁰ Entitled the Human Cloning Prohibition Act of 2001, the bill prohibits only reproductive cloning and specifically permits cloning technology for producing human stem cells.⁴¹ Intentional violation of the provisions of the bill may result in both criminal and civil penalties, the former carrying a penalty of a fine and imprisonment of not more than ten years, and the latter carrying a civil penalty of \$1 million or three times the gross pecuniary gain resulting from the violation, whichever is greater.⁴² The bill also adds Section 498C, Ethical Requirements for Nuclear Transplantation Research, to the Public Health Service Act and gives the Secretary of Health and Human Services exclusive authority to enforce the

38. Several bills were also introduced during the 105th and 106th Congresses, and various House and Senate subcommittees held a number of hearings. It should also be noted that on October 26, 1998, the Food and Drug Administration (“FDA”) published a “Dear Colleague” letter asserting jurisdiction in regulating cloning experiments. See Letter from Stuart L. Nightingale, Associate Commissioner, FDA, to Institutional Review Boards (Oct. 26, 1998), available at <http://www.fda.gov/oc/ohrt/irbs/irbletr.html>. The asserted regulatory jurisdiction has given rise to a number of questions regarding the propriety and plausibility of the FDA’s claim and the impact of such on federal legislative action. For an excellent discussion on this issue, see Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Statesmanship?*, 15 HARV. J.L. & TECH. 85 (2001). See also REPORT, *supra* note 3, § I(C)(1), at 13–14 (discussing whether the FDA has jurisdiction over human reproductive cloning and stating that the FDA “clearly [has] power over non-reproductive cloning when used as a treatment for human diseases or conditions.”).

39. See CAL. HEALTH & SAFETY CODE § 24185(c) (2001) (defining human reproductive cloning as “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, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being.”).

40. Human Cloning Prohibition Act of 2001, S. 1758, 107th Cong. (2001).

41. *Id.* § 4.

42. *Id.*

section.⁴³ Section 498C would require therapeutic cloning activities to adhere to Federal regulations for the protection of human subjects in research and impose civil monetary penalties of not more than \$250,000 for intentional violations of these regulations.⁴⁴ The bill was read twice and referred to the Senate Committee on the Judiciary.

In the House of Representatives on June 14, 2001, Representative Greenwood introduced House Bill 2172, entitled the Cloning Prohibition Act of 2001,⁴⁵ and on July 24, 2001, introduced a substantially similar bill, House Bill 2608, also entitled the Cloning Prohibition Act of 2001.⁴⁶ Both bills would amend the Federal Food, Drug and Cosmetic Act, specifically prohibiting human reproductive cloning. House Bill 2172 would make unlawful the shipment or transportation of a product of somatic cell nuclear transfer knowing the product is intended to be used to initiate a pregnancy,⁴⁷ whereas House Bill 2608 would also prohibit the receipt of such product.⁴⁸ Both bills would exempt the following from the prohibition:

- (1) The use of somatic cell nuclear transfer technology to clone molecules, DNA, cells, or tissues.
- (2) The use of mitochondrial, cytoplasmic, or gene therapy.
- (3) The use of in vitro fertilization, the administration of fertility-enhancing drugs, or the use of other medical procedures to assist a woman in becoming or remaining pregnant.
- (4) The use of somatic cell nuclear transfer technology to clone or otherwise create animals other than humans.
- (5) Any other activity (including biomedical, microbiological, or agricultural research or practices) not expressly prohibited⁴⁹

Each bill also requires individuals who intend to use human somatic cell nuclear transfer technology to register with the Secretary of Health and Human Services and to attest that the individual is aware of and will not violate the provisions of the bill.⁵⁰ The bills establish both civil monetary and criminal penalties, preempt any inconsistent State or local law and contain a ten-year sunset provision.⁵¹ Moreover, the bills would require the Institute of Medicine and the Secretary of Health and Human Services to enter into an agreement

43. *Id.*

44. *Id.*

45. Cloning Prohibition Act of 2001, H.R. 2172, 107th Cong. (2001).

46. Cloning Prohibition Act of 2001, H.R. 2608, 107th Cong. (2001).

47. H.R. 2172 § 2.

48. H.R. 2608 § 2.

49. *Id.* § 2; H.R. 2172 § 2.

50. H.R. 2608 § 2; H.R. 2172 § 2.

51. H.R. 2608 § 2; H.R. 2172 § 2.

under which the Institute of Medicine would conduct a study reviewing, evaluating and assessing the current state of knowledge about the biological properties of stem cells obtained from embryos, fetal tissues, and adult tissues.⁵² House Bills 2172 and 2608 were both referred to the House Committee on Energy and Commerce, and to the House Energy and Commerce Subcommittee on Health on June 25 and July 31, 2001, respectively.

Also providing for a prohibition on human reproductive cloning, Representative Ehlers introduced House Bill 1608, entitled the Human Cloning Prohibition Act of 2001, on April 26, 2001.⁵³ The bill states Congressional findings that, among others, genetic science, “including cloning technology and stem cell research, holds great promise for medical breakthroughs, including cures and treatments for diseases,”⁵⁴ while further finding that “[h]uman cloning raises serious moral, ethical, societal, and safety concerns that necessitate a legislative ban.”⁵⁵ House Bill 1608 would prohibit the knowing replacement of the nucleus of an oocyte with the nucleus of a human somatic cell, except if prior to replacement of the oocyte the nucleus of the human somatic cell has been modified so that the cell cannot develop to completion.⁵⁶ Violation of the bill’s provisions would carry civil and criminal penalties.⁵⁷ The bill was referred to the House Committee on the Judiciary and on June 14, 2001, referred to the House Judiciary Subcommittee on Crime.

While most of the human cloning-related bills establish both civil and criminal penalties, House Bill 1260, the Ban on Human Cloning Act, would impose only criminal penalties.⁵⁸ Introduced by Representative Kerns on March 28, 2001, the bill would make it unlawful for anyone to engage in human cloning and defines that term as a procedure by which the person “transfers the nucleus of a human somatic cell into an egg cell from which the nucleus has been removed.”⁵⁹ On June 14, 2001, the bill was referred to the House Judiciary Subcommittee on Crime.

Similar to House Bill 1260, on April 5, 2001 Senator Ben Nighthorse Campbell introduced Senate Bill 704, which would also

52. H.R. 2608 § 3; H.R. 2172 § 3.

53. Human Cloning Prohibition Act of 2001, H.R. 1608, 107th Cong. (2001).

54. *Id.* § 2.

55. *Id.*

56. *Id.* § 3.

57. *Id.*

58. Ban on Human Cloning Act, H.R. 1260, 107th Cong. (2001).

59. *Id.* § 2.

make it unlawful for anyone to engage in reproductive cloning.⁶⁰ The bill defines human cloning as:

(A) the use of somatic cell nuclear transfer or any other cloning technique for the purpose of initiating or attempting to initiate a human pregnancy;

(B) the implantation of a conceptus, blastocyst, or embryo created through somatic cell nuclear transfer into a mammalian uterus; or

(C) the creation of genetically identical siblings by dividing a conceptus, blastocyst, or embryo for the purpose of initiating or attempting to initiate a human pregnancy.⁶¹

Federal funds, moreover, could not be obligated or expended to conduct or support any research the purpose of which would be to engage in a human cloning procedure.⁶² Both civil and criminal penalties are provided for violation of the provisions of the bill.⁶³ Senate Bill 704 was referred to the House Energy and Commerce Subcommittee on Health.

Another bill, House Bill 1372, introduced by Representative Stearns on April 3, 2001, would also prevent the obligation or expenditure of Federal funds to conduct or support any project or research "that includes the use of human somatic cell nuclear transfer technology to produce an oocyte that is undergoing cell division toward development of a fetus."⁶⁴ Entitled the Human Cloning Research Prohibition Act, the bill also allows the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells other than human embryo cells or tissues and to use such techniques to create animals other than humans.⁶⁵ Furthermore, the Director of the National Science Foundation would be required to enter into an agreement with the National Research Council to review and report on implementation of the act within five years.⁶⁶ The bill also illustrates Congress's position regarding international prohibition.⁶⁷ House Bill 1372 was referred to the House Committees on Energy and Commerce and on Science. On April 12, 2001, it was

60. Human Cloning Prohibition Act, S. 704, 107th Cong. (2001).

61. *Id.* § 3.

62. *Id.*

63. *Id.* § 4.

64. Human Cloning Research Prohibition Act, H.R. 1372, 107th Cong. § 2 (2001).

65. *Id.* § 4.

66. *Id.* § 2.

67. *Id.* § 5 (expressing the sense of Congress that other countries should establish substantially equivalent restrictions).

referred to the House Science Subcommittee on Research, and four days later, the bill was referred to the House Energy and Commerce Subcommittee on Health.

Two substantially similar bills, House Bill 1644 and Senate Bill 790, both introduced on April 26, 2001, by Representative Weldon and Senator Brownback, respectively, would prohibit both therapeutic and reproductive cloning.⁶⁸ Any public or private person or entity, in or affecting interstate commerce, would be prohibited from performing or attempting to perform human cloning, participating in an attempt to perform human cloning or shipping or receiving the product of human cloning for any purpose.⁶⁹ Areas of scientific research not specifically prohibited, however, would be permissible, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants or animals other than humans.⁷⁰ Criminal and civil penalties are provided for violation of provisions of the bills.⁷¹ Senate Bill 790 was read twice and referred to the Committee on the Judiciary. House Bill 1644 was referred to the Committee on the Judiciary and to the Committee on Energy and Commerce. On May 4, 2001, House Bill 1644 was referred to the House Energy and Commerce Subcommittee on Health, and a hearing was held on the bill on June 20, 2001. The bill was also referred to the House Judiciary Subcommittee on Crime, which also held a hearing, on June 19, 2001.

The only bill to pass the House, House Bill 2505, would, like House Bill 1644, prohibit both reproductive and therapeutic cloning. Introduced by Representative Weldon on July 16, 2001, the Human Cloning Prohibition Act of 2001 would prohibit any person or entity in or affecting interstate commerce from knowingly (1) performing or attempting to perform human cloning, (2) participating in such an attempt, (3) shipping or receiving for any purpose an embryo produced by human cloning or any product derived from such embryo or (4) importing such an embryo.⁷² Other areas of scientific research, identical to the scientific research exceptions contained in House Bill 1644, would be allowed.⁷³ The bill also provides civil and criminal

68. Human Cloning Prohibition Act of 2001, H.R. 1644, 107th Cong. (2001); Human Cloning Prohibition Act of 2001, S. 790, 107th Cong. (2001).

69. H.R. 1644 § 3; S. 790 § 3.

70. H.R. 1644 § 3; S. 790 § 3.

71. H.R. 1644 § 3; S. 790 § 3.

72. Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. (2001).

73. *Id.* § 2. See H.R. 1644 and accompanying text.

penalties for violation of the provisions of the bill.⁷⁴ The General Accounting Office, moreover, would be required under the Act to conduct a study on the use of new medical developments using somatic cell nuclear transfer and evaluate current public attitudes and prevailing ethical views concerning the use of somatic cell nuclear transfer.⁷⁵

After referral to the House Committee on the Judiciary, the House Judiciary Subcommittee on Crime and two markup sessions, the House passed House Bill 2505 on July 31, 2001, by a vote of 265 to 162. On December 3, 2001, Senators Lott and Brownback proposed, and the Senate considered, a measure that would have imposed a six-month moratorium on all reproductive and therapeutic cloning activities. The amendment, which included the text of House Bill 2505, was combined with a controversial measure involving oil drilling in a national wildlife refuge. The amendment was set aside, despite the urging of the Bush Administration to pass House Bill 2505, since the Senate failed to invoke cloture, which would have required a vote on the substance of the amendment. Subsequently, the Senate has read House Bill 2505 twice, and on August 3, 2001, placed the bill on the Senate calendar.

III. CONCLUSION

The various federal bills introduced in the first session of the 107th Congress would either prohibit only reproductive cloning or prohibit both reproductive and therapeutic cloning. California has already banned human reproductive cloning, but as the California Advisory Committee on Human Cloning recommends, the State should reasonably regulate human non-reproductive cloning while indefinitely prohibiting human reproductive cloning. Implementation of that regulation, however, should be strong enough to effectuate the intent of the California Legislature, while at the same time provide flexibility in defining and identifying developments in the human biotechnology field. Issues of federalism, however, will continue to permeate any discussion or recommendation for regulation unless and until the federal government takes legislative action in the human cloning area.

To date, though, no human cloning-related federal legislation has been enacted. In that vacuum, California and other states have passed

74. *Id.*

75. *Id.* § 3.

comprehensive legislation prohibiting human reproductive cloning. Because California's prohibition is operative only until January 1, 2003, swift action—whether at the state or federal level—is all the more crucial. Such action, though, should neither be hasty nor reflexive to whims of scientists and religious leaders announcing claims to clone themselves and others. A guarded approach—balancing the benefits and burdens, advantages, and disadvantages of such technology—will allow for, perhaps, a better brave new world—“a world,” as Herder once said, in which “we ourselves create.”⁷⁶

76. ISAIAH BERLIN, *Herder and the Enlightenment*, in *THE PROPER STUDY OF MANKIND* 359 (Henry Hardy & Roger Hausheer eds., 1997) (quoting 8 JOHANN GOTTFRIED VON HERDER, *SÄMMLICHE WERKE* 252 (Berhard Suphan ed., 1913)).

