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THE CLONING FOR BIOMEDICAL RESEARCH DEBATE: DO THE PROMISES OF MEDICAL ADVANCES OUTWEIGH THE ETHICAL CONCERNS?

Jessica J. Monachello[†]

I. INTRODUCTION

Cloning is one of the most debated topics both in the United States and around the world.[1] Although cloning to produce children has been banned in most countries, cloning for biomedical research is still a topic of debate. This comment will focus on cloning for biomedical research. There are countries that are against cloning for biomedical research or that are proposing a moratorium on it, such as the United States,[2] while others that are taking great leaps towards making cloning for biomedical research a reality. The United Kingdom is such a country.[3]

This section will define cloning for biomedical research and stem cells, and will outline the potential benefits of such research. Part II will describe the history of cloning for biomedical research in the United States and what legislative measures are being proposed by the executive and legislative branches of the United States goverment. Part III will describe what regulations are in place in other countries and how they are approaching this controversial topic. This comment concludes by

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1. *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (July 2002), *at* http://www.bioethics.gov/reports/cloningreport/index.html (last visited Mar. 6, 2003).

2. *Id.*

3. *See* Medical Research Council, *UK Stem Cell Bank Launched*, *at* http://www.mrc.ac.uk/index/public-interest/public-topical_issues/public-stem_cells/public-stem_cell_bank-launched.htm (last visited Mar. 6, 2003).

proposing that cloning for biomedical research be allowed in the United States, contingent upon oversight by a regulatory committee. This will not only allow the United States to continue to be a leader in biotechnology, but also provide incentives for scientists to develop potential cures or treatments for the ailing people of this country.

A. *Definitions and Background Information*

Cloning for biomedical research is labeled in many ways, including "therapeutic cloning" and "human embryonic cloning."[4] This comment adopts the definition and label used by the President's Council on Bioethics in its July 2002 report to the President of the United States.[5] It defines "cloning-for-biomedical-research" as the "production of a cloned human embryo, formed for the (proximate) purpose of using it in research or for extracting its stem cells, with the (ultimate) goals of gaining scientific knowledge of normal and abnormal development and of developing cures of human diseases."[6] Cloning a human embryo is

> accomplished by introducing the nuclear material of a human somatic cell (donor['s cell other than a sperm or egg cell]) into an oocyte (egg) whose own nucleus has been removed or inactivated, yielding a product that has a human genetic constitution virtually identical to the donor of the somatic cell. (This procedure is known as "somatic cell nuclear transfer," or SCNT).[7]

During human embryonic development a single cell (the fertilized egg) differentiates into more than 200 cell types that make up the human body.[8] Up to about the eight-cell stage in the fertilization process all cells are "totipotent" (i.e. they can develop into any cell of the human body).[9] After five days, the cells have divided into approximately 50-100 cells (blastocyst stage), from which stem cells can be removed.[10] Human embryonic stem cells have the capacity of being transformed into almost any of the 200 types of cells in the human body.[11]

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4. *See* Nicholas Wade, *World War Breaks Out in Research on Stem Cells*, N.Y. TIMES, Dec. 21, 2002, at A1.

5. THE PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1.

6. *Id.*

7. *Id.*

8. The United Kingdom Parliament, *Stem Cell Research Committee*, para. 2.2, Feb. 13, 2002, *at* http://www.parliament.the-stationery-office.co.uk/pa/ld/ldstem.htm [hereinafter UK Committee].

9. *Id.* para. 2.3.

10. *Id.*

11. Daniella Goldberg, *Cloning Around with Stem Cells*, ABC SCIENCE ONLINE, *at* http://abc.net.au/science/slab/stemcells/default.htm (last visited Mar. 6, 2003).

Stem cells can be harvested from an early embryo but they can also be harvested from a fetus, from the placenta and umbilical cord, and from many other tissues of the body.[12] Stem cells harvested after the blastocyst stage (i.e. stem cells extracted past the 50-100 cell division or stem cells in the placenta and umbilical cord, also called adult stem cells) are described as "multipotent" as they have the potential to differentiate into a limited number of cells of the human body.[13]

B. Benefits of Cloning for Biomedical Research

Many scientists believe that there are tremendous possibilities for benefits to the human race if cloning for biomedical research is allowed.[14] Because human embryonic stem cells have the ability to differentiate into other cell types, they offer the potential to cure diseases such as cancer, diabetes, Parkinson's, Alzheimer's, multiple sclerosis and certain forms of heart disease.[15] They also offer the potential to help treat nervous system injuries, spinal cord injuries, and severe burns.[16]

Professor Bernie Tuch, Director of the Pancreas Transplant Unit at Prince of Wales Hospital in Sydney, Australia, is seeking a cure for diabetes through the use of human embryonic stem cells.[17] Professor Tuch believes that using stem cells might provide a way to replace the "insulin-producing cells that are missing in type I diabetes patients," thereby reversing the disease and eliminating the need for insulin injections.[18]

Dr. Leon McQuade, a molecular geneticist in the same hospital, has been working for months to turn mouse embryo cells into insulin-producing cells.[19] He believes that since these insulin-producing cells have been achieved in mice, soon the same achievement could be made for humans.[20] Dr. Karl Skorecki's team, at the Technion in Haifa, Israel, has also been performing the same tests on mice; his concern is how to apply this type of stem cell therapy to humans without using immuno-

12. UK Committee, *supra* note 8, para. 2.3.

13. *Id.* para. 2.4.

14. *See Cell Biology: Study on Adult Blood Stem Cells Raise Questions*, BLOOD WEEKLY, Oct. 31, 2002, *available at* 2002 WL 9268282 [hereinafter *Cell Biology*].

15. *See* Gabriel S. Gross, *Federally Funding Human Embryonic Stem Cell Research: An Administrative Analysis*, 2000 WIS. L. REV. 855, 856 (2000).

16. *See id.*

17. Goldberg, *supra* note 11.

18. *Id.*

19. *Id.*

20. *Id.*

suppressive drugs, which sometimes have been known to produce serious side effects.[21]

The immuno-suppressive drug problem could be overcome by using a patient's adult cell, inserting it into an egg that has had its nucleus removed (i.e., SCNT), thus creating a human embryo and removing its stem cell.[22] But as Dr. Quade points out, more tests are necessary to ensure that the cells continue to function properly after they are inserted into the patients' body even if no problems with rejection are encountered.[23]

Professor Alan Trounson's team, at Melbourne Monash University in Australia, has successfully created "mature nerve cells from human embryonic stem cells."[24] His team then successfully implanted these cells into newborn mice and the cells seem to be acting as normal brain cells.[25] This type of success, if applied to humans, could lead to the treatment of neurodegenerative diseases such as Parkinson's.[26]

Although some people believe that adult stem cells should be used for research in lieu of embryonic stem cells, recent findings have shown that adult stem cells might not hold the promised value in the treatment of diseases.[27] Researchers at Stanford tried to trace how blood stem cells adapted after being inserted into mice whose bone marrow had been destroyed.[28] They hoped these cells would generate both blood-making cells as well as cells that would generate other tissues of the body.[29] The researchers found that the blood stem cells only made blood cells, not any other types of cells.[30] The Stanford researchers stated that their study shows the only sure way of making multiple tissues from one cell is from embryonic stem cells, not from adult blood stem cells.[31] However, accordingly to Dr. Dennis Steindler, a stem cell researcher at the University of Florida, there is still too much research to be done on this subject and most experts believe that both adult and embryonic stem cell research should continue because it might lead to cures or new therapies for diseases.[32]

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21. *Id.*
22. *Id.*
23. Goldberg, *supra* note 11.
24. *Id.*
25. *Id.*
26. *Id.*
27. *See Cell Biology*, *supra* note 14.
28. *Id.*
29. *Id.*
30. *Id.*
31. *Id.*
32. *See id.*

II. CLONING FOR BIOMEDICAL RESEARCH IN THE UNITED STATES

In November 1998, Dr. James A. Thomson, a biologist at the University of Wisconsin, was the first to isolate an embryonic stem cell.[33] His work did not qualify for National Institute of Health (NIH) funding, so he started a separate lab with private funds to do his research.[34] Until 2001, the federal government had not provided any funding for human embryonic stem cell research.[35] After Dr. Thomson's announcement, President Bill Clinton created the National Bioethics Advisory Commission (NBAC) to review the issues concerning stem cell research.[36] In 1999, the NBAC released a report concluding "that the federal government should fund research on, and the derivation of, human ES [embryonic stem] cells, provided that only embryos leftover from fertility treatments were used."[37] The commission also proposed that Congress create an exception to the embryo research ban for the derivation of embryonic stem cells.[38]

In December of 1999, the National Institute of Health released a draft of its guidelines permitting federal funds to be given to privately funded research on embryonic stem cells, but with stringent oversight.[39] The guidelines only allowed research on cells derived from leftover or donated embryos from fertility treatments.[40] The final guidelines, released August 25, 2000 and backed by President Clinton, led to the solicitation of research grants.[41] A committee was set up to review grant applications to the NIH, but the first meeting in April 2001 was canceled as President Bush ordered the Secretary of the Department of Health and Human

33. American Association for the Advancement of Science, *Stem Cell Research*, *at* http://www.aaas.org/spp/cstc/issues/stemcells.htm (last modified Aug. 14, 2002) [hereinafter AAAS].

34. *Id.* Dr. Thomson's work was not eligible for funding because Congress put a ban on National Institute of Health (NIH)-funded human embryo research. In 1995, Congress attached the ban to a bill that gave NIH funds and it was retained each time the bill was appropriated. Because of this, the NIH contacted the Department of Health and Human Services (HHS) for counseling, and in 1999, the HHS declared that public funds could be used for research on human embryonic cells as long as the derivation of the cells that result in the termination of an embryo is carried out with private funds. *Id.*

35. *Id.*

36. *Id.*

37. *Id.*

38. AAAS, *supra* note 33.

39. *Id.*

40. *Id.*

41. *Id.*

Services (HHS) to review the guidelines.[42] Despite this seeming setback, researchers at Advanced Cell Technology, a company in the United States, claimed to have produced the first cloned human embryo in November 2001.[43] Although no stem cells were harvested, it was the longest surviving embryo to be cloned.[44]

A. President's View

President George Bush addressed human embryonic stem cell research and funding during his speech to the nation on August 9, 2001, due to substantial pressure from scientists, religious groups, and the public in general.[45] The President noted there was a fear that if federal funds were not provided to continue the research on stem cells in the United States, the country would lose not only its best and brightest scientists, but also lose its standing as a leader in science and medicine.[46] The President indicated that after much deliberation into the moral and ethical issues, he decided that federal funds would only be available for research on existing stem lines that have been derived: with the donors' informed consent, from excess embryos from fertility treatments, and without giving the donors any financial incentives.[47] To ensure these standards are followed and that the research conducted is both legal and ethical, he required that the NIH "examine the derivation of all existing stem cell lines and create a registry of those lines that satisfy this criteria."[48]

In the press release accompanying the speech, the White House noted that probably around sixty existing stem cell lines from around the world would fit the President's requirements and therefore be acceptable for federal funding.[49] He also stated that federal funds would not be granted for stem cell lines derived from newly destroyed embryos, for the creation of human embryos specifically for research, or for the cloning of human embryos.[50]

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42. *Id.*

43. Goldberg, *supra* note 11.

44. *Id.* The embryo only reached the six-cell stage. *Id.*

45. *See* President George W. Bush, Remarks by the President on Stem Cell Research to the Nation (Aug. 9, 2001), *available at* http://www.whitehouse.gov/news/releases/2001/08/print/20010809-2.html [hereinafter Bush].

46. *See id.*

47. Press Release, The White House: Office of the Press Secretary, Embryonic Stem Cell Research (Aug. 9, 2001), *at* http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html.

48. *Id.*

49. *Id.*

50. *Id.*

Following the President's announcement, the NIH started to implement the President's policy.[51] The NIH consulted with scientists around the world and found that there were sixty-four individual blastocysts that fit the President's guidelines.[52] The NIH created the Human Embryonic Stem Cell Registry, which has a list of all the human embryonic stem cell lines that meet the President's standards.[53]

On February 28, 2002, the NIH noted that scientists were already encountering difficulties with the standards set by the President.[54] The first difficulty concerns the supply of the existing stem cell lines; since these lines were only developed three years ago, the creators are still refining them, categorizing them and developing procedures to share their cells.[55] The second difficulty relates to the technique used to develop embryonic stem cells, as the WiCell Research Institute holds the patent to this technique.[56] However, the NIH has been working with the WiCell Research Institute to set up licensing agreement to ease this problem.[57] A third problem that scientists may face is that most of the embryonic stem cells were created outside the United States; therefore, not only is there a geographical issue, but also a legal problem.[58] Other countries either already have their own legislation or are planning to set their own guidelines regarding to the use of their existing stem cell lines.[59] At this time, the NIH is also trying to assist scientists by discussing these issues with the government of these countries, but this will further delay the process.[60] Finally, the NIH wants to educate scientists in the community and to create interest in this type of research.[61] Because this field is so new, there are not enough trained scientists in the United States ready to undertake the research; therefore, the NIH is providing a variety of

51. National Institutes of Health, *National Institutes of Health (NIH) Update on Existing Human Embryonic Stem Cells*, Aug. 27, 2001, *at* http://www.nih.gov/news/stemcell/082701list.htm.

52. *Id.*

53. National Institutes of Health, *NIH Strategies for Implementing Human Embryonic Stem Cell Research*, Feb. 28, 2002, *at* http://www.nih.gov/news/stemcell/022802implement.htm.

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *See* National Institutes of Health, *supra* note 53.

60. *Id.*

61. *Id.*

training opportunities for scientists from tutorials to symposia and fellowships.[62]

On September 25, 2002, Dr. Elias Zerhouni, the Director of the NIH, testified before the Senate regarding the developments in Stem Cell Research in the United States.[63] With regard to the problems encountered, Dr. Zerhouni reaffirmed that there was still a shortage of talented researchers in stem cell research and that there were still problems in the availability of the existing stem cells, but that the NIH was trying to ameliorate these problems by training scientists and granting awards to expand the available stem cells.[64]

Dr. Zerhouni mentioned that the research was still at its early stages as the NIH is still trying to draw the "most talented research scientists" to this type of research.[65] He also stated that the NIH was in the process of "supporting infrastructure awards to expand [existing] cell lines, refine culture methods, and establish improved methods to select the most desirable embryonic stem cell populations."[66] He indicated that the NIH is supporting research on adult stem cells lines to potentially develop therapies from these cell lines.[67] However, Dr. Zerhouni noted that he believed both research on the existing embryonic stem cells as well as on adult stem cells should continue simultaneously so that the potential of these cells to treat and develop new cures for human diseases can be fully understood.[68]

Dr. Zerhouni noted that the technology required to treat human diseases would require years to develop.[69] Before that can happen, scientists first would have to perform pre-clinical studies with non-human subjects.[70] These studies would include tests of long-term survival of the cells and "tests of the safety, toxicity, and effectiveness of the cells in treating animal models for disease."[71] The first phase of clinical trials on

62. *Id.*

63. *Hearing on Stem Cell Research, Senate Appropriations Committee, Subcommittee on Labor, Health, Human Services, Education and Related Agencies*, 107th Cong. (Sept. 25, 2002) [hereinafter Zerhouni] (statement of Dr. Elias Zerhouni, Director, NIH).

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

69. *See* Zerhouni, *supra* note 63.

70. *Id.*

71. *Id.*

humans will be conducted after these tests have been performed and the chance of harm to humans minimized.[72]

To date the NIH has approved five grants totaling $4.2 million dollars to scientists focusing on existing human embryonic stem cell research, and it has also issued thirty-two administrative supplements to already existing awards.[73] These supplements will allow thirty researchers to incorporate embryonic stem cell research into their current research.[74] To help further research in this area, the NIH has instituted a new stem cell task force, led by the Director of the National Institute on Deafness and Other Communication Disorders, Dr. James Battey.[75] Its job will be to "provide direction for the future in the form of recommendations for NIH-supported research initiatives."[76]

B. President's Council on Bioethics Proposal

President Bush, in his speech to the nation on August 9, 2001, instituted the President's Council on Bioethics to "monitor stem cell research, to recommend appropriate guidelines and regulations, and to consider all of the medical and ethical ramifications of biomedical innovation."[77] The Council, chaired by Dr. Leon Kass (a leading biomedical ethicist from the University of Chicago), among others, consists of doctors, scientists, ethicists, lawyers, and theologians.[78]

Following the President's speech to the nation, the President's Council met throughout a six-month period and on July 10, 2002 issued its first report, entitled *Human Cloning and Human Dignity: An Ethical Inquiry*,[79] in which the Council discusses both cloning to produce children and cloning for biomedical research.[80] It unanimously recommends that cloning to produce children should be banned.[81] However, on the topic of cloning for biomedical research, the Council is split into a majority opinion and a minority opinion.[82] To reach their decision, the Council discussed moral and public policy issues.[83] After significant discussion, the minority

72. *Id.*
73. *Id.*
74. *Id.*
75. Zerhouni, *supra* note 63.
76. *Id.*
77. Bush, *supra* note 45.
78. *Id.*
79. *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1.
80. *See id.*
81. *See id.*
82. *See id.*
83. *See id.*

opinion recommended that cloning for biomedical research be allowed with regulation.[84] In contrast, the majority of the council recommended that there be a "four-year moratorium on cloning-for-biomedical-research," with a "federal review of current and projected practices of human embryo research, pre-implantation genetic diagnosis, genetic modification of human embryos and gametes, and related matters, with a view to recommending and shaping ethically sound policies for the entire field."[85]

1. President's Council Minority Opinion

The Council members in favor of proceeding with cloning for biomedical research stated that the moral case for proceeding with the research involves an obligation to try to relieve human suffering and that research on cloned human embryos is one more path to achieve this goal.[86] These Council members note that four benefits of allowing cloning for biomedical research to relieve human suffering include cloning to: improve the understanding of human disease;[87] devise new treatments for human disease;[88] produce immune-compatible tissues for transplantation;[89] and assist in gene therapy.[90]

Although these council members favor proceeding with cloning for biomedical research, they have two different views of the moral issues.[91] One set of council members does not see any moral problems with such research, as they do not attach a moral status to the early embryo; they believe that an early human embryo should be treated just like any other human cell.[92] Therefore, the main standards used in the research is that of informed consent and scientific integrity.[93]

The other set of council members favors cloning for biomedical research, but has serious moral concerns, such as the status of a human embryo, the creation of human embryos solely for use in research, the development and use of cloned embryos past the first fourteen days, the exploitation of women who choose to donate their eggs, and the

84. *Id.*
85. THE PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1.
86. *Id.*
87. *Id.*
88. *Id.*
89. *Id.*
90. *Id.*
91. *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1.
92. *See id.*
93. *See id.*

implication that it might lead to cloning to produce children.[94] Despite their concerns, they still favor the research on human embryos, but only up to the first fourteen days of development and with appropriate rules and regulations to guide such research.[95] They favor the research because they believe that the early embryo should not be given the moral status of a human person, rather, should be allowed an intermediate moral status. Such embryos are not created for destruction, but to a service of life and medicine.[96]

The Council members that support cloning for biomedical research propose that regulation be carried out by a regulatory agency, which would control both federally and privately funded research.[97] This agency's purpose "would be to enforce certain general standards for the handling and use of cloned human embryos, to ensure that they are not created for frivolous purposes, used irresponsibly, or treated in ways that go beyond what American society deems morally acceptable."[98] The council members believe the agency should also be authorized to establish some or all of the following: what can and cannot be done with the human embryos once they are created, licensing of research on cloned embryos, guidelines on informed consent, registration and monitoring of each cloned embryo, establishment and enforcement of time after which an embryo may not be used in research, monitoring and regulation of financial transactions relating to research, and enforcement of regulations.[99] The members state that this regulatory system is needed not only "to regulate and limit the use of cloned embryos," but also to set "clear rules and limits to prevent abuses."[100] The council members believe the regulatory structure for the United States could be developed by studying the models already in place in other countries such as the United Kingdom's Human Fertilisation and Embryology Authority.[101]

2. President's Council Majority Opinion

The Council members proposing a moratorium or temporary ban on cloning for biomedical research noted that neither the researchers, patients, nor moralists could know to a certainty that there will be medical

94. *See id.*
95. *See id.*
96. *See id.*
97. *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1.
98. *Id.*
99. *Id.*
100. *Id.*
101. *Id.*

benefits to allowing cloning for biomedical research.[102] The council members also stated they had concerns with the respect or moral standing that the early human embryo deserved, since, if inserted into a woman, the embryo could potentially develop into a child.[103] They noted that human identity exists in the human embryo from conception and should not be taken advantage of by scientific endeavors.[104] These council members are concerned that allowing cloning for biomedical research, even with regulation, will create a slippery slope where one day it will be acceptable to clone a human baby.[105] Finally, the council members against cloning for biomedical research state that they are not "closing the door on medical progress," but believe that other avenues should be pursued instead of using cloned embryos, even if such avenues are slower.[106]

The council members proposing the moratorium note that this option would allow for an "enlarged debate on a question about which people currently differ (cloning-for-biomedical-research)."[107] The council members see several benefits to a moratorium on cloning for biomedical research. A moratorium would allow for the following: continued research in related fields to clarify the potential benefits of cloning for biomedical research, institution of a regulatory structure, and time for further debate on moral issues so that the decision on whether to continue or end the moratorium can be made carefully.[108] It would also allow policy makers to look at cloning for biomedical research in the context of embryo-research instead of under human cloning.[109]

C. *Federal and State Laws*

Debate concerning cloning in the United States Senate is growing due to claims by Clonaid[110] that the first cloned human baby was allegedly born

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102. *See id.*

103. *See* THE PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1.

104. *See id.*

105. *See id.*

106. *Id.*

107. *Id.*

108. *Id.*

109. THE PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1.

110. *See* David Chazan, *Who Are the Raelians?*, BBC NEWS, Dec. 28, 2002, *available at* http://news.bbc.co.uk/2/hi/health/2610795.stm. The Raelians are a religious sect. The group's founder, Claude Vorihon (Rael as he now is called), claims that he was contacted by aliens and was told humanity was created in a laboratory (i.e. cloned) by people of a different planet. *Id.*

on December 27, 2002[111] and due to President Bush's request that Congress "pass a law against all human cloning"[112] in his State of the Union address on January 28, 2003.

Both the United States House of Representative and Senate have taken up the issue of cloning.[113] After holding four hearings on cloning, the House of Representatives passed a strict ban on all human cloning in July 2001.[114] On March 5, 2002, the United States Congress debated a bill proposed by Senator Sam Brownback that would impose criminal penalties on any "attempts at transferring a human somatic cell nucleus into a human egg," whether for cloning to produce children or for cloning-for-biomedical purposes.[115] However, at the end of the Senate term the proposed bill had not been voted on.[116]

On February 5, 2003, two bills were introduced into the Senate. One bill, introduced by California Senator Dianne Feinstein and Utah Senator Orrin Hatch, would outlaw cloning to produce children while allowing cloning for biomedical research pursuant to regulation,[117] including a prohibition of using fertilized eggs fourteen days past conception, fines or imprisonment for cloning-to-produce children, the inability for donors to receive payment for their egg donations, and a requirement of informed consent from the donors.[118] The second bill, introduced by Kansas Senator Sam Brownback and Louisiana Senator Mary Landrieu, again proposed outlawing "all use of cloning technology involving human embryos."[119]

Some states have decided to bypass the federal government and the President in the controversy of cloning for biomedical research.[120]

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111. *Cloned Baby Claim Met with Doubt*, BBC NEWS, Dec. 27, 2002, *available at* http://news.bbc.co.uk/2/hi/health/2608655.stm.

112. President George W. Bush, State of the Union (Jan. 28, 2003), *available at* http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html.

113. *See* OFFICE OF LEGISLATIVE POLICY AND ANALYSIS: LINKING THE NATIONAL INSTITUTES OF HEALTH AND CONGRESS, LEGISLATIVE UPDATES, *available at* http://olpa.od.nih.gov/legislation/107/session2/7cloning.asp (last visited Mar. 6, 2003).

114. *Id.*

115. Tabitha M. Powledge, *US Cloning Debate Gathers Steam*, THE SCIENTIST, Mar. 7, 2002, *available at* http://www.biomedcentral.com/news/20020307/03.

116. *See id.*

117. Lisa Friedman, *Cloning Spurs Senate Sparring: Stem Cell Research Also on Agenda as Rival Bills, Celebrity Activists Bring New Twists to Controversial Debate*, OAKLAND TRIB., Feb. 6, 2003, *available at* 2003 WL 8912473.

118. *Id.*

119. *Id.*

120. *See* Amanda Onion, *Research Revolution? New California Stem-Cell Law Defines Federal Policy, Other States May Follow*, ABC NEWS, Oct. 8, 2002, *available at*

California is the first state to directly challenge the President by passing a state law that encourages embryonic stem cell research.[121] The bill states various reasons why California will allow stem cell research.[122] Some of the reasons noted are that there are millions of Americans suffering from crippling and degenerative diseases and while the cost of treatment for those diseases is high, there is hope that stem cell research may lead to substantial treatments for them. Other justifications include the United States and California being leaders in biomedicine and biotechnology. California's biotechnology industry is critical to the state's economy, and open and public research is essential to realizing the goal of finding new treatments for such diseases.[123]

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" with review by an approved institutional board.[124] The bill also states a medical professional in charge of fertility treatments shall give his or her patients appropriate information to make voluntary decisions as to what to do with their surplus embryos, be it storing them, donating them to other couples, discarding them, or donating them to research (via written consent).[125] Valuable consideration, not including "reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation," is strictly prohibited under the bill.[126]

Other states are following California's lead. Senators in the New Jersey Legislature have introduced a bill similar to California's, but the bill has yet to be ratified.[127] The New Jersey bill states similar reasons as to why embryonic stem cell research will be allowed in New Jersey.[128] The bill, like California's, permits "the derivation and use of human embryonic stem cells . . . including somatic cell nuclear transplantation."[129] It states that an institutional board will review each case to make sure that ethical

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http://abcnews.go.com/sections/scitech/DailyNews/stemlaws021008.html (last visited Mar. 6, 2003).

121. Scott Duke Harris, *Fighting the Feds: Bush Gets a Taste of Big State's Contrarian Ways*, SAN JOSE MERCURY NEWS, Nov. 3, 2002, *available at* 2002 WL 102438066.

122. *See* S.B. 253, 2001-2002 Reg. Sess. (Cal. 2001).

123. *Id.*

124. *Id.* The board would review and approve any research based on ethical considerations. *See* Onion, *supra* note 120.

125. S.B. 253, 2001-2002 Reg. Sess. (Cal. 2001).

126. *Id.*

127. *See* Onion, *supra* note 120.

128. *See* A.B. 2840, 210th Leg. (N.J. 2002).

129. *Id.*

and medical implications are considered and provides for informed consent for patients receiving fertility treatment and prohibits receipt of valuable consideration for human embryos.[130] The only difference between the two states' laws is that New Jersey's bill includes a penalty of $50,000 and/or imprisonment for people that violate the bill's provisions, whereas California does not mandate such a penalty in its instituted bill.[131] Other states such as New Mexico and Oregon are currently considering similar bills of their own.[132] Maryland and Virginia are instead "considering bills to create special panels dedicated to exploring the potential of stem-cell research."[133] The biggest advantage of these laws is that they would give researchers not only funding, but also a work environment free from hostility.[134]

In December 2002, Stanford University announced its intention to clone human embryos for stem cell research, taking advantage of California's law allowing cloning for biomedical research and "becoming the first U.S. university to publicly embrace the politically charged procedure."[135] Stanford said the project will be funded with public and private funds, and will be geared primarily to finding cures for cancer.[136] However, Stanford has also stated that it plans to share stem cells with outside researchers.[137] For now, the California bill and other states passing such bills provide researchers and proponents of cloning for biomedical research the "legal cover" to pursue their research.[138]

III. CLONING FOR BIOMEDICAL RESEARCH IN OTHER COUNTRIES

In contrast to the hesitation in the U.S., various other countries have forged ahead in cloning for biomedical research.[139] This section of the

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130. *Id.*

131. *Compare* S.B. 253, 2001-2002 Reg. Sess. (Cal. 2001), *with* A.B. 2840, 210th Leg. (N.J. 2002).

132. *See* Onion, *supra* note 120.

133. *Id.*

134. *See id.*

135. *University to Clone Embryos; Goal is to Produce Stem Cells*, NEWSDAY, Dec. 11, 2002, at A18.

136. *Id.*

137. *Id.*

138. *See* Carl T. Hall, *Stem Cell Storm's Eye Over UCSF, Stanford; State Law Called Key in Fostering Research Opposed by Bush*, SAN FRANCISCO CHRON., Dec. 21, 2002, at A1.

139. *See* Tim Friend, *Saudis Take Lead on Stem-Cell Cloning*, USA TODAY, July 8, 2002, *available at* http://www.usatoday.com/news/healthscience/science/2002-07-09-arabstemcell.htm.

comment discusses in detail the stance on cloning for biomedical research in three countries: the United Kingdom, Australia, and Singapore; and provides an overview of the policies in Canada, Saudi Arabia, Germany, Japan, and the United Nations.

A. United Kingdom

The United Kingdom has been one of the leaders in human fertilization and embryology since the 1990s.[140] In 1984, the Committee of Inquiry into Human Fertilisation and Embryology, chaired by Baroness Warnock, recommended the regulation of research on human embryos.[141] After extended discussions, the government of the United Kingdom adopted the Committee's recommendations in the Human Fertilisation and Embryology Act of 1990 (the Act).[142] The Act established the Human Fertilisation and Embryology Authority (HFEA), which gives the discretionary right to issue licenses for research on human embryos.[143]

The Act prohibits the research on embryos older than fourteen days and may not be performed unless the HFEA issues a license.[144] The HFEA will only grant a license if they are satisfied that the use of embryos is necessary for the purposes of research and only if the embryos are used for the following purposes:

> (a) promoting advances in the treatment of infertility, (b) increasing knowledge about the causes of congenital disease, (c) increasing knowledge about the causes of miscarriages, (d) developing more effective techniques for contraception, (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation, or for such other purposes as may be specified in regulations.[145]

In 1998, the HFEA and the Human Genetics Advisory Commission (HGAC) jointly recommended that two more licensing purposes be added to those mentioned above: "development of methods of therapy for mitochondrial disease; and the development of therapeutic treatments for diseased or damaged tissues or organs."[146] In September of 1999, the government of the United Kingdom assembled a group of experts to analyze the feasibility of research on human embryos and in 2001, the

140. UK Committee, *supra* note 8, para. 1.1.
141. *Id.* para. 1.2.
142. *See id.*
143. *Id.*
144. *Id.* para. 1.3.
145. *Id.*
146. UK Committee, *supra* note 8, para. 1.7.

House of Commons and then the House of Lords passed the Human Fertilisation Embryological Regulations of 2001.[147] The Regulations added three new purposes to the Act of 1990: "(a) increasing knowledge about the development of embryos, (b) increasing knowledge about serious disease, or (c) enabling any such knowledge to be applied in developing treatments for serious disease."[148]

In December of 2001, the government of the United Kingdom introduced and made law the Human Reproductive Cloning Bill, which prohibited cloning to produce children.[149] In March 2001, the House of Lords appointed a committee "to consider and report on the issues connected with human cloning and stem cell research arising from the Human Fertilisation and Embryology (Research Purposes) Regulations."[150]

On February 13, 2002, this committee made recommendations on the following topics: stem cell research, status of the early embryo, cell nuclear replacement and cloning, and legislation and regulation.[151] With regard to stem cell research, the council discussed the potential advantages of using embryonic versus adult stem cells for research.[152]

The committee's report states that research on mice has shown it is possible to isolate embryonic stem cells "from the blastocyst, culture and multiply them in the laboratory, in principle indefinitely, and induce them to differentiate into a wide range of different cell types."[153] Researchers have also taken these same cells, inserted them into eggs, implanted them into female mice and achieved normal offspring.[154] The committee sees this as proof that embryonic stem cells "can be grown and manipulated safely in culture" and that they will develop into all cell types of the body.[155] Because of such research, the committee believes there is significant potential to develop a wide range of therapies from human embryonic stem cells.[156]

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147. *Id.* paras. 1.8-1.10.

148. *Id.* para. 1.10.

149. *Id.* para. 1.14.

150. *Id.* para. 1.15.

151. The United Kingdom Parliament, Stem Cell Research Committee, *Summary of Conclusions and Recommendations*, Feb. 13, 2002, *available at* http://www.parliament.the-stationery-office.co.uk/pa/ld/ldstem.htm.

152. *See* UK Committee, *supra* note 8, paras. 3.3-3.14.

153. *Id.* para. 3.3.

154. *Id.*

155. *See id.*

156. *See id.* para. 3.22.

The committee also noted a potential for using adult stem cells for research because there is already proof that haematopoietic stem cells have helped to treat leukemia and other blood disorders.[157] One of the greatest advantages to using the adult stem cells of an ailing individual to treat their disease is that it avoids rejection by their immune system.[158] The committee also notes possible limitations to using adult stem cells, such as: "isolation of neural cells from a patient's brain,"[159] problems to date of isolating and growing stem cells in culture, difficulty of differentiating the adult stem cell into other cell types, and lack of sufficient research into this subject.[160] Therefore, the committee recommends that research on embryonic and adult stem cells continue concurrently since neither research "alone is likely to meet all therapeutic needs."[161] If research on adult stem cells is successful in the future, research on embryonic stem cells could become unnecessary.[162]

In their report, the committee discusses in detail the status of an early embryo.[163] First, they noted the Human Fertilisation and Embryology Act of 1990 awards the early embryo a "special status but not one that justifies its being accorded absolute protection."[164] Then the committee went on to say that just because a human tissue or cell is alive is not enough to award it full right to life,[165] and just because the embryo has a potential to become a person, it does not mean it will.[166]

The committee also noted that currently there is legislation allowing abortion (which destroys embryos), *in vitro* fertilization (which creates surplus embryos, most of which are eventually destroyed), and research on human embryos (the 1990 Act).[167] Therefore, based on the current laws and social attitudes, the committee concluded that research on human embryos should not be prohibited.[168]

The committee upheld the time allotted to doing research on human embryos at fourteen days as established in the 1990 Act.[169] This time frame

157. *See id.* para. 3.8.
158. UK Committee, *supra* note 8, para. 3.9.
159. *Id.* para. 3.10
160. *See id.* paras. 3.11-3.14.
161. *Id.* para. 3.22.
162. *Id.*
163. *See id.* paras. 4.1-4.28.
164. UK Committee, *supra* note 8, para. 4.5.
165. *Id.* para. 4.14.
166. *See id.* para. 4.12.
167. *Id.* para. 4.20.
168. *Id.* para. 4.21.
169. *Id.* para. 4.22.

has been widely accepted since in the first two weeks the nervous system in an embryo has still not developed.[170] Although the committee did not limit research on human embryos, it did recommend embryos should not be created just for research purposes unless "there is a demonstrable and exceptional need which cannot be met by the use of surplus embryos."[171] The committee also recommended that cell nuclear replacement (CNR) be permitted under strict regulation,[172] that the prohibition on reproductive cloning in the Human Reproductive Cloning Act of 2001 be endorsed,[173] and that the HFEA should continue to regulate research on human embryos including the use of CNR.[174]

According to the committee, the government should review the scientific advances in adult stem research and therapies by the end of the decade to see if "research on human embryos is still necessary."[175] Some of the other recommendations with regard to legislation and regulation proposed by the committee were: government review of funding of the HFEA,[176] HFEA review of licensing,[177] separation of clinical and research roles for donation of eggs or embryos,[178] developing a committee for review of clinical studies involving stem cells,[179] developing a stem cell bank responsible for keeping stem cell lines and monitoring their use,[180] and making sure that informed consent from donors is obtained in regards to embryonic stem cell lines for research.[181]

Two days after the committee's report, the HFEA "approved applications from two research groups to develop stem cell lines from human embryos."[182] One of the groups was licensed to develop stem cell lines to be used in developing therapies for Parkinson's disease, and the other group "has been approved to use stem cells to investigate blastocyst development and stem cell lines for diabetes and Parkinson's disease."[183]

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170. *See* UK Committee, *supra* note 8, para. 4.22.

171. *Id.* para. 4.28.

172. *Id.* para. 5.4.

173. *Id.* para. 5.21.

174. *See id.* para. 5.24.

175. *Id.* para. 8.4.

176. *See* UK Committee, *supra* note 8, para. 8.4.

177. *See id.* para. 8.6.

178. *Id.* para. 8.21.

179. *See id.* para. 8.23.

180. *See id.* para. 8.29.

181. *See id.* para. 8.33.

182. Susan Mayor, *Human Stem Cell Research Gets Green Light*, THE SCIENTIST, Mar. 5, 2002, *available at* http://www.biomedcentral.com/news/20020305/03.

183. *Id.*

The licenses were granted for the harvesting of stem cell lines from "spare" embryos created for *in vitro* fertilization, but only after receipt of informed consent by the donors.[184]

After the report by the committee, the Medical Research Council in the United Kingdom set up a National Stem Cell Bank Advisory Committee to develop "principals and practice in relation to the ethical, legal and regulatory issues associated with stem cell research and banking."[185] This committee is also working to generate standard donor information, consent forms, information for scientists concerning which licenses and accreditations they will need to be able to use the bank and do their research.[186] The stem cell bank is likely to house both adult and embryonic stem cell lines.[187] The stem cell bank will be monitored by a Steering Committee which will put together a "code of practice for the bank and for the use of stem cell lines, and will regulate the use of embryonic stem cell lines."[188] A local management committee and a User and Clinical Liaison Committee will also be established for the bank, which will report to the Steering Committee.[189]

Ian Wilmut, the leader of the team that cloned "Dolly the sheep,"[190] stated that he plans to pursue funding for cloning and performing research on human embryos.[191] His research proposal encompassed taking cells from patients with genetic diseases and using such cells to develop new medicine to treat the diseases.[192] To date, the proposal has still not been

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184. *Id.*

185. Medical Research Council, *House of Lords Report on Stem Cell Research*, *at* http://www.mrc.ac.uk/b3/index/public_interest/public-topical_issues/publicstem_cells/public-house_of_lords_stem_cell_report.htm (last visited Mar. 6, 2003).

186. *Id.*

187. Medical Research Council, *supra* note 3.

188. *Id.*

189. *Id.*

190. *See* Tim Beardsley, *A Clone in Sheep's Clothing*, SCIENTIFIC AMERICAN, Mar. 3, 1997, *available at* http://www.sciam.com/article.cfm?articleID=0009B07D-BD40-1C59-B882809EC588ED9F. "Dolly the sheep" was created by a team of scientists at the Roslin Institute in the UK (funded by PPL Therapeutics in Edinburgh, a biotechnology company). The researchers extracted DNA from adult cells (in Dolly's case the udder of an ewe) and inserted them into eggs of sheep that had their natural nucleus removed. The eggs were then cultured for a time and implanted into sheep that carried them to term. The cloned sheep, "Dolly the sheep," is an exact replica of the sheep that provided the adult cell. *Id.*

191. James Meek, *Cloning Team Looks to Human Embryos*, GUARDIAN UNLIMITED, Oct. 14, 2002, *available at* http://www.guardian.co.uk/uk_news/story/0,3604,811258,00.html.

192. *Id.*

approved by the Roslin Institute where Professor Wilmut conducts his research.[193]

B. Australia

Australia has a long history of considering human embryonic research.[194] In 1982, the National Health and Medical Research Council (NHMRC) "issued guidelines on the ethical aspects of research related to the use of assisted reproductive technology (ART) [or *in vitro* fertilization]."[195] In 1985, the Senate established a committee to look into the Human and Embryo Experimentation Bill of 1985 and to see if the research and manipulation of human embryos should be allowed.[196] The committee concluded that the embryos deserved respect and required protection from destruction.[197]

In 1993, the Australian Health Ethics Committee (AHEC) started to review the NHMRC guidelines and in June of 1996, it released the Ethical Guidelines on Assisted Reproductive Technology.[198] This guideline noted a variety of prohibited or unacceptable practices for embryos, but proposed allowing the use of excess embryos from *in vitro* fertilization "for research that may damage or destroy the embryo, under exceptional circumstances."[199] The AHEC, after releasing these guidelines, stated that all states should introduce comprehensive assisted reproductive technology legislation and recommended that the Commonwealth Minister for Health enact legislation in states that refused.[200]

In 1998, the Minister for Health and Aged Care asked the AHEC to provide him with a report on the "scientific, ethical and regulatory

193. *Id.*

194. *See generally* SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE, PROVISIONS OF THE RESEARCH INVOLVING EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2002 (October 2002), *available at* http://www.aph.gov.au/Senate/committee/clac_ctte/emb_cloning/report/contents.htm (reviews the history of the debate regarding cloning in Australia, including cloning for biomedical research and cloning to produce children) [hereinafter COMMUNITY AFFAIRS COMMITTEE].

195. *Id.* at 3. The NHMRC is the peak body of funding health and medical research in Australia. They only fund proposals for research that have been approved by the ethics and biosafety committees and that meet all the Commonwealth, State, and Territory laws. NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, STEM CELLS DERIVED FROM HUMAN EMBRYOS, Aug. 29, 2002, *available at* http://www.nhmrc.gov.au/issues/stem_cell.htm (last visited Mar. 6, 2003).

196. COMMUNITY AFFAIRS COMMITTEE, *supra* note 194, at 3.

197. *Id.*

198. *Id.* at 3-4.

199. *Id.* at 4.

200. *Id.*

considerations relevant to cloning of human beings."[201] In this report, the AHEC recommended the Government of Australia prohibit cloning to produce children, that all states limit their research on human embryos to the principles set out by the NHMRC, that statutory authorities be instituted to regulate such research, and that the Minister should encourage discussions on the potential benefits and detriments of the development of cloning techniques.[202]

In August 1999, the Minister for Health and Aged Care requested that "the House of Representatives Standing Committee on Legal and Constitutional Affairs" review the 1998 AHEC report.[203] In their report, released in August 2001, the majority of the Committee recommended: "the enactment of legislation to regulate human cloning and stem cell research;"[204] that this legislation include a ban on cloning to produce children with criminal penalties if the ban is not followed; and that a national licensing body be established to issue licenses for research, and for the creation and use of embryonic stem cells.[205] The Committee minority stated that they were opposed to this research as it included the destruction of human embryos.[206]

In December 2000, the government of Australia passed the Gene Technology Bill 2000.[207] This bill banned "human cloning, certain experiments involving animal eggs and certain experiments involving putting human and animal cells into a human uterus."[208]

On April 5, 2002, the Council of Australian Governments (COAG) decided that "the Commonwealth, States and Territories would introduce legislation banning human cloning and other unacceptable practices and establishing a national regulatory framework for the use of excess assisted reproductive technology (ART) embryos."[209] The COAG also agreed that the NHMRC would administer the instituted regulatory system.[210] Consistent with this agreement, the Commonwealth, on June 27, 2002,

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201. *Id.*

202. COMMUNITY AFFAIRS COMMITTEE, *supra* note 194, at 4.

203. *Id.* at 4.

204. *Id.* at 5.

205. *Id.*

206. *Id.*

207. *Id.*

208. COMMUNITY AFFAIRS COMMITTEE, *supra* note 194, at 5.

209. NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, A GUIDE TO THE: RESEARCH INVOLVING EMBRYOS AND PROHIBITION OF HUMAN CLONING BILL 2002 2 (Aug. 2002), *available at* http://www.nhmrc.gov.au/clonebil/index.htm.

210. *Id.*

introduced the Research Involving Embryos and Prohibition of Human Cloning Bill 2000 into Parliament for approval.[211]

The main objective of this act is to concentrate on the ethical concerns surrounding cloning.[212] Therefore, the act prohibits certain practices and regulates the use of certain embryos created via *in vitro* fertilization.[213] This bill specifically prohibits and makes it an offense to create cloned human embryos, to place a cloned human embryo in a human or animal, and to import a cloned human embryo into or out of Australia.[214] The bill defines a cloned human embryo as one "that is a genetic copy of another living or dead human, but does not include a human embryo."[215] This act would prohibit the creation of human embryos by *in vitro* fertilization or cloning techniques such as SCNT or other methods, for specific use in research either to derive embryonic stem cells or for any other reason not intended to achieve pregnancy in a woman.[216] The act also prohibits the development of human embryos outside the body of a woman after fourteen days.[217]

The act does allow the use of a human embryo in research if it is in the course of fertility treatment, in excess after a couple's fertility treatments (only with the couple's authorization), and only if the use has been approved in accordance with a license.[218] The only uses of excess human embryos that are allowed under this bill are either "an exempt use under the legislation; or licensed by the NHMRC Licensing Committee."[219] Exempt uses include storage of the embryos, removal from storage, transportation of embryos, observation, allowing them to die, diagnostic tests to see if they are suitable for implantation, donating them to another woman for the purpose of pregnancy, and any other use prescribed by regulation.[220] Licensing will be required for research into the effectiveness of new culture medium used for *in vitro* fertilization practice, further understanding the development and fertilization of embryos, training of personnel that will be conducting *in vitro* procedures, improvement of the current *in vitro* procedures and derivation of stem cells.[221]

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211. *Id.*
212. *Id.* at 4.
213. *Id.* at 6.
214. *Id.* at 8.
215. NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, *supra* note 209, at 8.
216. *See id.* at 9.
217. *Id.* at 10.
218. *Id.* at 12.
219. *Id.* at 13.
220. *Id.* at 13-14.
221. NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, *supra* note 209, at 14-15.

The NHMRC will ensure that after a license is issued, the researchers have obtained consent from the donors of the embryos, that the use of the embryos is in accordance with the restrictions instituted by the donors, and that if the uses of the embryos will destroy or damage the embryos, only embryos created before April 5, 2002 are used.[222] The bill also states how the NHMRC Licensing Committee will be instituted, how it will operate, and its reporting requirements.[223] It also includes information on how confidentiality will be kept,[224] how licenses will be reviewed,[225] how the legislation will be monitored and enforced,[226] and how "all States and Territories will [have to] introduce . . . a comprehensive and effective national scheme banning certain practices and regulating certain uses of excess . . . embryos."[227]

The bill, in accordance with COAG's views, lifts the prohibition on April 5, 2005 of using excess embryos created before April 5, 2002. It also provides for an independent review by the NHMRC of this bill two years after it receives Royal assent.[228]

The House of Representatives split the Research Involving Embryos and the Prohibition of Human Cloning Bill 2002, referenced above, into two bills: the Prohibition of Human Cloning 2002 and the Research Involving Embryos Bill 2002.[229] The House of Representatives passed the Research Involving Embryos Bill 2002 on September 25, 2002.[230] The only difference between this bill and the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 is that it only deals with regulation of activities that involve using human embryos; it does not include the prohibition of cloning to produce children.[231]

On August 21, 2002, the Senate appointed the Community Affairs Legislation Committee to review the combined bill (the Bill) and gather information from the community on the issue of research involving

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222. *Id.* at 18.

223. *See id.* at 19-21.

224. *See id.* at 22-23.

225. *See id.* at 24.

226. *See id.* at 25-26.

227. NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL, *supra* note 209, at 27.

228. *Id.* at 28.

229. COMMUNITY AFFAIRS COMMITTEE, *supra* note 194, at 116.

230. *See* Parliament of the Commonwealth of Australia, House of Representatives, *Research Involving Embryos Bill 2002*, H.R. REP. NO. 02183, *available at* http://search.aph.gov.au/search/ParlInfo.ASP?action=view&item=0&resultsID=1DI8Os (Oct. 13, 2002).

231. *See id.*

embryos.[232] On October 23, 2002, the committee submitted its findings in a split decision.[233] The majority of the committee concluded that surplus human embryos should not be used for destructive research (i.e., research that purposely destroys the embryo), that research on pre-existing human embryonic stem cells can continue as it is not dependent on the passage of this bill, that other research alternatives should be sought that do not include the destruction of embryos, and that amendments to this bill should be considered to account for the inadequacies of the current bill.[234]

The minority believes that the Bill should be passed, because if it is not, the country will have inconsistent regulation throughout its States and Territories, and no regulatory agency would be instituted to oversee this type of research.[235] The minority also believes that by not passing this Bill, researchers will be hampered as they will only have access to the existing stem cell lines, which will not be acceptable for future clinical research, and the country might be hurt as scientists and companies might leave to find liberal regulations in other countries.[236]

With regard to stem cell research, the minority stated that embryonic stem cell research should not be constrained or prohibited, as there is strong possibility that therapies may be developed from such research.[237] They also noted that just because adult stem cell research might lead to cures or treatments of diseases, that both embryonic and adult stem cell research should be continued, "with a view to understanding their relative merits and disadvantages."[238]

The minority also cites various reasons for the eventual need of embryonic stem cell lines, one being the FDA's prohibition of clinical trials with the current embryonic stem cell lines as they were created using mouse feeder cells, which could potentially transmit diseases to humans.[239] Another reason cited in favor of the creation of additional embryonic stem cell lines is that a larger panel of stem cell lines might be necessary to address immunological rejection.[240]

On November 28, 2002, the Parliament's Upper House voted to permit 70,000 frozen embryos that had been created for *in vitro*

232. COMMUNITY AFFAIRS COMMITTEE, *supra* note 194, at 1.

233. *See id.* at vii.

234. *Id.* at 140.

235. *Id.* at 145-46.

236. *Id.* at 146. The "[e]xisting stem cell lines have been created with mouse feeder cells;" therefore, research with human cells will eventually be needed. *Id.* at 157.

237. COMMUNITY AFFAIRS COMMITTEE, *supra* note 194, at 152.

238. *Id.* at 154-55.

239. *See id.* at 157.

240. *See id.* at 158.

fertilization be used for stem cell research.[241] However, researchers in Australia will not be allowed to create new embryos for research purposes, as the Prohibition of Human Cloning Bill 2002 makes it an offense to "create an embryo for research; engage in trade of human eggs, sperm or embryos, including giving (and accepting) financial inducements, including handling fees; [and] create embryonic stem cell lines from somatic cell donors."[242]

The city of Melbourne welcomes the news by the parliament, since it will be the home for the Center for Stem Cells and Tissue Repair set to open this year.[243] Scientists that will be a part of the Center believe that the Center backed by the now-ratified law will help to make Australia one of the leaders in stem cell research.[244]

C. Singapore

In a desire to benefit from the scientific advances both socially and economically, the Government of Singapore has decided to continue research on embryonic stem cells, but within a "regulatory framework."[245] The government based its decision on the Bioethics Advisory Committee's (BAC) report of June 2002, entitled *Ethical, Legal and Social Issues in Human Stem Cell, Research, Reproductive and Therapeutic Cloning.*[246]

The BAC was established in December 2000 by Singapore's Cabinet "to examine the ethical, legal and social issues arising from biomedical research and development in Singapore, and to recommend policies to the Ministerial Committee for Life Sciences on those issues."[247] The committee requested input from scientists, sociologists, theologians, professional organizations, and the public in general to understand the concerns and sentiments of these groups regarding embryonic stem cell

241. Grant Holloway, *Australia Oks Embryo Stem Cell Research* (Dec. 4, 2002), *available at* http://www.cnn.com/2002/WORLD/asiapcf/auspac/12/04/australia.stemcells.

242. COMMUNITY AFFAIRS COMMITTEE, *supra* note 194, at 176.

243. Holloway, *supra* note 241.

244. *See id.*

245. Tony Tan Keng Yam, Determinism and Reductionism: Genetic Science and the Person (July 19, 2002), *available at* http://www.bioethics-singapore.org/bac/detailed.jsp?artid=38&typeid=4&cid=6&bSubmitBy=false.

246. *See id.*

247. BIOETHICS ADVISORY COMMITTEE, ETHICAL, LEGAL AND SOCIAL ISSUES IN HUMAN STEM CELL RESEARCH, REPRODUCTIVE AND THERAPEUTIC CLONING 1 (2002), *available at* http://www.bioethicssingapore.org/bac/sum_date_name.jsp?typeid=1&rid=33&pid=33&cid=35.

research.[248] It also took into consideration what policies and regulations other countries have instituted.[249]

The committee discusses the ethical concerns of allowing stem cell research at great length,[250] stating that these issues need to be addressed so "science and the new medical treatments arising from it" can proceed.[251] It also uses two principles to guide their recommendations that the results of research be both just and sustainable.[252] The BAC defines just as an "obligation to respect the common good, that there must be fair sharing of the costs and benefits,"[253] and sustainable as "an obligation to respect the needs of generations yet unborn."[254] Finally, it also notes that their recommendation is based on "balancing of the spectrum of views held by various sectors" of their society.[255]

In its report, the BAC discusses embryonic stem cells, embryonic germ cells, and adult stem cells,[256] but notes that embryonic stem cells seem to have the highest potential for researchers, as they are pluripotent (i.e., could develop into any cell of the body).[257]

The BAC recommends that the derivation and use of adult stem cells be allowed with the informed consent of the donor.[258] It states that since other types of tissues, such as biopsy specimens or tissues removed during surgery, have been used in research to develop increased knowledge and treatments for diseases, there is no reason why adult stem cells should not be used for research as well.[259]

The committee also recommends that the derivation and use of germ cells be allowed with the informed consent of the donor, but the consent has to be independent of the decision to abort a fetus.[260] Embryonic germ cells are cells that "originate from the primordial reproductive cells of the developing [fetuses] and may be sourced from cadaveric [fetuses]."[261] The

248. *See id.* at 10-13.
249. *See id.* at 14-20.
250. *Id.* at 8-9.
251. *Id.* at 21.
252. *Id.*
253. BIOETHICS ADVISORY COMMITTEE, *supra* note 247, at 21.
254. *Id.*
255. *Id.*
256. *Id.* at 3.
257. *Id.* at 4.
258. *Id.* at 22.
259. BIOETHICS ADVISORY COMMITTEE, *supra* note 247, at 22.
260. *Id.* at 23.
261. *Id.* at 4.

BAC notes that abortions are currently legal in Singapore, and like donating tissue, donating aborted fetal tissue should be allowed.[262]

The BAC notes that one of the problems with allowing the derivation and use of embryonic stem cells is the status of the embryo.[263] It adopts an intermediate position where the embryo would be given a "special status as a potential human being, but is not of the same status as a living child or adult."[264] It also states that this respect would be weighed against the benefits of the proposed research; it would not be absolute.[265] Therefore, the BAC concludes that it supports embryonic stem cell research, but only when medical benefit would come from such research.[266]

Noting that embryonic stem cells can be derived from various sources, the BAC recommends that when embryonic stem cells are "required for research, they should, wherever possible, be drawn first from the existing ES [embryonic stem] cell lines,"[267] then from surplus embryos no longer needed for fertility treatments (donated and with informed consent),[268] and lastly, if necessary, by the creation of human embryos through SCNT or other cloning technology (i.e., cloning for biomedical research).[269]

The BAC acknowledges that there are potential advantages in cloning for biomedical research such as the "opportunity to derive stem cells which are genetically compatible with the person being treated," avoiding rejection problems if used in treatment, and enabling "scientists to learn about the mechanisms of reprogramming adult cells to behave like embryonic stem cells," possibly making it unnecessary to harvest embryonic stem cells.[270] Therefore, the BAC adopts the position that cloning for biomedical research should be permitted, but only "after the satisfaction of stringent conditions and guidelines as evaluated by a statutory body to be set up to license, audit and control human stem cell research."[271]

The BAC also acknowledges that there might be a possibility that cloning for biomedical research might lead to cloning to produce children, but that this possibility would be eliminated by strict prohibition of

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262. *Id.* at 23.
263. *Id.* at 24.
264. *Id.* at 25.
265. BIOETHICS ADVISORY COMMITTEE, *supra* note 247, at 25.
266. *Id.*
267. *Id.*
268. *Id.* at 26.
269. *Id.* at 27.
270. *Id.* at 28.
271. BIOETHICS ADVISORY COMMITTEE, *supra* note 247, at 28.

implantation of a cloned embryo into a womb.[272] The council recommends a complete ban on "the implantation of a human embryo created by the application of cloning technology into a womb, or any treatment of a human embryo intended to result in its development into a viable infant."[273]

The committee also recommends that only embryos that are less than fourteen days old be used to derive human embryonic stem cells, as this is before the development of the nervous system.[274] Finally, the BAC emphasizes that informed consent must also be required "from the donors of surplus embryos, gametes and cells."[275]

With regard to legislation, the BAC recommends the creation of "a statutory body to license, control and monitor all human stem cell research conducted in Singapore, together with a comprehensive legislative framework and guidelines."[276] The committee notes that the United Kingdom's Human Fertilisation and Embryology Authority could be used as a model in the development of Singapore's oversight authority.[277] The BAC states that the statutory body would also be able to audit any research involving human stem cells, instate and enforce penalties for deviation of the licenses, and draft provisions regarding "informed consent, commerce and sale of research materials."[278]

With regard to informed consent, the BAC recommends that donors of surplus embryos, cadaveric fetal tissue, eggs, and/or cells, be able to make informed voluntary decisions as to whether and how they choose to donate.[279] The donation should not be for financial or any other type of benefit to the donor, but it should not preclude the donor from receiving treatments from any medical treatment later developed.[280]

Finally, the BAC states that it believes the recommendations in its report "would lead to 'just' and 'sustainable' results. The results would be 'just', in that research with tremendous potential therapeutic benefits to mankind will proceed. The results would be 'sustainable' as such research has little biological or genetic impact on future generations, especially with the ban on the reproductive cloning."[281]

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272. *Id.* at 29.
273. *Id.* at 31.
274. *Id.* at 29.
275. *Id.* at 30.
276. *Id.* at 33.
277. BIOETHICS ADVISORY COMMITTEE, *supra* note 247, at 32.
278. *Id.* at 33.
279. *See id.* at 33-34.
280. *Id.* at 33.
281. *Id.* at 35.

Richard Sykes, the chairman of Singapore's biomedical sciences International Advisory Council (IAC), stated that now that Singapore has set guidelines for stem cell research, they have to attract scientists and researchers in that area.[282] He stated that having clear guidelines and government funding will not only help calm the fear of the public, but will also make sure that the research is not driven underground.[283]

Following the backing of the government, companies in Singapore, such as ES Cell International, are planning their advances into the world of stem cell research.[284] ES Cell International would like to be one of the first companies in the world to market cloned embryonic stem cells for clinical trials.[285] The company has stated it wants to create ten colonies of unprogrammed cells nourished from human cells (as opposed to animal cells) in an effort to make the cells safe for treating patients.[286] It is feared that if the existing stem cell lines were used for treatment of patients, there would be risks of transmitting animal diseases to the patients.[287] Therefore, the company hopes that its plan will not only give scientists new cell lines to use in developing treatments in the world but will also foster an increased pace of research in cloning for biomedical research.[288]

D. Other Countries and the United Nations

1. Canada

In Canada, the Canadian Royal Commission on New Reproductive Technologies issued a report in 1993 including the recommendation that certain research practices be prohibited and that a national regulatory agency be instituted to govern permissible assisted human reproductive activities.[289] Following this recommendation, the Canadian Government and Health Canada consulted with the public and other interested parties and in July 1995, the Canadian Government issued a "voluntary moratorium on nine applications of human reproductive and genetic technologies as the first phase in the development of an overall framework

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282. Audrey Tan, *S'pore Now Needs to Attract Experts for Stem Cell Research: Legislative Framework and Necessary Funding Already in Place*, THE BUS. TIMES SINGAPORE, Oct. 30, 2002, *available at* LEXIS, News & Business, Major World Publications.

283. *Id.*

284. *See Firm Here to Grow Top-Grade Stem Cells*, STRAITS TIMES, Oct. 31, 2002, *available at* 2002 WL 100444386.

285. *Id.*

286. *Id.*

287. *Id.*

288. *Id.*

289. COMMUNITY AFFAIRS COMMITTEE, *supra* note 194, at 108.

to regulate these technologies. The applications included human embryo cloning, sex selection, and the buying and selling of eggs, sperm and embryos."[290] The Government also instituted an advisory committee to monitor researchers' compliance.[291]

In 1996, the Human Reproductive and Genetic Technologies Bill, Bill C-47, was introduced.[292] It prohibited the selected items that previously have been given a voluntary moratorium by the Canadian Government.[293] This "Bill did not complete the legislative process before the calling of the 1997 federal election."[294] In May 2002, Bill C-56, An Act Respecting Assisted Human Reproduction, was introduced.[295] This bill would ban a variety of activities, such as: "creating a human clone for any purpose ([i.e.,] reproductive or therapeutic purposes); creating an *in vitro* embryo for any purpose other than creating a human being or improving assisted reproduction procedures; maintaining an embryo outside the body of a woman past the 14th day of development . . . selling or buying human embryos, or providing goods or services in exchange."[296] The bill also develops regulation for the use of human embryos including research allowed and what to do with embryos that are no longer needed after fertilization treatments.[297] It also includes that the Assisted Human Reproduction Agency of Canada would be required to issue licenses to ensure that guidelines are followed, as well as to ensure compliance by inspection of facilities and maintenance of a donor/offspring registry.[298] To date, the Canadian Parliament is still considering the Bill.[299]

2. Saudi Arabia

Saudi Arabia has a wealth of financial resources and an increasing biotechnology industry, and is planning to start a stem cell research program including cloning for biomedical research.[300] At this time, details on the Saudi Arabian research center have not been disclosed, but it has been said that the center should be operational within a year.[301]

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290. *Id.*
291. *Id.*
292. *Id.*
293. *Id.*
294. *Id.* at 109.
295. COMMUNITY AFFAIRS COMMITTEE, *supra* note 194, at 109.
296. *Id.*
297. *Id.* at 110.
298. *Id.*
299. *Id.*
300. Friend, *supra* note 139.
301. *Id.*

One of the biggest differences between the United States' hesitancy versus Saudi Arabia's eagerness to pursue embryonic stem cell research is the difference in religious beliefs.[302] Under Islamic law, life begins at 120 days after conception, which eliminates the moral dilemmas faced by Christian scientists in the United States concerning the status of early embryos.[303]

3. Germany

Although Germany is not allowing the creation of embryos for the purpose of harvesting their stem cells, in late March 2002, the parliamentarians voted to "allow the import of embryonic stem cells for scientific research, but only under close government control."[304] In July, 2002, Germany's Federal Cabinet issued regulations for the new embryonic stem cell research law, which allows researchers to use imported embryonic stem cells (created before January 1, 2002), but only if no other alternatives to these cells can be found.[305] The law also institutes penalties of up to three years' imprisonment or up to 50,000 euros for violations of this law.[306]

Germany has debated the allowance of embryonic stem cell cloning and research extensively, "in part because of the Nazis' grisly legacy of experimentation in eugenics."[307] In November of 2001, the National Ethics Council recommended that limited importation of stem cells be allowed for research.[308]

Although some believe that the parliamentary decision is an advance for embryonic stem cell research in Germany, it is actually not.[309] This is because before this decision, there were no laws against the importation of embryonic stem cell lines.[310] Now there will be restrictive laws regulating how stem cell lines are imported.[311]

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302. *Id.*

303. *Id.*

304. Lucian Kim, *Germany Tightens Stem-Cell Imports*, THE CHRISTIAN SCIENCE MONITOR, Feb. 1, 2002, *available at* http://www.csmonitor.com/2002/0201/p08s01-woeu.html.

305. *Germany's Stem Cell Law Takes Effect*, LIFESITE DAILY NEWS, July 12, 2002, *available at* http://www.lifesite.net/ldn/2002/jul/02071202.html.

306. *Id.*

307. Kim, *supra* note 304.

308. *Id.*

309. *Id.*

310. *Id.*

311. *Id.*

4. Japan

In 2000, the Japanese National Government issued "legislation governing human cloning and related techniques."[312] On June 6, 2001, the Japanese government instituted a law banning cloning to produce children.[313] However, in October 2001, the government in Japan approved guidelines for cloning for biomedical research, embryonic, and stem cell research.[314] The guidelines included obtaining consent from donors before using stem cells for research.[315]

5. United Nations

The United Nations has also taken up the discussion of embryonic stem cell research. The United Nations International Bioethics Committee (IBC) issued its report on April 2001.[316] After discussing the ethical, religious and scientific views on embryonic stem cell research, the IBC concluded that each nation should debate and decide whether to allow embryonic stem cell research; that if such research is allowed, a regulatory system should be set up to provide standards and guidelines; informed consent should be observed in regard to using surplus embryos from *in vitro* fertilization; alternative ways to harvest human stem cell lines should be pursued (i.e. adult stem cell lines); and respect for human dignity and the principles instated by the Universal Declaration of Human Rights of 1948 and the Universal Declaration on the Human Genome and Human Rights of 1997 should be observed.[317]

In November 2001, the United Nations General Assembly adopted a resolution establishing a committee to draft an international treaty on human cloning.[318] However, after a year of deliberation, the committee is still deadlocked because of conflicting views.[319] The United States'

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312. CTV News Staff, *What are Stem Cells?*, CTV.ca 2002, *available at* http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/20020828/stemcel_bgd020828/Health/story (last visited Mar. 6, 2003).

313. BIOETHICS ADVISORY COMMITTEE, *supra* note 247, at 17-18.

314. *Id.* at 17.

315. *Id.*

316. *See* UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANIZATION, THE USE OF EMBRYONIC STEM CELLS IN THERAPEUTIC RESEARCH: REPORT OF THE IBC ON THE ETHICAL ASPECTS OF HUMAN EMBRYONIC STEM CELL RESEARCH (Apr. 6, 2001), *available at* http://www.unesco.org/ibc/en/reports/embryonic_ibc_report.pdf [hereinafter IBC].

317. *Id.* at 13-14.

318. *Cloning: U.S. and Vatican Oppose France and Germany over Proposed New Treaty*, STEM CELL WEEK, Nov. 4, 2002, *available at* 2002 WL 25857966 [hereinafter *Cloning Treaty*].

319. *Id.*

proposed draft of the treaty includes a moratorium on all human cloning pending the institution of an international convention.[320] France and Germany disagreed with the United States and proposed that the treaty include a ban on cloning to produce children, leaving cloning for biomedical research for future consideration.[321] Diplomats say that the United States' proposal is endorsed by the Vatican, Philippines, Spain, Italy, Argentina and Costa Rica.[322] France states that the all-or-nothing approach by the United States could delay the adoption of the treaty banning cloning to produce children, which most countries agree is urgent.[323]

One of the problems of passing treaties through the United Nations is the delay in ratification.[324] For example, in this case, this treaty would have to be approved by the General Assembly, and then it would have to be signed and ratified by each individual country.[325] This process could take at least two years.[326]

IV. CONCLUSION

Although most nations agree and have passed laws banning cloning to produce children, a worldwide consensus on the topic of cloning for biomedical research seems virtually impossible. As noted by the United Nations, cloning for biomedical research should be debated in each nation individually before a world treaty can be passed, as there are great differences between nations on their specific moral, religious and societal beliefs.[327]

After reviewing the policies proposed or adopted by the countries included in this comment, the United States should allow cloning for biomedical research so that as a nation it can continue to be a leader in biotechnology. As noted by the NIH's director Elias Zerhouni, scientists involved in embryonic stem cell research are encountering problems with the availability of the stem cells,[328] as only the existing approved stem cell lines can be used in research. This could not only lead to a lack of

320. *Id.*
321. *Id.*
322. *Id.*
323. *See id.*
324. *See Cloning Treaty*, *supra* note 318.
325. *Id.*
326. *Id.*
327. *See* IBC, *supra* note 316, at 12-14.
328. *See* Zerhouni, *supra* note 63.

scientists interested in doing this type of research, but also to scientists leaving the United States to perform their research in other countries.

The purpose of embryonic stem cell research is to develop cures or help treat diseases that are currently killing or ailing millions of people in the United States. The United States currently has laws that allow the disposal of surplus embryos from fertility treatments and laws that allow abortions, both of which terminate the life of embryos. Most of those embryos, if allowed to come to term, would most likely constitute viable human beings. The United States also allows research on tissues removed from a patient's body, such as in the case of biopsies. Allowing research on embryos that would be eventually disposed of, with informed consent of the donor, would only be a progression of the currently allowed practices. The ethical issues surrounding cloning for biomedical research should not be ignored, but precedent should be followed in this regard.

Similarly, cloning embryos specifically to harvest their stem cells should also be allowed. Creating cloned embryos should not be banned because there might not be enough surplus embryos to use in research. As the United Kingdom has proposed and implemented, an oversight and regulatory committee (i.e., the HFEA)[329] can prevent abuses, including cloning to produce children by scientists, but still allow the research and development of therapies for the ailing and dying by using embryonic stem cells for research.

Since the United States has started the process of oversight with the NIH in regard to research involving the existing human embryonic stem cell lines,[330] it should expand that process by allowing cloning for biomedical research not only for the good of the ailing, but also to keep its scientists and remain a leader in biotechnology.[††]

329. UK Committee, *supra* note 8, para. 1.2.

330. Press Release, *supra* note 47.

[††] The author wishes to note to readers and reseachers that the information provided in this comment changes rapidly and is current only as of Feb. 8, 2003.