STEM CELL LEGISLATION: AN INTERNATIONAL AND COMPARATIVE DISCUSSION

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Stem cells, because of their scientific and biomedical potential, captured the attention of the international community and thrust scientific innovation and discovery into the forefront of international legal, political, religious, and ethical discourse. The potential scientific and medical promise of embryonic and adult stem cells spread rapidly throughout the international community and sparked heated debate regarding the future uses and applications of these versatile and unique cells. Since research involving stem cells also addresses equally difficult areas such as human cloning, human embryonic research, and the legal status of the early embryo, the discussions and resulting global legislative efforts have been highly charged and wrought with theoretical, as well as practical, challenges. Scientific research and innovation have never been easily legislated or regulated fields. The interplay between the need for scientific freedom to facilitate the development and advancement of cutting edge research in controversial areas such as stem cell research and human cloning and the legislative regulation of such activities has always been a delicate one. This needed balance has not always been achieved. The achievement of any tenuous balance between regulation and scientific research is affected by the nature of science itself. Every scientific discovery has its complications, as well as far-reaching corollary effects into other aspects of human society. Stem cell research is more problematic than other biomedical issues, such as organ transplantation or gene therapy, because of its ties to cloning. Cloning, another rapidly developing field of biomedical research has become the subject of legislative regulation along with stem cell research.

There are two types of cloning, therapeutic and reproductive. These two types of cloning are distinguished by the purposes to be fulfilled by the cloned embryos. Therapeutic cloning is tied to the production of stem cells and thus has a more direct connection to stem cell research than reproductive cloning because it provides a viable and rejection-free source of embryonic

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stem cells.[1] Thus, any law or regulation enacted or amended to deal with stem cell research would have to address cloning in some way. This has proved to be a complex and restrictive development and thus makes the current global legislative process addressing this research even more challenging and complicated.

Both the United Kingdom and the United States have been attempting to address stem cell research by means of legislation and are in the process of creating and developing different legislative schemes responsive to the interests and perceptions of their respective governments and populations. The United States and the United Kingdom provide an interesting vantage point for comparison regarding stem cell legislation. Both countries have a common law background and share some similar legal institutions and perspectives. However, their respective approaches and legislative schemes regarding stem cells are quite different and illustrate how two somewhat similar countries in terms of general legal background and perspective can vary widely with respect to this aspect of biomedical legislation. This comparative discussion will illustrate the difficulties resulting from an attempt for international legislative harmonization addressing stem cell research and is further demonstrated by examining the current legislative situation on the regional and international level. Given the wide variety of viewpoints on this topic, regional and international organizations face a difficult and slow road ahead, especially when member states run into similar roadblocks with respect to the scientific, legislative, and ethical consensus required to create useful and applicable legislation.

This Note will focus on the legislative responses to the area of stem cell research in the United Kingdom and the United States. Section I will describe the characteristics and origins of stem cells and the challenges inherent in utilizing this technology. Section II will discuss the legislative situation already in place in the UK and how Parliament is attempting to adapt current legislation to accommodate stem cell research and cloning. Section III will address the US position on stem cell research and how that position is influencing its attempts to create a statutory scheme regulating such research. Section IV examines the legislative situation at the regional and international level, focusing on the United Nations, the Council of Europe, and the European Union, and the directions these organizations are attempting to pursue, as well as the international impact of such approaches. Section V will examine where all of these legislative efforts leave both the United Kingdom and the United States and in what direction these two countries seem to be moving, domestically and internationally.

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1. Tissues resulting from stem cell lines acquired by cell nuclear replacement would be genetically compatible with the individual being treated and there would most likely be no rejection. Department of Health, *Donaldson Report Stem Cell Research: Medical Progress with Responsibility,* Box 9 at 24, *at* http://www.doh.gov.uk/cegc/stemcellreport.htm, (August 16, 2000) (on file with author).

SECTION I: THE SCIENCE BEHIND STEM CELLS

What are stem cells? What is it about the nature of these cells that has made their entry into the international public consciousness such a tumultuous one? Stem cells are unspecialized cells at an early stage of development.[2] Stem cells can divide and differentiate into numerous cell types that comprise the tissues and organs of the body.[3] Stem cells are also able to undergo self-renewal, a process "by which an unspecialized stem cell divides to produce two further unspecialized stem cells."[4] In the human body, most specialized cells do not actually divide but are replaced or replenished from populations of stem cells present in most of the tissues of the body.[5] Stem cells fulfill a central role in human growth and development and also provide a continuous source of new cells for the regeneration of diseased or damaged tissue.[6] Stem cells, both embryonic and adult[7], can theoretically replicate themselves indefinitely in culture and are able to generate more specialized cells as they proliferate.[8] The scientific and medical potential of stem cells comes from their ability to be stabilized and grown in the laboratory and influenced, when needed, to differentiate into more specialized, mature cells and tissues that could be utilized for treatment.[9]

Stem cells are present at all stages of human development, but their trademark versatility and abundance decrease with age and are their highest in the embryonic stage.[10] Embryonic stem cells are perceived to be able to produce any of the 200 different types of the specialized cells that make up the human body, such as blood, neural, and liver cells.[11] This specialization occurs through a process called differentiation, which involves less specialized cells developing into more specialized cells.[12] In order to appropriately and correctly understand stem cells, a basic grasp of human embryonic development is necessary. A significant amount of the inaccuracy and confu-

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2. Department of Health, *Donaldson Report Stem Cell Research: Medical Progress with Responsibility*, Section 2.6 at 17, *at* http://www.doh.gov.uk/cegc/stemcellreport.htm (Aug. 16, 2000) (on file with author).

3. *Id.*

4. *Id.*

5. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 2 § 2.2, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

6. *Id.*

7. With regard to stem cells, 'adult' and 'embryonic' refer to the source of the cells. Adult stem cells are obtained from adults, whereas embryonic stem cells are obtained from early embryos.

8. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 3 § 3.3, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

9. Department of Health, *Donaldson Report Stem Cell Research: Medical Progress with Responsibility*, Section 2.7 at 18, *at* http://www.doh.gov.uk/cegc/stemcellreport.htm (Aug. 16, 2000) (on file with author).

10. The Royal Society, *Stem Cell Research and Therapeutic Cloning*, *at* http://www.royalsoc.ac.uk/policy/stemcells.htm, (November 2000) (on file with author).

11. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 2, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

12. *Id.* at Box 2.

sion that infiltrates the stem cell debate comes from misconceptions regarding the stages of human development.

After fertilization, the resulting zygote[13] then undergoes numerous cell divisions in the next thirty-six hours.[14] For the first eight cell divisions after fertilization, all of the cells are considered totipotent, which means that each cell has the capacity to develop into all cell types required for human development, including the non-embryonic tissues such as the umbilical cord and the placenta.[15] Totipotent stem cells can be defined in two different ways. They are either cells that have the potential to develop into an adult organism if placed in the right environment or as cells that give rise to every cell line in the developing fetus.[16] Totipotent cells only exist for a short period during early embryonic development.[17] After five days of cell division, these totipotent cells begin to specialize, forming a hollow sphere of cells called a blastocyst.[18] The blastocyst has an outer layer of cells and within the hollow sphere, there is a cluster of cells called the inner cell mass.[19] It is from the inner cell mass that embryonic stem cells can be obtained and from which the embryo develops.[20] The cells from the inner cell mass cannot develop into an organism because the outer layer of cells, as well as some of the cells from the inner cell mass, have already differentiated and cannot form the supporting tissues for fetal development.[21] Thus, the inner cell mass can only proliferate and specialize into all the cell types found in the human body. As development proceeds beyond the blastocyst stage, the stem cells comprising the inner cell mass continue to differentiate and specialize into cells that are committed to expressing a particular function.[22] The inner mass cells are called pluripotent; these cells can give rise to almost all the cells in the human body except for those needed for fetal development.[23] Thus, their potential is not total, like the totipotent cells immediately following fertilization.[24] As differentiation continues, the amount of pluripo-

13. A zygote is the end result of the process of fertilization stemming from the fertilization of the female egg (oocyte) by the male sperm.

14. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 4 Section 4.2(b), *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

15. *Id.* at Chapter 2.

16. Nuffield Council on Bioethics, *Stem Cell Therapy: the ethical issues*, *at* http://www.nuffieldbioethics.org/stemcells/index.asp (Dec. 10, 2001) (on file with author).

17. *Id.*

18. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 2 § 2.3, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

19. *Id.* at Chapter 4 § 4.2(c).

20. *Id.*

21. Nuffield Council on Bioethics, *Stem Cell Therapy: the ethical issues*, *at* http://www.nuffieldbioethics.org/stemcells/index.asp (Dec. 10, 2001) (on file with author).

22. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 2, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

23. *Id.*

24. *Id.*

tent stem cells in the embryo begins to decrease, resulting ultimately in a smaller amount of stem cells in the human body.[25] Yet, most tissues in both the fetus and adult body do contain unspecialized stem cells that have the potential to differentiate into a specific cell type but are used to regenerate or repair damaged tissues.[26]

These more specialized cells are called multipotent and have a more restricted potential than the embryonic stem cells found in the inner cell mass prior to differentiation.[27] These multipotent cells give rise to most of the present cell types in the human body.[28] Tissues outside of the embryo, such as the placenta and the umbilical cord, also provide a source of multipotent stem cells and consist of the same genetic make-up as the embryo.[29] Hematopoetic stem cells, those found in the bone marrow of every child and adult, can also be found in minute numbers circulating within the bloodstream.[30] They can give rise to different cell types present in the blood but cannot develop into other differentiated cells, such as neural cells.[31] Pluripotent stem cells represent a very specific class of stem cells and can only be obtained from the blastocyst.[32] Other stem cells, as illustrated above, can be obtained from the embryo at later stages of development, but these stem cells are not pluripotent and resemble adult stem cells more than embryonic stem cells.[33]

Embryonic pluripotent stem cells can be obtained from three sources. First, as stated, embryonic stem cells can be obtained directly from the inner cell mass of early human embryos at the blastocyst stage created by in vitro fertilization.[34] Second, fetal tissue from terminated pregnancies can also provide a source of stem cells, which may be pluripotent or multipotent depending on the stage of embryonic development.[35] Third, cell nuclear replacement is a possible source of stem cells.[36] This procedure, otherwise

25. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 2 § 2.4, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

26. *Id.*

27. *Id.* at Chapter 2, Box 2.

28. *Id.*

29. *Id.* at Chapter 2 § 2.4.

30. These blood stem cells are responsible for continually replenishing our blood cells – white blood cells, red blood cells and platelets. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 2 at Box 2, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002). (on file with author)

31. *Id.*

32. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 2 § 2.5, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002). (on file with author)

33. *Id.*

34. Stem Cell Research and Regulations under the Human Fertilization and Embryology Act 1990 House of Commons Research Paper, *at* http://www.parliament.uk/commons/lib/research/rp2000/rp00-093.pdf (Dec. 13, 2000) (on file with author).

35. House of Lords, *Select Committee on Stem Cell Research Report*, Chapter 2 §§ 2.4 & 2.5, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

36. *Id.* at Chapter 2, Box 2.

known as therapeutic cloning, involves removing the nucleus of an egg cell and replacing it with the nucleus of a somatic cell. This procedure will be discussed further below.

Adult stem cells are also considered a potential source of stem cells but are not thought to possess the same level of versatility as the embryonic pluripotent stem cells; the majority of adult stem cells are thought only to have the potential to develop into the type of tissue from which taken from.[37] Adult stem cells are multipotent cells present in many tissues in the human body and are required for regeneration and repair. The therapeutic potential of adult stem cells has been demonstrated by the successful use of hematopoetic stem cells for the treatment of leukemias and other blood disorders.[38] Recent studies have illustrated that adult stem cells may contain greater therapeutic potential than previously perceived.[39] This potential increase in therapeutic applicability has allowed for further consideration of adult stem cells as a possible viable alternative source of stem cells. However, adult stem cells are difficult to isolate and maintain due to their limited availability in adult tissues.[40] Another roadblock to the overall therapeutic viability of adult stem cells is the inability of such cells, once isolated, to differentiate into other cell types.[41] Adult stem cells serve the purpose of regeneration and repair only in specific tissues and thus do not possess the wide elasticity apparent in embryonic stem cells. It has been suggested that re-differentiation of adult stem cells could possibly widen their use as a therapeutic alternative to embryonic stem cells.[42] Such understanding, at this point, regarding re-differentiation of adult stem cells, as well as the process of differentiation overall, is still very limited.[43] Some have suggested that developments regarding adult stem cells make research on embryonic stem cells unnecessary, thus removing the need for research involving embryos.[44] The majority of scientists do not share this view and do not perceive adult stem cells as an alternative to embryonic stem cells but rather as complimentary pathways to therapy.[45] The general view has emphasized the need for continuing research on all fronts of stem cell research, both adult and embryonic stem cells.

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37. Department of Health, *Donaldson Report Stem Cell Research: Medical Progress with Responsibility,* Section 2.13, *at* http://www.doh.gov.uk/cegc/stemcellreport.htm (Aug. 16, 2000) (on file with author).

38. House of Lords, *Select Committee on Stem Cell Research Report,* § 3.8, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002). (on file with author)

39. *Id.* at § 3.9.

40. *Id.* at § 3.11.

41. *Id.* at §§ 3.12 & 3.14.

42. House of Lords, *Select Committee on Stem Cell Research Report,* § 2 Box 3, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8302.htm (Feb. 13, 2002) (on file with author).

43. House of Lords, *Select Committee on Stem Cell Research Report,* § 3.12, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

44. *Id.* at § 3.16.

45. *Id.*

Both embryonic and adult stem cells hold promise that is only beginning to be understood. One aspect of stem cell research that has garnered a large amount of attention is the interplay between the availability of embryonic stem cells and cloning. Cloning has been mentioned as providing a possible source of embryonic stem cells that would be available for therapeutic and research demands that in vitro fertilization or other sources of stem cells might not be able to fulfill. Yet cloning is very problematic and has generated a lot of apprehension and debate in respect to its possible connections with stem cell research. Thus, it is important to clarify what cloning means, how cloning fits in with stem cell research, and why this connection is important for developing legislation addressing stem cell research.

There are two forms of cloning and both have been associated with and discussed in light of stem cell research: therapeutic cloning and reproductive cloning. Cell nuclear replacement is the process by which the nucleus of an adult specialized cell is inserted into a mature but unfertilized egg that has had its original nucleus deactivated and removed.[46] Following this procedure, if the recipient egg is induced, by means of chemical or hormonal stimulation, to divide, an embryo can be produced.[47] The term therapeutic cloning refers more to the use of the subsequent product of cell nuclear replacement rather than an actual procedure.[48] Thus, therapeutic cloning is the use of the resulting embryo created by cell nuclear replacement for research and therapeutic purposes, by generating embryonic stem cells for direct application in treatment.[49] In this situation, the embryo itself is only permitted to develop to the blastocyst stage and is not allowed to develop into an embryo or be implanted in a woman's uterus.[50] On the other hand, reproductive cloning refers to the actual implantation of the blastocyst resulting from cell nuclear replacement into a woman's uterus with the intent of producing a baby.[51] So the crucial distinction between reproductive and therapeutic cloning comes from the steps taken after cell nuclear replacement that reflect the purpose of performing the procedure. The main use of therapeutic cloning in stem cell research is to provide a source of stem cells tailored to a particular patient, thus mitigating the problem of rejection and the need for immunosuppression drugs.[52]

Embryonic stem cells hold promise as both a research tool and a potential treatment for a number of life-threatening diseases. Yet there are

46. House of Lords, *Select Committee on Stem Cell Research Report*, § 5.6, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

47. H.R REP. NO. 107-170, *at* http://www.house.gov/judiciary/legreports.htm (July 27, 2001).

48. House of Lords, *Select Committee on Stem Cell Research Report*, § 5.8, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002).

49. *Id.* at § 5.8

50. *Id.*

51. *Id.* at § 5.5.

52. Department of Health, *Donaldson Report Stem Cell Research: Medical Progress with Responsibility* § 2.28, *at* http://www.doh.gov.uk/cegc/stemcellreport.htm (Aug. 16, 2000) (on file with author).

many concerns associated with these cells, including whether they can be successfully cultivated in the laboratory, how these cells should be utilized, and where they should be obtained from, if at all. Governments are struggling to deal with both the promise of stem cells as well as the ethical and legal difficulties they present. Two countries attempting to work with these cells are the United Kingdom and the United States. They represent two divergent legislative approaches to stem cell research and they will determine if the potential of these highly versatile and therapeutically promising cells will be realized. But in order to address stem cells, both the United Kingdom and the United States have to address their potential sources. The concerns surrounding human cloning have infiltrated this debate and now play an important role as to the actual direction any legislative response will take.

SECTION II: THE UNITED KINGDOM

The United Kingdom has taken a very progressive stance towards stem cell research and human cloning, as compared to the rest of Europe and the United States. The focus of the stem cell research debate in the United Kingdom hinges on the Human Fertilization and Embryology Act 1990 (the Act), which was enacted to "regulate the practice of in vitro fertilisation and the creation, use, storage and disposal of embryos formed by this means."[53] However, the Act does not regulate research on stem cells once they are removed from embryos or research on stem cells acquired from non-embryonic sources such as adult stem cells or an aborted fetus.[54]

The specific scope of the Act, as stated in the Preamble of the Act, is to make provisions in connection with human embryos and any subsequent development of such embryos; to prohibit certain practices in connection with embryos and gametes; to establish the Human Fertilization and Embryology Authority; to make provision(s) about the person(s) who in certain circumstances are to be treated in law as parents of the child; and to amend the Surrogacy Agreements Act 1985.[55] The Act establishes a regulatory authority, the Human Fertilization and Embryology Authority (HFEA),[56]

53. House of Lords, *Select Committee on Stem Cell Research Report,* Chapter 1 § 1.1, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002) (on file with author).

54. Department of Health, *Donaldson Report Stem Cell Research: Medical Progress with Responsibility,* § 16, *at* http://www.doh.gov.uk/cegc/stemcellreport.htm (Aug. 16, 2000) (on file with author).

55. An Act to make provision in connection with human embryos and any subsequent development of such embryos; to prohibit certain practices in connection with embryos and gametes; to establish a Human Fertilisation and Embryology Authority; to make provision about the persons who in certain circumstances are to be treated in law as the parents of a child; and to amend the Surrogacy Arrangements Act 1985.
Human Fertilization and Embryology Act 1990 (c.37), *at* http://www.hmso.gov.uk/acts/acts1990/ Ukpga_19900037_en_2.htm#mdiv8 (November 1, 1990) (on file with author).

56. Article 5 of the Act addresses the composition, membership, and other administrative concerns related to the HFEA.

> (1) There shall be a body corporate called the Human Fertilisation and Embryology Authority. (2) The Authority shall consist of – (a) a chairman and deputy chairman, and (b)

which, under strict conditions, is responsible for monitoring and licensing clinics that carry out in vitro fertilization, donor insemination, and human embryo research.[57]

The purposes of the HFEA, as enumerated in Article 8 of the Act, specifically place most of the scope of the Act under the jurisdiction of the HFEA.[58] The HFEA, thus, is responsible for undertaking the review of information about embryos and subsequent embryonic development, as well as the review of provisions regarding treatment services and activities governed under the Act.[59] The HFEA is also responsible for publicising "the services provided to the public by the Authority or provided in pursuance of licences,"[60] as well as providing information and advice to those whom the licenses apply, those who are receiving treatment services, or those providing gametes and embryos for use under the scope of the Act.[61] Article 8(d) also provides for the broadening of the scope of the Act by permitting the HFEA to carry out any functions specified in subsequent regulations that are considered a general function of the HFEA.[62] Article 8(d) could permit stem cell research to be included under the Act because stem cell research could be considered a "general purpose" of the HFEA due to its close ties, in terms of sources and possible goals, to in vitro fertilization and human embryo research, which is what the HFEA does license for.

Under the general supervision of the HFEA, as enumerated under Article 9,[63] committees will be created and maintained in order to address one of the HFEA's main functions—the granting and maintaining of licenses regarding human embryo research.[64] A substantial portion of the Act addresses the subject of the licensing committees, including the formation of

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such number of other members as the Secretary of State appoints. (3) Schedule 1 to this Act (which deals with the membership of the Authority, etc.) shall have effect.

Id.

57. Nuffield Council on Bioethics, *Stem Cell Therapy: The Ethical Issues*, *at* http://www.nuffieldbioethics.org/filelibrary/doc/stem_cell_therapy2.doc (2000) (on file with author).

58. HFEA states:

> The Authority shall–(a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State, if he asks it to do so, about those matters, (b) publicise the services provided to the public by the Authority or provided in pursuance of licenses, (c) provide, to such extent as it considers appropriate, advice and information for persons to whom licenses apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so, and (d) perform such other functions as may be specified in regulations.

Human Fertilization and Embryology Act 1990 (c.37) Article 8, *at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_2.htm#mdiv8 (November 1, 1990) (on file with author).

59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. "The Authority shall maintain one or more committees to discharge the Authority's functions relating to the grant, variation, suspension, and revocation of licenses, and a committee discharging those functions is referred to in this Act as a 'license committee.'" Human Fertilization and Embryology Act 1990 (c.37) Article 9(1), *at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_2.htm#mdiv8 (November 1, 1990)

64. *Id.*

the licensing committees themselves as well as the scope, conditions, granting, and revocation of the licenses.[65] The Act also provides various civil and criminal sanctions for activities governed by the Act, as stated in Article 41.[66] The sanctions described by Article 41 mainly state what actions constitute an offense under the Act and occasionally provide possible punishments, such as imprisonment upon conviction, fines, or both.[67]

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65. Article 9 (license committees and other committees), Article 10 (licensing procedure), Article 11 (licenses for treatment, storage and research), Article 12 (general license conditions), Article 13 (conditions of licenses for treatment), Article 14 (conditions of storage licenses), Article 15 (conditions of research licenses), Article 16 (grant of license), Article 17 (person responsible/supervises the activities authorized by a license), Article 18 (revocation and variation of license), Article 19 (procedure for refusal, variation or revocation of license), Article 20 (appeal to Authority against determinations of license committee), Article 22 (temporary suspension of license). Human Fertilization and Embryology Act 1990 (c.37), http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_2.htm#mdiv8 (November 1, 1990).

66. *Id.* at Article 41. It states:

> (1) A person who— (a) contravenes section 3(2) or 4(1)(c) of this Act, or (b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence, is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both. (2) A person who—(a) contravenes section 3(1) of this Act, otherwise than by doing something which, by virtue of section 3(3) of this Act, cannot be authorised by a licence, (b) keeps or uses any gametes in contravention of section 4(1)(a) or (b) of this Act, (c) contravenes section 4(3) of this Act, or (d) fails to comply with any directions given by virtue of section 24(7)(a) of this Act, is guilty of an offence. (3) If a person—(a) provides any information for the purposes of the grant of a licence, being information which is false or misleading in a material particular, and (b) either he knows the information to be false or misleading in a material particular or he provides the information recklessly, he is guilty of an offence. (4) A person guilty of an offence under subsection (2) or (3) above is liable—(a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and (b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both. (5) A person who discloses any information in contravention of section 33 of this Act is guilty of an offence and liable— (a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and (b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both. (6) A person who— (a) fails to comply with a requirement made by virtue of section 39(1)(b) or (2)(b) or 40(2)(b)(ii) or (5)(b) of this Act, or (b) intentionally obstructs the exercise of any rights conferred by a warrant issued under section 40 of this Act, is guilty of an offence. (7) A person who without reasonable excuse fails to comply with a requirement imposed by regulations made by virtue of section 10(2)(a) of this Act is guilty of an offence. (8) Where a person to whom a licence applies or the nominal licensee gives or receives any money or other benefit, not authorised by directions, in respect of any supply of gametes or embryos, he is guilty of an offence. (9) A person guilty of an offence under subsection (6), (7) or (8) above is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both. (10) It is a defence for a person ("the defendant") charged with an offence of doing anything which, under section 3(1) or 4(1) of this Act, cannot be done except in pursuance of a licence to prove—(a) that the defendant was acting under the direction of another, and (b) that the defendant believed on reasonable grounds—(i) that the other person was at the material time the person responsible under a licence, a person designated by virtue of section 17(2)(b) of this Act as a person to whom a licence applied, or a person to whom directions had been given by virtue of section 24(9) of this Act, and (ii) that the defendant was authorised by virtue of the licence or directions to do the thing in question. (11) It is a defence for a person charged with an offence under this Act to prove—(a) that at the material time he was a person to whom a licence applied or to whom directions had been given, and (b) that he took all such steps as were reasonable and exercised all due diligence to avoid committing the offence.
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> *Id.*

67. *Id.*

The Act contains four additional Schedules, each of which expounds on a specific area governed by the Act that requires further elaboration. Schedule 1 addresses supplementary administrative provisions regarding the HFEA.[68] Schedule 2 sets out specific requirements regarding licensing activities.[69] Schedule 3 discusses the various forms of informed consent as related to the Act.[70] Schedule 4 delineates any amendments that are related to or affect other United Kingdom legislation.[71] Any amendments to the Act addressing stem cell research would be primarily under Schedule 2 regarding what activities may be licensed under the Act.

In addition to the specific activities required for the granting of a license under the HFEA as enumerated in Schedule 2, the Act also provides general restrictions on the use or storage of embryos regardless of their subsequent use. Article 3 of the Act sets out general prohibitions regarding embryos. Article 3(1) states that "[n]o person shall—(a) bring about the creation of an embryo, or (b) keep or use an embryo, except in the pursuance of a license."[72] The only way embryos may be kept or created in the United Kingdom, for research or treatment, is by means of a license granted by the HFEA for such a purpose. The licensing procedure of the HFEA provides an exception to the overall ban in the United Kingdom against creating, keeping, and using embryos. The approach by the United Kingdom may seem to be progressive, but such progression is permitted pursuant to strict and comprehensive legislative regulation. Article 3(2) states that "no person shall place in a woman—(a) a live embryo other than a human embryo, or (b) any live gametes other than human gametes."[73] This restriction does permit placing human embryos in women resulting from IVF, which was the main initial purpose of this Act. When taken with Article 3(1) above, an embryo cannot be created and placed into a woman unless the creation of that embryo is in pursuance with a license granted by the HFEA for that express purpose. Article 3(3) delineates four situations that cannot be authorized by a license: (a) keeping or using an embryo after the appearance of the primitive streak; (b) placing an embryo in an animal; (c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or; (d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.[74] Arti-

68. Human Fertilization and Embryology Act 1990 (c.37) Schedule 1, *at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_3.htm#sdiv1 (Sept. 20, 2000).

69. *Id.* at Schedule 2.

70. *Id.* at Schedule 3.

71. *Id.* at Schedule 4.

72. Human Fertilization and Embryology Act 1990 (c.37) Article 3(1)(a) & (b), *at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_2.htm#mdiv8 (Nov. 1, 1990).

73. "(2) No person shall place in a woman— (a) a live embryo, or (b) any live gametes other than human gametes." *Id.* at Art. 3(2)(a)–(b).

74. "(3) A licence cannot authorise— (a) keeping or using an embryo after the appearance of the primitive streak, (b) placing an embryo in any animal, (c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or (d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo." *Id.* at Art. 3(3).

cle 3(4) defines the primitive streak, as mentioned in Article 3(a), as being approximately equivalent to fourteen days, beginning with the day when the gametes[75] are mixed but "not counting any time during which the embryo is stored."[76] This requirement puts a developmental cap on what embryos may be kept or used in pursuance of a license granted by the HFEA. Hence, not only must any use or storage of an embryo be in pursuance of an activity permitted and licensed by the HFEA, the embryos used must also be of a specific developmental stage.

These general prohibitions set the foundation for the more specific licensing guidelines and requirements enumerated in Schedule 2 of the Act. Article 1(1) of Schedule 2 sets out when licenses for treatment can be granted.[77] Licenses for treatment generally seem to refer to procedures related to in vitro fertilization, but Article 1(1)(g) stipulates a catchall provision that also permits treatment licenses for any "such other practices as may be specified in, or determined in accordance with, regulations."[78] Article 1(3) also discusses other more general regulations regarding the granting of licenses, such as a license cannot "authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services."[79] This concept of "necessary or desirable" appears again in Schedule 2 and provides an interesting and perhaps problematic requirement regarding treatment and research. Article 1(4) stipulates another prohibition regarding activities authorized by a license, and Article 1(5) places a five-year time limit on the validity of licenses granted for purposes under Article 1.[80] Article 2 of Schedule 2 addresses licenses for storage of embryos.[81] Article 3(1) of Schedule 2 addresses situations where licenses can

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75. Gametes refer to human reproductive cells, such as egg and sperm.

76. "(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored." Human Fertilization and Embryology Act, *supra* note 72, at Art. 3(4).

77. A licence under this paragraph may authorize any of the following in the course of providing treatment services— (a) bringing about the creation of embryos *in vitro*, (b) keeping embryos, (c) using gametes, (d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose, (e) placing any embryo in a woman, (f) mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of testing the fertility or normality of the sperm, but only where anything which forms is destroyed when the test is complete and, in any event, not later than the two cell stage, and (g) such other practices as may be specified in, or determined in accordance with, regulations.

Human Fertilization and Embryology Act, 1990, c. 37, Art. 1(1), sched. 2 (Eng.), *at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_4.htm#sdiv2, (last modified Sept. 20, 2000).

78. *Id.* at Art. 1(1)(g).

79. *Id.* at Art. 1(3).

80. "(4) A licence under this paragraph cannot authorise altering the genetic structure of any cell while it forms part of an embryo. (5) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence." *Id.* at Art. 1(4)–(5).

81. *Id.* at Art. 2. It states:

(1) A licence under this paragraph or paragraph 1 or 3 of this Schedule may authorise the storage of gametes or embryos or both. (2) Subject to the provisions of this Act, a licence authorising such storage may be granted subject to such conditions as may be specified in the licence and may authorise storage in such manner as may be so specified. (3) A li-

be granted for research purposes.[82] Any amendment regarding stem cell research would be incorporated under Article 3(2) of Schedule 2. This article states that the HFEA cannot license human embryonic research of any kind unless it appears to the HFEA that such research is "necessary or desirable" 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 of contraception; (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.[83]

As with the article addressing treatment licenses, there is a catchall provision in Article 3(2) stating that research licenses may be granted "for other purposes as may be specified in regulations."[84] Article 3(3) further qualifies this last provision by stating "purposes may only be specified with a view to the authorisation of projects of research which increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied."[85] Article 3(6) also prohibits the granting of a license unless the HFEA is satisfied that any proposed use of embryos is "necessary for the purposes of the research."[86] This "necessary" requirement needed for any research license granted by the HFEA narrows the scope of what research projects related to human embryos can be licensed under the Act. Despite this restricted approach to research licensing, it does provide the HFEA with discretion in a rapidly progressing field of biotechnology and medicine. Perhaps the necessity requirement allows the HFEA to consider new research ventures that may not have been directly considered by the formulators of the Act while amendments that directly address such new developments are being created; it permits them to stay with the general "feel" of the Act while trying to legislate regarding new technologies.

How does this relate to stem cell research? What if a company or research facility wanted a license to utilize in vitro fertilization embryos for the creation of stem cell lines? This is not directly provided for in the five purposes stated in Article 3(2), and it has been argued that such research does not fall within the scope of the Act. But the "necessary" requirement demands that the HFEA only permit research, whether it falls under a new

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cence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

Id.

82. "(1) A licence under this paragraph may authorise any of the following— (a) bringing about the creation of embryos *in vitro*, (b) keeping or using embryos, for the purpose of a project of research specified in the license." Human Fertilization and Embryology Act, 1990, c. 37, Art. 3(1), sched. 2 (Eng.), *at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_4.htm#sdiv2, (last modified Sept. 20, 2000).

83. *Id.* at Art. 3(2).

84. *Id.*

85. *Id.* at Art. 3(3).

86. Article 3(6) states: "No licence under this paragraph shall be granted unless the Authority is satisfied that any proposed use of embryos is necessary for the purposes of the research.." *Id.* at Art. 3(6).

regulation that is not yet part of the Act or a currently existing one that it deems necessary. This allows the HFEA control over new research ventures that the legislative process may not have addressed yet. It also provides a precedent as to what new research ventures the HFEA might consider to be "necessary" and which ones they do not, thus providing direction for subsequent legislation but also informing researchers what work will thus be permitted and what will not. Any legislative provisions addressing stem cell research would focus mainly on the research potential and use of stem cells and any changes would likely be directed at amending Article 3 by adding two new categories under Article 3(2). But how did these new concerns come to the attention of the HFEA? Stem cell research was an obscure branch of cell and developmental biology and did not garner a significant amount of attention. After the successful cloning of the sheep, Dolly, in 1996[87], interest in the feasibility of cell nuclear replacement and other related procedures and research, including stem cell research, grew dramatically and the Act had to be re-examined in order to provide some sort of legislative scheme for these rapidly developing technologies.

In 1998, the HFEA and the Human Genetics Advisory Commission (HGAC) examined the issues arising from these developments and recommended in their report that the Secretary of State for Health consider amending Schedule 2 to include two new purposes for which the HFEA might issue research licenses.[88] As a result of this suggestion by the HFEA and the HGAC, an expert committee was created to address this issue in 1999 and initially recommended that research involving embryos, whether the embryos were created by in vitro fertilization or cell nuclear transfer, would "increase understanding about human disease and disorders and their cell-based treatments" and "should be permitted subject to the controls in the Human Fertilization and Embryology Act 1990."[89] In response to the report drawn up by this expert committee, the Parliament put forth draft regulations that extended the purposes for which human embryonic research was lawfully permitted.[90] These regulations, termed the Human Fertilization and Embryology (Research Purposes) Regulations 2001 were passed in the House of Commons on December 19, 2000[91] and by the House of Lords on

87. Dolly was the first mammal ever to be cloned from an adult mammal cell by means of cell nuclear transplantation. The announcement of Dolly's birth brought into focus the possibility of cloning humans and the accompanying moral, ethical, and legal implications. H. R. REP. NO. 107-170, *at* http://www.house.gov/judiciary/legreports.htm, (July 27, 2001).

88. The two new purposes are the development of methods of therapy for mitochondrial disease and the development of therapeutic treatments for diseased or damaged tissues or organs. *Stem Cell Research and Regulations under the Human Fertilization and Embryology Act 1990* (HC Library Research Paper (2000-01) no. 00/93), at 10, *at* http://www.parliament.uk/commons/lib/research/rp2000/rp00-093.pdf, (Dec. 13, 2000).

89. Department of health, *Donaldson Report on Stem Cell Research: Medical Progress with Responsibility* ¶ 33, *at* http://www.doh.gov.uk/cegc/stemcellreport.htm (Aug. 16, 2000). (on file with author)

90. *Stem Cell Research and Regulations under the Human Fertilization and Embryology Act 1990, supra* note 88, at 10-11.

91. House of Lords, *Select Committee on Stem Cell Research Report,* Chapter 1 § 1.10, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/3/8301/htm (Feb. 13, 2002).

January 22, 2001.[92] The Regulations added three new purposes to the Act: first, "increasing knowledge about the development of embryos," second, "increasing knowledge about serious disease," and third, "enabling any such knowledge to be applied in developing treatments for serious disease."[93]

The regulatory system established by the Act has worked quite well and the HFEA is considered the foundation for the entire regulatory system.[94] According to the House of Lords Select Committee on Stem Cell Research (the Committee),[95] the work of the HFEA is highly regarded in both the United Kingdom and abroad and commands the full confidence of the scientific and medical research community.[96] The HFEA also has been instrumental in addressing and reassuring public concerns about the effectiveness and sensitivity required regarding regulation in such an emotionally and ethically charged area of public policy.[97] There have also been few legal challenges to the rulings and media criticism has focused on the strictness of the rulings rather than their laxity.[98] The Act provides a solid legislative and regulatory framework for Parliament to work in regarding new legislation and amendments addressing stem cell research and human cloning. In terms of human embryo research, the Committee stipulated in the report that they had not received evidence of any instance in which the HFEA's handling of applications for licenses under the Act had been the subject of criticism.[99]

The Act's main focus is reproductive medicine, and the new proposed regulations require the HFEA to consider license applications for research addressing a wide variety of serious illnesses as well as the basic research underlying such research.[100] The Committee also recognized the rapid development and potential of adult stem cell research and the possibility that adult stem cell research could render further research on ES cells unnecessary.[101] The Act does provide for a built-in legislative brake on research on

92. *Id.*

93. *Id.*

94. House of Lords, *Select Committee on Stem Cell Research Report* Chapter 8 § 8.1, *at* http://www.publications.parliament.uk/pa/ld200102/ldselect/ldstem/83/8301.htm (Feb. 13, 2002).

95. The House of Lords passed a motion on March 7, 2001 appointing the 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." The main question underlying the appointment of the Committee was "whether the extension of the purposes in the 2001 Regulations is justified" and the Committee has examined issues such as "(a) the potential benefits of stem cell research; (b) whether, in the current state of scientific knowledge, there are satisfactory alternatives to research on human embryos; (c) the status of the early embryo; (d) the distinctions to be drawn, if any, between the use for research of "surplus" embryos (i.e. embryos left over from IVF treatment), of embryos created by IVF, and of embryos created by CNR; (e) the commercial interests involved; (f) the international context to the debate; (g) the possible need for further legislation; and (h) the possible need for further provision for the custody and regulation of stem cell "lines" derived from early embryos." House of Lords. Select *Committee on Stem Cell Research Report, supra* note 91, at § 1.15 & 1.19.

96. House of Lords, Select *Committee on Stem Cell Research Report, supra* note 91, at § 8.1.

97. *Id.*

98. *Id.*

99. *Id.* at § 8.2.

100. *Id.* at § 8.3.

101. House of Lords, Select *Committee on Stem Cell Research Report, supra* note 94, at § 8.4.

human embryos, since each proposal for a license has to be reviewed in order to determine that the same results could not be achieved by other research.[102] If the proposed 2001 Regulations did broaden the scope of the Act to permit applications for research involving embryonic stem cells, the regulations would operate in concert with the previously existing legislative restrictions already present in the 1990 Act. Since adult stem cell research has advanced at a rapid pace, the Committee recognized and emphasized the need to stay abreast of such developments. The Committee suggested that the UK government should review further developments regarding adult stem cells as well as stem cell banks.[103]

The 2001 Regulations were drafted to include research using stem cells from embryos created by in vitro fertilization and cell nuclear replacement based on the idea that embryos created by cell nuclear transfer should be considered embryos and fall under the scope of the Act. This approach was challenged in 2001 by judicial proceedings brought by the director of a pro-life organization that was opposed to human cloning.[104] The director sought a declaration stating that human embryos created by cell nuclear replacement fell outside the definition of an embryo in the Act.[105] The Government argued that an embryo created by cell nuclear transfer was "morphologically and functionally indistinguishable from an embryo produced by fertilisation."[106] The Queen's Bench Division held that an organism created by cell nuclear transfer without fertilization was not an embryo within the definition used in the Act.[107] The court also found that using the definition set forth by the Government would permit "an impermissible rewriting and extension of the definition."[108] The court awarded the declaration and stated that organisms produced by cell nuclear replacement were not subject to regulation under the1990 Act.[109] As a result of this decision, the concern was that by removing embryos produced by means of cell nuclear replacement from the scope of the 1990 Act, a loophole now existed for reproductive cloning that was virtually unregulated. The HFEA thus would not be able to implement a ban on reproductive cloning by refusing to license an application for this purpose.[110] On November 21, 2001, Parliament passed the Human Reproductive Cloning Bill in response to the concerns regarding

102. *Id.*

103. The HFEA, along with other agencies, has decided that there is a need for a stem cell bank that would provide scientists with access to embryonic stem cell lines "of guaranteed purity and provenance, and from sources which operate ethically-approved standards." *Id.* at § 8.26.

104. R (on the application of Quintavalle) v. Secretary of State for Health, LEXIS 2001 EWHC Admin 918 (Q.B. 2001).

105. *Id.*

106. *Id.*

107. *Id.*

108. *Id.*

109. R (on the application of Quintavalle) v. Secretary of State for Health, LEXIS 2001 EWHC Admin 918 (Q.B. 2001).

110. Explanatory Notes to Human Reproductive Cloning Act, 2001, c. 23, ¶ 3, *at* http://www.uk-legislation.hmso.gov.uk/acts/acts2001.htm (Nov. 22, 2001).

reproductive cloning in the United Kingdom.[111] The purpose of the bill is to prevent human reproductive cloning by making it a criminal offense to place in the womb of a woman a human embryo that has been created other than by fertilization.[112] Combined with the 1990 Act and the 2001 Regulations addressing stem cell research, this bill addressing reproductive cloning rounds out the United Kingdom legislative scheme addressing stem cell research and cloning and provides a solid and workable foundation for future legislation.

SECTION III: THE UNITED STATES

Unlike the United Kingdom, in the United States has not yet developed, a uniform national legislative approach to stem cell research has not yet been developed and the situation is ambiguous. Prior to August 2001, there was no federal funding for stem cell research and such research was carried out with private funds. There are currently no clear prohibitions or regulatory restrictions on private sector research regarding stem cell research and human cloning.[113] The August 2001 directive only refers to the requirements for the receipt of federal funds, not the prohibition of various forms of stem cell and cloning research.

The August 2001 directive provided limited federal funds for stem cell research; this funding, monitored by the National Institutes of Health, was allocated for research on stem cells that have already been extracted from embryos.[114] This policy excludes the use of leftover embryos from in vitro fertilization treatments from being used by research firms that intend to request federal funds. Research on adult stem cells and umbilical cord stem cells are fully funded whereas research that involves leftover frozen embryos from in vitro fertilization treatments does not receive federal funding.[115] The only aspect of research using frozen in vitro fertilization embryos that is approved for federal funding is research conducted on existing stem cell lines that were obtained from leftover in vitro fertilization embryos; the embryos used to create these lines also had to be donated by willing couples that did not receive monetary compensation for their donation.[116] No federal money will be allocated for research facilities that use donor embryos or cloned embryos.[117]

The federal funding policy does not permit the collection of sperm and egg donations specifically for the purpose of developing stem cells for

111. *Id.*
112. *Id.* at ¶ 6.
113. H.R REP. NO. 107-170, (2001), *at* http://www.house.gov/judiciary/legreports.htm.
114. Mitch Frank, *How Bush Got There,* TIME MAGAZINE, Aug. 20, 2001, at 18.
115. *Id.*
116. *Id.*
117. *Id.*

research.[118] Scientists argued that it was a more honest approach to create them for research, but it was perceived as a step towards a slippery slope leading to human cloning.[119] Again, this option is not closed off to private funding and most likely will continue, especially if the already existing stem cell lines prove to be insufficient.[120] Cloned embryos, whether created for therapeutic or reproductive purposes, will not be eligible for federal funds.[121] The House of Representatives passed a bill in November 2001 banning all cloning procedures,[122] and if the Senate follows suit, then all research, private as well as public and regardless of funding sources, involving any form of cloning will be illegal.[123] The President favors a ban that includes all forms of cloning, similar to the House of Representatives bill, whilst scientific advisory panels, such as the National Academy of Sciences Advisory Panel, tend to favor a ban that only includes reproductive cloning but not therapeutic cloning.[124] The Senate, however, was unable to reach a consensus regarding cloning at this time.[125]

The federal funding policy delineates a limited precedent for legislative development addressing stem cell research. At the time of the announcement of the policy, various bills were circulating in the House of Representatives and the Senate addressing stem cell research, cloning and their relationship to each other. Some of these bills address solely stem cell research while others attempt to prohibit cloning while protecting stem cell research. The balance has become increasingly difficult, especially in light of the research connections between human cloning and stem cell research and the possibility of a legislative ban on cloning in the United States. There is no current legislative starting point in the United States when it comes to regulating embryonic research. Various federal administrative bodies, such as the Food and Drug Administration,[126] have been suggested in various bills

118. *Id.*

119. Frank, *supra* note 114, at 18.

120. *Id.*

121. *Id.*

122. Rick Weiss & Ceci Connolly, *Experts urge Ban on cloned Babies but Panel Backs Embryo Research*, WASH. POST, *available at* http://bioethics.net/news/html/cloning.php (Jan. 19, 2002).

123. Frank, *supra* note 114, at 18.

124. Weiss & Connolly, *supra* note 122.

125. Helen Dewar, *Anti-Cloning Bills Stall in Senate; Vote Unlikely Soon*, WASH. POST, *available at* http://www.washingtonpost.com/wp-dyn/nation/specials/science/cloning/index.html (June 14, 2002).

126. The Food and Drug Administration (FDA) announced that it has the authority to regulate human cloning but that authority has been questioned by numerous experts and still remains unclear. According to the FDA, the authority comes partially from Public Health Services Act (PHS), which gives the FDA the "power to regulate 'biological products' that are used to treat medical conditions." The FDA claims that a human clone resulting from cell nuclear replacement is a 'biological product' intended to treat a medical condition, that condition being infertility. The FDA also states that it can regulate human cloning under the Food, Drug and Cosmetic Act because human clones resulting from cell nuclear replacement fall under the definition of "drugs." That act defines drugs as "articles" intended to affect the structure or any function of the body. The FDA considers a human clone as an "article" that affects the structure and functions of a woman's body by making her pregnant and would be subject to investigational new drug application requirements under the Food, Drug and Cosmetic Act. H.R. REP. NO. 107-170, at 2 (2001), *at* http://www.house.gov/judiciary/legreports.htm.

as starting points for the development of a regulatory regime regarding stem cell research and cloning.

The current legislative situation in the United States is very confusing and it will be some time before a comprehensive legislative regime exists addressing stem cell research and human cloning. The laws addressing the use of embryos, in both stem cell research and cloning, create a patchwork of legislation that makes it increasingly difficult to keep up with the rapidly changing pace of scientific technology. The statutory and regulatory scheme in the United Kingdom, on the other hand, acts as a starting point for the development of regulations for stem cell research and cloning.

A significant number of the bills under consideration by Congress address various aspects of stem cell research administration, storage, and development. The most recent bill, 2002 H.R. 4011, deals with an administrative need arising from the August 9, 2001 presidential stem cell directive.[127] The main aim of this bill, introduced in the House of Representatives on March 20, 2002, is to establish the Stem Cell Research Board that will conduct research on the effects of the August 9, 2001 presidential directive regarding stem cell research.[128] The Stem Cell Research Board, as established by the bill, would be charged with conducting research,[129] making recommendations to Congress regarding any legislation needed to address aspects such as funding or research,[130] conducting public forums addressing the status of federal funding,[131] and developing its own standards of conduct.[132] The primary focus of the Stem Cell Research Board seems to be centered on the issue of federal funding and how such funding shall be legis-

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127. "A bill to establish the Stem Cell Research Board to conduct research on the effects of the President's August 9, 2001, stem cell research directive, and for other purposes." Science of Stem Cell Research Act, H.R. 4011, 107th Cong. (2002), LEXIS 2002 107th CONG US HR 4011.

128. "Section 3 Establishment. There is established in the legislative branch a bipartisan commission to be known as the Stem Cell Research Board." *Id.*

129. Section 4 Duties. (a) Research. The Board shall conduct research on the following: (1) The effects, whether positive or negative, of the President's August 9, 2001, stem cell research directive, on the following: (A) The progress of advances in curing or remediating diseases or other medical conditions, including AIDS, Alzheimer's disease, anemia, arthritis, birth defects, blindness, brain injury, cancer, deafness, diabetes heart disease, kidney disease, liver disease, Lou Gehrig's disease, lung disease, multiple sclerosis, muscular dystrophy, Parkinson's disease, severe burns, sickle cell anemia, spinal cord injury, and stroke. (B) The progress of improvements in successful organ transplantation. (C) The development of any medical technology, including any halt or delay in such development. (D) Basic scientific research. (2) The effect of limiting Federal funding on the private stem cell research sector. (3) All aspects of the funding process of the National Institutes of Health for human adult and embryonic stem cell research.

Id.

130. "Section 4 Duties (b) Recommendations. In reports submitted under section 9, the Board shall make recommendations to the Congress on any legislation needed to reduce any inefficiencies in Federal funding of human embryonic stem cell research or to facilitate a more timely implementation of such research." *Id.*

131. "Section 4 Duties. (c) Public Forums. The Board shall conduct periodic public forums to review the status of stem cell research funding by the National Institutes of Health." *Id.*

132. "Section 4 Duties. (d) Standards of Conduct. The Board shall develop its own standards of conduct in consultation with the Committee on Standards of Official Conduct of the House of Representatives or the Select Committee on Ethics of the Senate, as applicable." H.R. 2863, 107th Cong. (2001), LEXIS 2001 107th CONG US HR 2863.

lated and implemented. The bill is an attempt to create a supervisory body to oversee the appropriation of federal funding for stem cell research and to make legislative recommendations in furtherance of that goal. An earlier bill, 2001 H.R. 2863,[133] has a similar aim to H.R. 4011 but with a more general scope. The bill, the Cell Development Research Act of 2001, directs the "Secretary of Health and Human Services to establish and maintain a panel to provide expert scientific recommendations in the field of cell development."[134] Instead of focusing primarily on advisory panels exclusively for stem cell research and development, as in H.R. 4011, this bill extends advisory panels to general cell development. Section 3 of the H.R. 2863 discusses the establishment of a cell development advisory panel by amending Section 505 of the Food, Drug, and Cosmetic Act.[135] The Secretary of Health and Human Services will create and maintain a single panel in the Food and Drug Administration whose job will be to provide expert scientific advice to the Secretary that includes recommendations "regarding any clinical investigation of a drug developed as a result of research in the field of embryology."[136] The bill also defined the field of cell development as including embryonic stem cell research, therapeutic cloning, preimplantation genetic diagnosis and early developmental biology.[137] What is beneficial about the proposal put forth in H.R. 2863 is that it recognizes the intercon-

133. *Id.*

134. *Id.*

135. *Id.*

> Section 3 Establishment of Cell Development Advisory Panel Subsection (n) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 355(n)) is amended by adding at the end the following: (9) Cell development advisory panel- (A) Establishment- The Secretary shall establish and maintain under this subsection a single panel in the Food and Drug Administration to provide expert scientific advice and recommendations to the Secretary in the field of cell development, including advice and recommendations regarding any clinical investigation of a drug developed as a result of research in the field of embryology and any approval for marketing of such a drug under this section or section 351 of the Public Health Service Act. (B) Promotion of Research - Such panel shall make policy recommendations with the goal of promoting research in the field of cell development. (C) Prohibition- Such panel shall not make any recommendation regarding the practice of fertility medicine. (D) Field of Cell Development- For purposes of this paragraph, the term 'field of cell development' includes embryonic stem cell research, therapeutic cloning, preimplantation genetic diagnosis, and early developmental biology.

Id.

136. *Id.*

> Section 3 Establishment of Cell Development Advisory Panel . . . (9) Cell development advisory panel...(A) Establishment - The Secretary shall establish and maintain under this subsection a single panel in the Food and Drug Administration to provide expert scientific advice and recommendations to the Secretary in the field of cell development, including advice and recommendations regarding any clinical investigation of a drug developed as a result of research in the field of embryology and any approval for marketing of such a drug under this section or section 351 of the Public Health Service Act.

Id.

137. "Section 3 Establishment of Cell Development Advisory Panel (9) Cell Development Advisory Panel . . . (D) Field of Cell Development—For purposes of this paragraph, the term 'field of cell development' includes embryonic stem cell research, therapeutic cloning, preimplantation genetic diagnosis, and early developmental biology." H.R. 2863, 107th Cong. (2001), LEXIS 2001 107th CONG US HR 2863.

nectedness between cell development, stem cell research, and therapeutic cloning. Perhaps having two different advisory boards under different legislative schemes is beneficial by providing various perspectives on a challenging issue. Yet the same difficulty that plagues the United States system generally is also a concern here at the introductory legislative level. Creating advisory boards that could provide useful expert advice in separate legislative schemes with no real overriding body could add to the confusion and lack of direction already complicating the United States system.

Some bills focus more on providing more specific guidelines and definitions for stem cell research with the overall purpose of clarifying and implementing the 2001 presidential directive. H.R. 2059 was brought before the House of Representatives on June 5, 2001, to amend the Public Health Service Act in order to provide for human embryonic stem cell generation and research.[138] The purpose of the bill is to delineate what means of generation and uses of human embryonic stem cells can be funded, supported or conducted with federal funding.[139] H.R. 2059 states that in order to carry out stem cell research, human embryonic stem cells used for such research can only be derived from embryos that have been donated from in vitro fertilization clinics.[140] These clinics also have to comply with two specified conditions before such embryos can be utilized for research. First, before the embryos could be considered for donation, such embryos could never have been intended to be implanted in a woman and thus were going to be discarded.[141]

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138. "A bill to amend the Public Health Service Act to provide for human embryonic stem cell generation and research." Stem Cell Research Act of 2001, H.R. 2059, 107th Cong. (2001), LEXIS 2001 CONG US HR 2059.

139. Section 2 Human Embryonic Stem Cell Generation and Research. Part H of the Title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after section 498B the following:

> Section 498C. Human Embryonic Stem Cell Generation and Research. (a) In General- Notwithstanding any other provision of law, the Secretary may only conduct, support, or fund research on human embryos for the purpose of generating embryonic stem cells and utilizing stem cells that have been derived from embryos in accordance with this section. (b) Sources of Embryonic Stem Cells- For purposes of carrying out research under subsection (a), the human embryonic stem cells involved shall be derived only from embryos that have been donated from in-vitro fertilization clinics after compliance with the following: (1) Prior to the consideration of embryo donation and through consultation with the progenitors, it is determined that the embryos will never be implanted in a woman and would otherwise be discarded. (2) The embryos are donated with the written informed consent of the progenitors. (c) Restrictions—(1) In General—The following restriction shall apply with respect to human embryonic stem cell research conducted or supported under subsection (a): (A) The research involved shall not result in the creation of human embryos. (B) The research involved shall not result in the reproductive cloning of a human being. (2) Prohibition - (A) In General- It shall be unlawful for any person receiving Federal funds to knowingly acquire, receive, or otherwise transfer any human embryos for valuable consideration if the acquisition, receipt, or transfer affects interstate commerce. (B) Definition- In subparagraph (A), the term 'valuable consideration' does not include reasonable payments associated with transportation, transplantation, processing, preservation, quality control, or storage.

Id.

140. "(b) Sources of Embryonic Stem Cells—For purposes of carrying out research...the human embryonic stem cells involved shall be derived only from embryos that have been donated from in vitro fertilization clinics after compliance with the following. . . ." *Id.*

141. "(b)(1): Prior to the consideration of embryos donation and through consultation with the progenitors, it is determined that the embryo will never be implanted in a woman and would otherwise be discarded." *Id.*

Second, the embryos could not be donated without the written informed consent of the donators.[142] This bill establishes restrictions on the proposed research, including a blanket prohibition on the creation of human embryos for the purposes of research and a specific prohibition on the reproductive cloning of a human being.[143] The bill also provides for further restrictions that prevent human embryos from being knowingly used or transported for valuable consideration in a way that affects interstate commerce.[144] In addition, the bill requires the Secretary, along with the director of the National Institute of Health, to issue guidelines that would include rules governing the derivation of stem cells from donated embryos.[145] The Senate has introduced a related bill, 2001 S. 723, the Stem Cell Research Act of 2001.[146] The main purpose of the bill is identical to H.R. 2059 and proposes to amend the Public Health Service Act by adding another section describing in more detail guidelines for stem cell generation and research.[147] S. 723 parallels the text of H.R. 2059 very closely and advocates the same suggestions, such as delineating under what conditions human embryonic stem cells can be obtained.[148]

The Stem Cell Research for Patient Benefit Act of 2001, 2001 H.R. 2747, requires the implementation of the National Institutes of Health guidelines for research using human pluripotent stem cells.[149] This bill requires the director of the National Institutes of Health to conduct or support research using human pluripotent stem cells from embryos and fetal tissue in accordance with the NIH guidelines as well as study and report to specific congressional committees on stem cells and the effectiveness of such guide-

142. "(b)(2): The embryos are donated with the written informed consent of the progenitors." *Id.*

143. "(c) Restrictions—(1) In General—The following restriction shall apply with respect to human embryonic stem cell research conducted or supported...(A): The research involved shall not result in the creation of human embryos. (B) The research involved shall not result in the reproductive cloning of a human being." Stem Cell Research Act of 2001, H.R. 2059, 107th Cong. (2001), LEXIS 2001 CONG US HR 2059.

144. "(c)(2) Prohibition—(A) In General—It shall be unlawful for any person receiving federal funds to knowingly acquire, receive, or otherwise transfer any human embryos for valuable consideration if the acquisition, receipt, or transfer affects interstate commerce." *Id.*

145. "(d) Guidelines—The Secretary, in conjunction with the Director of the National Institutes of Health, shall issue guidelines that expand on the rules governing embryonic stem cell research...to include rules that govern the derivation of stem cells from donated embryos under this section." *Id.*

146. Stem Cell Research Act of 2001, S. 723, 107th Cong. (2001), LEXIS 2001 CONG US S 723.

147. *Id.*

148. *Id.*

> A bill to amend the Public Health Service Act to provide for human embryonic stem cell generation and research. Section 2 Human Embryonic Stem Cell Generation and Research . . . (a) In General—Notwithstanding any other provision of law, the Secretary may only conduct, support, or fund research on human embryos for the purpose of generating embryonic stem cells and utilizing stem cells that have been derived from embryos in accordance with this section. (b) Sources of Embryonic Stem Cells—For purposes of carrying out research under subsection (a), the human embryonic stem cells involved shall be derived only from embryos that have been donated from in-vitro fertilization after compliance with the following...

Id.

149. "To require implementation of the National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, and for other purposes." Stem Cell Research for Patient Benefit Act of 2001, H.R. 2747, 107th Cong. (2001), LEXIS 2001 CONG US HR 2747.

lines.[150] The bill also establishes the Biomedical Advisory Commission that would be responsible for studying bioethical issues arising from research on human biology and applications of such research and emerging biomedical research, including the ethical, social, legal and regulatory issues concerning such research and its clinical applications.[151] Such a commission would be useful, especially since it will be incorporated under the National Institutes of Health, which is responsible for allocating federal funding. H.R. 2838, or the New Century Health Advantage Act, is similar to H.R. 2747 in general purpose; it also requires the Director of the National Institutes of Health to carry out and support human pluripotent stem cell research.[152] The bill does restrict the source of the human pluripotent stem cells to be used in the research supported by the National Institutes of Health; the human pluripotent stem cells can only be derived from human embryos created for fertility treatments and were later not needed.[153] H.R. 2838 does not establish an advisory board, as in H.R. 2747, but the bill does propose to repeal an earlier

150. Section 2 Implementation of National Institutes of Health Guidelines for Research using Human Pluripotent Stem Cells: The Director of the National Institutes of Health shall conduct or support research using human pluripotent stem cells from embryos and fetal tissue in accordance with the National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, as published in the Federal Register on August 25, 2000 . . . and corrected on November 21, 2000. . . . Section 3(b): Report: Not later than 5 years after the date of the enactment of this Act, the Director of the National Institutes of Health shall submit a report describing the findings and conclusions of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate. Section 4(c) Report—The Secretary shall ensure that, not later than 2 years after the date of the enactment of this Act, the study to be conducted under subsection (a) is completed and a report describing the findings and conclusions of the study is submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate.

Id.

151. Section 5 Biomedical Advisory Commission: (a) Establishment – There is established a commission to be known as the Biomedical Advisory Commission . . . (b) Duties— (1) Study—The Commission shall conduct studies on the following: (A): Bioethical issues arising from research on human biology and applications of such research. (B): Emerging biomedical research, including the ethical, social, legal, and regulatory issues concerning such research and its clinical applications. (2) Recommendations—Based on the results of the study, the Commission shall formulate such recommendations as it considers appropriate with the goal of realizing the development of effective therapies as quickly as possible, taking into account the relevant ethical, social, legal, and regulatory considerations. (c) Membership—(1) Appointment—The Commission shall be composed of 13 members as follows: (A) 1 member appointed by the President. (B) 3 members appointed by the Speaker of the House of Representatives. (C) 3 members appointed by the minority leader of the House of Representatives. (D) 3 members appointed by the majority leader in the Senate. (E) 3 members appointed by the minority leader of the Senate. (2) Qualifications––The members appointed under subparagraphs (B), (C), (D), and (E) of paragraph (1) shall include representatives from the legal, ethical, scientific, medical, patient, religious, and industry communities.

Id.

152. "To require the Director of the National Institutes of Health to conduct or support research using certain human pluripotent stem cells, and for other purposes." New Century Health Advantage Act, H.R. 2838, 107th Cong. (2001), LEXIS 2001 CONG US HR 2838.

153. "Section 3. Studies using Human Pluripotent Stem Cells. The Director of the National Institutes of Health shall conduct or support research using pluripotent stem cells derived from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment." *Id.*

prohibition regarding funding for certain human embryonic research projects.[154]

Stem cell banks have been suggested as a means to maintain and regulate sources of stem cell lines used for research. There have been bills introduced in both the House of Representatives and the Senate addressing stem cell banks. The Responsible Stem Cell Research Act of 2001, or H.R. 2096 provides for a national stem cell donor bank that would facilitate the "conduct and support of research using such cells."[155] The purpose of the National Stem Cell Donor Bank, as set forth in H.R. 2096, is to "seek and preserve donations of qualifying human stem cells and to make such donated cells available for biomedical research and for therapeutic purposes."[156] The underlying point behind these banks seems to be to curtail the creation of embryos for research purposes. If there is a nationally run stem cell bank that collects and manages these cells then scientists can utilize the already existing stem cell lines kept in the banks and not have any reason to create embryos for research purposes.

Similar bills have been introduced in the Senate discussing stem cell banks and research implementation guidelines. H.R 2096 was introduced to deal with the potential need for a stem cell bank by directing the Secretary of Health and Human Services to establish by contract a national stem cell donor bank to preserve qualifying human stem cells and to make those stem cells available for biomedical research.[157] The purpose of the donor bank, as stated in the bill, is to "seek and preserve donations of qualifying human stem cells and to make these donated cells available for biomedical research."[158] Here, qualifying human stem cells refers to human stem cells

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154. "Section 4. Repeal of Prohibition of Funding for Certain Research Involving Human Embryos. Section 510 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2001 (as enacted by section 1(a) of Public Law 106-554))prohibiting the use of funds for certain research involving human embryos), is hereby repealed." *Id.*

155. "To provide for a National Stem Cell Donor Bank regarding qualifying human stem cells, and for the conduct and support of research using such cells." Responsible Stem Cell Research Act of 2001, H.R. 2096, 107th Cong. (2001), LEXIS 2001 CONG US HR 2096.

156. *Id.*

> Section 3. National Stem Cell Donor Bank. (a) In General, The Secretary of Health and Human Services shall by contract establish and maintain a National Stem Cell Donor Bank...The purpose of the Donor Bank shall be to seek and preserve donations of qualifying human stem cells and to make such donated cells available for biomedical research and for therapeutic purposes. (b) Qualifying Human Stem Cells. For purposes of this Act, the term 'qualifying human stem cells' means human stem cells obtained from human placentas, umbilical cord blood, organs or tissues of unborn human offspring who died of natural causes (such as spontaneous abortion.)

Id.

157. *Id.*

> Section 3. National Stem Cell Donor Bank. (a) In General. The Secretary of Health and Human Services shall by contract establish and maintain a National Stem Cell Donor Bank...[T]he purpose of the Donor Bank shall be to seek and preserve donations of qualifying human stem cells and to make such donated cells available for biomedical research and for therapeutic purposes.

Id.

158. "The purpose of the Donor Bank shall be to seek and preserve donations of qualifying human stem cells and to make such donated cells available for biomedical research and for therapeutic purposes." *Id.*

"obtained from human placentas, umbilical cord blood, organs and tissues of a living or deceased human being"[159] as well as stem cells removed from the organs and tissues of unborn human offspring who died of natural causes.[160]

In addition to bills dealing strictly with stem cell research, a few bills have been introduced that attempt to combine stem cell research guidelines as well as cloning prohibitions. Bills, such as 2002 S. 1893[161] and 2002 S. 2439[162] attempt to prohibit human cloning while preserving "important areas of medical research, including stem cell research."[163] 2002 S. 1893 addresses this complex relationship by amending the Public Health Services Act by prohibiting human reproductive cloning while permitting therapeutic cloning for research purposes.[164] This bill generally prohibits the performance of human cloning as well as the receipt of products from somatic cell nuclear transplantation for the purpose of human cloning.[165] The bill also provides both criminal and civil sanctions for such actions.[166] It is noteworthy to mention here that the definition given in this particular bill for human cloning refers mainly to reproductive cloning by defining it as "asexual human reproduction by implanting or attempting to implant the product of nuclear transplantation into a woman's uterus (or substitute for a woman's uterus.)"[167] This definition makes a distinction between cloning for repro-

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159. *Id.*

> Section 3. National Stem cell Donor Bank. (b) Qualifying Human Stem Cells. For the purposes of this Act, the term 'qualifying human stem cells' means human stem cells obtained from human placentas, umbilical cord blood, organs or tissues of a living or deceased human being who has been born, or organs or tissues of unborn human offspring who died of natural causes (such as spontaneous abortion.

Id.

160. *Id.*

161. The purpose of this bill is to ban human cloning while protecting stem cell research and was introduced into the Senate on January 24, 2002. Human Cloning and Stem Cell Research Protection Act of 2001, S. 1893, 107th Cong. (2001), LEXIS 2001 CONG US S 1893.

162. Human Cloning Prohibition Act of 2002, S. 2439, 107th Cong. (2001), LEXIS 2001 CONG US S 2439.

163. *Id.*

164. Human Cloning and Stem Cell Research Protection Act of 2001, S. 1893, 107th Cong. (2002), LEXIS 2001CONG US 1893.

165. Section 2 Amendment to the Public Health Services Act: (a) Prohibition:

> [I]t shall be unlawful for any person or entity, public or private, in or affecting interstate commerce—(1) to perform or attempt to perform human cloning; or (2) to ship, receive, or import the product of nuclear transplantation for the purpose of human cloning; (d) Scientific Research: Nothing in this section shall be construed to restrict areas of biomedical, agricultural, and scientific research not specifically prohibited by this section, including somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues.

Id.

166. Section 2 Amendment to the Public Health Services Act (b) Penalties:

> (1) criminal penalties: any person or entity that is convicted of violating any provision of this section shall be fined under this section and imprisoned not more than 10 years, or both. (2): civil penalties: any person or entity that is convicted of violating any provision of this section shall be subject to a civil penalty of not less than $1,000,000 and, in the case of a violation that involves the derivation of a pecuniary gain greater than $1,000,000, an amount equal to not more than the amount of such gain multiplied by 2.

Id.

167. "Section 2 Amendments to the Public Health Services Act (c) Definitions: In this section: (1): Human cloning: the term human cloning means asexual human reproduction by implanting or attempting to implant

ductive purposes and cloning for research or therapeutic purposes; the only cloning that is subject to sanction, by this bill, is cloning utilized for reproductive purposes. In addition to this distinction between therapeutic and reproductive cloning, the bill also provides a research protection clause stating that "nothing in this section shall be construed to restrict areas of biomedical, agricultural, and scientific research not specifically prohibited by this section, including cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells and tissues."[168] S. 2439 also combines a prohibition on reproductive cloning with a protection of research clause stating that nothing regarding the prohibition of reproductive cloning will be understood to restrict practices not expressly prohibited by the bill.[169] A distinction is also made here between reproductive and therapeutic cloning[170], as in S. 1893, and S. 2439 also provides both civil and criminal sanctions for such actions somewhat similar to S. 1893.[171] The bill also adds a section dealing with the ethical requirements for nuclear transplantation research, such as informed consent, institutional and board review, and protection for safety and privacy.[172] These bills that only advocate a ban on reproductive cloning and permit therapeutic cloning for research purposes did not embody the approach the House of Representatives decided to take regarding human cloning. The Human Cloning Prohibition Act 2001 instead required a complete ban on all forms of human cloning and was passed by the House of Representatives on July 31, 2001.[173]

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the product of nuclear transplantation into a woman's uterus or a substitute for a woman's uterus." *Id.*

168. "(d) Scientific Research: Nothing in this section shall be construed to restrict areas of biomedical, agricultural, and scientific research not specifically prohibited by this section, including somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues." *Id.*

169. "Section 4. Prohibition on Human Cloning. (b) Prohibitions on Human Cloning—It shall be unlawful for any person or other legal entity, public or private—(1) to conduct or attempt to conduct human cloning; or (2) to ship the product of nuclear transplantation in interstate or foreign commerce for the purpose of human cloning in the United States or elsewhere. (c) Protection of Research—Nothing in this section shall be construed to restrict practices not expressly prohibited in this section." Human Cloning Prohibition Act of 2002, S. 2439, 107th Cong. (2001), LEXIS 2001 CONG US S 2439.

170. Section 4. Prohibition on Human Cloning. Definitions—In this section:

> (1) Human Cloning – the term 'human cloning' means implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus. (b) Ethical Requirements for Nuclear Transplantation Research: (a) Definitions—in this section: (2) nuclear transplantation- the term 'nuclear transplantation' means transferring the nucleus of a human somatic cell into an oocyte from which the nucleus or all chromosomes have been or will be removed or rendered inert.

Id.

171. (d) Penalties— (1) criminal penalties—whoever intentionally violates paragraph (1) or (2) of subsection (b) shall be fined under this title and imprisoned not more than 10 years. (2) Civil Penalties—whoever intentionally violates paragraph (1) or (2) of subsection (b) shall be subject to a civil penalty of $1,000,000 or three times the gross pecuniary gain resulting from the violation, whichever is greater. (3) Forfeiture—any property, real or personal, derived from or used to commit a violation or attempted violation of the provisions of subsection (b), or any property traceable to such property, shall be subject to forfeiture to the United States in accordance with the procedures set forth in chapter 46 of title 18, United States Code.

Id.

172. *Id.*

173. Human Cloning Prohibition Act 2001, H.R.2505, 107th Cong. (2001), LEXIS 2001 CONG US HR 2505.

The Human Cloning Prohibition Act 2001 (H.R. 2505) amends Title 18 of the United States Code by establishing a comprehensive ban on human cloning and prohibiting the importation of a cloned embryo, or any product derived from such embryo.[174] Any person or entity that is convicted of violating this prohibition is subject to a fine or imprisonment of not more than 10 years, or both.[175] In addition, H.R. 2505 provides a civil penalty of not less than $1,000,000 for any person who receives a monetary gain from cloning humans.[176] However, H.R. 2505 does not prohibit the use of cloning technology to produce molecules, DNA, cells, tissues, organs, plants, or animals.[177] In addition to federal legislation regarding human cloning, many states have enacted laws dealing with cloning; seven states currently prohibit cloning in some form.[178]

At first glance, it may not seem that legislation regulating or prohibiting human cloning would be relevant to the development of stem cell research legislation. However, H.R. 2505 is crucial to the subsequent direction or development that legislation addressing stem cell research will take in the following months. The current United States policy on stem cell research limits federal funding to stem cell lines established prior to August 2001 and permits research on excess embryos from in vitro fertilization.[179] However, private entities can choose to be ineligible for federal funding and continue to carry out research without these restrictions. By passing a bill, such as H.R. 2505, that proposes a blanket prohibition on cloning without differentiating between therapeutic and reproductive cloning, research entities that forego federal funds because of the imposed restrictions will find their work limited beyond the requirements for federal funding. The bill does not permit the creation or importation of embryos or products from embryos created

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174. Section 2 Prohibition on Human Cloning (a) In General:
> Title 18, United States Code, is amended by inserting after Chapter 15, the following: Chapter 16—Human Cloning Sec. 302. Prohibition on human cloning (a) In General—it shall be unlawful for any person or entity, public or private, in or affecting state commerce, knowingly—(1) to perform or attempt to perform human cloning; (2) to participate in an attempt to perform human cloning; or (93) to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo. (9b) Importation—it shall be unlawful for any person or entity, public or private, knowingly to import for any purpose an embryo produced by human cloning, or any product derived from such embryo.

Id.

175. "Section 2. Section 302(c). Penalties— (1) criminal penalty—any person or entity that violates this section shall be fined under this title or imprisoned not more than 10 years, or both." *Id.*

176. "(2) Civil penalty—any person or entity that violates any provision of this section shall be subject to, in the case of a violation that involves the derivation of a pecuniary gain, a civil penalty of not less than $1,000,000.00 and not more than an amount equal to the amount of the gross gain multiplied by 2, if that amount is greater than $1,000,000.00." *Id.*

177. "Section 302(d). Scientific Research—nothing in this section restricts areas of scientific research not specifically by this section, 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." *Id.*

178. State Human Cloning Laws, http://www.ncsl.org/programs/health/Genetics/rt-schl.htm, (May 9, 2002). (on file with author)

179. Mitch Frank, *How Bush Got There*, TIME MAGAZINE, Aug. 20, 2001, at 18.

by cloning for therapeutic purposes, regardless of the source of the funding for such projects. The restrictions on stem cell research after August 2001 are not prohibitions on the research itself but rather on the parameters of what federal funding. Here this bill prohibits research on cloning itself. Since therapeutic cloning is an important and viable source of stem cells, a blanket prohibition on all cloning will directly affect stem cell research. This interplay of seemingly unconnected regulations may prove to have quite an effect on the progress of scientific innovation regarding stem cells.

Some members of Congress claim that the only way to regulate cloning is with an absolute ban on that research in the United States.[180] Those opposed to a complete ban on cloning would prefer to see a ban that would only "prohibit cloning when there was an intent to create a pregnancy and would still allow scientists to clone human embryos for experimental purposes."[181] However, many feel that if any form of cloning, such as therapeutic cloning, that offers a benefit that arguably outweighs the inherent ethical difficulties, is permitted, then reproductive cloning will be virtually impossible to regulate.[182] The reasoning behind the complete cloning ban passed by the House of Representatives comes from the concern about regulating cloning and the early successes regarding the applicability of adult stem cells.[183] This research involving adult stem cells is promising but still considered to be scientifically and technologically limited and should not be considered as an alternative source to embryonic stem cell research.[184] Thus, such a cloning bill prohibiting therapeutic cloning would eliminate an important research tool in understanding stem cells and developing their therapeutic uses and applications.

Despite the seemingly undirected and confusing legislative situation currently in place in the United States, there are still many interesting and valid ideas regarding the legislative direction stem cell research should take in the near future. The United States system does not benefit from an overarching piece of legislation addressing a larger issue that affects both stem

180. H.R. REP. NO. 107-170, *at* http://www.house.gov/judiciary/legreports.htm, (July 27, 2001). (on file with author)

181. *Id.*

182. The concern here relates to what happens after the production of cloned embryos. Once embryos were cloned and available in laboratories, there would be no effective way to control what was done with them. Stockpiles of cloned human embryos "could be produced, bought and sold without anyone knowing it. Implantation of cloned embryos, a relatively easy procedure, would take place out of sight." *Id.*

183. As stated in the Congressional Report addressing H.R. 2505, the House of Representatives found, after hearing testimony on the issue, that "cloning human embryos for the sole purpose of destroying them for their stem cells is unnecessary because of the successes that scientists have had with adult stem cells." *Id.* Even though there has been promising research in involving the viability and applicability of adult stem cells, studies are still inconclusive.

184. Studies in animals have illustrated that an approach to stem cell research primarily relying on adult stem cells will be scientifically and technologically limited and in some cases the location of the adult stem cells will prevent easy or safe access. However, since there are no real legal or ethical restrictions regarding this research, important research should go forward in this area. But important biological differences do exist between embryonic and adult stem cells and adult stem cell research should not be considered an alternative source to embryonic stem cell research. National Bioethics Advisory Commission Ethical Issues in Human Stem Cell Research, *at* http://bioethics.georgetown.edu/bac/stemcell.pdf (Sept. 1999).

cell research and human cloning, such as HFE Act 1990, so the starting point for regulation, and in the case of cloning, prohibition, is not as clear. The various bills circulating in Congress do present different approaches and at least begin the dialogue as to where to go next.

SECTION IV: THE INTERNATIONAL SITUATION

Various international and regional organizations have been attempting to tackle stem cell research and related sub fields. The United Nations Educational, Scientific, and Cultural Organization (UNESCO), the Council of Europe and the European Union have begun to address the status of the embryo, stem cell research and human cloning by issuing various reports from investigative committees and slowly developing pertinent treaties and declarations. These international voices bring the debate into a global, rather than purely national arena and further illustrate and clarify the challenges to come regarding biotechnology and biomedical research and innovation. The perspectives of these international organizations shed light on how an issue as politically and ethically problematic and complex as stem cell research and human cloning can be effectively addressed beyond the national arena.

The International Bioethics Committee, under the ambit of UNESCO, published a report in April 2001 addressing the use of embryonic stem cells in therapeutic research.[185] The report focused on the question of whether it is "ethically acceptable to derive cells from a human embryo prior to its implantation in utero in order to cultivate and investigate these cells in the laboratory for therapeutic research."[186] The report also recognized the pluralistic nature of the opinions regarding embryo research and aimed at highlighting "the various ethical arguments with a view to facilitating the resolution at a national and international level, of a controversial matter."[187] The overall focus of the United Nations with respect to human rights treaties is to first provide a declaratory compass for member states to examine and then enact treaties that embody the ideals set out in the original declaration. This was the procedure the UN followed when developing the International Covenant for Civil and Political Rights ("ICCPR") and the International Covenant for Economic, Social, and Cultural Rights ("ICESCR"), both which were based on the Universal Declaration of Human Rights. It would not be surprising that this report from the International Bioethics Committee could be the start of a larger effort regarding biomedical concerns. The difficulty with such a declaration and perhaps a treaty is likely to be the lack of overall consensus regarding not only stem cell research but also cloning and

185. United Nations Educational, Scientific and Cultural Organization, International Bioethics Committee, The Use of Embryonic Stem Cells in Therapeutic Research (Report of the IBC on the Ethical Aspects of Human Embryonic Stem Cell Research), *at* http://www.unesco.org/ibc/en/reports/embryonic_ ibc_report.pdf (Apr. 6, 2001).

186. *Id.* at § I.

187. *Id.*

the status of the early embryo. Yet the UN does provide a much-needed international forum for these issues, and their reports could be very useful and instrumental in developments by regional organizations to address this area.

The International Bioethics Committee tackled a similar problem when it created the Universal Declaration on the Human Genome and Human Rights. Since the creation of the International Bioethics Committee in 1993, the organization has worked for the development of an "international instrument" for the protection of the human genome.[188] Once the Declaration was finalized, UNESCO unanimously adopted the document in 1997 and the General Assembly approved and endorsed it in 1998.[189] This sort of declaration on stem cell research or human cloning could be beneficial in directing international development in these areas. The International Bioethics Committee, as well as UNESCO, has recognized the divergent viewpoints surrounding stem cell research and thus realizes the difficulty of creating a document that would adequately address all of these variant concerns. Even though there are many resolutions from international organizations (most do originate from the UN or satellite groups) that address relevant concerns, such as the right to life and embryonic life, none of them directly addresses stem cell research. Such a model treaty could provide suggestions as to potentially appropriate provisions and language that other governments and groups could emulate.

Generally, most regional and international human rights treaties, such as the Universal Declaration of Human Rights of 1948,[190] the International Covenant on Civil and Political Rights of 1966,[191] and The African Charter on Human and People's Rights of 1981,[192] specifically delineate a right to life. The American Convention on Human Rights of 1969[193] extends this right to the conceived child.[194] But none of these declarations or treaties directly addresses the legal status of the embryo. Regional organizations, such as the Council of Europe, are making strides towards developing a regional treaty regime that does address different areas of biomedicine, such as protection of the human embryo and fetus,[195] biomedical research,[196] and organ transplantation.[197]

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188. The Universal Declaration on the Human Genome and on Human Rights, *at* http://www.unesco.org/ibc/en/genome/index.htm (Nov. 11, 1997).

189. *Id.*

190. Universal Declaration of Human Rights, *available at* http://www.un.org/Overview/rights.html (Dec. 10, 1948).

191. International Covenant on Civil and Political Rights, *available at* http://www.tufts.edu/departments/fletcher/multi/texts/BH498.txt (Dec. 16, 1966).

192. "Human beings are inviolable. Every human being shall be entitled to respect for his life and the integrity of his person. No one may be arbitrarily deprived of this right." African (Banjul) Charter on Human and People's Rights, *at* http://www1.umn.edu/humanrts/instree/z1afchar.htm (June 27, 1981). (on file with author)

193. American Convention on Human Rights, *at* http://www.cidh.oas.org/Basicos/basic3.htm (Nov. 22, 1969).

194. "Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life." *Id.* at Art. 4(1).

195. Council of Europe, General Information Draft Protocol on the Protection of the Human Embryo and

The Council of Europe's Convention for the Protection of Human Rights and the Dignity of the Human Being Regarding the Application of Biology and Medicine of 1997 (the Convention)[198] does not fully address embryo research and leaves the responsibility of legislation to each country with two conditions: 1) prohibition of producing human embryos for research purposes;[199] 2) adoption of rules designed to assure adequate protection for the embryo.[200]

In addition to these conditions, an additional Protocol to the Convention on the Prohibition of Cloning Human Beings[201] garnered approval in 1998 and has currently been entered into force in eleven member states as of January 3, 2001.[202] Two other protocols to the Convention, the Draft Protocol on Biomedical Research (July 18, 2001)[203] and the Draft Protocol on the Protection of the Human Embryo and Fetus[204], in addition to the Protocol

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Fetus, *at* http://www.legal.coe.int/bioethics/gb/html/txt_p_info2.htm.

196. Council of Europe, Draft Additional Protocol to the Convention on Human Rights and Biomedicine on Biomedical Research, *at* http://www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/ CDBI (July 18, 2001).

197. Council of Europe, Protocol No. 13 to the Convention for the Protection of Human Rights and Fundamental Freedoms, concerning Transplantation of Organs and Tissues of Human Origin, *at* http://conventions.coe.int/treaty/en/treaties/html/187.htm (Jan. 24, 2001).

198. Convention for the Protection of Human Rights and the Dignity of the Human Being Regarding the Application of Biology and Medicine, *at* http://conventions.coe.int/Treaty/EN/CadreListeTraites. htm, (April 4. 1997).

199. "The creation of human embryos for research purposes is prohibited." *Id.* at Article 18(2).

200. "Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo." *Id.* at Article 18(1).

201. The Protocol expounds on certain articles in the Convention of Human Rights and Biomedicine. The scope of the Protocol addresses the cloning of human beings. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine, On the Prohibition of Cloning Human Beings, *at* http://conventions.coe.int/Treaty/EN/CadreListetraites.htm (Jan. 12, 1998).

202. Cyprus, Czech Republic, Estonia, Georgia, Greece, Hungary, Portugal, Romania, Slovakia, Slovenia and Spain. *Id.*

203. The main purpose of this draft Protocol is to:

> build on the principles embodied in the Convention, with a view to protecting human rights and dignity in the specific field of biomedical research" and to "define and safeguard fundamental rights in biomedical research." The Protocol is intended to cover the complete range of biomedical research activities that involve interventions on human beings; research on embryos and fetuses in vivo and pregnant women will be covered by the Protocol. The Protocol will most likely address issues "such as the risks and benefits of research . . . scientific quality, independent examination of research by an ethics committee, information to be submitted to the ethics committee, information for research participants, confidentiality and the right to information, dependent persons, undue influence, safety, duty of care and research in states not party to the Protocol.

General Information; Draft Protocol on Biomedical Research, *at* http://www.legal.coe.int/bioethics/gb/html/txt_p_info.htm.

204. The working party responsible for the preparation of the Protocol is focusing on the ethical and legal problems linked to "possible intervention on human embryos and fetuses." It is anticipated that the Protocol will deal with the issue of consent as well as issues associated with professional standards, rules of conduct applicable to intervention on embryos or fetuses as well as prohibition of trading in embryos and fetuses. The draft Protocol will have several chapters, "including one on the protection of embryos in vitro, which will deal with the safety and quality of the in vitro fertilization procedure." There is also a plan to create provisions on the protection of embryos and fetuses in vivo and on embryonic and fetal cells and tissues. General Information; Draft Protocol on the Protection of the Human Embryo and Fetus, *at* http://www.legal.coe.int/ bioethics/gb/html/txt_p_info2.htm.

addressing human cloning, begin to provide a fairly comprehensive legislative regime for biomedical research.

The Charter of Fundamental Rights of the European Union[205] expressly prohibits reproductive cloning but does not directly address human embryo research.[206] The European Parliament, however, has stated its opposition to the creation of supernumerary embryos and therapeutic cloning,[207] while the European Group on Ethics in Science and New Technologies to the European Commission implemented Opinion 15, which calls for each country to forbid or permit embryonic research.[208] The Group does consider the creation of embryos with donated gametes as a source of stem cells as ethically unacceptable,[209] and it perceives the creation of embryos by cell nuclear replacement as premature.[210]

Several other nations and international organizations have also enacted laws or issued policy statements regarding stem cell research and human cloning.[211] In addition, the Denver Summit of Eight, the Council of Europe, the World Health Organization, UNESCO's International Bioethics Committee, the European Commission, and the Human Genome Organization have called for a worldwide ban on the cloning of human beings.[212]

V. CONCLUSION

Stem cell research is a complex and challenging field. It is evolving so rapidly that both international and national legislators are having difficulty keeping up with its progress. The laws in place in the United Kingdom provide a solid foundation that has proved to be adaptable when situations, such as reproductive cloning, arise. The 1990Act is also a stable vantage point from which new legislation can be developed and places the obtainment of embryonic stem cells under the jurisdiction of one legislative umbrella. There are still gaps, as the reproductive cloning situation illustrates. The United States situation is still in its infancy and is developing from nu-

205. Charter of Fundamental Rights of the European Union, *available at* http://ue.eu.int/df/docs/en/CharteEN.pdf. (Dec. 7, 2000).

206. United Nations Educational, Scientific and Cultural Organization. International Bioethics Committee, The Use of Embryonic Stem Cells in Therapeutic Research, Section 16, *at* http://www.unesco.org/ibc/en/reports/embryonic_ibc_report.pdf (Apr. 17, 2001). (on file with author)

207. The European Parliament set forth this position in September 7, 2000 Resolution. Resolution on Human Cloning, *at* http://www.europarl.eu.int/comparl/tempcom/genetics/links/b5_0710_en.pdf, (Sept. 7, 2000).

208. The Resolution, dated November 14, 2000, addresses the ethical aspects of stem cell research and use and states that "stem cell research based on alternative sources (spare embryos, fetal tissues and adult stem cells) requires a specific Community budget," *available at* http://europa.eu.int/comm/european_group_ ethics/docs/avis15_en.pdf. The Resolution also states that it is the responsibility of each member state to "forbid or authorize embryo research." *Id.* at § 2.4.

209. *Id.*

210. *Id.*

211. Argentina, Australia, Belgium, Canada, China, Denmark, France, Germany, Israel, Japan, Norway, Peru, Slovakia, South Korea, Spain, Sweden, Switzerland, and the United Kingdom already have laws or have announced plans to pass laws prohibiting the cloning of human beings. H.R REP. NO. 107-170, *at* http://www.house.gov/judiciary/legreports.htm (July 27, 2001).

merous directions. It is difficult to determine what direction the United States legislative scheme will take at this point or under what agency regulation of stem cell research will fall. The prohibition of cloning passed by the House of Representatives jumpstarted the legislative process but could not progress past the Senate.

Creating a treaty or a resolution on an international level may prove to be more problematic then beneficial. Stem cell research, with its ties to human cloning, garners very divergent responses worldwide. But it might be possible for the International Bioethics Committee to draft a model resolution similar to the one addressing the human genome to at least aid countries in developing legislation that adheres to an international standard but still respects different ethical beliefs.

Stem cells and cloning are an exciting scientific and legal frontier with much promise. The legislative developments in both the United States and the United Kingdom illustrate different approaches to a common issue and how such legislative developments will shape and ultimately determine the direction of stem cell research, not only in the United States and the United Kingdom, but worldwide.

212. *Id.*

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