Stem Cell Research: A Science and Policy Overview

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C O N N E X I O N S

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Chapter 1

An Introduction to Stem Cells

1.1 An Overview of Stem Cells[1]

1.1.1 Overview

Stem cells are cells that have the potential to replicate themselves for indefinite periods and to divide, producing one copy of themselves and one cell of a different type (**differentiation**). In humans, stem cells have been located in: the early stages of development after egg fertilization (around 5-6 days); the umbilical cord and placenta; and in several adult organs.

Regardless of their source all stem cells have two general properties:

- *Stem cells are capable of dividing and renewing themselves for long periods.* Unlike muscle cells, blood cells, or nerve cells – which do not replicate themselves – stem cells can divide continuously and keep their innate properties.
- *Stem cells are undifferentiated and can give rise to multiple cell-types.* Stem cells do not have any tissue-specific structures that allow them to perform specialized functions. They cannot carry molecules of oxygen through the bloodstream like red blood cells or release signals to other cells, such as permitting the body to move or speak, as nerve cells do. Although stem cells do not have any tissue-specific structures, they can give rise to differentiated cells, including red blood cells and nerve cells.

Stem cells have varying abilities to differentiate into different cell-types (see Figure 1). One type of stem cell can give rise to any other cell-type of a given organism (for example, an embryonic stem cell). Other stem cells can only give rise to cells of a given tissue type (for example, bone marrow can produce blood stem cells) or only give rise to a few cell-types in a given tissue.

Scientists are just beginning to understand the **signals** in a body which can trigger cell differentiation. These signals can be created within a cell, triggered by a cell's genes, or by a neighboring cell that releases chemicals to promote differentiation in other cells. Determining what these signals are and what stem cells require to differentiate into different cell-types is a crucial research area which must be explored in order to utilize stem cells for therapies.

When cells differentiate, their abilities become more restricted. They often follow only a few prescribed pathways and can lose the capacity to replicate themselves. The ability of stem cells to replicate and remain unspecialized until they are needed is an important area of research vital to understanding human development.

Stem cells offer a new look at old problems and diseases such as burns and diabetes. Although the field is relatively new, the impact of new discoveries could profoundly change medical research and therapy. Many of these new approaches involve the use of **somatic cell nuclear transfer** (sometimes known as **therapeutic cloning**) to produce recipient-specific tissue by creating embryonic stem cell lines.

[1] This content is available online at <http://cnx.org/content/m14829/1.1/>.

This new area of research has great potential, but it is not without its controversies. Many ethical dilemmas are produced with the creation and destruction of human blastocysts as well as the potential to clone an entire human being (**reproductive cloning**). No matter where society designates the boundary to be for this research, or whether or not stem cells can live up to our high expectations, a great deal can be learned through careful and thoughtful studies.

The Potential Uses of Embryonic Stem Cells

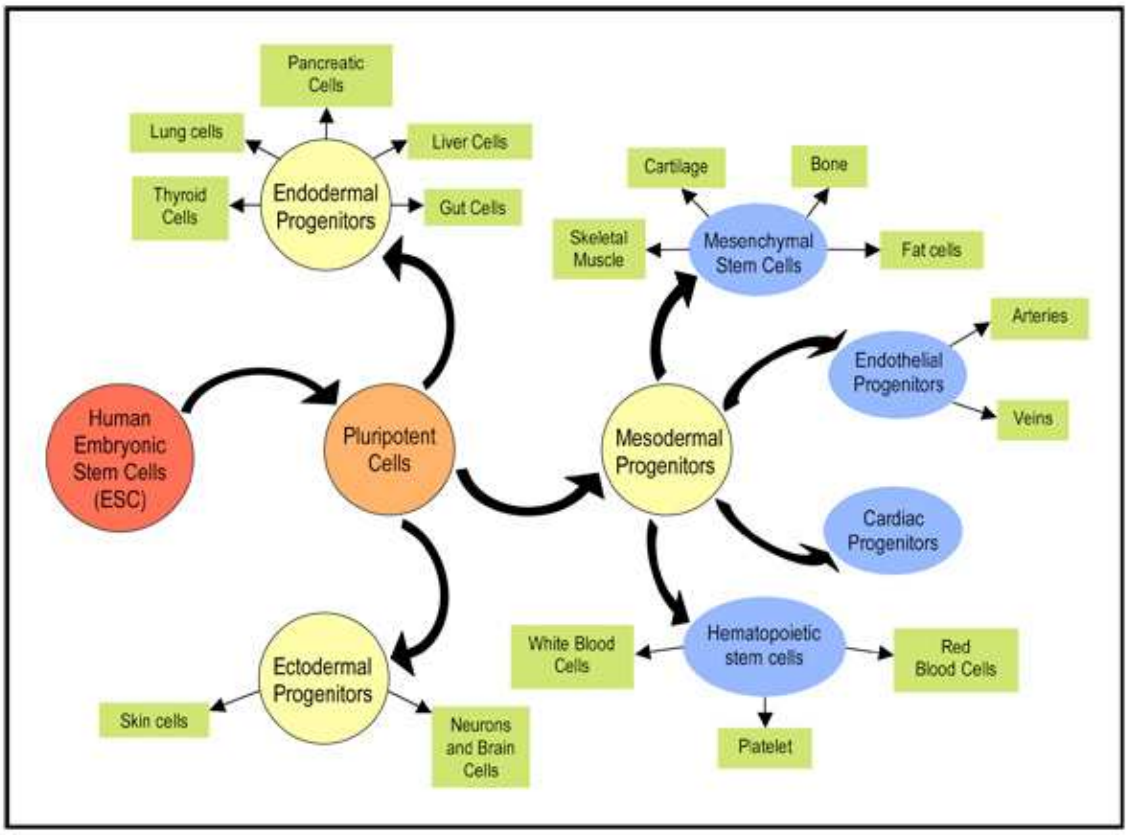

Figure 1.1

1.1.1.1 Embryonic Stem Cells

Embryonic stem cells are derived exclusively from a fertilized egg that has been grown ***in vitro*** for 5 to 6 days to form a **blastocyst**. Within a blastocyst there is a small group of about 30 cells called the **inner cell mass**, which will give rise to the hundreds of highly specialized cells needed to make up an adult organism. Embryonic stem cells are obtained from this inner cell mass. For research purposes, embryonic stem cells are produced specifically from eggs that have been fertilized in vitro, or in a laboratory and not inside a woman's body, or ***in vivo***. Embryonic stem cells can come from a frozen fertilized egg or an egg which is fertilized in vitro.

Embryonic stem cells can and do differentiate into all the specialized cells in the adult body. They could be induced to provide an unlimited source of specific and clinically important adult cells such as bone, muscle, liver or blood cells (See Figure 2).

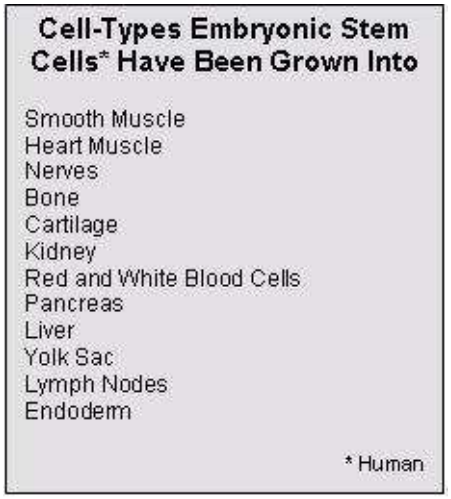

Figure 1.2

1.1.1.2 Adult Stem Cells

Adult stem cells are unspecialized or undifferentiated cells found among specialized cells in an adult tissue or organ. In some adult tissues, such as in bone marrow, muscle, or brain tissue, discrete populations of adult stem cells generate replacements for cells that are lost through disease, injury, or normal wear and tear. Adult stem cells are thought to reside in an area of each tissue where they may remain **quiescent**, or non-dividing, for many years until they are activated by disease or tissue injury. Where they are found, adult stem cells consist of a very small population of cells within each tissue.

Some adult stem cells retain the ability to form into specialized tissues other than the one from which they originated. For example, blood (**hematopoietic**) cells have not been proven to differentiate into nerve, skeletal muscle, cardiac muscle, or liver cells (see Figure 3). There is some evidence that brain stem cells can differentiate into blood or skeletal muscle cells. However, adult stem cells have a limited number of tissues they can differentiate into and do not have the same potential as embryonic stem cells to become any cell-type.

The environment that adult stem cells grow in has an important, but poorly understood, effect on their fate. The relationship between the adult stem cell environment and its ability to differentiate into other cell-types has also not been fully explained.

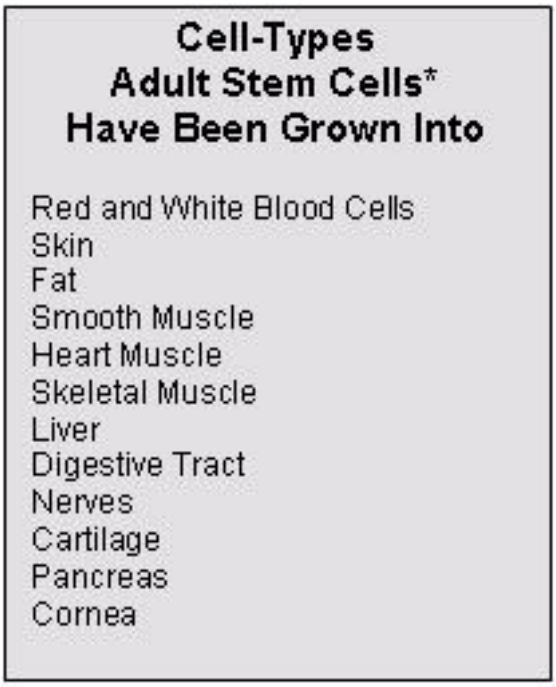

Figure 1.3

1.1.1.3 Distinctions between Embryonic and Adult Stem Cells

Most importantly, adult and embryonic stem cells differ in the type of differentiated cells they can become. While embryonic stem cells can be induced to differentiate into any cell-type, adult stem cells cannot. Most adult cells can only differentiate into the types of cells found in their environment or in the particular tissue or organ where they reside. Therefore in many vital organs, adults do not have the stem cells necessary to regenerate damaged areas; thus scar tissue will develop instead.

Another key difference between embryonic and adult stem cells is the volume of cells one can isolate and grow *in vitro*. Large numbers of embryonic stem cells can be grown *in vitro* from a single blastocyst. On the contrary, adult stem cells are rare and methods of growing them still need to be perfected. In addition, due to their limited numbers, it is difficult to isolate a group of adult stem cells in pure form, without having them contaminated with differentiated cells.

1.1.2 Potential Uses of Stem Cells

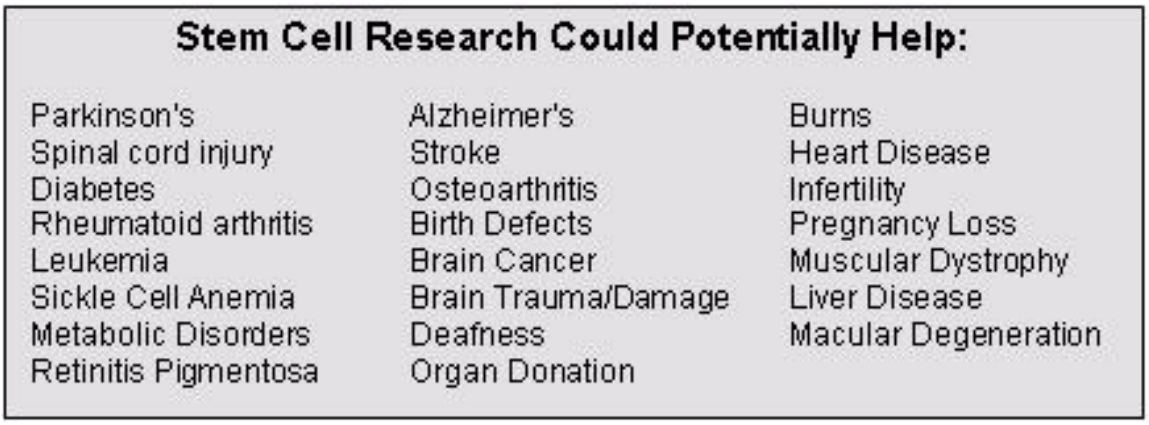

Figure 1.4

1.1.2.1 Stem Cells

While stem cell research is in its infancy and many of its proposed uses are hypothetical, the research has generated excitement among many scientists for its potential. One of the vital components of ongoing work is understanding the very nature of these cells; that is, to determine the conditions necessary to maintain undifferentiated stem cells as well as differentiating them along specific pathways. In order to truly determine whether or not these cells can be used therapeutically, more research must be conducted to understand the nature of the cells.

Although we are only beginning to discover what stem cells are capable of doing, scientists have proposed several potential uses.

1. **Abnormal Cell Division**. Many serious medical conditions, such as cancer and birth defects, are due to abnormal cell divisions or the inability of cells to turn themselves on and off properly. Having a better understanding of stem cells and their genetic and molecular controls would yield information about diseases and reveal potential strategies for therapies.
2. **Drug Testing.** Stem cells could be used to test new drugs or medications by differentiating them to the particular cell-types that the drugs are targeting. This would offer a short-cut for scientists to sort out chemicals that can be used to treat diseases. By testing new drugs on stem cell lines, we could perform rapid screening of hundreds of thousands of chemicals that now are tested by more time-consuming processes. This could also potentially decrease the time that it takes to get a drug to market.
3. **Cell-Based Therapies**. Stem cells could be used for **cell-based therapies**. Stem cells could be directed to differentiate to a specific cell-type that then could be used as a renewable source of replacement cells and tissues. In order to be useful for cell-based therapies, stem cells must be made to:

- *Differentiate into desired cell-types.* It is necessary for stem cell techniques to be improved until they can consistently and efficiently differentiate into a specific cell or type of cells without contamination by undifferentiated or improperly differentiated cells.

- *Proliferate extensively and generate sufficient quantities of tissue.* The protocols for differentiating stem cells need to be refined so that large quantities of tissue can be produced in a relatively efficient manner.

- *Survive in the recipient after the transplant.* Scientists must determine that the cells are healthy and viable after transplantation. They also should establish that the stem cells are localized to the correct tissue in the recipient.

- *Function appropriately for the duration of the recipient's life.* Not only do the cells need to be localized and survive, but they must also behave like the original cells. Currently, there is not sufficient data showing that stem cells are functional in their new environment when they are transplanted into organs. For cell-based therapies to be successful, the new cells need to function correctly and interact properly with the original tissue.

- *Avoid harming the patient in any way.* One concern about using undifferentiated cells or stem cells is the risk of the stem cells having genetic abnormalities which could cause them to be cancerous or to be rejected due to tissue immune incompatibility. Adequate testing is necessary to make sure the cells used are healthy.

1.1.2.2 Embryonic Stem Cells

One of the most promising uses for embryonic stem cells is the study of the complex events that occur during human development. The earliest stages of human development have previously been difficult or impossible to study. By using embryonic stem cells, these studies can be performed with the goal of preventing or treating birth defects, infertility, and pregnancy loss.

The use of embryonic stem cells can also help scientists identify how undifferentiated cells become differentiated. Since these cells have the ability to become any type of cell in the adult body, they have a larger potential for medically viable tissues which can be derived and used in cell-based therapies.

1.1.3 References and Further Suggested Readings

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2. NIH, Stem Cell Basics: http://stemcells.nih.gov/info/basics/[3]
3. National Research Council and Institute of Medicine. (2002) Stem Cells and the Future of Regenerative Medicine. Washington D.C.: National Academy Press: http://www.nap.edu[4] .
4. Embryonic Stem Cell Research at the University of Wisconsin-Madison: http://www.news.wisc.edu/packages/stemcells/facts.html#1[5]
5. National Parkinson Foundation: http://www.parkinson.org[6] .
6. Juvenile Diabetes Research Foundation: http://www.jdrf.org[7] .
7. Wilmut, I., et. al. (1997) Viable Offspring Derived from Fetal and Adult Mammalian Cells. Nature 385:810-13.

To contact us, please visit our contact page (Chapter 5).

[2] http://www.isscr.org/
[3] http://stemcells.nih.gov/info/basics/
[4] http://www.nap.edu/
[5] http://www.news.wisc.edu/packages/stemcells/facts.html#1
[6] http://www.parkinson.org/
[7] http://www.jdrf.org/

1.2 Cloning[8]

1.2.1 Cloning

Somatic cell nuclear transfer (SCNT) is when the genetic material (**nucleus**) of an unfertilized egg is removed and replaced with the genetic material of a normal cell. The egg is then activated and allowed to grow. After it is allowed to grow into a **blastocyst**, **embryonic stem cells** are obtained from the **inner cell mass**. These embryonic stem cells can then be induced to become other differentiated cell-types. (See Figure 1)

Much of the promise for embryonic stem cells lies in the potential of **deriving** or creating cell lines which are specific to a person. This technique can be used to create cell lines and study the development of different diseases (sometimes called **therapeutic cloning**). For instance, by using a skin cell from a patient suffering with Parkinson's disease one could create a cell line that would show the researcher how the cell progressed from a normal to a diseased state. Not only could scientists study specific genetic diseases, but they could also create tissues that are compatible with the original donor.

Further, this technique can also be used to create tissues that are recipient-specific. In organ and tissue transplantation, a great concern is the rejection of transplanted tissue by the recipients' immune system. If new cell lines were created to be identical to the recipient, this would no longer be a problem.

[8]This content is available online at <http://cnx.org/content/m14833/1.1/>.

Somatic Nuclear Cell Transfer

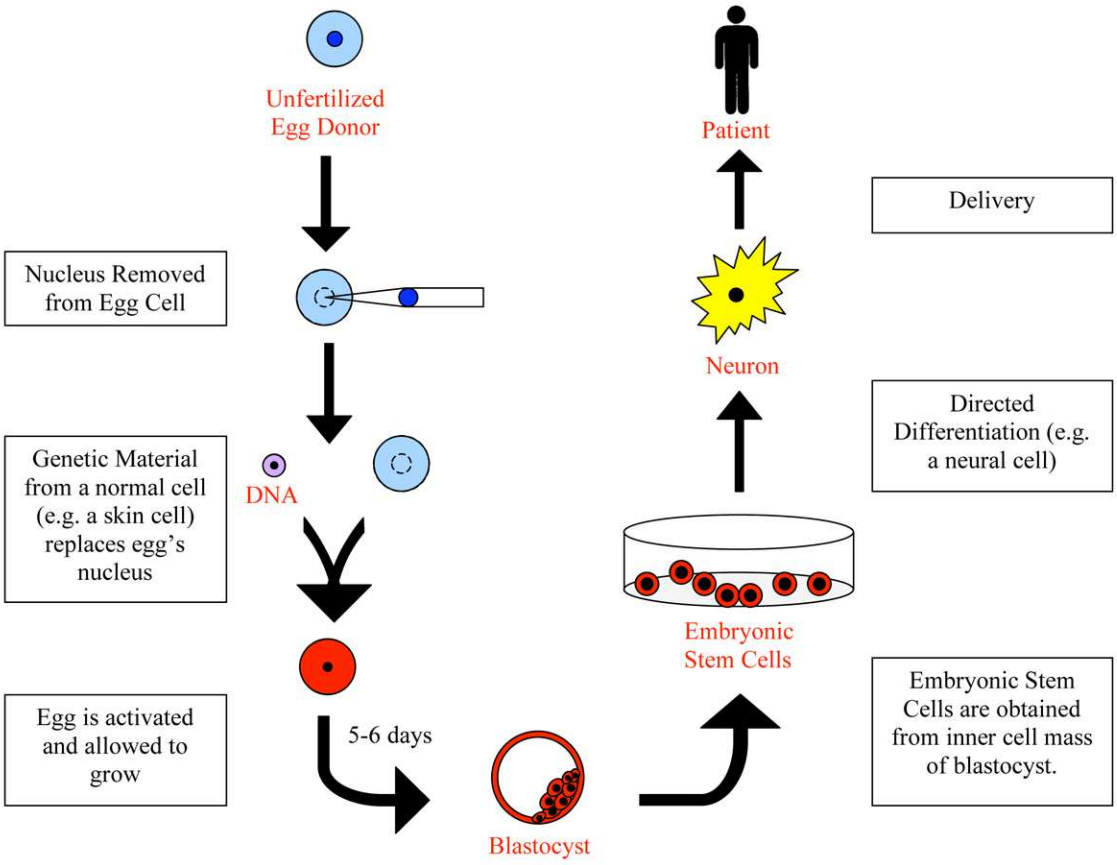

Figure 1.5

Reproductive Cloning is when an egg undergoes somatic cell nuclear transfer and the resulting cell is allowed to grow to an infant that is an exact genetic copy of the somatic cell donor. Attempts at reproductive cloning have been error-prone and inefficient, resulting in the failure of most clones to develop. The most famous clone, Dolly (a sheep), was only created after multiple attempts and failures and then lived a shortened life (Wilmut et al, 1997).

Another option for creating stem cells without using egg cells has been discovered in mice. When four specific genes are added to a normal cell (such as a skin cell) the cell become deprogrammed, and regains its ability to be differentiated into many different types of tissue and to divide indefinitely. This innovative procedure has problematic aspects though; one of the necessary genes contributes to cancer in some of the mice studied, and genes are introduced into the skin cells by way of a retrovirus, which may also cause adverse effects in any tissue cultures grown using this method. However, if this procedure were ever adapted to human cells, the issue of immune rejection of grafted tissue would be eliminated, as the stem cells are genetically identical to the donor cells.

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1.3 Case Study: Junvenile Diabetes and Stem Cell Research[9]

1.3.1 Case Study: Juvenile Diabetes and Stem Cell Research

Juvenile diabetes, also known as type 1 diabetes, is essentially an **autoimmune disease** where one's own body starts attacking itself. In juvenile diabetes the body specifically destroys a pancreas cell, the **ß-cell**, which produces **insulin**. Insulin is an important hormone that balances blood sugar levels. Unregulated sugar levels in the blood can lead to severe problems such as kidney failure, blindness, stroke, and even death. Patients with juvenile diabetes are required to take multiple injections of insulin daily or have a continuous infusion of insulin through a pump just to survive. Also, they must constantly monitor their food intake and daily activities.

Scientists have been working for years to find a cure and are extremely optimistic about the potential use of stem cells to replace destroyed ß-cells. In a recently published study using mice, Harvard researchers determined that new ß-cells in the pancreas are formed through the replication of pre-existing ß-cells, rather than **adult stem cells** creating new ß-cells. These are the very cells being attacked and therefore their numbers are limited. This result means that in order to cure juvenile diabetes, scientists must rely on another source of ß-cells, such as **embryonic stem cells**, to generate new ß-cells.

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[9] This content is available online at <http://cnx.org/content/m14831/1.1/>.

Chapter 2

American Stem Cell Research Policy

2.1 American Stem Cell Research: Politics and Policies[1]

2.1.1 Overview

In February of 1997, Dr. Ian Wilmut announced the creation of the first cloned mammal. The report, published in the science journal *Nature*, described a lamb, "Dolly," which was cloned using **somatic cell nuclear transfer (SCNT)**. This landmark paper and the media attention it received created an immediate reaction from the public and politicians in Washington, D.C. who were concerned about the potential cloning of humans using this technique. Since Dolly's creation, congressional leaders have been trying to find a way to prevent human cloning and other allegedly unethical medical procedures while still allowing medical research to proceed unhindered.

In late 1998, the issue was further complicated by the announcement from researchers at the University of Wisconsin-Madison, led by Dr. James Thomson, who **derived** the first human **embryonic stem cells** from **blastocysts**. This marked the beginning of a new area of medical science, human embryonic stem cell research. With this new breakthrough, the issue of human cloning became considerably more complex, since SCNT was now linked to potential disease-curing research.

With each congressional session, a new crop of conflicting bills arises from both the House and the Senate, and congressional hearings are called to bring witnesses in to validate either side, but no resolution appears to be in sight. Although many polls have shown that the vast majority of Americans disapprove of research which could produce a cloned human (79% in a 2005 poll by Research!America), there is still much public debate about the ethics of embryonic stem cell research. This debate resonates in the Congress and generates the current stalemate where lawmakers are unable to reach a consensus about medical research relating to embryonic stem cells.

2.1.2 Pre-"Dolly" Regulation

In the 1970s, rules were developed to govern the federal funding of research on human embryos for **in vitro fertilization (IVF)**. The rules specified that all federally funded research on human **embryos** would need to be approved by a congressionally appointed ethics advisory board. Although the board met once, it was dissolved in 1980 without ever federally funding embryonic research. In 1993, this rule was rescinded, but the Dickey Amendment, a **Department of Health and Human Services (DHHS)** 1996 appropriation rider, subsequently banned any federal funding of human embryo research and each year this amendment has been attached to the appropriation bill for the DHHS. Since that time, no federal funds have been allowed for embryo (and therefore embryonic stem cell) research, but private funding of research on embryos has been allowed and is completely unregulated.

[1] This content is available online at <http://cnx.org/content/m14828/1.1/>.

2.1.3 Post-"Dolly" Debate

In February of 1997 after the public announcement about "Dolly", President Clinton charged the **National Bioethics Advisory Council (NBAC)** to study the issue of human cloning. In June of that year, NBAC released a report which determined that **reproductive cloning** was immoral and requested that a moratorium should be established until subsequent laws prohibiting it were passed (with a sunset period of 3-5 years). The members also suggested that the law be written so it would not interfere with biomedical research. Taking their suggestions, President Clinton offered a legislative proposal to bar anyone (either federally or privately funded) from attempting to clone a human through SCNT for 5 years. President Clinton's proposal was announced after several bills in the House and Senate had already been introduced (see Table 1). However, due to the fear that Congress was acting too quickly and might bar valid research, the majority needed to pass these bills was never attained and thus no legislation limiting such cloning was ever successfully passed into law.

Table I-Bills From 106th Congress

Bill	Sponsor	Action
S. 368	Sen, Bond (R-MO)	The government would be permanently banned against using federal funds for cloning an individual.
H.R. 922	Rep. Ehlers (R-MI)	*Human Cloning Research Prohibition Act.*
		The government would be permanently banned against using federal funds for cloning an individual.
H. Doc 105-97	Pres. Clinton	*The Cloning Prohibition Act of 1997.*
		It would bar everyone in the country, both private and publicly funded, from attempting to create a baby through SCNT. The act would only last five years. It would fine anyone who violated the act $250,000.
S. 1574	Sen. Campbell (R-WY)	*Human Cloning Prohibition Act.*
		The bill would bar federal funding of research designed to clone a human or create a human embryo. It would fine violators $5000.
S. 368	Sen, Bond (R-MO)	*Human Cloning Prohibition Act.*
		The government would be permanently banned against using federal funds for cloning an individual. It would make the creation of a human embryo through SCNT a criminal act with a 10 year prison sentence. It would also prohibit importing human embryos which were created by SCNT and create a National Commission to promote a national dialogue on bioethics.
S. 1602	Sen. Feinstein (D-CA)	*Prohibition of Cloning Human Beings Act of 1998.*
	Sen. Kennedy (D-MA)	The bill would forbid the creating of a human by SCNT and bar federal funding for 10 years. Violators would be fined $1 million.

Figure 2.1

In November of 1998, after Dr. Thomson announced the creation of the first human embryonic stem cell line, President Clinton asked NBAC to specifically address human embryonic stem cell research, which had not been discussed in 1997. In 1999, the NBAC recommended that federal funding should be used to support both the research and creation of human embryonic stem cells. They also suggested amending the ban on embryo research (the Dickey Amendment) to allow the derivation and use of embryonic stem cells.

However, before the results of the NBAC deliberations were announced, the **National Institutes of Health (NIH)**, specifically the legal council for the DHHS, determined that federal law (the Dickey Amendment) prohibited the use of federal funds to create human embryonic stem cell lines, but they did believe that it was legal to fund research on already existing lines. Private sources were never barred from deriving their own human embryonic stem cell lines and were actively pursuing this area of research. The NIH released guidelines for the federal funding of human embryonic stem cell research for public comment in 1999, followed

by an updated version in 2000 in the **Federal Register**. Before NIH was able to grant money in response to research proposals, a new administration (President George W. Bush) took office and the previous rulings by the DHHS and NIH were set aside.

Meanwhile in the Senate, the Specter-Harkin bill (S.2015) was introduced as the **Stem Cell Research Act of 2000**. It called for the federal funding of the derivation and use of human embryonic stem cells from spare donated embryos (IVF), as long as the research did not lead to "reproductive cloning of a human being." This marked the first of many bi-partisan bills that Congress would see on this issue. The Specter-Harkin bill, like many future bills, was not passed into law.

When President Bush took office, one of his first actions was to temporarily stop all federal funding of human embryonic stem cell research (no grant had been given) while his administration considered their actions. On August 9, 2001, after several months of deliberation, President Bush announced that he would allow the federal funding of the research of human embryonic stem cells, but only those that had been derived before the date of the announcement could be used. Thus, no new embryonic stem cells could be created with federal funds, nor could federal funds be used to do research on new lines create after the August 9, 2001 deadline. NIH estimated at the time that there were as many as 60-75 cell lines available for research. However, since that time, NIH has revised its numbers downward. By the 2004 presidential campaign, NIH had only 22 lines available (see insert "Effect of President Bush's Stem Cell Policy").

Since the President's August 9, 2001 decision, embryonic stem cell policy has remained unchanged. In November 2001, President Bush established the **President's Council on Bioethics (PCB)**, a group of experts (similar the NBAC), to address the issues of human cloning, embryonic stem cell research and other bioethical issues. In Congress, new bills were introduced in the 107th and 108th congress, and the Weldon-Stupak bill was passed in House in 2001 and 2003 to ban all forms of cloning and the use of SCNT, but neither passed in the Senate. Almost every year we see each political side introduce their version of a law which would outlaw all human cloning or only reproductive cloning and either outlaw or permit the use of embryonic stem cells, but nothing has been signed into law.

Perhaps the most interesting part of the congressional debate is the fact that views on the topic do not necessarily follow traditional party lines or a person's opinion on abortion or right to life. This new debate has produced the most unlikely bipartisan partnerships and has resulted in a deadlock in Congress, which has sharply constrained federally funded research on embryonic stem cells and human cloning. At the same time, the deadlock has virtually left the privately funded research involving embryonic stem cells and human cloning completely unregulated.

Momentum for expanding federal funding for embryonic stem cell research began to build again as the 2004 presidential campaigns kicked into gear. In April of 2004, 206 members of the House of Representatives (out of 435) signed a letter to President Bush urging him to expand the current federal policy on embryonic stem cell research to include new lines developed after August 9, 2001. Following the House's lead, the Senators that advocated embryonic stem cell research also wrote a letter to President Bush with 58 signatures (out of 100). On May 10, 2004 former First Lady Nancy Reagan publicly supported embryonic stem cell research at a fundraiser for juvenile diabetes. Although privately she had supported the research with personal letters to congressmen, this was her first public statement on the topic. Nancy Reagan and the Reagan family are often thought of as icons for the Republican Party and conservative ideals. This public acceptance led the way for other Republicans to support the issue. One month later, President Reagan, a victim of Alzheimers, passed away. Stem cell research was immediately brought into the forefront as a campaign issue for the 2004 election. Senator Kerry supported the expansion of the research, while the President Bush explained his current policy and promised to maintain the status quo.

With the return of President Bush to office in 2005, the possibility for changing the current federal policy seems unlikely. However, in May 2005, the U.S. House of Representatives passed the **Stem Cell Research Enhancement Act,** perhaps the most significant legislative advance in the support of stem cell research (see Table II). Its passage was the result of an initiative from the leaders in both parties. The bill amends the Public Health Service Act to provide for stem cell research by stating that cells donated from excess supplies from IVF clinics are viable for use. It stipulates that these donations are to be made from embryos determined never to be implanted in a woman and under informed consent without any financial

inducements. The bill goes on to say that reports of research carried out under these guidelines should be presented each fiscal year. The Stem Cell Research Enhancement Act needed to be passed by the U.S. Senate, and although the Senate Majority Leader, Senator Bill Frist (R-TN) promised to bring it forward in 2005, the vote did not occur until July 2006. As he promised in May 2005, President Bush vetoed the bill on July 19, 2006 (the first use of the Presidential veto by Bush) and Congress was unable to override it.

Table II-Bills from 109th Congress

Bill	Sponsor	Action
H.R. 810	Rep Castle (R-DE)	*Stem Cell Research Enhancement Act.*
	Rep DeGette (D-CO)	This bill authorizes federal funding of research on human embryonic stem cells regardless of the date they were derived. All embryos must be from donates excess from IVF clinics.
		Passed in the House in May 2005.
S. 471	Sen. Specter (R-PA)	*Stem Cell Research Enhancement Act.*
	Sen. Hatch (R-UT)	Companion bill to H.R. 810.
	Sen. Feinstein (D-CA)	Passed in the Senate July 2006.
	Sen. Kennedy (D-MA)	
	Sen. Harkin (D-IA)	

Figure 2.2

With or without the expansion of federal funding, some states (such as California, Massachusetts, and New Jersey) are beginning to pick up the reins by passing their own laws related to embryonic stem cell research (see page 15 "State Cloning Legislation"). In November 2004, Californians (with 59% of the vote) approved Proposition 71, or the **California Stem Cell Research and Cures Initiative**, which called for the creation of a California Institute for Regenerative Medicine (CIRM) and authorized $3 billion of state funds to support the effort over the next five years. The proposal also established the right to conduct embryonic stem cell research in California, but prohibits reproductive cloning. President Bush's policy only limits federal funding, but does not make the research itself illegal therefore the states are able to determine how they wish to regulate and fund research using state funds. CIRM supports embryonic stem cell (and adult stem cell) research regardless of the date the cells were generated, to create new cell lines, and to use SCNT to create cell lines with specific genes. This new institute is expected to attract stem cell researchers and investors to California allowing it to corner the market on any promising findings.

Despite the passage of Proposition 71, several obstacles have delayed its implementation in California. A lawsuit by taxpayer groups contended that CIRM could not sell bonds backed by taxpayer money to fund research, because it is not under direct state control. Bond sales that would be used to fund the institute are on hold until the lawsuit is settled. In April 2006, the court ruled in favor of CIRM, but the case is still in appeals. Furthermore, CIRM needed time to determine the rules for awarding grants, conducting research, and handling patent rights before it started funding grants. However, in April 2006 CIRM was still able to award their first round of grants, which totaled $12.1 million, and in July 2006 California Governor Arnold Schwarzenegger agreed to give the institute a $150 million loan to help while litigation was pending.

2.1.4 Summary

The debates on stem cell research essentially started in 1997, after the first mammal, "Dolly," was cloned. Through the past decade, the United States government has not been able to agree on the best policy. The Bush Administration put into place a policy that allows some research to proceed, but at the same time it fails to address the research that is taking place with private and other non-federal funds. Recently, Congress finally settled their stalemate and passed legislation to increase the number of cell lines derived from leftover IVF eggs. Unfortunately, this was vetoed, leaving the question of regulation of this research unresolved. Whether we should fund embryonic stem cell research and **therapeutic cloning** and how to regulate the current research done with private funds are questions U.S. lawmakers still need to address.

Example 2.1: Effects of President Bush's Stem Cell Policy
In an effort to appease the advocates for embryonic stem cell research, but still stay true to his conservative base, President Bush allowed federal funding of research on human embryonic stem cells derived on or before August 9, 2001. At the time of the announcement, the NIH believed that there were 60-75 lines which met the qualification for federal funding. Since the announcement, scientists have found several problems with the cell lines which were approved:

1. Currently there are only 22 lines available for distribution by the NIH (the other lines were unavailable for distribution). Many of the other cell lines were either unavailable to researchers or had contamination problems, chromosomal abnormalities, or were unstable.
2. All the cells had been created using mouse cells; therefore, they cannot be used in humans for fear of spreading mouse viruses in humans. It also has been shown recently that all the lines tested contained mouse proteins on their surface which causes them to be rejected by the immune system in a human. This means the cells are unlikely to ever be used for medical purposes.
3. Older cell lines are more susceptible to chromosomal abnormalities than newer lines. So over time, the current stem cell lines will degrade and are not medically viable.
4. Several of the lines have been difficult to grow, giving them very limited uses.
5. Each approved cell line has the propensity to grow into only one specific cell-type. This decreases the breadth of research opportunities for scientists.
6. The cell lines lack genetic diversity necessary to create therapeutic treatment for a broad number of patients
7. There is an absence of disease-specific cell lines, thereby limiting stem cell research on genetic diseases.

Improvements in how scientists can grow the cells in vitro have made new cell lines created in other countries and from private funding (now numbering over 150 lines) more appealing than the lines approved for federal funding. This discourages scientists from using the cell lines, applying for the federal funds, or even entering the field. Most scientists, especially new faculty and graduate students, rely heavily on public funding during their careers.

This policy also limits the availability of subsequent discoveries to the general public. Since private firms will own any therapies derived from such research and may charge heavily to recoup their investments, they have no incentives to publicly release their data.

2.1.5 Reference and Further Suggested Readings

1. Thomas, Legislative Information on the Internet: http://thomas.loc.gov[2]
2. American Association for the Advancement of Science. (2003) Regulating Human Cloning. Washington D.C.: AAAS: http://www.aaas.org/spp/cstc/briefs/cloning/index.shtml[3]

[2] http://thomas.loc.gov/
[3] http://www.aaas.org/spp/cstc/briefs/cloning/index.shtml

3. California Institute for Regenerative Medicine: http://www.cirm.ca.gov/[4] .
4. National Research Council and Institute of Medicine. (2002) Stem Cells and the Future of Regenerative Medicine. Washington D.C.: National Academy Press: http://www.nap.edu[5] .
5. National Research Council and Institute of Medicine. (2002) Scientific and Medical Aspects of Human Reproductive Cloning. Washington D.C.: National Academy Press: http://www.nap.edu[6] .
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2.2 State Cloning Legislation[9]

2.2.1 State Cloning Laws

NOTE: The information in this section is provided to illustrate the diversity of approaches various states are taking with regard to regulation of human cloning and embryonic stem cell research. The brief summary is based on a review of relevant literature and websites and should be considered preliminary.

2.2.1.1 Overview

While the United States has not passed any federal legislation concerning ESC research and human cloning, individual states have started passing their own laws. Sixteen states have legislation involving human cloning. Arkansas, California, Connecticut, Illinois, Indiana, Iowa, Maryland, Massachusetts, Michigan, New Jersey, North Dakota, Rhode Island, South Dakota, and Virginia have passed legislation to prohibit reproductive cloning. Arkansas, Indiana, Michigan, North Dakota, and South Dakota also prohibit therapeutic cloning (cloning for research). Virginia fails to define "human being," and so it is unclear if therapeutic cloning is banned. Arizona, Indiana, and Michigan specifically prohibit the use of state funds for any human cloning, while Missouri prohibits public funding for reproductive cloning only. California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, New Jersey, and Rhode Island specifically allow therapeutic cloning. California, Connecticut, Illinois, Maryland, and New Jersey have also gone so far as to fund such research using state money.

Twenty-six states have no legislation addressing either cloning or embryonic stem cell research and therefore have no policy on record. However, almost all of these states have pending legislation. Louisiana is the only state that bans research on IVF embryos, but this does not cover therapeutic or reproductive cloning as long as the blastocyst comes from another source such as being created from a sperm or unfertilized egg cell. Thus cloning is not explicitly restricted in Louisiana.

[4] http://www.cirm.ca.gov/
[5] http://www.nap.edu/
[6] http://www.nap.edu/
[7] http://www.nap.edu/
[8] http://www.bioethics.gov/reports/stemcell/index.html
[9] This content is available online at <http://cnx.org/content/m14835/1.1/>.

2.2.1.1.1 States with Bans on Research Destroying Embryos

Louisiana, Michigan, Minnesota, North Dakota, South Dakota, and Pennsylvania.

2.2.1.1.2 States with Bans on Reproductive and Therapeutic Cloning (SCNT)

Arkansas, Indiana, Michigan, North Dakota, South Dakota, and Virginia (because 'human being' was left undefined in the legislation)

2.2.1.1.3 States with Bans Only Reproductive Cloning

California, Connecticut, Illinois, Iowa, Maryland, Massachusetts, New Jersey, and Rhode Island.

2.2.1.1.4 States with Bans on Public Funds

For Embryonic Stem Cell Research: Nebraska (using money from the tobacco settlement fund only)
For Cloning: Arizona, Indiana, and Michigan
For Reproductive Cloning: Missouri

2.2.1.1.5 States Funding Embryonic Stem Cell Research

California (California Institute for Regenerative Medicine), Connecticut (Connecticut Stem Cell Research Grants Program), Illinois (Illinois Regenerative Medicine Institute), Maryland (Maryland Stem Cell Research Fund), Massachusetts (Life Sciences Investment Fund), New Jersey (The Stem Cell Institute of New Jersey and the New Jersey Stem Cell Research Grants Program), Wisconsin (Stem Cell Products, Inc)

2.2.1.1.6 States with Restrictions Effecting Embryonic Stem Cell Research, but no Legislation on Cloning

Nebraska, New Hampshire, Minnesota, Ohio, Oklahoma, and Pennsylvania.

2.2.1.1.7 States with no Legislation on either Cloning or Embryonic Stem Cell Research

Alabama, Alaska, Colorado, Delaware, Florida, Georgia, Hawaii, Idaho, Kansas, Kentucky, Maine, Mississippi, Montana, Nevada, New Mexico, New York, North Carolina, Oregon, South Carolina, Tennessee, Texas, Utah, Vermont, Washington, West Virginia, and Wyoming

2.2.2 References and Further Suggested Readings

1. National Conference of State Legislatures: http://www.ncsl.org/programs/health/genetics/rt-shcl.htm[10] , http://www.ncsl.org/programs/health/genetics/embfet.htm[11] and http://www.ncsl.org/programs/health/genetics/geneticsDB.cfm[12]
2. California Institute for Regenerative Medicine: http://www.cirm.ca.gov/[13]
3. Connecticut Legislature: www.cga.ct.gov/2005/BA/2005SB-00934-R01-BA.htm[14] .
4. Maryland Legislature: http://mlis.state.md.us/2006rs/bills/sb/sb0144t.pdf[15] .
5. Illinois Governor's Office: www.illinois.gov/gov/execorder.cfm?eorder=39[16] .
6. State of New Jersey: www.state.nj.us/scitech/stemcell/[17] .

[10] http://www.ncsl.org/programs/health/genetics/rt-shcl.htm
[11] http://www.ncsl.org/programs/health/genetics/embfet.htm
[12] http://www.ncsl.org/programs/health/genetics/geneticsDB.cfm
[13] http://www.cirm.ca.gov/
[14] http://www.cga.ct.gov/2005/BA/2005SB-00934-R01-BA.htm
[15] http://mlis.state.md.us/2006rs/bills/sb/sb0144t.pdf
[16] http://www.illinois.gov/gov/execorder.cfm?eorder=39
[17] http://www.state.nj.us/scitech/stemcell/

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Chapter 3

World Stem Cell Policies

3.1 Overview of World Human Cloning Policies[1]

3.1.1 Overview

NOTE: The information in this section is provided to illustrate the diversity of approaches various different parts of the world are taking with regard to regulation of human cloning and embryonic stem cell research. The brief summary is based on a review of relevant literature and websites and should be considered preliminary.

World policies on human or **reproductive cloning** range from complete prohibition to no policies on record. Over 30 countries, including France, Germany, and the Russian Federation, have banned human cloning altogether. Fifteen countries, such as Japan, the United Kingdom, and Israel, have banned human reproductive cloning, but permit **therapeutic cloning**. A few countries such as Hungary and Poland do not explicitly prohibit embryonic stem cell research or therapeutic cloning, partially because their legislation was drafted before embryonic stem cells were first produced (1998). Many other countries, similar to the United States, have yet to pass any official legislation concerning human cloning allowing all types of stem cell and cloning research to occur.

In addition to countries developing their own policies, several international organizations, including the United Nations, the Council of Europe, and the European Union, have published human cloning policies and recommendations, which are described below. Several other organizations including the African Union and the Arab Leagues have discussed the issue, but have yet to release a formal declaration. Furthermore, the International Society for Stem Cell Research (ISSCR) and a group led by Johns Hopkins Phoebe R. Berman Bioethics Institute, known as the Hinxton Group, are working to outline principles for human embryonic stem cell international collaboration and cooperation.

[1] This content is available online at <http://cnx.org/content/m14834/1.1/>.

World Cloning Legislature

	ESC*	Ther.	Ban**			ESC	Ther.	Ban**
Argentina	×		×		Latvia	×		×
Australia	×		×		Lithuania			×
Austria			×		Netherlands	×		×
Belgium	×	×			New Zealand	×	×	
Brazil	×		×		Norway			×
Canada	×		×		Panama	×		×
Chile	×		×		Peru	×		×
China	×	×			Poland			×
Columbia	×	×			Portugal	×		×
Costa Rica			×		Russian Federation	×		×
Czech Republic	×		×		Singapore	×	×	
Denmark	×		×		Slovakia			×
Ecuador			×		Slovenia	×		×
Egypt	×		×		South Africa	×		×
Estonia	×		×		South Korea	×	×	
Finland	×	×			Spain	×		×
France	×		×		Sweden	×	×	
Georgia	×		×		Switzerland	×		×
Germany	×		×		Taiwan	×		×
Greece	×		×		Thailand	×	×	
Hungary	×				Trinidad & Tobago			×
Iceland	×		×		Tunisia	×		×
India	×				Turkey	×	×	
Iran	×				Ukraine	×		
Ireland			×		United Kingdom	×	×	
Israel	×	×			United States	×	×	
Italy			×		Uruguay	×		
Japan	×	×			Vietnam	×		×

Table 3.1

*Some prohibit the derivation of embryonic stem cells, but do not specifically prohibit the research using existing lines.

**Ban refers to countries which banned human cloning (both reproductive and therapeutic).

3.1.1.1 United Nations

On March 8, 2005, the United Nations General Assembly adopted the nonbinding 'Declaration on Human Cloning', by which member states were called on to adopt "all measures necessary to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life." The vote was 84 in favor (including United States, Germany, and Italy), 34 against (including United Kingdom, South Korea, and Brazil), 37 abstaining (including South Africa and Israel) and 35 were absent. This Declaration is arguably weakened by the fact that it was not even passed by a majority of the UN membership.

Many countries, in formal explanations of their votes, expressed disappointment that there was no consensus on the language of the declaration and said that it was regrettable that it did not cover the well-known differences between reproductive cloning and therapeutic cloning (somatic cell nuclear transfer). The original mandate to the Legal Committee was to elaborate on the issue in an international treaty against human reproductive cloning. Instead, text of the declaration blurred the line separating reproductive and therapeutic cloning.

3.1.1.2 Council of Europe

The Council of Europe is an international organization of 46 countries in Europe, which was established in 1949. The Council was set up to defend human rights and democracy, develop continent-wide agreements to standardize social and legal practices and promote European interests. Membership to the Council is open to all European democracies, which accept the principle of the rule of law and guarantee fundamental human rights and freedoms to their citizens.

The Council of Europe has several conventions that can be applied to human embryonic stem cell research and human cloning. The Council's 1997 Convention on Human Rights with Regard to Biomedicine highlights the "need to respect the human being both as an individual and as a member of the human species." The protocol on cloning states that "any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited." While this specifically bans reproductive cloning it does not necessarily ban therapeutic cloning. The Council left the interpretation of 'human being' to national Parliaments, allowing therapeutic cloning where it is accepted. In several European countries without specific stem cell or cloning legislation (Bulgaria, Croatia, Cyrus, Moldova, Romania, and San Marino) this convention is interpreted to mean that they allow human embryonic stem cell cloning, but ban both reproductive and therapeutic cloning.

3.1.1.3 European Union

The European Union is an intergovernmental and supranational union containing 25 member states from Europe. It was established in 1950 by six countries (Belgium, France, Germany, Italy, Luxembourg, and the Netherlands) and dealt with economic and trade issues. It now has an additional 19 member states (Denmark, Ireland, United Kingdom, Greece, Portugal, Spain, Austria, Finland, Sweden, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia) for a total of approximately 450 million people and deals with a wide range of issues including health, the environment, and international peace and stability.

The European Union supports funding embryonic stem cell research (where permitted), but has banned the funding of human cloning. There is no legal ban on therapeutic cloning, but the European Union will not fund research using SCNT to create embryos. It allows for countries to determine within their border what embryonic stem cell research can be funded allowing that it is carefully regulated, peer reviewed, scientifically sound, directed towards sustainable goals, and ethically sound.

3.1.2 References and Further Suggested Readings

1. The Database of Global Policies on Human Cloning and Germ-line Engineering: http://www.glphr.org/genetic/genetic.htm[2]
2. Global Lawyers and Physician for Human Rights: http://www.glphr.org[3]
3. Stem Cell Policy: World Stem Cell Map: www.mbbnet.umn.edu/scmap.html[4]
4. European Commission, Directorate General – Research: Survey on opinions from National Ethics Committees or similar bodies, public debate, and national legislation in relation to human embryonic stem cell research and use. Volume I: EU Member States, July 2004: http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm[5] , Volume II: Countries associated to FP6 and Third Countries, July 2004: http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm[6]
5. UNESCO (United Nations Educational, Scientific, and Cultural Organization). National Legislation Concerning Human Reproductive and Therapeutic Cloning, July 2004: http://unesdoc.unesco.org/images/0013/001342/134277e.pdf[7]
6. The International Stem Cell Forum (May 2007) http://www.stemcellforum.org
7. The Hinxton Group World Policies Website (May 2007): http://hinxtongroup.org/wp.html
8. The Hinxton Group Consensus Statement, March 2006: http://www.hopkinsmedicine.org/bioethics/finalsc.doc[8] .
9. The Phoebe R. Berman Bioethics Institute. (March 2006) International Policy Trends: Embryonic Stem Cell Research.

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3.2 World Cloning Policies[9]

3.2.1 North America

3.2.1.1 United States

- Officially, embryonic stem cell research, therapeutic cloning and reproductive cloning are legal as there is currently no federal regulation or policies overseeing it.
- Reproductive and therapeutic cloning are specifically not federally funded. However, research on human embryonic stem cells is federally funded if these cell lines were created before August 9, 2001. Private industry research is not affected by these policies and is allowed to proceed with the creation of new stem cell lines.
- Some individual states have made their own laws against reproductive and/or therapeutic cloning. (See State Cloning Legislation module)

3.2.1.2 Canada

- Embryonic stem cell research is permitted, but reproductive cloning and therapeutic cloning are banned.

[2] http://www.glphr.org/genetic/genetic.htm
[3] http://www.glphr.org/
[4] http://www.mbbnet.umn.edu/scmap.html
[5] http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm
[6] http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm
[7] http://unesdoc.unesco.org/images/0013/001342/134277e.pdf
[8] http://www.hopkinsmedicine.org/bioethics/finalsc.doc
[9] This content is available online at <http://cnx.org/content/m14836/1.1/>.

- Researchers can use an embryo from IVF if it is no longer needed for reproductive purposes and consent is given by the donor. Creating a human clone is restricted to improving or providing instruction in assisted reproduction procedures.

3.2.1.3 Costa Rica

- Embryonic stem cell research, as well as therapeutic and reproductive cloning, is banned.

- Any manipulation of an embryo's genetic code is prohibited, as well as any experimentation on the embryo (two laws as of 1995 and 1998).

3.2.1.4 Panama

- Embryonic stem cell research is not specifically prohibited, but therapeutic and reproductive cloning and the funding of such activities are as of 2004.

3.2.1.5 Trinidad and Tobago

- Embryonic stem cell research as well as therapeutic and reproductive cloning is banned.
- The law states that the manipulation of **ovum**, **zygotes**, and/or embryos for the purpose of producing one that is genetically equivalent to a living or deceased human being, embryo, zygote, or **fetus** – or implantation of this – is prohibited. The ovum may not be retrieved to be fertilized, to mature outside of the human body, or to be implanted (as of 1999).

3.2.1.6 El Salvador

- Embryonic stem cell research as well as therapeutic and reproductive cloning is banned.

3.2.2 South America

3.2.2.1 Argentina

- Embryonic stem cell research is permitted, but all forms of cloning (reproductive and therapeutic) are banned.
- The law specifically states that experiments concerning cloning of human cells in order to generate human beings are prohibited.

3.2.2.2 Brazil

- Embryonic stem cell research is allowed on IVF embryos that have been frozen for at least three years. Therapeutic cloning and reproductive cloning are banned (Bio-Safety Law, March 24, 2005).

3.2.2.3 Chile

- Embryonic stem cell research is not specifically prohibited, but therapeutic and reproductive cloning and the funding of such activities are.
- The law states that the cloning of human beings and interventions which results in the creation of a human being genetically identical to another is prohibited.

3.2.2.4 Columbia

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- The criminal code (2000) prohibits fertilization of a human ovum with intent other than procreation and prohibits genetic manipulation for the purpose of reproductive cloning. The code does allow the fertilization of human ova for research and diagnostic purposes, if there is a therapeutic goal.

3.2.2.5 Ecuador

- Embryonic stem cell research as well as therapeutic and reproductive cloning is banned.
- Research on human embryos (and therefore cloning) is prohibited as of June 1998.

3.2.2.6 Peru

- Embryonic stem cell research is not specifically prohibited, but therapeutic and reproductive cloning are banned.
- Fertilization of a human ovum with intent other than procreation is prohibited, as well as human cloning (General Health Law, 1997).

3.2.2.7 Uruguay

- Embryonic stem cell research and therapeutic cloning are not specifically prohibited, but reproductive cloning is.

3.2.3 Europe

3.2.3.1 Austria

- Embryonic stem cell research as well as therapeutic and reproductive cloning is banned.
- Reproductive medicine is acceptable only within stable heterosexual relationships for the purpose of reproduction. Embryos can be used only for implantation in the woman who has donated the **oocytes**, and for no other purposes. Donation of **embryos** or **gametes** is prohibited (Federal Law of 1992 Regulating Medically Assisted Procreation).

3.2.3.2 Belgium

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned as of May 2003.

3.2.3.3 Czech Republic

- Embryonic stem cell research is permitted using lines created from unused IVF eggs.

3.2.3.4 Denmark

- Embryonic stem cell research is not specifically prohibited, but therapeutic and reproductive cloning and the funding of such activities are as of 2003.

3.2.3.5 Estonia

- Embryonic stem cell research is allowed, but reproductive and therapeutic cloning are banned.

3.2.3.6 Finland

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- The act defines embryo as a fusion of gametes, so therapeutic cloning is permitted, but reproductive cloning is prohibited (Medical Research Act of 1999).

3.2.3.7 France

- Embryonic stem cell research is allowed, but therapeutic and reproductive cloning are banned.
- Research on human embryonic stem cells is now allowed until embryos are 6-8 days old. Embryos cannot be created specifically for research – scientists must use existing embryos from IVF. Embryonic stem cell lines are typically imported from abroad.

3.2.3.8 Georgia

- Embryonic stem cell research is not specifically prohibited, but therapeutic and reproductive cloning are.
- Human cloning through the use of genetic engineering is prohibited (1997 Law on Health Care).

3.2.3.9 Germany

- Embryonic stem cell research is permitted, but all forms of cloning (reproductive and therapeutic) are banned.
- It is Illegal to create any new stem cell lines after December 2001.

3.2.3.10 Greece

- Embryonic stem cell research is permitted, but reproductive cloning is banned.

3.2.3.11 Hungary

- Embryonic stem cell research is not specifically prohibited, but reproductive and therapeutic cloning are.
- The national law (1997) does not explicitly address or prohibit embryonic stem cell research or therapeutic cloning.

3.2.3.12 Iceland

- Embryonic stem cell research is permitted using lines created from unused IVF eggs and for development or fertility research.
- Reproductive and therapeutic cloning are prohibited (Act on Artificial Fertilisation, 1996).

3.2.3.13 Ireland

- Embryonic stem cell research as well as therapeutic and reproductive cloning is banned.
- Human cloning is prohibited because the "right to life of an unborn child is equal to that of the mother" as stated in the Constitution of Ireland.

3.2.3.14 Italy

- Embryonic stem cell research, as well as therapeutic and reproductive cloning are banned.

3.2.3.15 Latvia

- Embryonic stem cell research is permitted, but therapeutic and reproductive cloning are prohibited, as of the 2002 Law on Sexual and Reproductive Health.

3.2.3.16 Lithuania

- Embryonic stem cell research as well as therapeutic and reproductive cloning are prohibited.
- Human embryos may be subjects only of clinical observations (non-invasive investigations).

3.2.3.17 The Netherlands

- Embryonic stem cell research is permitted, but all forms of cloning (reproductive and therapeutic) are banned.
- There is a five year moratorium (ending in 2007) prohibiting therapeutic cloning.

3.2.3.18 Norway

- Embryonic stem cell research, as well as therapeutic and reproductive cloning is banned.
- Research on embryos and the use of techniques aimed at the production of genetically identical individuals is prohibited (The Medical Use of Biotechnology, 1995).

3.2.3.19 Poland

- Human reproductive cloning and embryonic research are specifically prohibited.
- Human embryos may not be used for non-therapeutic research.

3.2.3.20 Portugal

- Embryonic stem cell research is permitted, but reproductive cloning is banned and therapeutic cloning is implicitly prohibited.
- The law states that the cloning of human beings is prohibited (National Council of Ethics for the Life Sciences, 1997).

3.2.3.21 Russian Federation

- Embryonic stem cell research is not specifically prohibited, but therapeutic and reproductive cloning are.
- For a five-year period starting in 2002, human cloning is prohibited, as well as the import and export of human cloned embryos (Law on Temporary Prohibition of Human Reproductive Cloning, 2002).

3.2.3.22 Slovakia

- Embryonic stem cell research as well as therapeutic and reproductive cloning are banned.

3.2.3.23 Slovenia

- Embryonic stem cell research is not specifically prohibited, but therapeutic and reproductive cloning are.
- Human cloning for reproductive and therapeutic purposes is prohibited by the Law on Medically Assisted Reproduction (2000) and the Penal Code (2002).

3.2.3.24 Spain

- Embryonic stem cell research is permitted, but reproductive and therapeutic cloning are banned.
- Any therapeutic intervention, investigation, or research activity in pre-embryos in vitro, pre-embryos, or embryos and fetuses in utero will be authorized only if it does not alter the genetic makeup of the embryo, and as long as it is not aimed at one particular individual or race-selection. Research on in vitro embryos is allowed with parental consent, after the embryos have been frozen for five years or more.

3.2.3.25 Sweden

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned. (Act 1991/115 and Government Bill 2003/04:148)

3.2.3.26 Switzerland

- Embryonic stem cell research is allowed on excess stocks of embryos produced naturally for artificial insemination.
- Therapeutic and reproductive cloning are banned.

3.2.3.27 Turkey

- Embryonic stem cell research is not specifically prohibited.
- Therapeutic cloning is allowed, but reproductive cloning is not (as of 1996).

3.2.3.28 Ukraine

- Embryonic stem cell research and therapeutic cloning are not specifically permitted, but reproductive cloning is banned.

3.2.3.29 United Kingdom

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- Therapeutic cloning is regulated by **Human Fertilization and Embryology Authority (HFEA)** in order to understand the development of embryos and to develop treatments for serious disease.

3.2.4 Asia

3.2.4.1 China

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- "Guidelines for Research on Human Embryonic Stem Cells" released in 2004 by China's Ministry of Science and Technology, and Ministry of Health.

3.2.4.2 India

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- The Indian Council of Medical Research released the Consultative Document on Ethical Guidelines for Biomedical Research on Human Subjects (2000), which cover the guidelines.

3.2.4.3 Japan

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- Production of cloned human embryos will be limited to basic research or regenerative medicine only (Bioethics Committee of the Council for Science and Technology Policy).

3.2.4.4 Singapore

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- The law allows the harvesting of stem cells from cloned human embryos, but it prohibits cloned embryos from developing more than two weeks.

3.2.4.5 South Korea (Republic of Korea)

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- The government approved research on somatic cell nuclear transfer based on guidelines of National Ethics Committees.

3.2.4.6 Taiwan (Republic of China)

- Embryonic stem cell research is allowed on excess stocks of embryos produced naturally for artificial insemination.
- Reproductive and therapeutic cloning are banned, as is the creation of embryos for research purposes.

3.2.4.7 Thailand

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.

3.2.4.8 Vietnam

- Embryonic stem cell research is not specifically prohibited, but therapeutic and reproductive cloning are.
- Human cloning and surrogacy banned as of May 2003.

3.2.5 Oceania

3.2.5.1 Australia

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- Researchers must apply for a license to experiment with embryos

3.2.5.2 New Zealand

- Embryonic stem cell research and therapeutic cloning are permitted, but reproductive cloning is banned.
- In 2004, the Human Assisted Reproductive Technology Bill was amended to ban reproductive cloning and genetically engineered babies.

3.2.6 Middle East

3.2.6.1 Egypt

- Bans reproductive cloning and potentially therapeutic cloning.
- The researcher is prohibited from conducting research involving mixing lineages.

3.2.6.2 Iran

- Embryonic stem cell research is permitted.

3.2.6.3 Israel

- Embryonic stem cell research and therapeutic cloning is permitted, but reproductive cloning is banned.
- Human reproductive cloning and germline genetic engineering is prohibited.

3.2.7 Africa

3.2.7.1 South Africa

- Embryonic stem cell research is permitted, but all forms of cloning (reproductive and therapeutic) are banned.

3.2.7.2 Tunisia

- Embryonic stem cell research is not specifically prohibited, but therapeutic and reproductive cloning are as of 1997.
- The law states that any technology related to human cloning is banned.

3.2.8 References and Further Suggested Readings

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2. Global Lawyers and Physician for Human Rights: http://www.glphr.org[11]
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4. European Commission, Directorate General – Research: Survey on opinions from National Ethics Committees or similar bodies, public debate, and national legislation in relation to human embryonic stem cell research and use. Volume I: EU Member States, July 2004: http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm[13] , Volume II: Countries associated to FP6 and Third Countries, July 2004: http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm[14]
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6. The International Stem Cell Forum (May 2007) http://www.stemcellforum.org
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9. The Phoebe R. Berman Bioethics Institute. (March 2006) International Policy Trends: Embryonic Stem Cell Research.

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[10] http://www.glphr.org/genetic/genetic.htm
[11] http://www.glphr.org/
[12] http://www.mbbnet.umn.edu/scmap.html
[13] http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm
[14] http://www.europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm
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[16] http://www.hopkinsmedicine.org/bioethics/finalsc.doc

Chapter 4

Glossary[1]

4.1 Alphabet

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

[1] This content is available online at <http://cnx.org/content/m14759/1.1/>.

Chapter 5

Contact Us[1]

5.1 Contact Us

Please feel free to contact us regarding questions about the reference materials.

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[1] This content is available online at <http://cnx.org/content/m14763/1.1/>.
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[4] http://www.ruf.rice.edu/~neal/stemcell

Glossary

A **Adult Stem Cells**

An unspecialized or undifferentiated cell found among specialized cells in a tissue or organ, which can renew itself and differentiate into a specialized cell.

Autoimmune Disease

A disease where one own body starts attacking itself and destroying itw own cells.

B **Blastocyst**

A pre-implanted embryo of 30-150 cells that is 5-6 days old.

C **Cell-Based Therapies**

Treatment in which stem cells are induced to differentiate into the specific cell type required to repair damaged or depleted adult cell populations or tissues.

Characterizing Stem Cells

Determining how a cell grows, where the cell came from, how it was derived, and if there are any chromosomal abnormalities.

Cloning

In biology, it is the act of producing an exact copy of a sequence of DNA, cell, tissue, or organism.

D **Department of Human and Health Services (DHHS)**

The United States government's principal agency for protecting the health of all Americans. It provides essential human services, especially for those who are least able to help themselves.

Deriving

The creation of a cell line from one original cell or set of cells.

Differentiation

The process of unspecialized cells transforming into specialized cells.

E **Embryo**

In humans, the developing organism from the time of fertilization until the end of the eighth week, when it becomes known as a fetus.

Embryonic Stem Cell

An unspecialized or undifferentiated cell found in the inner cell mass of a blastocyst, which can renew itself and differentiate into a specialized cell.

Endoderm

The internal layer of cells of an embryo; eventually gives rise to the digestive tract, lungs, and associated structures.

F **Fetus**

A developing human from the eighth week after fertilization to birth.

G **Gamete**

A mature sexual reproductive cell (sperm or egg) having a single set of unpaired chromosomes.

H **Hematopoetic Stem Cell**

An adult stem cell from which all white and red blood cells evolve.

Human Fertilisation and Embrology Authority (HFEA)

The governmental authority in the United Kingdom that regulates in vitro fertilization and embryo research.

I **In Vitro Fertilization (IVF)**

An assisted reproduction technique in which fertilization is accomplished outside the body.

In Vitro

From the Latin for "in glass"; in a laboratory dish, test tube, or artificial environment.

In Vivo

In the living subject; the natural environment.

Inner Cell Mass

A small group of about 30 cells in a blastocyst which will give rise to the hundreds of highly specialized cells needed to make up an adult organism; embryonic stem cells are derived from this group.

Insulin

A hormone in the body that balances blood sugar levels.

J Juvenile Diabetes

Also known as type 1 diabetes, it is an autoimmune disease where the ß-cells in the pancreas are destroyed and therefore the individual loses some or all of his/her ability to regulate and produce insulin. If left untreated, it can have severe side effects such as kidney failure, blindness, stroke and even death.

N National Bioethics Advisory Council (NBAC)

A committee of experts during the Clinton administration that was formed in 1995 to provide advice and make recommendations to appropriate government entities related to bioethical issues. Their charter expired in October 2001.

National Institutes of Health (NIH)

An agency of the Department of Human and Health Serves, its mission is the pursuit of knowledge about nature and behavior of living systems. It provides leadership and direction to programs designed to improve health by conducting and supporting research: in the causes, diagnosis, prevention, and cure of human diseases; in the processes of human growth and development; in the biological effects of environmental contaminants; in the understanding of mental, addictive and physical disorders; in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

Nucleus

A structure within a living cell that contains the cell's DNA and controls its metabolism, growth, and reproduction.

O Oocyte

A female cell that develops into an ovum (egg) after meiosis; an egg before maturation.

Ovum

The female reproductive cell or egg (plural is ova).

P Pluripotent

The ability of a single cell to develop into many different cell types of the body.

President's Council on Bioethics (PCB)

A committee of experts during the Bush administration that was formed in 2001 (after the NBAC was disbanded) to provide the President with advice on bioethical issues that may emerge as a result of biomedical science and technology.

Proliferation

Expansion of a population of cells by the continuous division of single cells into two identical cells.

Q Quiescent

A cell that does not divide or replicate.

R Reproductive Cloning

When an egg undergoes somatic cell nuclear transfer and the resulting cell is allowed to grow to an infant that is an exact copy of the donor.

S

Signals

Internal and external factors that control the changed in cell structure and function.

Smooth Muscle

Also known as "involuntary muscle," these muscles perform automatic tasks such as peristalsis and blood vessel constriction. Named smooth muscle because of smooth, rather than striated, appearance under a microscope.

Somatic Cell

Any cell of a plant or animal other than the germ (sperm or egg) cell.

Somatic Cell Nuclear Transfer (SCNT)

When the genetic material (nucleus) of an egg is removed and replaced with the genetic material of a normal cell.

Stem Cell

An unspecialized cell that can replicate itself for indefinite periods through cell division and under certain conditions becomes a specialized cell.

T

Therapeutic Cloning

When embryonic stem cells created by somatic cell nuclear transfer are studied in vitro and used for cell-based therapies, but never are implanted in a female or grown past 14 days.

U

Undifferentiated Cell

A primitive cell that does not have any tissue-specific structures that allows it to perform specialized functions. It has not changed to become a specialized cell.

Z

Zygote

The cell (and the organism that develops from the cell) resulting from the union of an ovum and spermatozoon (also referred to as a fertilized ovum).

ß

ß-cell

A cell in the pancreas which is responsible responsible for the production and regulation of insulin.

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