Cloning: A Policy Analysis

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Table of Contents

Executive Summary

Cloning is a scientific term used to describe the process of genetic duplication. Somatic cell nuclear transfer (SCNT) is the cloning technique that has drawn attention in recent years. This technique, in which the nucleus from a body cell is transferred to an egg cell to create an embryo that is virtually genetically identical to the donor nucleus, has the potential to be used for research, therapy, and reproduction.

The term cloning invokes strong responses among Americans. Opposition to cloning arises from several concerns, including concerns about the destruction of human embryos, usurping Divine authority, interfering with the natural order, the exploitation of the women from whom human eggs are obtained, and the impact of cloning human beings on those who are cloned. Support for cloning originates primarily from its potential to yield fundamental new research insights and to lead to new therapies to treat devastating illnesses. A minority of Americans also would support the use of cloning to produce children.

Within the United States, different religious, political, and academic organizations, as well as government advisory panels, have issued statements or recommendations regarding reproductive, research, and therapeutic cloning. These entities have reached divergent conclusions on these issues – with some advocating a ban on all cloning activities and others maintaining that cloning should be allowed, and even encouraged, for research and therapy only. These divergent views in turn are based on different underlying values, including the view of the moral worth of a human embryo, conceptions of human personhood and human dignity, the importance of human individuality, the imperative to heal the sick, the right to reproductive autonomy, and the proper role of government in socially charged and ethically complex issues.

Currently, the federal government does not explicitly prohibit SCNT. Because it requires the destruction of embryos, SCNT to create human embryos cannot be undertaken using federal funds, regardless of whether the research is undertaken for the purpose of research, therapy or reproduction. The Food and Drug Administration has stated that human reproductive cloning would be unlawful unless an application were first submitted to the agency. FDA also would need to approve the clinical use of any therapies derived from SCNT research before they were administered to humans.

Several bills have been introduced in Congress to prohibit reproductive cloning. Some of these bills also would prohibit research and therapeutic cloning, while others would permit it. None of these bills has been enacted. In addition, twelve states have enacted laws explicitly addressing reproductive, research, and therapeutic cloning. Some of these states prohibit all cloning whereas others permit research and therapeutic cloning while prohibiting reproductive cloning. Many states currently are considering legislation addressing cloning.

Many other countries have also entered the debate over human cloning and, unlike the United States, have passed laws that either ban all uses of cloning or permit research and therapeutic cloning while prohibiting reproductive cloning. The United Nations has been unable to pass a binding Convention against reproductive cloning because of disagreement among member countries concerning the inclusion of research and therapeutic cloning.

Considerable media attention has depicted public opinion as fixed and relatively stable over time, occupying primarily distant ends of a philosophical spectrum – there is little media discussion of shades of grey in this debate. While it is true that a majority of the American public opposes the use of cloning for reproduction, and that this view is relatively consistent over time, opinions regarding the appropriateness of research and therapeutic cloning are more fluid.

In 2004, the Genetics and Public Policy Center conducted a survey of 4,834 Americans about their attitudes concerning reproductive genetic technologies including cloning. The survey found that many Americans have incomplete or incorrect knowledge concerning the status of cloning technology. Consistent with the findings of previous surveys, the survey found that the vast majority of Americans disapprove of cloning for reproduction, and a smaller majority disapprove of the use of cloning to create embryos for research.

Americans' opinions about cloning are not firmly held and likely are being influenced by their positions on more familiar issues such as abortion and the value of biomedical research to develop new therapies and treatments for the sick. Given this situation, it is not surprising that lawmakers in Washington and in various state legislatures have not been able to reach consensus on laws to regulate cloning, or how cloning ultimately might be used in medicine.

While human cloning technology is still in its infancy, the science is outpacing the public's understanding and the formulation of coherent public policy. Therefore, the time is now to engage the public in discussions about the legal, ethical and societal issues cloning raises. We hope this report will contribute to public understanding and to the development of sound public policy.

Introduction

The term cloning evokes powerful emotions in the American public. Some, focusing primarily on its potential to create genetically identical human beings, fear a Brave New World-like civilization in which people intentionally are designed for the use and control of those more powerful. Some also view the intentional creation of a human being who is identical to another as the height of human hubris, an ill-conceived attempt to usurp Divine authority or, alternatively, to upset the balance of nature. Others oppose cloning because it requires the destruction of human embryos.

At the same time, many scientists and patients, among others, support the use of cloning because of its potential to yield new and fundamental insights into human development and the causes of disease and new therapies to treat devastating illnesses. A small minority of the public also would support its use to bear children were it technologically feasible because it could help couples bear genetically related children who otherwise could not.

These widely disparate concerns, fears and hopes have created a political impasse at the federal level. However, at the state level — as well as in other countries — numerous laws have been passed banning, or alternatively promoting, certain uses of cloning.

In order to better understand how cloning has come to provoke such varied societal responses, it is first necessary to understand the range of scientific techniques encompassed in this term. Cloning is a scientific term used to describe the process of genetic duplication, e.g., the duplication of a strand of DNA, a cell, or an entire organism. In the case of cloning an entire organism, scientists have experimented with different techniques. The technique that has been the focus of attention in recent years is somatic cell nuclear transfer (SCNT), which has been used to create cloned animal and human embryos as well as to produce cloned animals.

SCNT, while a single technique, has the potential to be used for several different purposes. **Research cloning** has been used in the laboratory to create stem cells whose nuclear genome is identical to that of the source of the donated nucleus. Scientists believe that genetically-identical cell lines will be uniquely valuable for studying human development and disease. **Therapeutic cloning** refers to the potential use of stem cells from cloned embryos to treat degenerative diseases through the transplantation of genetically-matched cells or tissues. **Reproductive cloning** has been used in animals to create genetically identical offspring of already existing animals; Dolly, the cloned sheep who was presented

Somatic cell nuclear transfer (SCNT) involves transfering the nucleus of a somatic, or body, cell (such as a skin cell) and inserting it into an oocyte (egg cell) from which the original nucleus has been removed. The oocyte is then artificially induced to divide and to become an embryo that has the identical nuclear DNA as the donor of the somatic cell.

In **research cloning,** SCNT is used to create embryos, and cells from these embryos are used to generate embryonic stem cells – a process which entails the destruction of the embryo. These stem cells have the identical nuclear DNA as the source of the donated nucleus. Scientists seek to use these cells to better understand fundamental molecular mechanisms that underlie cellular differentiation and the development of certain diseases. In 2004, scientists in South Korea reported that they had derived, for the first time, human embryonic stem cells through SCNT.

In **therapeutic cloning**, stem cells obtained through SCNT are induced to differentiate into a specific tissue that could provide the source of the donated nucleus with a genetically matched tissue transplant. Therapeutic cloning can also be considered to be one aspect of research cloning, since research would be required before administering any cloning-based therapy to humans. Therapeutic cloning research is currently being pursued in non-human animals.

In **reproductive cloning**, the embryo created via SCNT is transferred to a uterus to create offspring with the identical nuclear genetic makeup as the donor of the cell from which the nucleus was obtained. The procedure has so far been used to clone a variety of animals.

to the world in 1996, is the most publicized example. While a few scientists and cloning proponents have announced their intention to produce cloned human babies, they have presented no credible evidence of success.

Research, therapeutic, and reproductive cloning using human embryos raise a variety of ethical concerns. The use of SCNT to produce cloned embryos, whether to derive stem cells or to attempt to produce a live-born child, entails the destruction of most or all of these embryos. In the case of research and therapeutic cloning, these embryos will be destroyed in the process of obtaining stem cells. In the case of reproductive cloning, many cloned embryos likely would be unsuitable for transfer to a uterus and would either be destroyed or used for research. The use of SCNT therefore poses an ethical challenge to those who believe that embryos have intrinsic moral worth. It should be noted that research with embryonic stem cells obtained using IVF embryos raises these same concerns as well. However, some who support the use of IVF embryos that are no longer needed as part of fertility treatment draw the line at SCNT because it involves the deliberate creation of an embryo for research.

Reproductive cloning in humans raises additional ethical issues. A central ethical concern for many people is the health risks that would be incurred by the individual born as a result of cloning. Data from animals indicate that cloned offspring suffer health problems not seen in their non-cloned counterparts. Others focus on the potential psychological impact on the child who is born via cloning, and worry that the child's sense of self and personal autonomy will be compromised if he or she is treated as merely a copy of an existing individual, particularly if that individual is the parent. Some also worry that cloned individuals will be viewed as not-quite-human and face societal discrimination. Some oppose cloning based on their view that it is a misguided and dangerous attempt to circumvent the natural order.

Because their stated ends are not to produce a human being, research and therapeutic cloning do not raise all of the same concerns as reproductive cloning. However, like reproductive cloning, they entail the destruction of embryos. Some fear that improving SCNT methods through research cloning will make reproductive cloning possible — even inevitable. Some women's health and reproductive rights advocates also worry that because cloning currently relies on a ready supply of women's eggs it will lead to the exploitation of women.

On the other side of the debate are advocates of stem cell research, who view stem cells from cloned embryos as an integral part both of basic research and of the development of therapies for degenerative diseases such as Parkinson disease. They maintain that a rigid barrier between these benign uses and reproductive cloning must — and as a practical matter can — be achieved. They contend that the moral worth of the embryo created through SCNT must be balanced against the potential benefit of stem cells from cloned embryos to provide new research discoveries and therapies for already-existing human beings, and that the result of such balancing should be to permit, and moreover even to support, such research.

On the policy front, SCNT touches on two political hot buttons: The use of human embryos in research and the creation of cloned babies. There appears to be widespread agreement among policymakers and the U.S. public, as well as in other countries, that reproductive cloning should not be permitted at this time, both because of the potential harms to cloned offspring and because of other ethical concerns it raises. In contrast, there is wide divergence of political and public opinion in the United States and abroad regarding the use and government funding of SCNT to derive human embryonic stem cells for research and therapy.

For now, research, therapeutic and reproductive cloning inextricably are linked in Congressional debate, which has led to a legislative impasse. Within the 50 states, laws have been passed that either (1) ban the use of SCNT for any purpose, whether for reproduction, research, or therapy, (2) ban the use of SCNT for reproduction, and/or (3) authorize — and in some cases allocate funding for — the use of SCNT for research and therapeutic purposes.

In the current political landscape, the views on all sides appear to be deeply entrenched. While in other contexts the Genetics and

Public Policy Center has used the development of policy options as a tool to assist policymakers and the public in responding to new reproductive genetic technologies, the choices in reproductive and research cloning are few and have been clearly outlined by several eminent groups before us. However, those deeply invested in this debate often speak in a jargon that may obscure the issues for the uninitiated and impede clear and cogent discussion. We hope that by clearly delineating the issues – scientific, legal, ethical, and societal – by describing the approaches that have been considered or adopted at the state, federal, and international levels, and furthermore, by sharing the results of our public opinion survey on these issues, we will help to promote a public debate that is both informed and balanced.

Cloning: Scientific Overview

Sexual reproduction in humans and other mammals entails the union of a sperm and egg cell. All other cells of the body contain two copies of the autosomal (non-sex) chromosomes plus either two X chromosomes (in the case of a female) or an X and a Y chromosome (in the case of a male). In contrast, sperm and egg cells contain one copy of each autosomal chromosome, and sperm contribute an X or a Y chromosome while egg cells always contribute one X chromosome. Sperm and egg unite to form a cell that contains the full complement of chromosomes in the genome. That cell, in turn, divides to form an embryo that has the potential to develop into a baby (Figure 1).

Unlike sexual reproduction, somatic cell nuclear transfer (SCNT) bypasses the union of sperm and egg cell. SCNT entails removing the nucleus from a somatic (non-sex) cell, such as a skin cell, and inserting that nucleus into an egg cell whose own nucleus has been removed. The egg cell is then artificially induced to divide and form an embryo.[48,140,196,229]

What is done with the embryo following SCNT marks the point of divergence between research or therapeutic cloning and reproductive cloning. The cloned embryo may be grown in culture to the blastocyst stage, at which point stem cells — which are capable of generating a wide variety of specialized cell types[204] — can be harvested. Alternatively, the embryo can be transferred to a uterus. If the cloned embryo is successfully gestated, the result is an organism that contains the identical nuclear DNA as the donor of the somatic cell, although it may not contain the same mitochondrial DNA as the donor (see box). Reproductive cloning has been achieved in several non-human mammals.[19,28,67,118,231]

Mitochondrial DNA

Most of the human genome is contained in a structure within the cell called the nucleus, referred to as nuclear DNA. However, a small portion of the human genome is found in cellular structures called mitochondria, sometimes called the powerhouse of the cell because they produce the energy that the cell needs to function. Mitochondria have a separate genome, which encodes a small number of proteins used by the mitochondria to carry out their activities. Unlike nuclear DNA, almost all of a person's mitochondria come from the mother's egg. Thus, SCNT would result in a genetically identical organism only if both the egg and the somatic cell nucleus used were from the same donor.

Reproductive Cloning in Non-Human Mammals

Scientists have been attempting to clone animals through SCNT for several decades. They cite several potential benefits from this research: (1) an efficient way to create herds of genetically-modified farm animals, (2) preservation of endangered species, (3) production of human therapeutic proteins in genetically-modified cloned animals, (4) use of genetically-modified cloned animals as a source of organs for human transplantation, (5) gaining a better understanding of cellular differentiation and reprogramming capabilities that could be the basis for human cellular therapies, and (6) better models to study new treatments for human disease.[41,48,148,227] However, SCNT cloning thus far has been a very inefficient process, and cloned animals have exhibited serious health problems. This section describes the status of research in non-human mammals.

Nuclear transfer first was used in 1952 to study early development in frogs.[20] In the 1980s, the technique was used to clone cattle and sheep, using cells taken from early embryos.[47,53] In 1995, Ian Wilmut, Keith Campbell, and colleagues at the Roslin Institute in Scotland created live lambs — Megan and Morag — from embryo-derived cells that had been cultured in the laboratory for several weeks.[26] This was the first time live animals had been produced from cultured cells and their success opened up the possibility of introducing much more precise genetic modifications into farm animals.

In 1996, Dr. Wilmut and colleagues used a nucleus extracted from a mammary cell of a six-year-old sheep to create Dolly, born on July 5, 1996.[229] Dolly was the first animal cloned from a nucleus obtained from an adult animal cell. The ability to use an adult cell demonstrated that the DNA

in our cells is not "fixed" but can, under certain circumstances, be "reprogrammed" and induced to perform new functions.[229]

But, while Dolly appeared (and presumably acted) like a normally-conceived sheep, she developed health problems, such as arthritis, unusual for a sheep of her age.[226] She was euthanized as a result of these problems in 2003.[215,226]

Since the birth of Dolly, reproductive cloning using SCNT has been used to produce a variety of mammals,[231] including mice,[216] rabbits,[28] pigs,[118] cats[67] cows,[130,197,210] and a mule.[230] In December 2004, the company Genetic Savings & Clone announced the sale of the first cloned pet to a woman in Texas whose previous cat had died.[172]

Notwithstanding these research and commercial mammalian cloning examples, SCNT to date has been a very inefficient process, in that most embryos created via SCNT do not implant, and most of those that do implant do not complete gestation.[63] Indeed, Dolly was not produced on the first try; rather, she was Wilmut and colleagues' 278th attempt.[166] Overall, only about one percent to four percent of embryos produced through SCNT lead to live births,[228] reflecting the challenges posed by SCNT.

In addition to its very low efficiency, animal cloning data indicate that cloned animals have a higher incidence of miscarriage or newborn death, experience a higher rate of severe birth defects, exhibit anomalies in gene expression known as imprinting disorders, demonstrate aberrant gene expression, and age faster and subsequently have shorter life expectancies than animals produced through sexual reproduction.[97,234] When they have used adult cells to create cloned embryos, scientists have observed that cloned animals seem to age in synchrony with the animal from which their genetic material was obtained.[199]

Cellular aging is evidenced by shortening of the telomeres – the section of DNA at the end of the chromosomes. When Dolly died, scientists found that her telomeres were significantly shorter than what would be expected in a sheep her age; this indicated that Dolly's cells were the same age as the donor sheep from which she was cloned.[199] In other species, scientists have observed that gene expression in cloned animals differs from naturally conceived animals; this raises concerns over the possible accumulation of

Early Research in Cloning : Embryo Splitting

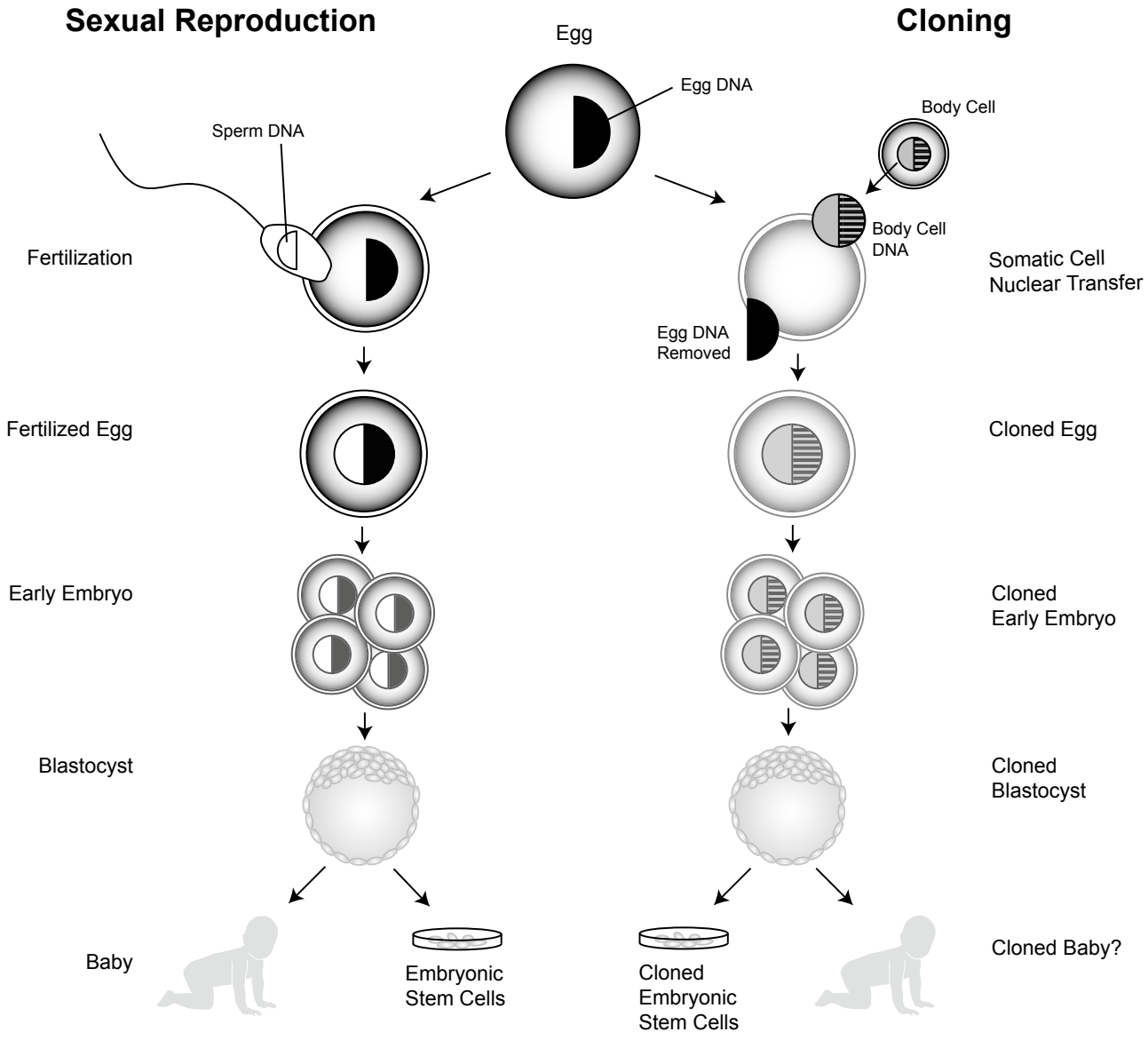
Before the SCNT technique was developed, scientists used other methods to obtain genetically identical organisms. In the late 19th century, Hans Driesch created genetically identical sea urchins by dividing a two-cell stage embryo into two separate cells, which each formed a new embryo that developed into a sea urchin. In 1902, Hans Speimann ran a series of experiments using salamanders. Similar to Driesch, Speimann separated a two-celled embryo of a salamander to create two individual salamanders. Speimann took the process a step further when he was able to produce a salamander from one cell that he had removed from a 16-cell stage embryo.[47,53]

In 1993, researchers at George Washington University announced that they had cloned human embryos using the technique of embryo splitting, in which embryos were split at the two-, four-, or eight-cell stage and each group of cells thereafter was permitted to divide.[123] The embryos split at the eight-cell stage were able to divide to the 32-cell stage. None of the embryos was transferred to a human being. The researchers' presentation of their results at an October 1993 scientific meeting generated significant media attention and controversy in the scientific community. The researchers had not sought IRB approval before conducting their experiment, and they were subsequently disciplined by the university and forced to destroy their data. Subsequently, a non-governmental organization, the National Advisory Board on Ethics in Reproduction (NABER), issued a report, *Human Cloning through Embryo Splitting*.[141] The report concluded that some uses of human embryo splitting would be ethical, such as to improve the chances of IVF success, while others would be unethical, such as to produce twins whose births are separated by a time interval.

mutations in somatic cells, as well as genetic programming errors which can lead to higher rates of disease and disability.[71,90,162]

Researchers have been attempting to generate cloned non-human primate (e.g., rhesus and macaque) embryos.[198] The genetic similarity between humans and non-human primates makes non-human primates a particularly attractive target for SCNT research. Scientists believe primates cloned using SCNT will help elucidate essential developmental biology mechanisms and provide better animal models for research.[198] However, thus far they have met with only modest success. While cloned primate embryos have been obtained using SCNT and have been transferred for gestation, no pregnancy has been reported.[198] Cloned non-human primate embryos have exhibited misaligned chromosomes and the absence

Figure 1: Sexual Reproduction and Cloning



Human Stem Cells in Research and Therapy

Stem cells are cells found in the body of humans and other mammals that are unique because they (1) have the ability to divide indefinitely to produce identical daughter cells and (2) can differentiate (become specialized) into other cell types with specific functions. In contrast, other cells in the body, such as skin cells or nerve cells, are permanently committed to perform a specific function. There are many different kinds of stem cells, and they differ in their "plasticity," meaning their capacity to differentiate into other cell types. In the body, stem cells provide an important cellular repair mechanism. In some adult tissues, such as bone marrow, muscle and brain, discrete populations of adult stem cells generate replacements for cells that are lost through normal wear and tear, injury, or disease.[148]

Human stem cells can be obtained from adult tissues, fetal tissue and human embryos. Small numbers of adult stem cells circulate in the blood (known as peripheral blood stem cells), and limited numbers of stem cells also can be isolated from bone marrow and other adult tissues. Fetal stem cells, known as embryonic germ cells, are isolated from the primordial germ cells — those destined to become the egg or sperm cells — of the gonadal ridge of the 5-10 week old fetus. Human embryonic stem cells are derived from the inner cell mass of an embryo, a structure that appears at the 4th or 5th day of embryonic development (known as the blastocyst stage) and that contains cells that will differentiate into the different tissues of the human body and the placenta. The cells of the inner cell mass can be grown in culture in the laboratory to become embryonic stem cells.[148]

Human embryonic stem cells are "pluripotent," meaning that they can develop into almost all of the more than 200 different cell types that comprise the human body. By contrast, adult stem cells are generally limited to differentiating into the cell types of their tissue of origin. However, some evidence suggests that adult stem cells can, under the right experimental conditions, be "reprogrammed" to generate cells of a different cell type. However, questions remain about the longevity and potential of adult stem cells.[148]

Those who advocate research with human embryonic stem cells cite their importance for research and as a potential source of human therapies.[56] In research, they foresee that human embryonic stem cells may yield greater understanding of the early events in human development and the genetic, molecular, and cellular processes that lead to spontaneous abortion and birth defects.[147] Human embryonic stem cells also could be used to test the safety of candidate therapeutic drugs as well as to screen potential toxins.[147]

Researchers foresee the potential use of human embryonic stem cells to replace or restore tissue damaged by disease or injury.[99] Using stem cells, they believe it may be possible for patients to regenerate needed cells or tissues in their body. Conditions for which such therapy has been discussed include Parkinson disease, diabetes, and spinal cord injuries.[39,148] There are many basic science and preclinical phases of research that must occur before human clinical trials can begin, although some success already has been reported in some non-human animals.

Human embryonic stem cells are more plentiful, easier to isolate and grow in the laboratory and have a greater ability to differentiate than adult stem cells.[56,148] Also, because they are derived from an adult, adult stem cells may have accumulated more mutations (e.g., through exposure to environmental agents and through the accumulation of errors through replication).[56] At the same time, research with adult stem cells is believed to be important for understanding tissue-specific differentiation, and, potentially, for therapy, particularly as stem cells are being found in a greater number of adult tissues.[148] Currently, hematopoietic (blood cell generating) stem cells from bone marrow are used clinically to treat certain cancers and other diseases that affect blood cell production.[148]

of structures necessary for cell division, which may help explain the failures.[198]

Some have argued that there are insurmountable biological barriers preventing successful reproductive cloning in humans;[5,96,199] others believe these to be only temporary technical barriers.[198]

There has been to date no documented case of human reproductive cloning, although a sect known as the Raelians has made numerous unsubstantiated claims that they have produced children using this method.[43,193] In the summer of 2001, Panos Zavos of the Andrology Institute of America in Lexington, Kentucky and Italian fertility specialist Severino Antinori announced at the National Academy of Sciences their intention to begin cloning human beings.[173,205] The scientists stated they already had recruited infertile couples to participate, and that their laboratory would be located at an undisclosed location outside the United States and Europe.[173,205] In 2002, Antinori announced that one of the women in the program was pregnant with a cloned fetus.[238] No birth was ever reported, although Zavos claimed in 2003 to have produced a cloned human embryo.[237]

Research Cloning: State of the Science

Much of what is known about embryonic stem cells derives from research in mice. In 1981, researchers reported methods for growing mouse embryonic stem cells in the laboratory.[126] Until recently, the debate over using human embryonic stem cells obtained using either in vitro embryos or cloned embryos was largely theoretical, as scientists were not able to isolate either type of stem cell in the laboratory. However, in 1998, James Thomson of the University of Wisconsin isolated cells from the inner cell mass of an early embryo and developed the first human embryonic stem cell line in a laboratory setting.[204] Since then, other researchers have also been able to develop stem cell lines from human IVF embryos.[224] Even more recently, in 2004, researchers in South Korea derived human embryonic stem cells from an embryo created through SCNT.[92] These scientists obtained 242 oocytes from 16 research subjects, and transferred a nucleus from each donor's cumulus cell (a cell adjacent to the egg cell) into each oocyte. From these oocytes, 30 SCNT-derived embryos were grown in culture, and the inner cell mass was obtained from 20 of these. Stem cells were derived from the inner cell mass of only one cloned embryo.

This experiment has not been replicated, although scientists in the United States have been able to grow SCNT-derived embryos to the six-cell stage.[30] Researchers are attempting to produce cloned primates using the methods used by the South Korean scientists to produce cloned human embryonic stem cells, and some believe these methods have overcome the barriers to reproductive primate cloning.[198]

Those who advocate obtaining embryonic stem cells using cloned embryos argue that SCNT-derived stem cells have potential advantages over their non-cloned counterparts, both for research and therapy. In the research context, they claim that SCNT can be used to create stem cell lines that are uniquely useful because they can be tailor-made to study a particular disease.[65] This may be a particularly useful tool for understanding the biological mechanism causing the disease process when the gene for a disease has not been identified.[225] The potential therapeutic advantage of stem cells from cloned embryos is that they will contain the identical nuclear genetic material as the individual who donated the nucleus. In theory, if such stem cells were used to generate tissues for transplantation, they would be less likely to be rejected by the donor's immune system.[227]

In addition some forsee that stem cells from cloned embryos may one day help doctors determine what drug to prescribe a patient and in what dose. [227]

Arguments For and Against Human Cloning

Within the United States, different religious, political, and academic organizations, as well as government advisory panels, have issued statements or recommendations regarding reproductive, therapeutic, and research cloning. These entities have reached divergent conclusions on these issues – with some advocating a ban on all cloning activities and others arguing that cloning should be allowed for research purposes only. These divergent views in turn are based on different underlying values, including the view of the moral worth of a human embryo, conceptions of human personhood and human dignity, the importance of human individuality, the imperative to heal the sick, the right to reproductive autonomy, and the proper role of government in societally charged and ethically complex issues. This section reviews the arguments that have been made opposing or supporting reproductive, research, and therapeutic cloning. Table 1 reviews the positions of a wide variety of religious, political, medical, scientific, and legal organizations in the United States on reproductive, research and therapeutic cloning.

Arguments to Prohibit Reproductive Cloning

Reproductive cloning would lead to the destruction of human embryos

Animal experience with SCNT demonstrates that the process of obtaining cloned embryos is very inefficient. Most attempts to obtain a cloned embryo fail, and most cloned embryos that are transferred to a uterus do not complete gestation. Human cloning also likely would entail the loss of many embryos. In addition, cloned animal embryos exhibit genetic abnormalities. For this reason, were human reproductive cloning to be attempted, the technique of preimplantation genetic diagnosis likely would be used to select embryos that do not exhibit obvious genetic abnormalities.

Some traditions, guided by religious or other precepts, regard the human embryo as a human being at the earliest stage of development, possessing the same dignity and entitled to the same protections afforded a born individual. For these groups, reproductive cloning is morally wrong because it would entail the "loss of many lives in attempts to achieve a single live birth."[27] Others do not consider an embryo to be a full human being but nevertheless consider it "nascent human life" or potential life, and therefore ascribe to it high moral worth.[171] For them, reproductive cloning also would raise moral concerns because it leads to embryo destruction.

Reproductive cloning would usurp the Divine plan or interfere with the natural order

Human reproductive cloning would, for the first time, allow offspring to be produced using the genetic contribution of only one individual. For some, this shift from two genetic contributors to one would be a radical and unwelcome departure from the natural procreative process, one that would "usurp the authority of God."[121] Some argue that reproductive cloning "does not meet biblical standards for procreation in which children are begotten, not made."[23]

Some fear the human consequences of the change in human reproduction that reproductive cloning would entail. As the National Bioethics Advisory Commission noted in its 1997 report, *Cloning Human Beings*,[142] growing technological mastery over nature historically has been met with concern based on the capacity for new technologies to be used for both good and evil. In the case of reproductive cloning, some see only harm from the substitution of "procreation" with the "biological manufacturing of humans,"[23] a transition that they believe will ultimately lead to the dehumanization of life.[23]

Reproductive cloning would violate human dignity

Some express their opposition to reproductive cloning in terms of its effect on human dignity.[171] They argue that human cloning would undermine human dignity because it would "set aside the truth of the human person, treating human beings as commodities to be manufactured, manipulated, and marketed for the alleged good of other, more powerful human beings."[150] In addition cloning "could not possibly respect the intrinsic value of the person created, because a cloned person

will not be created simply for their value as a person."[190] Rather, "[t]here will always be an intended and specific utility attached to a cloned person because he or she was created with a particular genetic make-up for some purpose."[190] Others worry that the result of this commodification will be to "devalue the relationship of humans to each other and to their culture."[42] Some go so far as to equate reproductive cloning with Nazi medical experiments because of its devaluation of human beings.[150]

Some have pointed out that assaults on human dignity can affect not only the individual directly involved but also the larger society, and that these broader societal effects must be taken into account. As the President's Council on Bioethics stated in its report, *Human Cloning and Human Dignity*: "A society that allows dehumanizing practices – especially when given an opportunity to try to prevent them – risks becoming an accomplice in those practices."[171] The Council noted that a society that cloned human beings "thinks about human beings ... differently than does a society that refuses to do so."[171] Thus the Council urged consideration of whether reproductive cloning "is an activity that we, as a society, should engage in."[171]

Reproductive cloning would cause grave risks to human health

For some, the potential risks to women and the children born as a result of cloning are the paramount reason to prohibit its use, at least at the present time. Those who argue based on safety note that animal data from SCNT demonstrate that most cloned animal embryos that are implanted die before gestation is complete or shortly after birth and that many exhibit abnormalities. They further note that the inefficiency of the process would mean that many human eggs would be required, and that the process of securing an ample supply of eggs would expose women to risk.[37,160]

In its 2002 report, *Scientific and Medical Aspects of Human Reproductive Cloning*, the National Academy of Sciences (NAS) concluded that the scientific and medical criteria used to evaluate the safety of reproductive cloning must be: (1) the potential morbidity and death of the woman carrying the cloned fetus and of the newborn and (2) the risk to women donating the eggs.[140] The NAS identified three criteria that would need to be fulfilled before the safety of human reproductive cloning could be established: (1) improved animal cloning procedures together with reduction in observed abnormalities, or a demonstration that humans would be different with regard to these defects; (2) a demonstration that cloned embryos are normal with respect to imprinting and reprogramming; and (3) the development of methods to monitor cloned embryos and fetuses for cloning-related defects.[140]

Similarly, the American Medical Association has taken the position that physicians should not participate in attempts in produce children through cloning in part because of the potential physical and psychosocial harms that could result to children born as a result.[8]

While new medical technologies always carry some degree of risk, some argue that reproductive cloning adds a special ethical concern because a person who was not able to consent, i.e., the cloned child, will be subject to the risks. Those who make this argument acknowledge that this is true regarding all reproduction, but argue that the risks entailed in cloning are distinct from those accompanying other forms of reproduction.[171]

Reproductive cloning would deprive the cloned individual of the "right to an open future"[54]

Some oppose reproductive cloning because they fear the psychological effect on the children born as a result.[189] They worry that a child explicitly created with a nuclear genome that is identical to one of his or her parents or to a lost loved one will face a lifelong burden of expectations based on that genetic equivalence. Some fear that the child will lose the ability to develop an independent identity because he or she will have a genome that already has been lived by another.[45]

In its report on the ethics of human cloning, the Ethics Committee of the American Society for Reproductive Medicine found reproductive cloning to

be unethical in part because of its concern that unreasonable expectations on the part of both the parents of the cloned child and the cloned child himself or herself could lead to "harmful typecasting" and prevent the child from "forging a unique identity."[9] In addition, the Committee expressed concern about the impact on the cloned individual of "too much information" about the future, such as that the nucleus donor suffered from a genetic illness.[9]

Others condemn those who would seek to produce a child through cloning. As one legal academic has stated: "Duplicating yourself is sterile, self-absorbed, and ultimately destructive. Moreover, creating a clone in your own image is to curse your child by condemning it to be only an echo."[13]

Reproductive cloning would disturb the "delicate balance of marriage"[120]

Some who oppose human reproductive cloning argue that it would undermine the marital relationship because the set of genetic instructions for the child would derive solely from one parent. The child thus would stand in an "asymmetric relationship" with his or her mother and father.[120] Because of the re-ordering of family relationships that would ensue, some argue that reproductive cloning is a "fundamental assault on the created order of God."[120]

Others point out the value that sexual procreation has for the marital relationship because it reminds the couple that the "act of love is not simply a personal project undertaken to satisfy one's own needs,"[129] but rather "a participation in a form of life that carries its own inner meaning."[129] In this way, the child becomes the fruit of the couple's shared love. In contrast, when "the sexual act becomes only a personal project, so does the child."[129]

Reproductive cloning would alter parent-child relationships and lead to the commodification of children

Some people worry that the creation of children through cloning will change parental attitudes from one of wonder and gratitude to one of ownership and control.[4,49] As the National Bioethics Advisory Commission pointed out, while parents already exercise great control over their offspring, SCNT would offer parents complete control over a child's genome, something that they heretofore could not specify.[142] The Commission noted that some view the desire for such precise specification as implying a "lack of acceptance" for children who don't develop according to expectations, an implication that is "fundamentally at odds with the acceptance, unconditional love, and openness characteristic of good parenting."[142]

Some also worry about the confusion in legal parentage that will result from cloning. They note that a cloned child may have genetic material from as many as four individuals who otherwise have no connection to the child; the nucleus donor, the egg donor (mitochondrial DNA), and the parents of the nucleus donor. In addition, they note that the status of the gestational parent must be taken into account. They argue that current laws are not adequate to address these new relationships.[50] For this reason, the American Bar Association's House of Delegates, while adopting a resolution opposing reproductive cloning, called for a national law or policy that would "establish the legal parentage, including the legal rights and obligations that flow" from a cloned individual."[6] It should be noted that other new reproductive technologies (e.g., surrogacy, gamete donation) already have raised parentage questions that courts have had to resolve[93] and that new legal approaches are being considered in an attempt to respond to new parent-child relationships created through new reproductive technologies.[144]

Reproductive cloning would lead to discrimination against cloned individuals

While all who have addressed the issue have insisted that a cloned individual would be entitled to the same rights, freedoms, and protection as all other human beings,[6] some nevertheless worry about the potential domination and control of cloned individuals because they were created for the benefit of others rather than for their intrinsic worth as human beings.[190] Discrimination also could result, it is argued, from the fact that the genetic makeup of the

cloned person would be known to the parents and discoverable by others, such as employers and insurers.[94]

In its resolution opposing cloning, the American Bar Association's House of Delegates also recognized the possibility that reproductive cloning may have occurred or would occur in the near future. Thus, the House of Delegates expressed its support for national law or policy that would establish a "presumption that a live birth resulting from reproductive cloning is a human being"[6] and "guarantee that any such human being is a person, legally separate and distinct from its biological progenitor, with all rights accorded to any other live born human being under existing law."[6]

Reproductive cloning would decrease human diversity

Some oppose reproductive cloning because they fear that it will reduce the genetic diversity that occurs through sexual reproduction and "could result in permanent, heritable changes to the human gene pool."[104] They argue that it is impossible to predict which genes will confer advantages, and that reducing diversity will render the species vulnerable. For this reason, they view reproductive cloning as a "highly dangerous innovation."[104] Others, however, counter that the numbers of people that would need to be cloned in order to have any effect on genetic diversity is so great that, as a practical matter, loss of diversity will not occur.[59]

Separate from the loss of genetic diversity, some also fear its impact on societal tolerance for human difference. They argue that inherent in the desire to clone is the desire for conformity and elimination of human variety. They fear that a "society that supported cloning as an acceptable procreative technique, would imply that variety is not important. Especially in a multicultural nation like the United States, where diversity and difference are of the essence, any procedure that reduced our acceptance of differences would be dangerous."[104]

Arguments to Permit Reproductive Cloning

Proponents of reproductive cloning, who comprise a minority of the American public, fall into two groups. Some believe that while it is not yet safe it would be ethical under certain circumstances if safety could be assured. For example, the World Transhumanist Association's Statement on Cloning supports the "full reproductive rights to the use of cloning and other assistive technologies by competent adults after these have been demonstrated as safe and effective for human use"[233] but states that the "use of cloning technology on humans at this stage of its development is highly unethical"[233] because of the lack of animal safety data and that if attempted "could significantly set back public acceptance of transhuman technologies."[233] Others favor attempting reproductive cloning right now; as described below, two fertility researchers have indicated their readiness to use the technology, although they have presented no evidence that they have succeeded in producing a cloned child. Those who advocate reproductive cloning have made one or more of the following arguments in support of their position.

Reproductive cloning would allow couples who currently cannot to have children genetically related to themselves

Some support reproductive cloning because it would afford an opportunity to those who currently are unable to produce genetically related children to do so.[76,163] Unlike other forms of assisted reproduction, such as the use of donated gametes, cloning would not introduce the nuclear genome of a third party. For example, if a couple had a genetic condition leading to infertility, one member of the couple could be cloned so that one parent would have a biological connection to the child. By some accounts, there could be significant demand for cloning for this purpose. In March 2001, scientists Severino Antinori (Italy) and Panos Zavos (U.S.A.) announced they were ready to begin reproductive cloning for infertile couples; they reported that close to 700 American couples already had volunteered.[173]

Cloning also could be used to produce biologically related children if one member of a couple carried a genetic mutation he or she did not want to pass on to the child. Finally, some

have noted approvingly that cloning could allow gay couples to produce children genetically related to one member of the couple.[163] Others within the gay community have argued, however, that resources would be "far better spent advocating for equal access to existing means of family building."[29]

Reproductive cloning should be permitted as part of procreative liberty

Related to the potential benefit of reproductive cloning for couples unable to have biologically related offspring is the argument that the government should not interfere with the right of individuals to reproduce in any manner they choose. While the Supreme Court has in other contexts recognized a right to procreative liberty (e.g., contraception, abortion), no court has had occasion to address whether the Constitution protects the right to reproduce through cloning, and it has been the subject of much academic debate.[58,61,101,107,191,192] Some argue that procreative liberty should extend to reproductive cloning. While they acknowledge the ethical difficulties inherent in cloning, they maintain that "individuals, doctors, and scientists — not politicians" are best equipped to deal with these issues.[174] Further, they take a generally optimistic view of the societal impact. For example, Libertarian Party chair Steve Dasbach disputed claims that cloning would lead to "armies of identical Frankenstein-like people," stating that "cloning can't recreate an individual human being, with his or her unique personality, beliefs, talents, and goals. It can only reproduce a genetically identical 'blank slate' upon which a new personality — formed by a lifetime of experience and learning — will gradually emerge."[174] Similarly, World Transhumanist Association chair Nick Bostrom has argued: "This is an opportunity for us to overcome some of our prejudices. Scaremongers have argued that a clone would somehow have a diminished degree of humanity. If the claim of human cloning is borne out, we will be faced with the concrete choice between rejecting this view, and denying the dignity of a living human baby."[233]

Some who argue for the freedom to clone cite as potential benefits improved parenting by those who are familiar with the genome contained in their child and a greater sense of identity on the part of clones because they know where their genome came from.[76]

Arguments to Prohibit Research and Therapeutic Cloning

Research and therapeutic cloning would require the destruction of human embryos

Like reproductive cloning, research cloning would require the destruction of embryos. But, unlike reproductive cloning, embryos cloned for research would have no prospect of normal human development since the sole purpose of their creation is for the derivation of stem cells. Some who consider the embryo to constitute a full human being or at least nascent human life consider it immoral under any circumstances to create an embryo solely as a "means to some other end," particularly when that requires the destruction of the embryo.[105] They view the embryo as "an integrated, developing, genetically whole human creature in the earliest days of life" rather than simply a cluster of cells.[38] They argue that there is something "fundamentally different, fundamentally corrupting, fundamentally dangerous about allowing ... the manufacture of human embryos for the purpose of their dissection and use for parts."[105] It should be noted that embryo-based arguments against research cloning are similar to ethical arguments made in opposition to embryonic stem cell research with non-cloned embryos, particularly arguments against creating IVF embryos solely for research that requires their destruction.

Research and therapeutic cloning could harm women's health

Research and therapeutic cloning would require the eggs of women. Because of its inefficiency, many eggs would likely be required. Some people have expressed the concern that the need for women's eggs will cause risks to the women who contribute these eggs, as well as coercion — in particular of poor women — to supply them.[37] They cite the dangers posed by the drugs that would be administered to stimulate production of the eggs

and the "inability to obtain true informed consent from egg donors given the current lack of adequate safety data."[160] One proponent of this view has argued that "any responsible stem cell research plan would specifically postpone embryo cloning research with human eggs until better data make true informed consent possible for any woman considering the donation of eggs for research."[160] Those worried about the ethical problem of egg procurement also note that therapeutic cloning would require multiple eggs per patient. Others, however, view the claim of risk to women as exaggerated and the alleged harms from ovulation-stimulating drugs as not supported by scientific evidence. For example, recent data have failed to find a strong link between the use of ovulation stimulating drugs and breast or ovarian cancer.[21,22] Some also view as ethically misguided the use of gametes — the seeds of the next generation — for purposes having nothing to do with reproduction.[171]

There are alternatives to research and therapeutic cloning that would not require the destruction of human embryos

Some opponents of research and therapeutic cloning argue that there are alternative sources of stem cells available that would not require embryo destruction or the use of SCNT.[44] They point to adult stem cells and cord blood stem cells as providing the potential for research and therapeutic advances.[44] They argue that while saving lives and healing the sick are fundamental values, they should not be undertaken at the expense of weak, early, and vulnerable forms of human life that are equally deserving of respect.[44] They also point to clinical experience and research, where adult stem cell therapies have already demonstrated real successes with patients, and to evidence that embryonic stem cells may be difficult to control sufficiently for cell replacement purposes. Many scientists, however, argue that using only non-embryonic sources of stem cells would foreclose important avenues of research and prevent the development of new therapies, and that adult stem cells lack the crucial plasticity of embryonic stem cells.[56]

A proposal to obtain embryonic stem cells using SCNT while avoiding ethical concerns regarding embryo destruction is being considered by the President's Council on Bioethics. Councilmember William Hurlbut has proposed "altered nuclear transfer" to produce a "biological entity that, by design and from its very beginning, lacks the attributes and capacities of a human embryo."[91] Such an entity — which he has termed an "artifact" — would lack the ability to ever develop into a human being, and therefore lack the moral standing of an embryo. At the same time, it would be a potential source of pluripotent stem cells. Some scientists have criticized this proposal as unlikely to be scientifically feasible and as a waste of time and resources.[131] Others charge it would not avoid the problem of destroying human life but merely would create a damaged embryo that is destined to die.[194,195]

Research and therapeutic cloning inexorably would lead to reproductive cloning

Some who might otherwise support research cloning because of its potential benefits oppose it because they believe that once the SCNT technology is available for one purpose, it inevitably will be used for reproductive cloning. They argue that the "slippery slope" to human reproduction is too great a threat and that once we master the technique of producing cloned human embryos, those seeking to clone human children will be able to do so.[38] Others dispute the "slippery slope" concern based on their belief that reproductive cloning will never be scientifically feasible because there are inherent biological barriers that will be difficult, if not impossible, to overcome.[5,96]

Arguments to Permit Research and Therapeutic Cloning

Research cloning provides a unique capacity to conduct research on human diseases

Some scientists contend that embryonic stem cells from cloned embryos will "help unlock secrets of developmental and pathogenic events that might not be revealed otherwise."[222] They argue that SCNT will permit the creation of stem cell lines from patients with particular diseases and that studying these cells will

lead to better understanding of the fundamental mechanisms underlying the disease process.[222] They contend that stem cells from cloned embryos would be a uniquely useful tool to create cell lines from patients with heritable diseases and from diseased cells — such as cancer cells — to better illuminate the mechanisms of disease.[222] Creating cell lines in this manner would be particularly useful for tissues that otherwise are difficult to study, such as the nerve cells of the brain.[140] They further state that using stem cells from cloned embryos from both patients and healthy people would allow scientists "to compare the development of such cells and to study the fundamental processes that modulate predilections to diseases."[140] Finally, they argue that these stem cell lines would be superior to those obtained using excess IVF embryos because the latter "do not reflect the diversity of the general population."[51]

Therapeutic cloning may lead to alleviation of human suffering and cures for costly and debilitating diseases by providing genetically matched tissue for transplantation

Proponents of therapeutic cloning argue that embryonic stem cells from SCNT-created embryos may lead to uniquely beneficial therapies for degenerative diseases for which treatments are either non-existent or inadequate. They also argue that stem cells cloned from a patient's own body would not cause immunological rejection. As the Biotechnology Industry Organization has stated: "[Therapeutic cloning] …could allow an individual's own cells to be used to treat or cure that person's disease, without risk of introducing foreign cells that may be rejected. Thus, cloning is vital to realizing the potential of stem cell research and moving it from the lab into the doctor's office."[18] Proponents contend that although the benefits of embryonic stem cell research have yet to be realized, the possibility for treatments and cures is compelling enough to warrant the use of stem cells from cloned embryos,[111] since therapies developed through this research could "save countless numbers of lives, and increase the quality of life of countless others."[207]

The notion that alleviating the suffering of living human beings is a moral imperative is a common rationale of supporters of research cloning. In June 2004, the Coalition for the Advancement of Medical Research sent a letter to President Bush, signed by 140 organizations, urging him to relax the federal ban on generating stem cell lines for research. The group argued "embryonic stem cells stand as a crucial link to the scientific puzzle that may mitigate the pain and suffering of more than 100 million Americans."[111]

Similarly, some religious groups have argued in support of research cloning because of its potential to heal those who are sick. The Jewish Reform movement views the moral imperative to pursue research as the "embodiment of the mitzvah of healing."[183] Similarly, two Orthodox organizations have issued a statement that "our tradition states that an embryo in vitro does not enjoy the full status of human-hood and its attendant protections"[164] and that, therefore, "if cloning technology research advances our ability to heal humans with greater success, it ought to be pursued since it does not require or encourage the destruction of life in the process."[164]

Another religious group that recently has expressed support for research cloning is the Islamic Organization for Medical Sciences. Leaders called for Muslim states to support stem cell research and research cloning based on revisions to the First International Islamic Code of Medical and Health Ethics.[69] Muslim scholars argue that embryos lack the same sanctity as in Christian traditions, and therefore, are not regarded as human beings in any sense. However, some resistance still remains among Muslim leaders as evidenced by conflicting laws in Arab states regarding punishment for scientists who attempt any form of cloning.[106]

Research cloning should be permitted as part of the freedom of scientific inquiry

Some view bans of research cloning — as well as on embryonic stem cell research more generally — as a threat to the freedom of scientific inquiry. For example, the American Bar Association has opposed as a violation of individual freedom any legislation that would prohibit research cloning: "Government action that would ban all forms of cloning, and thereby foreclose all potential

avenues of medical advancement offered by therapeutic cloning, poses a direct and serious threat to freedom of scientific inquiry."[7]

Some worry that it could impede the acquisition of fundamental new insights in human biology, and assert that there is a fundamental Constitutional right to freedom of scientific inquiry that would be abridged were cloning prohibited.[75] They note that research is an inherently serendipitous enterprise and that foreclosing research opportunities could have negative consequences for the scientific enterprise.

The Role of Federal Bioethics Commissions in the Cloning Debate

Both Presidents Bill Clinton and George W. Bush have appointed expert bioethics commissions, comprising experts in science, medicine, law, and ethics, and have sought their advice regarding research and reproductive cloning. In 1995, President Clinton issued an executive order establishing the National Bioethics Advisory Commission (NBAC). Following the announcement that Dolly had been cloned, President Clinton directed NBAC to evaluate thoroughly the legal and ethical issues related to human cloning and report back within 90 days.[184] In June 1997, the NBAC issued a report entitled *Cloning Human Beings*.[142] The NBAC focused its recommendations solely on reproductive cloning, and recommended that (1) the moratorium on the use of federal funding to support the use of SCNT to clone a human being be continued for a limited time, (2) the federal government issue an immediate request to all relevant parties in the private sector to comply voluntarily with the federal moratorium, and (3) the federal government ask all professional and scientific societies to issue position statements asserting that any attempt to create a child through SCNT would be regarded as "irresponsible, unethical, and unprofessional." The NBAC in 1999 also issued a second report, *Ethical Issues in Human Stem Cell Research,*[143] to further explore issues related to research cloning. The report recommended that federal funding for deriving new stem cell lines be permitted for stem cell research using embryos left over from infertility treatments. The NBAC further recommended that federal funding not be used for the time being to support research involving the creation of embryos solely for research purposes or research on embryos made using SCNT, but that the question should be revisited based on the results of such research in the private sector.

In November 2001, in conjunction with his announcement regarding federal funding of stem cell research, President Bush stated that he would appoint "a President's council to monitor stem cell research, to recommend appropriate guidelines and regulations, and to consider all of the medical and ethical ramifications of biomedical innovation." The President's Council on Bioethics issued *Human Cloning and Human Dignity* in 2002.[171] Regarding cloning-to-produce children, as the Council termed it, there was unanimous opposition by the 17 members of the Council. However, with respect to cloning-for-biomedical-research, a term that encompassed both research and therapeutic cloning, seven members of the Council favored allowing it subject to government regulation, seven members supported a permanent ban, and three members supported a four-year moratorium. In 2004, consistent with its initial charter, the Council released *Monitoring Stem Cell Research*,[170] in which it described current federal policy regarding stem cell research, provided an overview of the ethical and policy debates surrounding the research, and reported on recent scientific developments in human stem cell research.

Table 1: Human Cloning Position Statements / Policies by U.S. Organizations*

Organization	Support Reproductive Cloning	Support Research/ Therapeutic Cloning	Source
Alpha-1 Foundation	No	Yes	Statement of the Alpha-1 Foundation and Alpha-1 Association Supporting the introduction of the Human Cloning Ban and Stem Cell Research Protection Act of 2003 http://www.alphaone.org/publicpolicy/whats_new/2003_senate_statement.html
American Association for the Advancement of Science	No	Yes	AAAS Urges United Nations to Endorse Cloning for Research Purposes (2003) http://www.aaas.org/news/releases/2003/1103cloning.shtml
American Association of Medical Colleges	No	Yes	AAMC Supports Senate Bi-Partisan Cloning Bill (2002)http://www.aamc.org/newsroom/pressrel/2002/020430.htm
American Association of Pro-life Obstetricians and Gynecologists	No	No	Position Statement on Human Cloning - American Association of Pro-Life Obstetricians and Gynecologists (2002) http://cloninginformation.org/info/aaplog-cloning_position_statement.htm
American Bar Association	No	Yes	House of Delegates Resolution (2004), and accompanying Report http://www.abanet.org/leadership/2004/annual/dailyjournal/109.doc
American Bioethics Advisory Commission	No	No	Ban Human Cloning: A Report of the American Bioethics Advisory Commission http://www.all.org/abac/clon-txt.htm
Alliance for Aging Research	No	Yes	Alliance for Aging Research Position Statement on January 24, 2002 Congressional Hearing on Cloning http://www.agingresearch.org/press/012402_harkin.html
American College of Obstetricians and Gynecologists	No	Yes	Statement of The American College of Obstetricians and Gynecologists on the "Human Cloning Ban and Stem Cell Research Protection Act of 2003" http://www.acog.org/from_home/publications/press_releases/nr02-05-03.cfm
American Medical Association	No	Yes	H-460.915 Cloning and Stem Cell ResearchE-2.146 Cloning-For-Biomedical-ResearchE-2.147 Cloning to Produce Children http://www.ama-assn.org
American Psychiatric Association	No	Yes	Somatic Cell Nuclear Transfer Position Statement (2003) http://www.psych.org/edu/other_res/lib_archives/archives/200309.pdf
American Society for Biochemistry and Molecular Biology	No	Yes	Letter to UN Regarding Proposed Worldwide Human Cloning Ban (2003) http://www.asbmb.org/ASBMB/site.nsf/web/C64892C98F380BB585256E52005A855B?OpenDocument
American Society for Cell Biology	No	Yes	Position Paper on Cloning (2001) http://www.ascb.org/publicpolicy/cloning.htm
American Society for Microbiology	No	Yes	Public Policy Statements: Cloning Ban (1998) http://www.asm.org/Policy/index.asp?bid=3113

Table 1 (cont.): Human Cloning Position Statements / Policies by U.S. Organizations*

Organization	Support Reproductive Cloning	Support Research/ Therapeutic Cloning	Source
American Society for Reproductive Medicine	No	Yes	ASRM Position on Cloning and Related Issues http://www.asrm.org/Media/misc_announcements/cloning/asrmpositioncloning.html
American Society of Hematology	No	Yes	Statement on Nuclear Transfer and Human Reproductive Cloning http://www.hematology.org/government/policy/nuclear_transfer.cfm
American Nurses Association	No	Yes	Human Cloning by Means of Blastomere Splitting and Nuclear Transplantation (2000) http://www.nursingworld.org/readroom/position/ethics/Etclone.htm
Association of Reproductive Health Professionals	No	Yes	AHRP Position Statements (last updated February 24, 2005)
Americans to Ban Cloning	No	No	Foundational Statement (2001) http://cloninginformation.org/statement.htm
Biotechnology Industry Organization	No	Yes	UN Cloning Vote: BIO's letter to the (Members of the U.N. General Assembly (2004) http://www.bio.org/bioethics/background/20041116.asp
California Nurses Association	No	No	CNA's Position Statement on Embryonic Stem Cell Research (2004) http://www.calnurse.org/?Action=Content&id=680
Cancer Research and Prevention Foundation	No	Yes	Advocacy: 108th Congress Issues http://www.preventcancer.org/advocates/advocates_issues.cfm
Center for Bioethics and Human Dignity	No	No	Human Cloning: The Need for A Comprehensive Ban (2001) http://www.cbhd.org/resources/cloning/position_statement.htm
Central Conference of American Rabbis	No	Yes	Resolution on Stem Cells, Gene Therapy, and Cloning (2003) http://data.ccarnet.org/cgi-bin/resodisp.pl?file=stemcell&year=2003M2
Christian Medical and Dental Associations	No	No	Ethics Statement: Human Cloning (1998) http://www.cmdahome.org/index.cgi?BISKIT=2248309194&CONTEXT=art&art=330 Testimony of CMA Member C. Christopher Hook, M.D. (2001)http://www.cmdahome.org/index.cgi?BISKIT=2248309194&CONTEXT=art&cat=100120&art=2209
Christopher Reeve Paralysis Foundation	No	Yes	CRPF Position Statement on Nucleus Transplantation (2002) http://www.christopherreeve.org/Research/Research.cfm?ID=158&c=23
Clone Rights United Front	Yes	Yes	Mission Statement: The Clone Bill of Rights http://www.clonerights.com/mission_statement.htm

Table 1 (cont.): Human Cloning Position Statements and Policies by U.S. Organizations*

Organization	Support Reproductive Cloning	Support Research/ Therapeutic Cloning	Source
Clonaid	Yes	Yes	http://www.clonaid.com
Coalition for the Advancement of Medical Research	No	Yes	CAMR Position Statement on Somatic Cell Nuclear Transfer (2002) http://www.stemcellfunding.org/funding/news.asp?id=142
Council for Responsible Genetics	No	No	CRG Position Statement on Cloning (2001) http://www.genewatch.org/programs/cloning/position.html
Family Research Council	No	No	William Saunders, Esq., Should the Senate Ban Cloning? (2001) http://www.frc.org/get.cfm?i=PD02A1
Federation of American Societies for Experimental Biology (FASEB)	No	Yes	FASEB Statement on Human Somatic Cell Nuclear Transplantation (SCNT) and Embryonic Stem Cells (2004)http://www.faseb.org/opa/ppp/nr_2x12x4_stem.pdfFASEB Statement on Human Cloning and Human Cloning Legislation (2001) http://www.faseb.org/opa/ppp/humclone.html
Focus on the Family	No	No	Position Statement on Human Cloning (2005) http://www.family.org/cforum/fosi/bioethics/facts/a0035757.cfm
Genetic Alliance	No	Yes	Hearing on Human Cloning, House Committee on Energy and Commerce Subcommittee on Oversight and Investigations (2001) (statement by Sharon Terry)http://www.geneticalliance.org/ws_display.asp?filter=policy_statements_human_cloning
Human Cloning Foundation	Yes	Yes	Mission Statement http://www.humancloning.org/about.php
Libertarian Party	Yes	Yes	Press Release (1997) http://www.lp.org/press/archive.php?function=view&record=86
Lutheran Church – Missouri Synod	No	No	Missouri Synod's Position on Cloning (1998) http://www.lcms.org/pages/internal.asp?NavID=2116
Lutherans for Life	No	No	Position Statement on Cloning http://www.lutheransforlife.org/Who%20Are%20We/position_statements_of_lfl.htm#Human%20Cloning
National Academy of Sciences	No	Yes	Scientific and Medical Aspects of Human Reproductive Cloning (2002)
National Bioethics Advisory Commission	No	Yes (no federal funds)	Cloning Human Beings (1997)
National Health Council	No	Yes	National Health Council Position Statement: Human Cloning and Human Cloning Legislation (2001) http://www.nationalhealthcouncil.org/advocacy/cloning.htm

Table 1 (cont.): Human Cloning Position Statements and Policies by U.S. Organizations*

Organization	Support Reproductive Cloning	Support Research/ Therapeutic Cloning	Source
National Organization of Episcopalians for Life	No	No	NOEL Believes Cloning is Far Too Risky (2002) http://www.nprcouncil.org/pressreleases/cloning-noel.htm
National Patient Advocate Foundation	No	Yes	Statement of Principles on Stem Cell Research (2005) http://www.npaf.org/statements.php?p=66
National Pro-Life Religious Council	No	No	Statement on Human Cloning (2002) http://www.nprcouncil.org/pressreleases/cloning-nprc.htm
National Society of Genetic Counselors	No	Yes	Position of NSGC on Somatic Cell Nuclear Transfer (SCNT) or Cloning for Therapeutic and Reproductive Purposes (2004) http://www.nsgc.org/about/position.asp#17
Our Bodies Ourselves (Boston Women's Health Book Collective)	No	No	Statement on Human Cloning (2001) http://www.ourbodiesourselves.org/clone3.htm
Paralysis Project of America	No	Yes	Stem Cell Research Position Statement http://www.paralysisproject.org/position_stemcell.html
Parkinson's Action Network	No	Yes	Statement by Elisabeth Bresee Brittin,Executive Director, Parkinson's Action Network (2002) http://www.parkinsonsaction.org/whatwedo/LisStatementonSCNT.pdf
Presbyterians Pro-Life	No	No	Statement on Human Cloning and the Brownback/Landrieu Bill http://www.nprcouncil.org/pressreleases/cloning-presbyterian.htm
President's Council on Bioethics	No	No (10)**Yes (7)	Human Cloning and Human Dignity (2002)
Reproductive Health Technologies Project	No	Yes	RHTP statement on development and use of somatic cell nuclear transfer (SCNT) for reproductive and research purposes (2003) http://www.rhtp.org/emerging_issues/issues_cloning.htm
RESOLVE, the National Infertility Association	No	Yes	RESOLVE and the Cloning Debate http://www.resolve.org/main/national/advocacy/stemclone/index.jsp?name=advocacy&tag=stemclone
Southern Baptist Convention	No	No	SBC Resolution On Human Cloning (2001) http://www.sbc.net/resolutions/amResolution.asp?ID=572
Stem Cell Action Network	N/A	Yes	Mission Statement http://www.stemcellaction.org/
Union of Orthodox Jewish Congregations of America	No	Yes	Joint Statement by the Union of Orthodox Jewish Congregations of America and the Rabbinical Council of America http://www.ou.org/public/Publib/cloninglet.htm

Table 1 (cont.): Human Cloning Position Statements and Policies by U.S. Organizations*

Organization	Support Reproductive Cloning	Support Research/ Therapeutic Cloning	Source
United Methodist Church	No	No	Book of Resolutions: Human Cloning (2000) http://www.umc.org/interior_print.asp?ptid=4&mid=1085
United States Conference of Catholic Bishops	No	No	Press Release: USCCB Official Urges Congress to Support Bill that Prohibits Human Cloning, Reject Alternate Bill That Doesn't (2003) http://www.usccb.org/comm/archives/2003/03-073.shtml
Women of Reform Judaism	N/A	Yes	44th Assembly Resolutions: Stem Cell Research: Therapeutic Cloning (2003) http://wrj.rj.org/reso/stemcellresearch.html
World Transhumanist Association	No	Yes	WTA Statement on Cloning (2002) http://transhumanist.org/index.php/WTA/statements/wtacloning200202/

* This table is based on an Internet search conducted in March 2005 and may not contain position statements by organizations that do not post their position statements or policies on their websites. In addition, because of inherent search engine limitations, there are likely organizations that have not been included.
** Seven members of the PCB supported a four-year moratorium on research cloning, while three favored a permanent ban.

Federal Oversight of Cloning in the United States

Federal

To date there has been no credible evidence presented that cloning technology has been used to produce a human baby. Nevertheless, claims by individuals in both the United States and other countries that they have either cloned a human[110] or intend to do so [173,221,237,238] have led to an examination of whether current federal laws or regulations would preclude such activity or whether new laws are needed to ensure that human reproductive cloning is not attempted in the United States. At the same time, the ability to derive stem cells from IVF and cloned embryos, and the potential to use them for research and therapeutic purposes, has prompted the federal government to consider whether federal funding may be used to support research and therapeutic cloning and research with stem cells derived from cloned embryos or whether the federal government should restrict funding for, or directly restrict the conduct of, these activities.

Federal Funding Prohibition for Cloning

Currently it is illegal to use federal funds in order to (1) create a cloned human embryo, (2) attempt to make a baby using a cloned embryo, or (3) derive stem cells from an embryo, whether the embryo is obtained through IVF or SCNT. However, a limited number of existing embryonic stem cell lines derived from IVF embryos have been designated for use in federally funded research, as will be discussed below.

The federal government prohibits the use of federal funds to support research in which embryos are created, destroyed, or will be subjected to more than a specified level of risk. The 1996 Dickey-Wicker amendment prohibits the use of federal funds for (1) the "creation of a human embryo or embryos for research purposes" and (2) research "in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204 and 46.207, and subsection 498(b) of the Public Health Service Act."[15]

The Dickey-Wicker amendment defines the term "human embryo" to include "any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."[15]

The Dickey-Wicker amendment originally was enacted with the goal of restricting federal funding of research with human embryos. Shortly after the birth of Dolly, President Clinton sought to ensure that the Dickey-Wicker amendment would be interpreted by federal agencies to preclude federal funding of human reproductive cloning as well. Thus, in a memorandum to the heads of executive departments and agencies, he stated: "Federal funds should not be used for cloning of human beings. The current restrictions on the use of Federal funds for research involving human embryos do not fully assure this result ... these restrictions do not explicitly cover human embryos created for implantation and do not cover all Federal agencies. I want to make it absolutely clear that no Federal funds will be used for human cloning. Therefore, I hereby direct that no Federal funds shall be allocated for cloning of human beings."[223]

The interpretation of the Dickey-Wicker amendment with respect to the funding of research with embryonic stem cells has changed over time. Under President Clinton, the NIH took the position that federal funds could be used to work with embryonic stem cell lines but not to derive them from embryos. In a 1999 memorandum issued by then General Counsel of the Department of Health and Human Services (HHS) Harriet Rabb,[132] she stated that federal law prohibited federal funding of specified research with an embryo, which in turn was defined under the law as an "organism."[132] According to the memorandum, since stem cells are not organisms, they are not embryos, and therefore are not subject to the prohibition.[57,132] This meant that so long as the stem cells were derived — and the embryos destroyed — using only private funds, research using those stem cells would be eligible for federal funding.[57,132]

Shortly thereafter, NIH Director Harold Varmus announced that funding would be made available for research on stem cells once

appropriate guidelines were in place. On August 25, 2000, final guidelines for oversight of funding for stem cell research were published in the Federal Register.[149] Pursuant to Dickey-Wicker, NIH could not directly fund the derivation of stem cells from human embryos. Further, stem cells could be derived only from embryos donated by patients of IVF clinics with their informed consent. The NIH guidelines also specified that federal funds could not be provided for 1) research in which stem cells are used to create a human embryo, 2) research in which human embryos are combined with animal embryos, 3) research on stem cells for the purpose of reproductive cloning of a human, 4) research that derives stem cells from SCNT, i.e., from cloned embryos, 5) research that uses stem cells derived from SCNT, or 6) research on stem cells that were derived from human embryos created solely for research purposes.[149]

The NIH Guidelines were, however, superseded following the election of President George W. Bush. On August 9, 2001, President Bush announced that embryonic stem cell research would receive federal funding, but only for research using embryonic stem cell lines derived prior to that day, in which the embryos already had been destroyed.[224] In other words, federal funds could not be used for research on any embryonic stem cells derived after August 9, 2001, since this would entail additional destruction of embryos. However, non-federally funded embryonic stem cell research continued and the National Academy of Sciences has recently developed voluntary guidelines for this research.

Estimates of the number of stem cell lines derived prior to the Bush announcement and therefore eligible for federal funding varied; in testimony before Congress then Secretary of HHS, Tommy

Federal Funding for Embryo Research: An Historical Perspective

While the Dickey-Wicker amendment, so named after its sponsors Rep. Jay Dickey (R-AR) and Rep. Roger Wicker (R-MS), is the first explicit legislative prohibition of federal funding for embryo research, a moratorium on funding for such research already was in place prior to that enactment. In 1978, the first baby was born using the technique of in vitro fertilization. At the time, an Ethics Advisory Board (EAB) was created to provide recommendations on whether federal funds should be provided for IVF research. Although the EAB recommended that the federal government should fund such research, the guidelines to do so were never adopted by HHS, and the EAB was dissolved. Since federal regulations governing human embryo research required review by an EAB, a de-facto moratorium on federal funding was placed on IVF research and other types of embryo research that developed out of IVF, including SCNT using human embryos. In 1993, the EAB review requirement was eliminated, effectively lifting the moratorium on the use of federal funds for research.[142,171]

In 1994, the NIH created the Human Embryo Research Panel; its mission was to assess the moral and ethical issues associated with the use of human embryos in science and issue guidelines for the review and conduct of this type of research. The recommendations issued by this panel included providing federal funding for SCNT, and to creating embryos solely for research purposes, under strict conditions when specially justified. At the same time, the panel cautioned against federal funding for certain types of cloning, including blastomere separation and blastocyst division, until further review of these processes was completed. Finally, the Panel recommended that federal funding should not be provided for research in which a cloned embryo is placed in utero with the intent of developing a human being. Although the Human Embryo Research Panel's report unanimously was endorsed by the NIH Advisory Committee to the Director, President Clinton issued a different directive on December 2, 1994. Specifically, the President directed the NIH not to provide funding for the creation of human embryos for research purposes. However, the directive did not apply to research on spare embryos from IVF clinics. Therafter, the NIH began to prepare guidelines for funding of research using embryos donated from patients in IVF clinics. However, these plans were derailed on January 26, 1996 with the enactment of the Dickey-Wicker amendment to appropriations legislation and its subsequent reauthorization in the following years.[142,171]

Thompson, stated that there were 64 stem cell lines available for research,[202] but some have claimed a higher number.[111] Subsequently, it was determined that many fewer embryonic stem cell lines — by different accounts 19 or 22 — were viable for research.[112,147]

Under the Bush policy, NIH reviews grant proposals for scientists interested in obtaining federal funds for research on any of the authorized stem cell lines; in addition, the NIH is responsible for ensuring that federal grant money is used only for research on federally approved cell lines.[147]

Some have raised concerns about the limited number of human embryonic stem cell lines available. In April 2004, 206 members of Congress wrote the President requesting that he change his policy to permit federal funding for stem cell research using surplus embryos created through IVF.[108] The letter cited the chilling effect on research in the United States. In a letter responding to the request, NIH Director Elias Zerhouni cited the activities that had been undertaken to support stem cell research consistent with the President's policy, and also stated that he anticipated that more stem cell lines complying with the policy would be available in the future.[112] While he acknowledged that "[f]rom a purely scientific perspective, more cell lines may well speed some areas"[112] of human embryonic stem cell research, he reiterated the President's position that taxpayer funds should not "sanction or encourage further destruction of human embryos that have at least the potential for life."[112]

The letter from members of Congress also raised the concern that the existing cell lines are contaminated with mouse feeder cells, which are used to help grow stem cells in the laboratory.[108] Some have argued that this contamination would make it unsafe to use these cells in human therapies.[46] For example, scientists recently reported that human embryonic stem cell lines grown on mouse feeder cells contain a mouse-derived molecule to which most humans have antibodies, which could lead to immunological rejection of the cells were they administered to humans.[125]

In his letter, NIH Director Zerhouni stated that "[c]ontact with feeder cells is one of many safety considerations that need to be assessed before clinical application of this technology."[112] He reiterated the statements by FDA representatives that "cell lines grown on human feeder layers are not necessarily safer for clinical trials than stem cells grown on mouse feeder layers."[112] FDA's letters to researchers regarding the safety concerns raised by human embryo co-culture with animal cells are discussed below.

Other Federal Laws Pertaining to Cloning

In addition to controlling funding, Congress also can prohibit directly activities it deems undesirable or it can require federal oversight of activities whose unregulated consequences it fears. Congress' power to enact such laws is limited in the sense that it must have jurisdiction grounded in constitutional authority; however, the courts have adopted a fairly expansive interpretation of what activities Congress can undertake consistent with the Constitution.

Although many bills have been introduced that would prohibit or restrict human cloning, none has been enacted. However, laws of more general applicability thus far appear to have deterred reproductive cloning efforts and also provide some oversight for research and therapeutic cloning.

Food and Drug Administration

The Food and Drug Administration (FDA) has stated on several occasions that it has the authority to regulate reproductive cloning. While FDA has never clearly articulated the basis for its jurisdiction, its assertions of authority appear to have had the desired effect, at least for the moment, of preventing reproductive cloning from taking place in the United States.[133] FDA's authority with respect to therapeutic cloning is more readily discernible, as the agency has oversight authority over all products that are intended to treat or prevent disease. FDA has no direct role in the oversight of research cloning, but may have indirect oversight to the extent that data from such research may be used to support an application for approval of a new therapy.

FDA is charged with ensuring the safety and effectiveness of a

variety of health-related products, including drugs and biologics. FDA's authority derives from the Federal Food, Drug, and Cosmetic Act (FD&C Act)[52] and the Public Health Service Act (PHS Act).[182] While these statutes were enacted long before the issues of stem cells or cloning even remotely were considered, they are, arguably, broad enough to encompass some aspects of their regulation. These statutes apply to all products that meet the relevant statutory definitions, whether developed using private or government funds. Although FDA oversight would not be triggered solely by the creation of a cloned embryo, the agency could have jurisdiction over the transfer of that embryo or cells derived from it into a human being. In addition, FDA has indirect oversight over the laboratory procedures used to create the cloned embryo or the stem cells derived from it in that these procedures will be reviewed as part of a determination of the safety and effectiveness of the end product.

In the wake of the 1997 announcement by Richard Seed, a U.S. physicist, that he intended to clone a human being,[165,221] FDA has taken the position, in informal statements, letters to researchers and Congressional testimony, that it has the authority to regulate human reproductive cloning and, moreover, would not permit efforts to create a human being using a cloned embryo. First, on January 20, 1998, Acting FDA Commissioner Michael Friedman, in an interview on a national radio talk show, stated

Congress' Response to Cloning: Many Bills, No Law

Since 1997, numerous Congressional hearings have been held and more than 30 bills related to human reproductive, research and therapeutic cloning have been introduced in Congress. Some have garnered little attention, whereas others have sparked significant debate. Some bills have sought to ban the use of SCNT for any purpose, whereas others have sought to bifurcate reproductive from research and therapeutic cloning and to ban the former while protecting the latter. Some have sought to prohibit federal funding of research related to human cloning and/or stem cells derived from cloned embryos whereas others have sought to prohibit the underlying activities. With two exceptions, none of the introduced bills have been voted on.

Representative Vernon Ehlers (R-Mich.) introduced the first two bills related to human cloning in March 1997. The Human Cloning Prohibition Act (H.R. 923) would have made it unlawful to use "human somatic cell for the process of producing a human clone," and would have imposed a civil penalty of not more than $5000 for violation of the prohibition. [79] The Human Cloning Research Prohibition Act (H.R. 922) would have prohibited the expenditure of federal funds to "conduct or support ... research that involves the use of a human somatic cell for the process of producing a human clone."[86]

Subsequent bills became lengthier, often contained purposes and findings explaining their intent, and also attempted to define key terms such as cloning and somatic cell nuclear transfer. For example, in February 1998, shortly after the announcement by Richard Seed that he intended to clone a human being, Sen. Christopher Bond (R-MO) together with ten other Senators including Sen. Bill Frist (R-TN), introduced the Human Cloning Prohibition Act of 1998 (S. 1599).[80] This bill would have made it unlawful to "use human somatic cell nuclear transfer technology" for any purpose or to import an embryo produced through this technology.[80] The bill would have imposed penalties of up to 10 years in prison, as well as civil penalties. Several other bills that would similarly have sought to prohibit all uses of SCNT were introduced in the 105th Congress. These attempts sharply were opposed by some Democrats, who argued that a ban on research cloning would undermine scientific progress and stymie the discovery of potentially life-saving therapies. On the same day as the Bond bill was introduced, Sen. Diane Feinstein (D-CA) and Sen. Edward Kennedy (D-MA) introduced the Prohibition on Cloning of Human Beings Act of 1998 (S. 1602), which would have prohibited "any attempt, in this country or elsewhere, to clone a human being, that is, to use the product of somatic cell nuclear transfer to create a human being genetically identical to an existing or deceased human being."[180] At the same time, the bill would have protected research not explicitly prohibited by the bill, including the use of SCNT to "clone molecules, DNA, cells, and tissues."[180]

Sen. Sam Brownback (R-KS) has, in several different bills introduced in several different sessions of Congress, sought to prohibit the use of SCNT for any purpose. For example, in 2003, together with Sen. Mary Landrieu (D-LS), he

Congress' Response to Cloning: Many Bills, No Law (cont.)

introduced S. 245, The Human Cloning Prohibition Act of 2003, which declared it unlawful "for any person or entity, public or private, in or affecting interstate commerce, knowingly (1) to perform or attempt to perform human cloning; (2) to participate in an attempt to perform human cloning; or (3) to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo."[83] The bill defined human cloning as "human asexual reproduction, accomplished by introducing the nuclear material of a human somatic cell into a fertilized or unfertilized oocyte whose nucleus has been removed or inactivated to produce a living organism (at any stage of development) with human or predominantly human genetic constitution."[83] The bill also called on the General Accounting Office (GAO) to study the necessity of SCNT for the purposes of medical research and to report back to Congress in four years.

In contrast, others in the Senate have sought to prohibit reproductive cloning while protecting research and therapeutic cloning. For example, in 2002, Sen. Arlen Specter (R-PA), joined by 11 others including Sen. Orrin Hatch (R-UT) and Sen. Strom Thurmond (R-SC), introduced the Human Cloning Ban and Stem Cell Research Protection Act of 2002 (S. 2439).[77] The bill also would have prohibited human cloning, defined as "implanting or attempting to implant the product of nuclear transplantation into a uterus or the functional equivalent of a uterus,"[76] and would have established ethical requirements for nuclear transplantation research, including informed consent and institutional review board review. The bill was not voted on. In 2003, Sen. Hatch, along with five other Senators, introduced the Human Cloning Ban and Stem Cell Research Protection Act of 2003 (S. 303),[78] which was similar to the 2002 bill but contained a prohibition on maintaining an unfertilized blastocyst in the laboratory more than 14 days from its first cell division (not including the time of storage at temperatures below zero degrees centigrade).

The House has twice voted on a bill that would prohibit all uses of SCNT. In 2001, Rep. Dave Weldon (R-FL), together with three other representatives, introduced the Human Cloning Prohibition Act of 2001 (H.R. 2505).[81] The bill would have prohibited human cloning, using the same definition as the Brownback-Landrieu Senate bill. The bill passed in the House by a vote of 265-162. An amendment by Rep. James Greenwood (R-Pa.) that would have banned reproductive cloning while permitting human research and therapeutic cloning was defeated in the House by a vote of 231-174. The bill was not voted on in the Senate. The bill was again introduced in the House in 2003 (H.R. 534),[82] and passed by a vote of 241-155. This bill also was not voted on in the Senate. Other bills that were introduced in the House sought to prohibit only reproductive cloning while permitted research and therapeutic cloning.

In the 109th Congress, the Brownback (S. 658)[84] and Weldon (H.R. 1357)[85] bills have been re-introduced, as has a bill by Rep. Cliff Stearns (H.R. 222)[87] to prohibit federal funding for research using SCNT in human cells.

that FDA had regulatory authority over human reproductive cloning and was prepared to exercise that authority.[220] While he stopped short of stating that FDA would ban attempts to clone humans, he stressed that FDA "would ask for the scientific data that shows that it is safe, that there is adequate expertise behind it, that the facilities are satisfactory, [and] that the individuals involved have the proper experience and training."[88] FDA reiterated its position a month later in a letter to Senator Edward Kennedy,[116] who was sponsoring legislation to ban human reproductive cloning. The letter assured the Senator that FDA's authority was sufficient to ensure that human reproductive cloning "does not proceed until basic questions about safety are answered."[116]

In October 1998, Stuart Nightingale, then Associate Commissioner for Medical Affairs, sent a letter to several hundred institutional review boards "confirming" FDA's jurisdiction over "clinical research using cloning technology to create a human being,"[117] and informing the IRBs of the FDA regulatory process required before an investigator could proceed with such a clinical investigation.[117] The letter stated that, in accordance with FDA regulations applicable to all regulated products, anyone seeking to conduct clinical research to create a human being first would be required to submit an investigational new drug (IND) application to FDA.[36] However, "since FDA believes that there are major unresolved safety questions

pertaining to the use of cloning technology to create a human being, until those questions are appropriately addressed in the IND, FDA would not permit any such investigation to proceed."[117]

On March 28, 2001, Kathy Zoon, Director of FDA's Center for Biologics Evaluation and Research (CBER), testified before a House subcommittee hearing concerning federal regulation of human cloning.[201] She identified the regulatory documents underlying FDA regulation of a variety of biological products and stated that the "use of cloning technology to clone a human being would be subject to both the biologics provisions of the Public Health Service (PHS) Act and the drug and device provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act."[201]

FDA's pronouncements concerning human reproductive cloning appear to have deterred at least some would-be cloners; according to Clonaid, a company that supports reproductive cloning, "following several visits from U.S. government representatives in our facilities, CLONAID™ decided to pursue its human cloning project in another country where human cloning is legal."[31] Nevertheless, the agency never explicitly has articulated the precise nature of the product or products of human reproductive cloning subject to regulation. FDA instead has relied on its general authority to regulate clinical studies of unapproved new drugs and biological products. FDA's announcements appear aimed – and often timed – to inhibit attempts to make cloned human beings in the United States.[133] While the agency may well have jurisdiction to regulate reproductive cloning,[98] FDA has been criticized for failing to follow administrative law principles in asserting its jurisdiction.[133] Some also have questioned whether FDA regulation of cloning could ever be sufficient, given that the agency's mandate is to regulate safety and effectiveness, and not to make judgments about the ethical and social implications of the products under its jurisdiction.[62,169]

FDA's authority to regulate embryonic stem cells, whether from in vitro fertilized or cloned embryos, is more straightforward but is limited to evaluating the safety and effectiveness of proposed clinical applications of these cells. FDA's jurisdiction to regulate drugs and biological products includes oversight of cellular and tissue-based therapies. FDA's approach to the regulation of cellular and tissue-based therapies is evolving, and is marked by three key features: (1) a case-by-case approach, (2) reliance on informal guidance documents in addition to formal rulemaking as a way to communicate with the regulated industry, and (3) the desire to leave as many regulatory options as possible open to the agency in order to account for new or changing circumstances.[60] FDA would evaluate a proposed therapeutic use of embryonic stem cells using the same approach as it would for any other cellular therapy.

FDA has sent letters to sponsors and researchers asserting FDA's jurisdiction to regulate particular cellular and tissue products. First, in November 2000, FDA sent a letter to researchers asserting the agency's jurisdiction over "fetal cells and tissues intended for use in humans."[115] Second, in July 2001, FDA sent a letter to sponsors and investigators asserting FDA's jurisdiction over "human cells used in therapy involving the transfer of genetic material by means other than the union of gamete nuclei."[114] The letter cited as examples of such products (1) cell nuclei, (2) oocyte nuclei, (3) ooplasm, and (4) genetic material contained in a genetic vector, transferred into gametes or other cells. The letter states that the "use of such genetically manipulated cells (and/or their derivatives) in humans constitutes a clinical investigation" requiring the submission of an IND.[114] This letter would appear also to apply to cells derived from embryos created through SCNT.

FDA's jurisdiction begins at the point at which a researcher seeks to investigate the safety and effectiveness of a therapy in a human being. Prior to introducing stem cells into humans, an investigator first would need to submit an IND application to FDA articulating the scientific basis for the investigation as well as the laboratory and animal data supporting introduction in humans.[36] FDA regulations also require that the investigator obtain IRB approval before proceeding.

FDA would review an IND to determine if there was adequate

evidence of safety to support proceeding in humans. FDA specifically has addressed safety concerns related to co-culture of embryos with animal cells. In May 2001, FDA sent letters to Sen. Edward Kennedy and Sen. Judd Gregg in response to inquiries regarding xenotransplantation safety concerns resulting from co-culture with non-human cells.[109] The letters stated that the xenotransplantation concerns were not unique to stem cells and that the "use of irradiated mouse feeder layers in deriving" human embryonic stem cells raises concerns similar to other xenotransplantation products.[109] The letter stated that FDA does not prohibit the use of mouse feeder layers to make human embryonic stem cell products, that "appropriate testing and precautions are necessary," but that FDA regulation "should not impose a substantial impediment to xenotransplantation product development," including the development of human embryonic stem cells.[109]

In March 2002, FDA issued a letter to researchers asserting the agency's jurisdiction over "cells or tissues intended for transplant into a human recipient that have ex-vivo contact with live nonhuman animal cells, tissues, or organs."[113] The letter advised that the transfer of such human embryos into a human would constitute a clinical investigation requiring an IND. FDA stated that it did not intend to take enforcement action with respect to embryos that already had been co-cultured with live nonhuman animal cells, but that it would like to discuss its concerns with researchers and physicians and make recommendations regarding follow-up of patients who had received such materials.[113]

FDA's pronouncements to date indicate that the agency has safety concerns with respect to co-culture of human and non-human cells that are intended for clinical administration, but that these concerns will not necessarily preclude the development of a product relying on such methods. FDA has issued guidance documents indicating the scientific issues that researchers should be aware of in using these methods.

In addition, FDA also might consider possible safety issues arising from the SCNT procedure itself. FDA could not, however, take into account concerns other than safety and effectiveness (e.g., moral worth of the embryo) in making its determination.

If FDA permitted an IND to proceed for a therapeutic application of cloned or non-cloned human embryonic stem cells, and if the investigator obtained clinical evidence of safety and effectiveness, the manufacturer then would need to submit a biological license application (BLA) for approval to market the therapy.[34] The BLA must contain sufficient evidence of safety and effectiveness to justify use of the biological product in humans. In addition, FDA pays particular attention to the manufacturing process and facilities used to manufacture biologics to ensure their safety.

Other Federal Laws

Other federal laws also would apply to the cloning of human embryos. For example, donors of both eggs and somatic cell nuclei for cloning could be considered research subjects, depending on the context. Researchers working in an institution that receives federal funds therefore could be required to follow federal human subjects protections regulations in obtaining these eggs,[35] but the rules would not necessarily apply to privately-funded research. These rules also would apply if data from the research were going to be used to support FDA approval of a new product.[33] In addition, federal law that protects the privacy of medical information[70] also would pertain to information obtained from egg donors.

State Laws Pertaining to Cloning

States have been called the "laboratories" of democracy because of their capacity to experiment with new approaches to social and economic issues.[158] As the debate over reproductive and research cloning legislation has reached what appears to be a stalemate at the federal level, some state legislatures in the United States already have decided the issue for their citizens, but have adopted widely divergent positions. As of April 1, 2005, 12 states have passed laws directly addressing reproductive cloning, research cloning and therapeutic cloning, and several other state legislatures have introduced bills on the subject (see Table 2). State laws restricting embryo research also may affect a researcher's ability to conduct research with embryonic stem cells in that state, whether or not the stem cells are derived from cloned embryos. In this chapter, we summarize the state legislative responses to date.

States That Ban Research, Therapeutic and Reproductive Cloning

Five states, Arkansas,[14] Iowa,[95] Michigan,[134,135,137] North Dakota,[161] and South Dakota,[200] have passed laws clearly prohibiting reproductive, research and therapeutic cloning. In addition, Virginia has passed a law that prohibits reproductive cloning, but whose effect as to research and therapeutic cloning is unclear. Most of these laws explicitly are modeled on federal anti-cloning bills (see box pg. 34 & 35). These state laws typically define human cloning as human asexual reproduction accomplished through SCNT into a human oocyte to produce a living organism at any stage of development that possesses a human or predominantly human constitution. The laws impose criminal and in some cases civil penalties on both human cloning and activities related thereto (such as the shipment or receipt of cloned embryos or the shipment or receipt of gametes for the purpose of cloning).

Michigan law, in contrast, forbids any individual to "engage or attempt to engage in human cloning,"[137] but human cloning is defined as "the use of human somatic cell nuclear transfer technology to produce a human embryo."[134] The law imposes both civil and criminal penalties of up to $10 million dollars as well as up to 10 years in prison for violation of the law.[136]

Virginia law defines human cloning as "the creation of or attempt to create a human being by transferring the nucleus from a human cell from whatever source into an oocyte from which the nucleus has been removed."[211] The law states that no person shall (1) perform human cloning, (2) implant or attempt to implant the product of somatic cell nuclear transfer into a uterine environment so as to initiate a pregnancy, (3) possess the product of human cloning, or (4) ship or receive the product of a somatic cell nuclear transfer in commerce for the purpose of implanting the product of somatic cell nuclear transfer into a uterine environment so as to initiate a pregnancy.[212] However, the law states that it "shall not be construed to restrict biomedical and agricultural research or practices unless expressly prohibited herein, including research or practices that involve the use of (i) somatic cell nuclear transfer or other cloning technologies to clone molecules, including DNA, cells, or tissues; (ii) gene therapy; or (iii) somatic cell nuclear transfer techniques to create animals other than humans."[213] The term "human being" is not defined in the law. Some argue that the research exemption includes research on cloned embryos and embryonic stem cells derived from them,[145] while others contend that the law is intended to ban the use of SCNT cloning to make an organism at any stage of development.[209] Absent judicial review of the statute, its impact cannot be conclusively determined.

States That Prohibit Reproductive Cloning but Permit or Support Research and Therapeutic Cloning

State laws permitting research or therapeutic cloning cite several common justifications: (1) the imperative of alleviating human suffering, (2) the economic loss caused by diseases that could be avoided through stem-cell based therapies, (3) the threat of job loss in the scientific sector if stem cell research is foreclosed, (4) the general benefits of stem cell research that may be realized, and (5) the historic record of scientific inquiry in the state.

Four states — California, New Jersey, Rhode Island, and, most recently, Massachusetts — expressly permit SCNT for research or therapeutic purposes, while banning the use of the procedure for reproduction. Rhode Island appears to have been the first state to bifurcate the cloning issue into the two constituent parts of reproduction and research. Rhode Island's law, enacted in 1998, states that "No person or entity shall utilize somatic cell nuclear transfer for the purpose of initiating or attempting to initiate a human pregnancy."[186] Interestingly, the law also prohibits reproductive cloning by dividing a blastocyst, zygote, or embryo. However, the law explicitly exempts from the prohibition "research practices" using SCNT or other cloning technologies to clone molecules, DNA, cells, and tissues."[186] In the statement of purpose and intent accompanying the law, the legislature recognized that "recent medical and technological advances have had tremendous benefit to patients, and society as a whole,"[185] and that "biomedical research for the purpose of scientific investigation of disease or cure of a disease or illness should be preserved and protected and not be impeded by regulations involving the cloning of an entire human being."[185] Therefore, it stated that the purpose of the legislation was to "place a ban on the creation of a human being through division of a blastocyst, zygote, or embryo or somatic cell nuclear transfer, and to protect the citizens of the state from potential abuse deriving from cloning technologies"[185] but not to prohibit "the cloning of human cells, genes, tissues, or organs that would not result in the replication of an entire human being."[185] It also clarified that the ban was not "intended to apply to in vitro fertilization, the administration of fertility enhancing drugs, or other medical procedures used to assist a woman in becoming or remaining pregnant, so long as that procedure is not specifically intended to result in the gestation or birth of a child who is genetically identical to another conceptus, embryo, fetus, or human being, living or dead."[185] The law expires in 2010.[187]

While Rhode Island's cloning law would seem incontrovertibly to permit research cloning, some argue that another law addressing fetal research has the indirect effect of prohibiting research that destroys human embryos to derive embryonic stem cells. An older law prohibits research on a "live human fetus" that would jeopardize its life or health.[188] The statute defines the term "fetus" to include an embryo or neonate.[188]

In 2002, the California legislature enacted laws that banned efforts to create a human being using SCNT[24] and that permitted research using stem cells "from any source" including those derived from SCNT cloned embryos.[25] In November 2004, Californians boosted momentum for stem cell research in their state, when 59 percent of voters approved a ballot initiative known as Proposition 71 ("Prop 71"): The California Stem Cell Research and

Table 2: State Laws Addressing Human Cloning

State	Reproductive Cloning Allowed?	Research/ Therapeutic Cloning Allowed?	Use of State Funds Restricted?	State Funding Appropriated
AR	No	No	No	No
CA	No	Yes	No	Yes
IA	No	No	No	No
LA	No	No	Yes	No
MA*	No	Yes	No	No
MI	No	No	Yes	No
MO	N/A	N/A	Yes	No
NJ	No	Yes	No	Yes
ND	No	No	No	No
SD	No	No	No	No
RI	No	Unclear	No	No
VA	No	Unclear	No	Yes

* Bills have passed both state House and Senate, but have not yet become law

Cures Initiative.[235] The proposition established a right under the state constitution to conduct stem cell research, including research with cloned stem cells, and authorized approximately $3 billion in state funds over a 10-year period to develop stem cell research initiatives.[72,73,235,236] Funds will be alocated both for building infrastructore, such as the California Institute for Regenerative Medicine, as well as for public and private research institutions in California seeking to conduct stem cell research.[181,235]

In 2003, the New Jersey legislature enacted a law making it a crime to knowingly engage, or assist, directly or indirectly, in the cloning of a human being.[154] The law defines "cloning of a human being" as "the replication of a human individual by cultivating a cell with genetic material through the egg, embryo, fetal and newborn stages into a new human individual."[154] At the same time, however, the legislature enacted a law declaring that it was the public policy of New Jersey to permit research "involving the derivation and use of human embryonic stem cells, human embryonic germ cells and human adult stem cells, including somatic cell nuclear transplantation."[155] Such research must "be conducted with full consideration for the ethical and medical implications of this research," and "be reviewed, in each case, by an institutional review board operating in accordance with applicable federal regulations."[155] The law thus sanctioned the creation of embryos for research, and did not limit the stage of development to which an embryo could be grown in the laboratory.

In announcing this policy, the legislature noted the "crippling economic and psychological burden of chronic, degenerative and acute diseases" to patients and society, the United States' historical role as "a haven for open scientific inquiry and technological innovation,"[156] the potential harm to the state's biomedical industry that limits on stem cell research would cause, and that "[p]ublicly funded stem cell research, conducted under established standards of open scientific exchange, peer review and public oversight, offers the most efficient and responsible means of fulfilling the promise of stem cells to provide regenerative medical therapies."[156] At the same time, however, the legislature found that stem cell research, "including the use of embryonic stem cells for medical research, raises significant ethical and public policy concerns."[156] Thus, the legislature declared that the public policy of the state must "balance ethical and medical considerations, based upon both an understanding of the science associated with stem cell research and a thorough consideration of the ethical concerns regarding this research; and be carefully crafted to ensure that researchers have the tools necessary to fulfill the promise of this research."[156] In 2004, New Jersey appropriated $6.5 million to build the Stem Cell Institute of New Jersey;[175] the governor proposed increasing funding for the institute to $380 million in early 2005.[153]

Finally, on March 31, 2005, the Massachusetts House of Representatives passed legislation prohibiting reproductive cloning and authorizing embryonic stem cell research, including SCNT, by a vote of 117-27.[11,16] The state Senate had previously approved a similar bill by a vote of 35-2.[10,55] The two bills will need to be reconciled, after which the law will go to Governor Mitt Romney for signature.[16] While the Governor is widely expected to veto the bill, there appear to be sufficient votes by the legislature to override the veto.[16]

States That Ban Use of State Funds to Conduct Research and Therapeutic Cloning

Missouri law, enacted in 1998, prohibits the use of state funds "for research with respect to the cloning of a human person."[139] The law defines "cloning" as "the replication of a human person by taking a cell with genetic material and cultivating such cell through the egg, embryo, fetal and newborn stages of development into a new human person."[139]

Under the Nebraska Health Care Funding Act, also enacted in 1998, no funds allocated pursuant to that Act may be spent on "research or activity of any kind involving ... the use of human embryonic stem cells or for the purpose of obtaining other funding for such use."[151]

Kentucky law prohibits the use of public funds for research into or the performance of in vitro fertilization if the procedures result in the intentional destruction

of human embryos.[102] Since the derivation of stem cells requires the destruction of human embryos, this law would likely prohibit funding of research in which stem cells were derived from embryos, although it would not necessarily preclude funding of research using embryonic stem cells derived without state funding.

In addition to banning cloning and stem cell research outright, Michigan law also prohibits the use of state funds "to engage in or attempt to engage in human cloning."[137]

State Embryo Research Laws

Several states that have not enacted legislation restricting reproductive or research cloning activities have older laws on the books that limit or prohibit the use of embryos in research. Some of these laws, depending on how they are interpreted, could have the effect of prohibiting research, therapeutic, and reproductive cloning.

States with laws addressing embryo research are Louisiana,[119] Maine,[124] Massachusetts,[127] Minnesota,[138] New Hampshire,[152] New Mexico,[157] and Pennsylvania.[167,168] The language and restrictions of these laws differ. For example, in Massachusetts, research with embryos is prohibited unless it has been approved by an institutional review board and a copy of the approval and the research protocol have been filed with the District Attorney.[127] The new law that is expected to go into effect would supersede this requirement. In contrast, Louisiana law provides that no "in vitro fertilized human ovum will be farmed or cultured solely for research purposes."[119] Pennsylvania law prohibits the conduct of any nontherapeutic medical procedure on an unborn child, and defines an "unborn child" as "an individual organism of the species homo sapiens from fertilization until live birth."[167]

Pending Legislation in the States

The passage of Proposition 71 in California set off a ripple effect throughout state legislatures across the country. Since the start of the 2005 legislative session, bills have been introduced in Arizona, Connecticut, Illinois, Indiana, Kansas, Kentucky, Maryland, Mississippi, Missouri, Nebraska, New York, Tennessee, Texas, and Washington. Some of these bills would prohibit reproductive as well as research and therapeutic cloning, while others would prohibit only reproductive cloning, and still others would allocate funding for stem cell research. Some states appear to be motivated by a fear of losing jobs and researchers to California. Others seek to make explicit their opposition to SCNT for any purpose. Mirroring the debate in Congress, in some cases bills have been introduced in the same state legislature seeking contradictory results.

Kentucky's experience demonstrates the deep divides evidenced in the cloning debate that can preclude the passage of legislation over the course of many years. Kentucky, which is home to University of Kentucky physiology professor and outspoken cloning proponent Panayiotis M. Zavos, has considered legislation to ban human cloning since 2002.[203] In that year, the Kentucky House of Representatives introduced the Kentucky Human Cloning Prohibition Act of 2002 (H.B. 138).[74,103] The bill, which tracked the language of the federal Brownback-Landrieu bill, would have prohibited all human cloning for any purpose. The bill passed the Kentucky House of Representatives with little debate, with some members stating afterwards that they did not realize the implications for research cloning.[203] After the effect of the bill on research cloning was realized, the Senate heard hours of testimony and engaged in emotional debate on the issue. The Senate voted to amend the bill to permit research with existing stem cell lines, but the bill was tabled after Senate Republican leaders opposed it.[203] The bill was reintroduced in the 2003 and 2004 sessions, and again is under consideration in the 2005 session.[102]

International Cloning Policy

Unlike the United States, many countries have enacted laws that ban cloning activities either in whole or in part. At the same time, the United Nations has sought to ban reproductive cloning without success, because of a stalemate over whether to prohibit research and therapeutic cloning.

In November 1997, the United Nations Educational, Scientific, and Cultural Organization (UNESCO) issued the Universal Declaration on the Human Genome and Human Rights,[208] which argued that there is an inextricable link between respect for the human genome and human dignity. The Declaration stated that practices "contrary to human dignity" included applications of cloning with the intent to create a human being. Thus, the Declaration sought to emphasize the genome's symbolic value as the "heritage of humanity," the dignity of the human person, and the rejection of genetic reductionism. All 186-member states of UNESCO unanimously accepted the terms of the declaration. The United States was not a member of UNESCO at that time.

Although it constitutes a forceful avowal regarding the need for ethical standards to govern scientific advancements in genetics, the Declaration does not have legal force. It therefore serves only as guidance for member nations.

The United Nations also has considered a convention banning human cloning but such a convention has not been adopted. While there appears to be widespread agreement among member countries that cloning to produce a baby represents a threat to human dignity and poses serious medical, physical, psychological, and social dangers, and potentially may lead to the exploitation of women,[176] there is disagreement among member nations about the acceptability of research cloning. In August 2001 France and Germany proposed that the United Nations develop an "international convention against the reproductive cloning of human beings."[217] The Vatican

In Focus: UK Human Fertilisation and Embryology Authority

The Human Fertilisation and Embryology Authority (HFEA) is a regulatory body within the United Kingdom responsible for licensing and monitoring of clinics that carry out IVF, donor insemination, and human embryo research. The HFEA was established in 1991 pursuant to the Human Fertilization and Embryology Act (HFE Act 1990). In 2001, in response to a challenge by the Pro-Life Alliance, the High Court ruled that the HFE Act did not grant the HFEA authority to regulate embryos created by SCNT (called Cell Nuclear Replacement or CNR in the United Kingdom).[40] The Court held that embryos created via SCNT did not meet the Act's definition of a human embryo. Thereafter, the British parliament passed the Human Reproductive Cloning Act 2001,[89] which prohibits reproductive cloning. Ultimately, a higher court ruled that a human embryo created by cloning was within the scope of the HFE Act.[12]

The HFEA has granted two licenses to researchers seeking to conduct cell nuclear transfer for research purposes. In August 2004, the HFEA granted the first license to the Newcastle Centre for Life. The license did not specify a particular disease, but rather was for research intended to "increase knowledge about the development of embryos and enable this knowledge to be applied in developing treatments for serious disease."[178] The Lawyers Christian Fellowship has sought judicial review of the HFEA's grant of this license, arguing that its actions are unlawful.[128] In February 2005 the HFEA granted a license to the Roslin Institute in Edinburgh to conduct cell nuclear replacement for the purpose of studying motor neuron disease, particularly in those patients whose condition cannot be linked to the genes already identified as causing the disease.[177]

The HFEA publicly has endorsed research to obtain cloned embryonic stem cells. In a statement released February 12, 2004, the HFEA applauded the announcement of Korean scientists' advances in stem cell research as a "responsible use of technology" for an "important area of research."[179] At the same time, the HFEA referred to reproductive cloning as an "abhorrent" practice and emphasized the role of the HFEA in the United Kingdom as a governing body to protect against such unethical practices.[179]

and the United States subsequently argued that both reproductive and research cloning should be included.[217] Two proposals for a convention ultimately emerged: The first, a proposal submitted by Belgium and embodying the French and German position, proposed a ban on reproductive cloning; the second, submitted jointly by Costa Rica and United States, proposed a ban on all cloning, whether for reproduction, research, or therapeutic purposes.[217] Neither the Belgian nor the U.S./Costa Rican proposal for a convention has been voted on.

On March 9, 2005, the United Nations General Assembly adopted a U.S.-backed Declaration on Human Cloning by a vote of 84-34, with 37 abstentions. The Declaration, which is not binding on any members, called on member states 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."[176] Some member nations, including the United Kingdom, have criticized the Assembly for failing to restrict the convention only to reproductive cloning, and have indicated their intent to pursue research cloning despite the Declaration.[122]

In 1998, 19 European countries within the Council of Europe signed the Protocol on the Prohibition of Cloning Human Beings, which committed their countries to ban by law "any intervention seeking to create human beings genetically identical to another human being, whether living or dead."[1] The Protocol, which is part of the Convention on Human Rights and Biomedicine, permits the cloning of cells for research purposes. Signatories to the agreements are Denmark, Estonia, Finland, France, Greece, Iceland, Italy, Latvia, Luxembourg, Moldova, Norway, Portugal, Romania, San Marino, Slovenia, Spain, Sweden, Macedonia and Turkey.[1] To date, more than half of the Council of Europe states have signed the Protocol.

Several countries have passed country-specific laws explicitly addressing reproductive and research cloning (Table 3).[206,219,232] In addition, some countries that have not addressed human cloning specifically have laws banning or restricting embryo research. These laws also could have the effect of prohibiting SCNT to create embryos; for example, a law that prohibited the creation of embryos for research also could implicitly ban the creation of an embryo through SCNT. Similarly, the constitutions of some countries are worded in a manner that would appear implicitly to ban SCNT. For example, Ireland's constitution provides that "The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate that right."[66] This has been interpreted by some as an implicit ban on reproductive as well as research and therapeutic cloning. Less clear is whether prohibitions on cloning or on research with human embryos also would include research with cloned stem cells – such questions can only be answered based on case by case review of a specific country's statute and the manner in which it has been interpreted within that country's legal system.[218]

While it is perhaps tempting to look for simple explanations for a country's approach to cloning — for example by correlating it with the dominant religious tradition of that country — such a simplistic approach would be unwise. As ethicist LeRoy Walters, who has conducted an intensive study on the international landscape for embryo and cloning research, has noted: "[a]ny attempt to discover tidy correlations between the range of national and regional perspectives … is fraught with difficulty and may, in fact, be doomed to fail."[218] This difficulty stems in part from the different relationships within a country between the government and its religious groups, as well as the pluralism within particular religious traditions. Nevertheless, he notes that countries "in which the majority or a substantial minority of persons identify themselves as Christians" are more likely to adopt restrictive policies concerning both embryonic stem cell research and, by extension, research cloning.[218] Countries in which Catholicism is strong are likely influenced by the Vatican's position on cloning, which holds that cloning for any purpose violates the sanctity of human life.[3] On the other hand, countries in which either Judaism or Islam is well represented tend to favor human embryonic stem cell

Table 3: Country-specific International Laws, Regulations, or Guidelines on Human Cloning*

Country	Permit Reproductive Cloning	Permit Research Cloning	Source
Argentina	No	No	Decree No. 200/97 A Prohibition on Human Cloning Research (1997).Regional laws:Law no. 712 (2001) Buenos AiresLaw no. 6581 (1998) Province of Mendoza Law no. 9072 (2003) Province of Cordoba
Australia	No	No	Prohibition of Human Cloning Act No. 144 (2002) Gene Technology Act (2000)Act No. 51 (2003) (Tasmania)
Belgium	No	Yes	Law concerning research on embryos in vitro (2003)
Brazil	No	No	Law 8.974 (1995) on the Uses of Genetic Engineering Techniques and Release of Genetically Modified Organisms Into the Environment, as interpreted by the Brazilian Biosafety Technical Commission of the Ministry for Science and Technology in 1997.
Canada	No	No	The Assisted Human Reproduction Act (2004)
China (Republic)	No	Yes	Ministry of Public Health, Rules on Assisted Reproductive Technologies for Human Beings (2003) Ministry of Health, Ethical Principles on Assisted Reproductive Technologies for Human Beings and Human Sperm Bank (2003)Ministry of Science and Technology and Ministry of Health, Ethical Guidelines on Human Embryonic Stem Cells (2004)
China (Hong Kong)	No	No	Government of the Hong Kong, Special Administrative Region, The Human Reproductive Technology Ordinance No. 47 (amended 2002)
Costa Rica	No	No	Decree No. 24029-S: A Regulation on Assisted Reproduction (1995).
Colombia	No	Yes	Criminal Code (2000)
Denmark	No	No	Act no. 460 on Medically Assisted Procreation in connection with medical treatment, diagnosis and research, 1997 (amended 2003) Act no. 503 on a Scientific, Ethical Committee System and the Handling of Biomedical Research Projects (1992)
Estonia	No	No	Penal Code (2001)The Patents Act (amended 2003) (prohibits patenting of processes for cloning human beings)
Finland	No	No	Medical Research Act no. 488/1999 (1999)
France	No	No	Bioethics Law (2004)
Georgia	No	No	Law on the rights of the patients (2000)Law on Health Care (1997)
Germany	No	No	Embryo Protection Act (1990)
Greece	No	No	Law No. 3089 on Medically Assisted Reproduction (2002)General Council for Health Statement (1988)
Hungary	No	Yes	Law no. 154 on public health (1997)

Table 3 (cont.): Country-specific International Laws, Regulations, or Guidelines on Human Cloning

Country	Permit Reproductive Cloning	Permit Research Cloning	Source
Iceland	No	No	Artificial Fertilisation Act No. 55 (1996) Iceland Ministry of Health and Social Security, Regulation No. 568/1997 on Artificial Fertilisation (1997).
India	No	Yes	Indian Council of Medical Research (ICMR), Draft Guidelines for Stem Cell Research/Regulation (2004)Department of Biotechnology, Ministry of Science and Technology, Government of India Ethical Policies on the Human Genome, Genetic Research and Services (2001).
Italy	No	No	Assisted Medical Procreation Law (2004).
Israel	No	Yes	The Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law, 5759-1999 (amended 2004). Pursuant to recommendation by Bioethics Committee of the National Academy of Sciences and Humanities of Israel, the Ministry of Health empowered the National Helsinki Committee for Genetic Research in Humans to review applications for the creation of human embryos using SCNT.
Japan	No	Yes	Law regulating the technique of human cloning and other similar techniques (2000) Minister of Education, Culture, Sports, Science and Technology, Guidelines in Relation to Handling of Specified Embryos (2001) (to be revised pursuant to July 2004 report by Bioethics Committee of the Council for Science and Technology to permit the creation of embryos for research purposes under strict conditions)
Latvia	No	No	Law on Sexual and Reproductive Health (2002)
Netherlands	No	No	The Embryos Act (2002)
New Zealand	No	N/A	Human Assisted Reproductive Technology Act No. 92 (2004)
Norway	No	No	Law No. 79 (prohibition of therapeutic cloning) (2002)Law No. 100 (the Biotechnology Law) (2003)
Panama	No	No	Law No. 3 Human Cloning Prohibition (2004).
Peru	No	No	Law No. 26842, General Health Law (1997)Law No. 27636, Criminal Code: Genetic Manipulation (2002).
Portugal	No	No	Opinion No. 21/CNECV/97 on the Ethical Implications of Cloning," National Council of Ethics for the Life Sciences
Russian Federation	No	Yes	Law on the Temporary Prohibition of Human Cloning (2002)
Singapore	No	Yes	Bioethics Advisory Committee of Singapore, Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning (2002)Human Cloning and Other Prohibited Practices Act (2004)

Table 3 (cont.): Country-specific International Laws, Regulations, or Guidelines on Human Cloning

Country	Permit Reproductive Cloning	Permit Research Cloning	Source
Slovakia	No	No	Health Care Law (1994)Slovak Penal Code (2003)
Slovenia	No	No	The Law on Medically Assisted Reproduction (2001)
South Africa	No	Yes	National Health Act (December 31, 2003)
South Korea	No	Yes	Life Ethics Law (2004)
Spain	No	No	Law No. 35/1988 on Assisted Human Reproduction Techniques (1988, modified by Organic Law No. 10/995 of 23 November 1995 and amended by Law 45/2003)
Sweden	No	Yes	Activities involving human eggs for research or treatment purposes act (amending the act of March 14, 1991) (effective April 1, 2005).
Switzerland	No	No	Federal Act on Research on Surplus Embryos and Embryonic Stem Cells (Embryonic Research Act) (2004)Federal Order on the revision of the Federal Constitution" (1998)
Thailand	No	Yes	Medical Council of Thailand, Regulations on Human Cloning No. 21/2544 (2002)National Center for Genetic Engineering and Biotechnology (BIOTEC), National Health Foundation (NHF), Bioethics and Advanced Biomedical Research Project, Stem Cell Guideline (2003)
Tunisia	No	No	National Medical Ethics Committee, Opinion No. 3 (1997)
Turkey	No	N/A	Regulation on In Vitro Fertilization and Embryo Transfer Centers (1996)
Ukraine	No	N/A	Ban on Human Reproductive Cloning Bill (2004)
United Kingdom	No	Yes	Human Reproductive Cloning Act (2001)Human Fertilisation and Embryology Act (amended 2001)
Vietnam	No	No	Decree by government (2003)

* Because many of the original legal sources are in a foreign language or otherwise inaccessible, this table was compiled using several secondary sources, including the following: WHO International Digest of Health Legislation[232] (keyword search cloning); The Website of William Hoffman,[219] which tracks international stem cell and cloning policies; Database of Global Policies on Human Cloning and Germ-line engineering, maintained by Global Lawyers[66] and Physicians; BIONET;[17] UNESCO,[206] National Legislation Concerning Human Reproductive and Therapeutic Cloning (2004); and LeRoy Walters, Human Embryonic Stem Cell Research: An Intercultural Perspective.[218] Where sources conflicted or were ambiguous, verification was attempted using secondary sources such as newspaper articles. This table does not include laws that prohibit or restrict embryo research if the country does not also have laws that address human cloning or genetic manipulation of embryos. As with the other tables in this report, policies including a moratorium are counted as "No" and are not separately distinguished.

research, in general, and several Jewish and Muslim scholars also have argued in favor of research cloning.[218]

In addition to religious outlook, economic considerations may help explain the divergent international approaches. Countries that are investing heavily in the area of embryonic stem cell research in the hope of long-term economic return are more likely to adopt permissive policies regarding research cloning. Separating reproductive from research cloning, and banning one while permitting the other, may be a means to protect their research investment.[218] Some countries supporting research cloning while opposing reproductive cloning also have argued that cloning for research purposes is a "responsible use" of technology, given the potential benefits it may have in the treatment of disease.[178]

U.S. Public Opinion About Human Cloning

By all accounts and every survey of U.S. public opinion, most Americans oppose the use of cloning for reproduction. What is lost in that declarative statement — which routinely is echoed in mass media and political rhetoric, and drives much of the policy discussion about cloning — is that Americans actually have much more nuanced opinions regarding the use of cloning for research and therapeutic purposes, and that these opinions still are anything but immutable. One measure of the fluidity of U.S. public opinion about therapeutic and research cloning is that the survey results one gets depend to a great extent on the manner and context in which the questions are asked. For instance, whether the word "cloning" or the phrase "somatic cell nuclear transfer" is used in the survey and whether and how the potential harms and benefits of cloning are identified have a direct impact on level of approval. Opinion also seems to be influenced by the media environment at the time of polling. This section first reviews the results of several public opinion surveys on research and therapeutic cloning, and highlights the effect of context and wording on outcomes. Second, this chapter reviews the results of a survey conducted by the Genetics and Public Policy Center in 2004 of 4,834 Americans regarding reproductive genetic technologies, including cloning.

Survey Methods

The Study of Attitudes Towards Genetic Technologies 2004 Survey (2004 survey) collected data from 4,834 Americans about their attitudes toward reproductive genetic technologies between April 16 and May 9, 2004. This internet-based survey, administered by Knowledge Networks (http://www.knowlegenetworks.com), is the largest survey of American opinions on this topic to date. The respondents were sampled randomly from Knowledge Network's web-enabled research panel designed to be representative of the entire U.S. population. The panel is representative because it was selected using high-quality probability sampling techniques, and it was not limited to current Web users or computer owners. Households were selected using random digit dialing (RDD) and each household was provided with free hardware and Internet access as needed for research participation. Research subjects for the 2004 Survey were U.S. residents over age 18. Statistical results are weighted to correct for known selection probabilities, for demographic discrepancies, and to account for oversampling of Blacks. The overall survey completion rate of the survey was 73 percent. The survey instrument and research protocol were approved by the Johns Hopkins University Institutional Review Board. All data reported as "significant" or "statistically significant" in the text of this document met criteria at $p<.05$ in a chi-square test.

Numerous surveys indicate that a majority of Americans support research on stem cells derived from "extra" embryos donated by IVF clinics; surveys by Beliefnet/ABC News, and Ipsos indicate a level of support of between 58-75 percent.[2] However, specifying that the embryo is obtained through cloning or failing to specify the source of the embryo leads to a lower level of approval.[159] For instance, in a Gallup Poll only 38 percent of respondents endorsed the use of cloned embryos for research.[64] When the word cloning is not used, but the term somatic cell nuclear transfer is defined, there appears to be significant public support for the technology. A recent survey conducted by the Coalition for Advancement of Medical Research reported that 72 percent of a nationally representative sample of the public approved of "SCNT stem cell research"; the word 'cloning' was not mentioned in the question.[32]

Whether or not the potential benefits of stem cell research and research cloning are specified in the question also can affect approval. In a survey conducted by the Juvenile Diabetes Research Foundation,[100] interviewers asked whether participants would support stem cell research on donated embryos for a list of eight well-known diseases or injuries; 65 percent of respondents approved of research for this purpose.[214] Another poll, conducted by the Alliance for Aging Research,[68,159] asked participants whether scientists should use stem cells obtained from "very early human embryos" to find cures for serious diseases such as Alzheimer and Parkinson disease. Sixty-two percent of respondents agreed that they should, and 32 percent disagreed. In contrast, when

the National Council of Catholic Bishops conducted a survey in which they asked the general public whether they would "want their federal tax dollars to be used to destroy live embryos in the first week of development for experimentation," 70 percent of respondents opposed funding of such research.[146,159]

Clearly, how questions about cloning and stem cell research are posed to the public can have considerable bearing on the results of opinion polls. The socio-political climate in which the survey is fielded also may affect the level of support. The Virginia Commonwealth University has fielded annual surveys from 2001 to 2004 that have included the question: "On the whole, how much do you favor or oppose medical research that uses stem cells from human embryos?"[214] The source of the embryos was not specified. In September 2001, 48 percent of respondents either strongly favored or somewhat favored this approach. In September 2002, only weeks after President Bush imposed a moratorium on the derivation of stem cell lines, the level of approval for the same question had dropped to 35 percent; in September 2003, as national attention shifted to other issues, approval rose again to 47 percent, and then increased slightly to 53 percent in September 2004.[214]

Similarly, in 2001, following President Bush's announcement, 54 percent of surveyed respondents agreed that stem cell research was "morally wrong", although a significant proportion stated that although wrong, stem cell research still might be necessary.[64,159] However, less than a year later in May 2002 as media attention shifted to foreign policy, the proportion of respondents who identified stem cell research as morally wrong had dropped to 39 percent.

Table 4: Survey questions on cloning in The Study of Attitudes Towards Genetic Technologies (2004)

1. Is it scientifically possible to produce a cloned human embryo?
2. Is it scientifically possible to produce a cloned human baby?
3. Do you approve of scientists working on ways to create a cloned human embryo for research?
4. Do you approve of scientists working on ways to create a cloned human baby?
5. Do you think human embryo cloning for research should be allowed at all?
6. Do you think human cloning to create a baby should be allowed at all?
7. [If said yes, cloning should be allowed] Should government regulate cloning based on quality and safety?
8. [If said yes, cloning should be allowed] Should government regulate cloning based on ethics and morality?

In this section, we will discuss the findings of the Genetics and Public Policy Center's nationally representative survey of Americans, and highlight how opinions can differ based on sex, age, race, religious affiliation, income, education, and political party. We also will discuss how the context in which our questions (see Table 4) were presented during the survey likely influenced responses regarding cloning.

Survey Results

Awareness of Genetic Technologies

As far as you know, is it scientifically possible to produce a cloned human embryo?

As far as you know, is it scientifically possible to produce a cloned human baby?

Many of the Americans we surveyed were uncertain about the existing state of cloning technologies. Overall, only 18 percent reported that it was not yet scientifically possible to clone a human baby, while 38 percent indicated they did not know; 45 percent stated that it is scientifically possible to produce a cloned human baby (Figure 2). At the same time, 56 percent of those surveyed correctly stated that cloning a human embryo for research purposes is scientifically possible (Figure 2). A significant proportion, nearly 35 percent, reported they did not know if it was possible, while slightly more

than 9 percent indicated they believed it was not possible.

Approval of Research Cloning

In general, would you approve or disapprove of scientists working on ways to create a cloned human embryo for research?

Seventy-six percent of Americans in our survey did not approve of cloning human embryos for research purposes (Table 5). There were notable statistically significant differences in demographic characteristics ($p<.05$). More adults over age 50 disapproved of research cloning (81 percent) compared to younger age groups. Nearly one-third more men as women approved of cloning embryos for research purposes. A greater proportion of respondents with no religious affiliation reported approval of research cloning (42 percent), compared to those with religious affiliations; for instance, only 7 percent of Fundamentalist or Evangelical Christians approved of research cloning. Twice as many participants (35 percent) with post-graduate degrees approved of research cloning, compared to participants with no college education (18 percent). A significantly greater proportion of Democrats (27 percent) approved of research cloning compared to Republicans (18 percent).

Approval of Reproductive Cloning

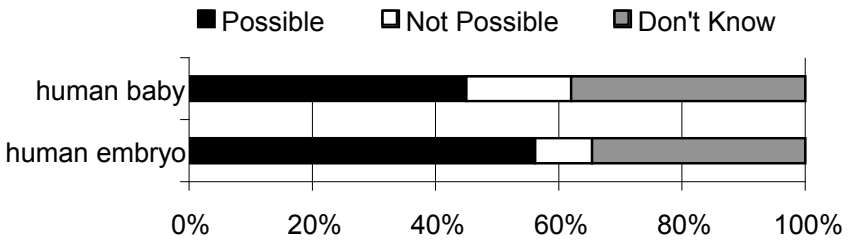
In general, would you approve or disapprove of scientists working on ways to create a cloned human baby?

The vast majority of the Americans we surveyed (88 percent) disapproved of using cloning to create a human baby (Table 6). Similar to research cloning, there were notable statistically significant differences ($p<.05$). Men were twice as likely as women to approve of cloning to produce a baby: 16 percent versus fewer than 8 percent. Younger respondents were more likely to approve of reproductive cloning than those over age 50. Far fewer Evangelical or Fundamentalist Christians approved of reproductive cloning compared to other religions and those with no affiliation. In addition, more Democrats (14 percent) and those with other party affiliations (13 percent) approved of reproductive cloning, compared to Republicans (8 percent). Differences in approval by race and ethnicity were very small.

If you could clone a loved one, would you?
If you could clone yourself, would you?

Only a small proportion of the Americans we surveyed reported they would clone a loved one, if given the opportunity, or clone themselves if they could (Tables 7 & 8). Statistically significant differences in demographic characteristics were observed ($p<.05$). While slightly more men (9 percent) than women (7 percent) stated they would clone someone they loved, men were twice as likely as women to say they would clone themselves. Older respondents, Evangelical or Fundamentalist Christians, and Republicans were less likely than their comparison groups to say they would clone a loved one.

Figure 2: Is it scientifically possible to produce a cloned human embryo or a cloned human baby?



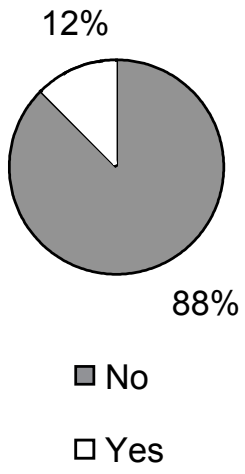
Source: 2004 Survey

Oversight and regulation of human cloning

Do you think human cloning to create a baby should be allowed at all?

The majority of Americans we surveyed overwhelmingly stated cloning to create a human baby should not be allowed at all (88 percent) (Table 9; Figure 3). In terms of statistically significant differences by demographic characteristics ($p<.05$): twice as many men (16 percent) as women (8 percent) stated they would allow reproductive cloning. At the same time, nearly twice as many respondents under age 50 agreed reproductive cloning should be allowed, compared to those over age 50 (15 percent versus 8 percent). Fewer Blacks stated reproductive cloning should be allowed than Whites or Hispanics. A greater proportion of respondents without a religious affiliation stated reproductive cloning should be allowed, while those respondents with a religious affiliation were less approving (i.e., 23 percent versus 4 percent of Evangelical Fundamentalists).

Figure 3: Do you think human reproductive cloning should be allowed at all?

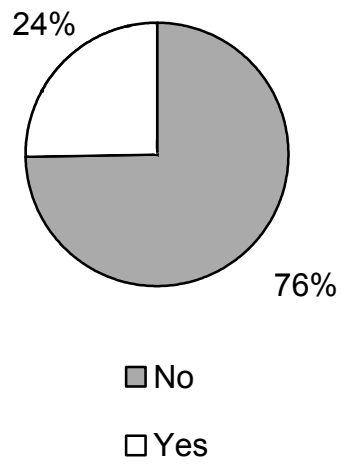


Source: 2004 Survey

Do you think human embryo cloning for research should be allowed at all?

The majority (76 percent) of respondents we surveyed believed research cloning should not be allowed at all (Table 10; Figure 4). It should be noted, however, that these questions did not state the potential benefits or harms of research cloning. Statistically significant differences by demographic characteristics were observed ($p<.05$). Many more men than women agreed that research cloning should be allowed (30 percent versus 19 percent), while younger age groups expressed greater approval than the over 50 cohort. Similar to opinions about reproductive cloning, Blacks again were less approving of research cloning than Whites or Hispanics. Not surprisingly, vast differences were observed by religious affiliation; for instance, only slightly fewer than 7 percent of Fundamentalist Evangelicals stated research cloning should be allowed, compared to over 45 percent of respondents who reported no religious affiliation. Large differences in opinion also were seen by education; more than twice as many participants with a post-graduate degree agreed research cloning should be allowed, compared to participants with no college education. Finally, fewer Republicans (19 percent) than Democrats and other party affiliations (28 percent & 24 percent, respectively) expressed support for allowing research cloning.

Figure 4: Do you think human embryo cloning for research should be allowed at all?



Source: 2004 Survey

If respondents stated yes, either research or reproductive cloning should be allowed, further questions were asked about the extent of regulation of cloning in general. It should be noted however, that these regulation questions did not specify whether cloning was for reproductive or research purposes.

Among participants who stated that cloning for either research or

reproductive purposes should be allowed, the majority (85 percent) felt that government regulation for quality and safety was imperative. Within this group, differences of opinion in regulation by political party were small; only slightly more Democrats and those with other party affiliations approved of government regulation for quality and safety compared to Republicans (84 percent & 83 percent compared to 81 percent).

Fifty-four percent of participants who stated that cloning for either research or reproductive purposes should be allowed also stated that it should be regulated based on ethics and morality. A greater proportion of respondents with ties to organized religions (between 55-65 percent, depending on religious affiliation) endorsed government regulation based on ethics and morality, compared to respondents with no religious affiliation, although a significant proportion of the latter group (43 percent) still believed regulation based on ethics and morality was necessary.

Conclusion

Our survey, together with several others that have been conducted on the subject, demonstrate that differences in question wording and context result in a great deal of variation in survey results, and consequently an unclear picture of Americans' opinions about cloning. In our survey, the questions regarding research and reproductive cloning were asked within the context of a larger poll to assess American attitudes toward reproductive genetic technologies. The questions preceding those on cloning queried attitudes about preimplantation genetic diagnosis, prenatal genetic testing, in-vitro fertilization, scientific research, and the moral worth of human embryos. This survey did not include information regarding the benefits or harms of various applications of cloning, nor did it use the term "stem cell," a term that most Americans are now familiar with.

Americans are unclear about what is currently possible in existing cloning technology. The multiple surveys of American attitudes toward cloning show that a vast majority opposes reproductive cloning and that this view has been relatively consistent over time. At the same time, these surveys show significant variability in levels of approval for research cloning, making it difficult to know where the American public truly stands on this issue. These differences in findings likely are attributable to the wording of survey questions, as well as the socio-political environment at the time of the survey. It could be argued that Americans' opinions about research cloning are not firmly held and survey questions are tapping into and reflecting positions on more familiar issues such as abortion and the value of biomedical research.

The juxtaposition of reproductive cloning — about which the majority of Americans have consistent negative opinions — with research and therapeutic cloning — about which public opinion is more fluid — has led to a public policy patchwork quilt. The consistent linking of these issues has led to a political stalemate at the federal level and in some states. Other states, in contrast, have adopted widely divergent positions either permitting or even supporting research and therapeutic cloning while prohibiting reproductive cloning, or prohibiting cloning entirely. Many countries have put into place policies that either prohibit all cloning or prohibit reproductive and permit research and therapeutic cloning.

Notwithstanding the uncertain policy landscape, research cloning continues to be done both domestically and internationally. While effective use of cloning for research and therapeutic – and moreover for reproductive – purposes remains a distant possibility for scientific reasons, the time is now to foster meaningful national conversations about the legal, ethical, and societal issues raised by these various uses of cloning, as a prelude to the development of sound public policy.

Table 5: Do you approve of scientists working on ways to create a cloned human embryo for research?

Demographic Characteristics		Strongly Approve	Approve	Disapprove	Strongly Disapprove
Total		4.5%	19.1%	32.8%	43.6%
Sex	**Men**	6.0%	22.8%	32.2%	39.1%
	Women	3.2%	15.7%	33.3%	47.8%
Age	**18-29**	6.0%	22.6%	26.9%	44.6%
	30-49	4.7%	20.7%	31.6%	43.0%
	50+	3.5%	15.3%	37.5%	43.7%
Race/ethnicity	**White**	4.7%	20.1%	31.3%	43.9%
	Black	3.9%	14.7%	34.6%	46.8%
	Hispanic	4.3%	18.1%	39.8%	37.9%
Religion	**Protestant***	4.6%	20.6%	33.5%	41.4%
	Fund/Evang**	.9%	6.2%	30.2%	62.7%
	Roman Catholic	3.6%	18.2%	36.4%	41.7%
	Other Christian***	4.4%	18.5%	30.3%	46.8%
	Other (Non Christian)	6.0%	23.4%	34.6%	36.0%
	No Religion	9.9%	32.4%	30.1%	27.6%
Income	**Under 25k**	5.0%	16.6%	33.1%	45.3%
	25k-49.9k	4.0%	18.5%	34.3%	43.1%
	50k-74.9k	4.3%	21.6%	28.5%	45.5%
	75+k	5.0%	22.4%	33.8%	38.7%
Education	**No College**	3.4%	14.7%	36.0%	45.9%
	Some College	5.4%	19.9%	30.2%	44.5%
	College	5.5%	25.4%	27.0%	42.0%
	Post Grad	6.3%	28.7%	33.8%	31.2%
Political Affiliation	**Republicans**	2.9%	14.6%	31.3%	51.3%
	Other	4.9%	18.2%	36.0%	41.0%
	Democrats	5.9%	21.4%	35.6%	37.1%

* Protestant includes respondents who self-identified as Protestant, excluding those who additionally self-identified as Fundamentalist or Evangelical.
** Fundamentalist/Evangelical includes all Protestant or Other Christian respondents, who additionally self-identified as either Fundamentalist or Evangelical.
*** Other Christian includes all who self-identified as Other Christian, excluding those that additionally self-identified as Fundamentalist or Evangelical.

Table 6: Do You Approve Of Scientists Working On Ways To Create A Cloned Human Baby?

Demographic Characteristics		Strongly Approve	Approve	Disapprove	Strongly Disapprove
Total		2.7%	8.9%	35.5%	52.9%
Sex	**Men**	3.8%	12.1%	35.0%	49.1%
	Women	1.7%	5.9%	35.9%	56.5%
Age	**18-29**	4.1%	10.2%	29.0%	56.7%
	30-49	2.3%	10.4%	35.9%	51.4%
	50+	2.3%	6.6%	38.8%	52.4%
Race/ethnicity	**White**	2.5%	9.0%	34.2%	54.3%
	Black	2.8%	6.4%	36.3%	54.5%
	Hispanic	2.9%	9.3%	42.5%	45.3%
Religion	**Protestant***	2.9%	7.7%	38.0%	51.3%
	Fund/Evang**	.8%	3.2%	29.9%	66.1%
	Roman Catholic	2.4%	7.7%	38.6%	51.3%
	Other Christian***	2.1%	8.3%	34.8%	54.8%
	Other (Non Christian)	4.0%	16.4%	32.6%	47.0%
	No Religion	4.7%	17.5%	34.4%	43.4%
Income	**Under 25k**	3.2%	9.0%	35.3%	52.5%
	25k-49.9k	2.2%	8.6%	36.3%	52.9%
	50k-74.9k	2.7%	10.7%	32.4%	54.1%
	75+k	2.5%	7.1%	37.9%	52.5%
Education	**No College**	2.4%	8.0%	36.9%	52.8%
	Some College	3.5%	11.0%	33.0%	52.5%
	College	1.7%	7.9%	32.9%	57.5%
	Post Grad	3.4%	8.6%	40.8%	47.1%
Political Affiliation	**Republicans**	1.8%	6.1%	34.7%	57.5%
	Other	3.5%	9.0%	39.0%	48.6%
	Democrats	3.6%	10.3%	38.5%	47.6%

* Protestant includes respondents who self-identified as Protestant, excluding those who additionally self-identified as Fundamentalist or Evangelical.
** Fundamentalist/Evangelical includes all Protestant or Other Christian respondents, who additionally self-identified as either Fundamentalist or Evangelical.
*** Other Christian includes all who self-identified as Other Christian, excluding those that additionally self-identified as Fundamentalist or Evangelical.

Table 7: If you could clone a loved one, would you?

Demographic Characteristics		Yes	No
Total		7.7%	92.3%
Sex	**Men**	8.5%	91.5%
	Women	6.9%	93.1%
Age	**18-29**	11.0%	89.0%
	30-49	7.6%	92.4%
	50+	5.8%	94.2%
Race/ethnicity	**White**	6.6%	93.4%
	Black	10.6%	89.4%
	Hispanic	10.0%	90.0%
Religion	**Protestant***	7.9%	92.1%
	Fund/Evang**	3.0%	97.0%
	Roman Catholic	6.8%	93.2%
	Other Christian***	9.3%	90.7%
	Other (Non Christian)	10.7%	89.3%
	No Religion	11.4%	88.6%
Income	**Under 25k**	9.3%	90.7%
	25k-49.9k	7.9%	92.1%
	50k-74.9k	6.4%	93.6%
	75+k	5.3%	94.7%
Education	**No College**	8.4%	91.6%
	Some College	7.8%	92.2%
	College	5.6%	94.4%
	Post Grad	7.5%	92.5%
Political Affiliation	**Republicans**	4.1%	95.9%
	Other	10.4%	89.6%
	Democrats	8.4%	91.6%

* Protestant includes respondents who self-identified as Protestant, excluding those who additionally self-identified as Fundamentalist or Evangelical.
** Fundamentalist/Evangelical includes all Protestant or Other Christian respondents, who additionally self-identified as either Fundamentalist or Evangelical.
*** Other Christian includes all who self-identified as Other Christian, excluding those that additionally self-identified as Fundamentalist or Evangelical.

Table 8: If you could clone yourself, would you?

Demographic Characteristics		Yes	No
Total		6.9%	93.1%
Sex	**Men**	9.5%	90.5%
	Women	4.5%	95.5%
Age	**18-29**	11.2%	88.8%
	30-49	6.9%	93.1%
	50+	4.4%	95.6%
Race/ethnicity	**White**	5.7%	94.3%
	Black	8.8%	91.2%
	Hispanic	10.9%	89.1%
Religion	**Protestant***	6.6%	93.4%
	Fund/Evang**	2.3%	97.7%
	Roman Catholic	6.0%	94.0%
	Other Christian***	6.5%	93.5%
	Other (Non Christian)	11.9%	88.1%
	No Religion	13.1%	86.9%
Income	**Under 25k**	8.5%	91.5%
	25k-49.9k	6.7%	93.3%
	50k-74.9k	6.9%	93.1%
	75+k	3.9%	96.1%
Education	**No College**	6.7%	93.3%
	Some College	8.4%	91.6%
	College	6.2%	93.8%
	Post Grad	4.9%	95.1%
Political Affiliation	**Republicans**	3.3%	96.7%
	Other	8.9%	91.1%
	Democrats	7.1%	92.9%

* Protestant includes respondents who self-identified as Protestant, excluding those who additionally self-identified as Fundamentalist or Evangelical.
** Fundamentalist/Evangelical includes all Protestant or Other Christian respondents, who additionally self-identified as either Fundamentalist or Evangelical.
*** Other Christian includes all who self-identified as Other Christian, excluding those that additionally self-identified as Fundamentalist or Evangelical.

Table 9: Should Human Cloning To Create A Baby Be Allowed At All?

Demographic Characteristics		Yes	No
Total		11.6%	88.4%
Sex	**Men**	15.9%	84.1%
	Women	7.6%	92.4%
Age	**18-29**	14.9%	85.1%
	30-49	12.9%	87.1%
	50+	8.3%	91.7%
Race/ethnicity	**White**	11.8%	88.2%
	Black	7.1%	92.9%
	Hispanic	13.2%	86.8%
Religion	**Protestant***	10.1%	89.9%
	Fund/Evang**	3.9%	96.1%
	Roman Catholic	9.2%	90.8%
	Other Christian***	12.5%	87.5%
	Other (Non Christian)	21.9%	78.1%
	No Religion	22.9%	77.1%
Income	**Under 25k**	12.2%	87.8%
	25k-49.9k	10.7%	89.3%
	50k-74.9k	13.5%	86.5%
	75+k	10.2%	89.8%
Education	**No College**	10.0%	90.0%
	Some College	14.1%	85.9%
	College	10.5%	89.5%
	Post Grad	14.9%	85.1%
Political Affiliation	**Republicans**	8.7%	91.3%
	Other	12.4%	87.6%
	Democrats	13.2%	86.8%

* Protestant includes respondents who self-identified as Protestant, excluding those who additionally self-identified as Fundamentalist or Evangelical.
** Fundamentalist/Evangelical includes all Protestant or Other Christian respondents, who additionally self-identified as either Fundamentalist or Evangelical.
*** Other Christian includes all who self-identified as Other Christian, excluding those that additionally self-identified as Fundamentalist or Evangelical.

Table 10: Do you think human embryo cloning for research should be allowed at all?

Demographic characteristics		Yes	No
Total		24.4%	75.6%
Sex	**Men**	29.7%	70.3%
	Women	19.4%	80.6%
Age	**18-29**	29.8%	70.2%
	30-49	25.3%	74.7%
	50+	20.2%	79.8%
Race/ethnicity	**White**	26.2%	73.8%
	Black	16.6%	83.4%
	Hispanic	21.8%	78.2%
Religion	**Protestant***	25.2%	74.8%
	Fund/Evang**	6.8%	93.2%
	Roman catholic	22.5%	77.5%
	Other Christian***	23.6%	76.4%
	Other (non Christian)	32.1%	67.9%
	No religion	45.2%	54.8%
Income	**Under 25k**	22.3%	77.7%
	25K-49.9K	22.1%	77.9%
	50K-74.9K	26.6%	73.4%
	75+K	31.2%	68.8%
Education	**No college**	17.7%	82.3%
	Some college	26.2%	73.8%
	College	33.5%	66.5%
	Post grad	38.0%	62.0%
Political Affiliation	**Republicans**	18.6%	81.4%
	Other	23.7%	76.3%
	Democrats	27.5%	72.5%

* Protestant includes respondents who self-identified as Protestant, excluding those who additionally self-identified as Fundamentalist or Evangelical.
** Fundamentalist/Evangelical includes all Protestant or Other Christian respondents, who additionally self-identified as either Fundamentalist or Evangelical.
*** Other Christian includes all who self-identified as Other Christian, excluding those that additionally self-identified as Fundamentalist or Evangelical.

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