HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 285 Human Cloning
SPONSOR(S): Kallinger and others
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 1726 (i)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care	8 Y, 6 N	Mitchell	Collins
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

HB 285 provides that the bill may be cited as the "Human Cloning Prohibition and Responsibility Act of 2002." According to the bill's sponsor, the purpose of the bill is to prohibit human asexual reproduction, and make scientists, not the state, responsible for their actions. The bill prohibits human cloning and provides civil penalties of not less than $1 million and criminal penalties, including minimum term of imprisonment of 10 years. The bill provides time limitations for bringing both civil and criminal actions and provides procedures for enforcement.

Specifically, the bill provides that it is unlawful for any person to knowingly:

- Perform or attempt to perform human cloning;
- Participate or assist in an attempt to perform human cloning; or
- Ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo.

The term "human cloning" is defined as "human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism, at any state of development, that is genetically virtually identical to an existing or previously existing human organism."

The bill also provides definitions of "asexual reproduction" and "somatic cell."

Legal remedies are provided in this bill for individuals created through cloning; the individual's spouse, dependents and blood relatives; and any woman, and her spouse and dependents, impregnated with the individual.

The bill includes a statutory construction provision that nothing in the bill shall be construed to restrict areas of scientific research that are not specifically prohibited by the bill. It states that research is permitted in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, tissues, organs, plants, or animals, or cells other than human embryos.

The bill provides an effective date of upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[X]	N/A[]
2. Lower taxes?	Yes[]	No[]	N/A[X]
3. Expand individual freedom?	Yes[]	No[]	N/A[X]
4. Increase personal responsibility?	Yes[X]	No[]	N/A[]
5. Empower families?	Yes[X]	No[]	N/A[]

For any principle that received a "no" above, please explain:

The bill makes cloning illegal and creates a civil and criminal process for enforcement of the prohibition.

B. EFFECT OF PROPOSED CHANGES:

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The bill defines "asexual reproduction" as "reproduction not initiated by the union of oocyte and sperm." "Somatic cell" is defined as "a diploid cell having a complete set of chromosomes obtained or derived from a living or deceased human body at any stage of development."

A person who violates the prohibition against human cloning commits a felony of the second degree and shall be sentenced to a minimum term of imprisonment of 10 years. Any person who violates the prohibition against human cloning and derives pecuniary gain from such cloning, is subject to a civil penalty of not less than $1 million and not more than an amount equal to the amount of the gross pecuniary gain derived from the violation multiplied by 2, if that amount is greater than $1 million.

The bill includes a statutory construction provision that nothing in the bill shall be construed to restrict areas of scientific research that are not specifically prohibited by the bill. It states that research is permitted in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, tissues, organs, plants, or animals, or cells other than human embryos.

Legal remedies are provided in this bill for individuals created through cloning; the individual's spouse, dependents and blood relatives; and any woman, and her spouse and dependents, impregnated with the individual. Damages may be sought for physical, emotional, economic and other injuries. Additionally, persons participating in the production by human cloning of an individual shall be jointly

and severally liable to the individual and legal guardian for the costs of guardianship during minority, as well as the costs of a guardian ad litem. The bill specifies that all liabilities survive the death of the individual and that the rights of recovery shall be cumulative to all other legal rights. Furthermore, the bill provides that the liabilities created shall be strictly enforced without regard to negligence or fault. The bill provides jurisdiction of Florida courts for any injured person domiciled in Florida.

The bill empowers the Florida Attorney General to bring civil actions to enforce the rights and obligations of this act on behalf of the state or any resident of the state.

The bill provides that certain legal actions must be commenced within specified periods of time. Civil actions must be commenced before the expiration of 5 years after the death of the individual produced by human cloning. Prosecutions for felony violations must be commenced within 4 years after the violation is reported to law enforcement, or within 21 years after the birth or destruction of an individual produced by human cloning, whichever occurs first.

The bill provides an effective date of upon becoming law.

CURRENT SITUATION

Although it is a national issue and has been addressed in other states, human reproductive cloning is not currently prohibited in Florida.

In January, 2002, the National Academy of Sciences review panel on “Scientific and Medical Aspects of Human Reproductive Cloning” stated that human reproductive cloning should not now be practiced. The panel reported that human reproductive cloning is dangerous and likely to fail. Dr. Weissman, chair of the review panel, said the group unanimously supported the proposal that there should be a legally enforceable ban on the practice of human reproductive cloning.

What is cloning?

The possibility of human cloning was raised when Scottish scientists at the Roslin Institute created the much-celebrated sheep "Dolly" (Nature 385, 810-13, 1997). The issue aroused worldwide interest and concern because of its scientific and ethical implications. It also generated uncertainty over the meaning of "cloning" which is an umbrella term traditionally used by scientists to describe different processes for duplicating biological material.

What are the different types of cloning?

According to the Cloning Fact Sheet of the U.S. Human Genome Project (HGP), when the media report on cloning in the news, they are usually talking about only one type of cloning, called reproductive cloning. According to the HGP, there are different types of cloning, and cloning technologies can be used for other purposes besides producing the genetic twin of another organism.

The three main types of cloning technologies are:

- Recombinant DNA technology or DNA cloning,
- Reproductive cloning, and
- Therapeutic cloning.

Recombinant DNA Technology or DNA Cloning

According to the HGP, the terms "recombinant DNA technology," "DNA cloning," "molecular cloning" or "gene cloning" all refer to the same process: the transfer of a DNA fragment of interest from one organism to a self-replicating genetic element such as a bacterial plasmid. The DNA of interest can

then be propagated in a foreign host cell. This technology has been around since the 1970s, and it has become a common practice in molecular biology labs today.

To "clone a gene," a DNA fragment containing the gene of interest is isolated from chromosomal DNA using restriction enzymes and then united with a plasmid that has been cut with the same restriction enzymes. When the fragment of chromosomal DNA is joined with its cloning vector in the lab, it is called a "recombinant DNA molecule." Following introduction into suitable host cells, the recombinant DNA can then be reproduced along with the host cell DNA.

Recombinant DNA technology is important for learning about other related technologies, such as gene therapy, genetic engineering of organisms, and sequencing genomes. Recombinant DNA technology is important in agriculture where genes from different organisms that improve taste and nutritional value, or provide resistance to particular types of disease, can be used to genetically engineer food crops.

Reproductive Cloning

Reproductive cloning is a technology used to generate an animal that has the same nuclear DNA as another currently or previously existing animal. Dolly was created by reproductive cloning technology. In a process called "somatic cell nuclear transfer," scientists transfer genetic material from the nucleus of a donor adult cell to an egg whose nucleus, and thus its genetic material, has been removed. The reconstructed egg containing the DNA from a donor cell must be treated with chemicals or electric current in order to stimulate cell division. Once the cloned embryo reaches a suitable stage, it is transferred to the uterus of a female host where it continues to develop until birth.

According to the HGP, Dolly or any other animal created using nuclear transfer technology is not truly an identical clone of the donor animal. Only the clone's chromosomal or nuclear DNA is the same as the donor. Some of the clone's genetic materials come from the mitochondria in the cytoplasm of the enucleated egg.

Scientists have been cloning animals for many years. In 1952, the first animal, a tadpole, was cloned. Before the creation of Dolly, which was the first mammal cloned from the cell of an adult animal, clones were created from embryonic cells. Dolly's success proved that the genetic material from a specialized adult cell, such as an udder cell programmed to express only those genes needed by udder cells, could be reprogrammed to generate an entire new organism. Since Dolly, researchers have cloned a number of large and small animals including sheep, goats, cows, mice, pigs, cats, rabbits, and a gaur. All these clones were created using nuclear transfer technology.

Risks of Reproductive Cloning

According to the National Academy, all reproductive cloning is expensive and highly inefficient. More than 90% of cloning attempts fail to produce viable offspring. More than 100 nuclear transfer procedures could be required to produce one viable clone. Dolly was only one success out of 276 tries.

In addition to low success rates, cloned animals tend to have more compromised immune function and higher rates of infection, tumor growth, and other disorders. About 30% of clones born alive are affected with "large offspring syndrome" and other debilitating conditions. Several cloned animals have died prematurely from infections and other complications.

The HGP reports Dolly, the first mammal to be cloned from adult DNA, was put down by lethal injection Feb. 14, 2003 at age six, although most Finn Dorset sheep live to be 11 to 12 years of age. Prior to her death, Dolly had been suffering from lung cancer and crippling arthritis.

According to the HGP, some scientists believe that errors or incompleteness in the reprogramming process cause the high rates of death, deformity, and disability observed among animal clones.

Hundreds of cloned animals exist today, but the number of different species is limited. Attempts at cloning certain species such as monkeys, chickens, horses, and dogs, have been unsuccessful.

Human Reproductive Cloning

The National Academy of Sciences report on the “Scientific and Medical Aspects of Human Reproductive Cloning” (2002) identifies human reproductive cloning as an assisted reproductive technology that would be carried out with the goal of creating a newborn genetically identical to another human being. The method used to initiate the reproductive cloning procedure is the same as that used for other mammals, nuclear transplantation or somatic cell nuclear transfer.

Risks of Human Reproductive Cloning

According to the National Academy of Sciences, human reproductive cloning is likely to have negative outcomes similar to other species, and should not be practiced. Many clones die in utero -- even at late stages or soon after birth -- and those that survive frequently exhibit severe birth defects. In addition, female animals carrying cloned fetuses may face serious risks, including death from cloning-related complications. For these and many other reasons identified in their report the National Academy supports a legally enforceable ban on human reproductive cloning.

According to the National Academy report, because many eggs are needed for human reproductive cloning attempts, human experimentation could subject more women to adverse health effects -- either from high levels of hormones used to stimulate egg production or because more women overall would be sought to donate eggs, which involves surgery with its own inherent risks, the panel noted.

A recent report in Science (April 11, 2003), finds that there may be permanent barriers to reproductive cloning of primates and humans (Science v. 300, p 297). According to Dr. Gerald Schatten, at the University of Pittsburgh, School of Medicine, unlike other mammal species in which adult animals have been successfully cloned, the eggs of rhesus monkeys are robbed of a key set of proteins during the cloning procedure. The same appears to be true for human cells. According to Dr. Schatten, that loss causes genetic chaos in cloned monkey embryos, with chromosomes distributed almost at random. As a result, the embryos look fine at an early stage, but are completely incapable of further development. In a statement released with the report, Dr. Schatten says, "charlatans who claim they have cloned humans clearly don't understand the biology." Given the high rate of abortions, neonatal deaths and health problems that occur in clones, he warns against any attempt at human cloning.

Therapeutic Cloning/Use of Stem Cells

The report of the National Academy of Sciences distinguished a related but different procedure from reproductive cloning which the panel denoted as “nuclear transplantation to produce stem cells” -- but which is also has been called “nonreproductive cloning,” “therapeutic cloning,” “research cloning,” or “somatic cell nuclear transfer to produce stem cells.”

According to Dr. Bert Vogelstein, who chaired the National Academy committee that wrote the report on “Stem Cells and the Future of Regenerative Medicine” (2001), the term "therapeutic cloning" is a misnomer, and one that scientists don't like to use, because it implies the creation of a human clone. Instead, the process uses somatic cell nuclear transfer to place the cell nucleus of the potential transplant recipient into an egg that has had its nucleus removed. Then, in a culture dish, scientists try to coax the remade cell into dividing like a fertilized egg to produce stem cells, which could be used for tissue that is almost genetically identical to the transplant recipient. Stem cells are unspecialized cells that can renew themselves indefinitely and, under the right conditions, differentiate into all types of cells.

According the National Academy, although stem cell research is still in its infancy, it gives hope to millions of people suffering from diseases such as diabetes and Parkinson's, or from injuries to their

spinal cords, that healthy tissue grown from stem cells can someday be used to replace their diseased or damaged tissue. According to the Academy, there are few other treatment options on the horizon for many of these diseases.

Use of embryonic stem cells:
One therapeutic cloning technique is the production of embryonic stem cells for clinical and research purposes. Unlike reproductive cloning, the creation of embryonic stem cells by nuclear transplantation does not involve implantation of a cloned embryo in a uterus.

Because embryonic stem cells are designed to multiply and mature in embryos their use for therapeutic purposes in humans has encountered serious problems, however. In adult tissues they are genetically unstable and can mutate into tumors or mature into inappropriate tissues. Cells derived from cloning may also face rejection due to the presence of foreign genes from egg mitochondria when the egg from one donor source and the nucleus is from another.

In June of 2002, the British Department of Health issued "A Report from the Chief Medical Officer's Expert Group Reviewing the Potential of Developments in Stem Cell Research and Cell Nuclear Replacement to Benefit Human Health," which concluded:

> There are a number of technical and safety issues that have been raised by the early work on stem cells and cell nuclear replacement, including:
> - Whether the supply of spare eggs (oocytes) for therapy would be adequate;
> - Whether cells and tissues derived from cell nuclear replacement would develop normally or whether defects are likely to arise;
> - Whether stem cells and subsequent tissues will "age" normally;
> - Whether such tissues will be more prone to develop malignancy; and
> - Whether tissues generated from a reprogrammed adult nucleus would overcome the problems of rejection after transplantation as theory suggests they should.

The Institute of Science in Society (ISIS), an international organization of scientists from 57 countries for the ethical use of science to serve mankind's needs, has issued a similar statement that concludes: "The risks of cancer, uncontrollable growth, genome instability and other hurdles make embryonic stem cells a bad investment in terms of finance as well as health benefits." (I-SIS Report 23, Jan. 2001)

The ISIS added that adult stem cells "are more likely to generate affordable therapies that can benefit everyone."

Use of adult stem cells:
Recent research indicates adult stem cells derived from cloning are a better source of potential therapies. Adult stem cells do not involve the use of embryos. Adult stem cells may face less chance of rejection and other problems encountered by embryonic cells because:
- Genes used by the immune system to identify "self" from "non-self" are poorly expressed in the embryonic state.
- Robust growth of embryonic stem cells may cause them to be identified as cancerous and cause an immune response to remove them.

Human Cloning Laws in Other States

The National Conference of State Legislatures reports that nine states have laws pertaining to human cloning. The issue was first addressed by the state of California, which banned reproductive cloning, or cloning to initiate a pregnancy, in 1997. Since then, seven other states-Arkansas, Iowa, Louisiana, Michigan, Rhode Island and Virginia and most recently North Dakota-have enacted measures to prohibit reproductive cloning. Michigan and Iowa extend their restrictions to therapeutic cloning, or cloning for research purposes. Virginia's law also may prohibit human cloning for any purpose, but it

may be unclear because the law does not define human being. Finally, Missouri forbids the use of public funds for human cloning research.

Federal Action

Over the past several years, federal law has prohibited the Department of Health and Human Services from funding human embryo research. Through and executive directive in December 1994, President Clinton prohibited federal funding on research to support the creation of human embryos for research purposes and directed the National Institute of Health not to allocate resources for such research. The order banning funding for such research was followed by a legislative ban in 1996 enacted in the National Institute's funding measure. Congress has passed a similar ban annually since that time.

The original congressional ban stated that federally appropriated funds could not be used for the creation of a human embryo or embryos for research purposes or for 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 C. F. R. 46.208(a)(2) and 42 U. S. C. § 289g(b).

The ban defined "human embryo or embryos" to include any organism, not protected as a human subject under 45 C. F. R. 46 (Human Subject Protection regulations) that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes (sperm or egg.) The rider language has not changed significantly over the years. In the subsequent fiscal years after FY1996, the rider was enacted in Title V (General Provisions) of the Labor, Health and Human Services and Education appropriations acts. The prohibition does not ban fetal tissue research, although other restrictions apply.

On July 31, 2001, the U.S. House of Representatives, by a vote of 265-162, passed H.R. 2505, sponsored by Rep. Dave Weldon (R-Fl.), which would ban all human cloning in the United States. This bill uses definitions of cloning and the prohibitory language contained in that bill. The bill provides that anyone who clones or attempts to clone a human being, as well as anyone involved in the trafficking of cloned embryos would face up to 10 years in prison and civil penalties of at least $1 million. Certain "cloning techniques" would still be allowed as long as they do not produce human embryos.

The federal legislation purports to regulate interstate commerce, but there is some doubt, given recent U.S. Supreme Court rulings, that medical processes like cloning are under the Congress' interstate commerce authority. By contrast, most federal health regulations are based upon the Congress' spending powers.

Other

The United Kingdom has also banned scientists from using cloning techniques to produce babies. The Human Reproductive Cloning Act of 2001 went into effect in December 2001 and prohibits the planting of cloned embryos in a womb. The law does not prohibit cloning altogether, only the implanting of embryos in a womb.

C. SECTION DIRECTORY:

Section 1. Creates s. 877.27, F.S., relating to the Human Cloning Prohibition and Responsibility Act, to provide a short title; to provide definitions; to prohibit human cloning; to provide penalties, statutory construction, civil remedies, and enforcement.

Section 2. Amends s. 95.11, F.S., relating to limitations of actions, other than recovery of real property, to provide a limit for the commencement of actions relating to human cloning as provided in s. 877.27(6), F.S.

Section 3. Amends s. 775.15, F.S., relating to the Florida Criminal Code, time limitations, to require prosecution for felony violation of human cloning to commence within 4 years after the violation is reported to law enforcement or within 21 years after the birth or destruction of an individual produced by human cloning, whichever occurs first.

Section 4. Provides an effective date of upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See fiscal comments.

2. Expenditures:

   See fiscal comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   See Fiscal Comments.

2. Expenditures:

   See Fiscal Comments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

See Fiscal Comments.

D. FISCAL COMMENTS:

The potential number of persons who might be prosecuted under this law is indeterminate. The minimum prison term specified under the bill is 10 years. The civil penalty provided is not less than $1 million and not more than an amount equal to the gross pecuniary gain derived from the violation multiplied by 2, if that amount is greater than $1 million.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES