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HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH REGULATION
ANALYSIS

BILL #: HB 805

RELATING TO: Human Cloning Prohibition

SPONSOR(S): Representatives Kallinger, Fasano, and others

TIED BILL(S): None.

ORIGINATING COMMITTEE(S)/COUNCIL(S)/COMMITTEE(S) OF REFERENCE:

(1) HEALTH REGULATION YEAS 8 NAYS 0
(2) CRIME PREVENTION, CORRECTIONS & SAFETY
(3) COUNCIL FOR HEALTHY COMMUNITIES
(4)
(5)

I. SUMMARY:

THIS DOCUMENT IS NOT INTENDED TO BE USED FOR THE PURPOSE OF CONSTRUING STATUTES, OR TO BE CONSTRUED AS AFFECTING, DEFINING, LIMITING, CONTROLLING, SPECIFYING, CLARIFYING, OR MODIFYING ANY LEGISLATION OR STATUTE.

This bill may be cited as the "Human Cloning Prohibition and Responsibility Act of 2002." It 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," "somatic cell," and "oocyte."

The bill provides an effective date of upon becoming law.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes []	No [x]	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes []	No [x]	N/A []
4.	Personal Responsibility	Yes []	No []	N/A [x]
5.	Family Empowerment	Yes []	No []	N/A [x]

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

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

B. PRESENT SITUATION:

Human cloning is not currently prohibited in Florida.

The term "cloning" refers to three different procedures with three different goals. The three different types of "cloning" are:

- Embryo cloning: A medical technique which produces monozygotic (identical) twins or triplets. It duplicates the process that nature uses to produce twins or triplets. One or more cells are removed from a fertilized embryo and encouraged to develop into one or more duplicate embryos. Twins or triplets are formed, with identical DNA. This has been done for many years on various species of animals, however only very limited experimentation has been done on humans.

- Adult DNA cloning (also known as a cell nuclear replacement): This technique produces a duplicate of an existing animal. It has been used to clone a sheep and other mammals. The DNA from an embryo is removed and replaced with the DNA from an adult animal. Then, the embryo is implanted in a womb and allowed to develop into a new animal. This process, according to current reports, has not been tried on humans. It has the potential of producing a twin of an existing person.

- Therapeutic cloning: This is a procedure that starts off like adult DNA cloning. However, the stem cells are removed from the embryo with the intent of producing tissue or a whole organ for transplant back into the person who supplied the DNA. The embryo dies in the process. The goal of therapeutic cloning is to produce a healthy copy of a sick person's tissue or organ for transplant. This technique would be vastly superior to relying on organ transplants from other people. The supply would be unlimited, so there would be no waiting lists. The tissue or organ would have the sick person's original DNA; no immunosuppressant drugs would need to be taken.

There appear to be at least three specific human health or public health considerations relating to the issue of the cloning of humans:

- The aging process for cloned mammals;
- The cross-species viral, microbial, and/or bacterial uncertainties; and
- The reasons for which human cloning would be undertaken.

Cloning of embryos has been used in mice experiments since the late 1970's, and in animal breeding since the late 1980's. However, in 1997, an international debate was sparked with the announcement by researchers at Scotland's Roslin Institute of the world's first cloned sheep, named Dolly. Dolly was not the first cloned sheep, there were 'Morag' and 'Megan' before her, but what made her unique was that she was cloned using a cell taken from an adult sheep rather than using an embryonic cell. This was a new technique which had never before been fully successful in mammals. Even using this technique most animal clones die, usually during the embryonic development. Significant numbers of the clones that survive the embryonic development phase are stillborn and many of the few clones that do survive have life-threatening abnormalities. It took 277 attempts to create the clone Dolly, and Dolly has a significant genetic abnormality which may impact her lifespan.

While cloning has been extensively utilized in agricultural applications, and to some extent with livestock, it is likely that much of the early research relating to cloning of humans has been done in secret. The first publicly acknowledged cloning on human embryos was done by Robert J. Stillman at the George Washington Medical Center in Washington, D.C., in 1994. These experiments used genetically flawed embryos that were not viable (unable to mature), derived from an ovum that had been fertilized by two sperm. What resulted were ova which could not mature into fetuses. These ova were split and each produced one or more clones which were also unable to mature into fetuses.

The goals and purposes for cloning range from making copies of those that have deceased to better engineering the offspring in humans and animals. Cloning could also directly offer a means of curing diseases or a technique that could extend means to acquiring new data for the sciences of embryology and how organisms develop as a whole over time.

Currently, the agricultural industry demands nuclear transfer to produce better livestock. Cloning could massively improve the agricultural industry as the technique of nuclear transfer improves. Change in the phenotype of livestock is accomplished by bombarding livestock embryos with genes that produce livestock with preferred traits. However, this technique is not efficient as only 5 percent of the offspring express the preferred traits.

The goal of transgenic livestock is to produce livestock with ideal characteristics for the agricultural industry and to be able to manufacture biological products such as proteins for humans. Farmers are attempting to produce transgenic livestock. However, such techniques are not sufficiently efficient due to the minimal ability to alter embryos genetically. The method would be for the researchers to harvest and grow adult cells in large amounts compared to embryos. Scientists can then genetically alter these cells and find which ones did transform and then clone only those cells.

Advocates of human cloning propose a number of possible uses for the production of human clones, including:

- Artificial procreation: The first and most obvious area of interest is artificial procreation. Infertile couples could produce a clone of one parent as an alternative to the traditional means of having a child. (From a strictly genetic point of view, however, the child would be a monozygotic twin of the cloned parent.) Homosexual couples could also make use of cloning to reproduce. Finally, some parents might want to store tissues of their children to have the option of cloning a child who might die prematurely.

- Biomedical applications: Researchers claim that human cloning would advance certain areas of biomedicine including both reproductive and non-reproductive cloning. Reproductive cloning implies the birth of a human individual genetically identical to an already existing human being. Non-reproductive cloning would involve letting a clone develop until the embryonic stage without transferring the embryo to the uterus of a woman. The embryo would be kept in a petri dish for future medical use. Such applications of this process could include oncology treatment, products for regenerative medicine, and result in accelerated drug discovery and development.

- Transgenic applications: Transgenic technology occurs when the genetically engineered segment of DNA (a DNA construct) is transferred into the genetic material of another species to allow for the targeted expression of important human therapeutic and nutritional supplements in the milk of lactating female livestock. Some current research using this technology includes treatment for certain patients with: hereditary emphysema, cystic fibrosis, and pancreatitis. Other research includes development for sealant for wounds and xenotranplantation.

The use of non-reproductive cloning as a basic biotechnological procedure could have at least the following four applications:

- Culturing tissues and organs of patients who suffer from a deficiency in the functioning of those tissues or organs: Through the use of cloning, scientists can create tissue that is genetically compatible with a patient by taking the nucleus from any of the patient's cells and creating a clone embryo. The embryo is maintained in a culture in a petri dish. A culture of embryonic stem cells (ES cells) can then be produced from the central part of this embryo (the so-called inner cell mass). This is a fairly recent development for scientists. A sample of that “culture” can then be induced to develop into specific kinds of cells and tissues, such as brain tissue and pancreas tissue. The “cultured” tissue can then be transplanted into the patient from whom the nucleus was removed. There is no risk of the patient's immune system rejecting this tissue, because it is genetically identical to his or her own tissue.

- Extensive genetic selection of embryos In-Vitro: Currently, it is already possible to screen embryos for the presence of one or two genetic disorders. This process is called pre-implantation genetic diagnosis. It involves removing one or two cells from the embryo for examination and diagnostic testing. The combination of cloning by nuclear transfer and the culturing of embryonic stem cells will make it possible to screen more embryos for a larger number of possible genetic defects. Scientists can simply create embryonic stem cell cultures from the embryos targeted for screening. The cell cultures allow for more extensive investigation of genetic “baggage” from the targeted embryo. Most typically, only those embryos with the most favorable genetic constitution will be selected for implantation within the mother to make the journey to birth.

- Genetic modification of the germ lines: This means altering the genes of human beings and their progeny. While, at the moment, this practice is too risky to attempt to perform on human beings, as scientific knowledge increases it is likely that some scientists, in the future, will feel comfortable trying it.

- Transgenic virus transfer: There is a risk of disease transfer between transgenic animals and the animal from which the transgenes were derived. If an animal producing drugs in its milk becomes infected by a virus, the animal may transmit the virus to a patient using the drug.

Several aspects of cloning invoke human rights objections and should give pause because, despite headlines and photographs of Dolly the sheep and cloned cows, pigs, goats, and mice, most animal clones still die, usually during embryonic development, while others are stillborn with monstrous abnormalities. While most of the genetic abnormalities result in the death of the clone, many of the abnormalities do not appear until much later in life. In a recent study by South Korean researchers, it was discovered that the DNA of cloned embryos contained significant abnormalities and that appeared to be the reason why so few cloned embryos survive. Scientists acknowledge that even in the surviving embryos, these mistakes are unavoidable in genetic engineering. Some scientists and ethicists have raised concerns that cloning could lead some governments to attempt to develop a “master race” similar to that attempted in Nazi Germany or to produce a subclass of worker drones. Of course, there are also substantial and extensive religiously-based concerns and objections to the indiscriminate use of cloning of humans.

In March of 1997, President Clinton banned the use of federal funds for human cloning research. This moratorium currently remains in effect. Many scientists around the world are abiding by a self-imposed moratorium on cloning humans, and several countries have laws that forbid cloning.

On July 31, 2001, the U.S. House of Representatives voted 265-162 to ban all human cloning in the United States by passage of H.R. 2505, sponsored by Rep. Dave Weldon (R-Fla.), a physician. 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 other cloning bill before the House, H.R. 2172, sponsored by Rep. James Greenwood, (R-Pa.), was defeated. It would have banned cloning aimed at initiating a pregnancy but would have allowed cloning for research purposes. In the Senate, Sen. Sam Brownback (R-Kan.), introduced S 790, a similar ban on cloning.

So far, four states have passed laws banning the cloning of humans: California, Louisiana, Missouri, and Rhode Island. In addition, Michigan prohibits the use of state funds to be used for human cloning except for the purpose of scientific research or cell-based therapies. Furthermore, Illinois, Indiana, Massachusetts, New York, Texas, and Virginia are all in the process of considering some form of bans on human cloning.

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.

The National Academy of Sciences recommended recently that human reproductive cloning -- cloning to create a baby -- be legally banned. "Human reproductive cloning should not now be

practiced. It is dangerous and likely to fail," Dr. Irving Weissman, the chairman of the panel that made the recommendation, said while presenting the findings at a news conference.

Despite these misgivings, the panel said the issue of human reproductive cloning should be revisited in five years if a medical and scientific review suggests techniques may be safer, and if there is a public consensus that a review is warranted. While the panel called for human cloning to be banned, it said that ban should not extend to the nuclear transfer technique, or cloning embryos for the purpose of extracting stem cells for the treatment of disease, "because of its considerable potential for developing new medical therapies for life-threatening diseases."

The group cited an earlier Academy of Sciences report that also supported this technique -- also called therapeutic cloning -- for stem cell research. Dr. Bruce Alberts, president of the National Academy of Sciences, said the group decided to tackle the subject of human reproductive cloning to help inform public debate on the issue. He said the panel looked only at medical and scientific aspects of cloning, including protection of human subjects; it did not consider the ethical or moral implications of the research.

In a news conference, Weissman explained that the panel had consulted experts in animal cloning, assisted reproductive technologies, medical and legal policy, and groups who want to clone a human, before coming to its conclusion. It focused, he said, on the safety of the woman carrying the clone, the safety of the baby, and the risk to the egg donor. Data from animal studies show that there are serious risks to the mother, and that many cloned animals die or have severe abnormalities. The rate of animal cloning successes, said panelist Dr. Mark Siegler, is "astonishingly low." "There's no reason to believe that if carried out on human cells that (cloning) would be successful," he said.

Behavioral abnormalities are another concern, said panelist Dr. Maxine Singer. There is no animal data to determine whether clones might have behavioral problems, which would be of serious concern in any human cloning attempt. To be considered safe, the panel said, cloning techniques must be improved so that the rate of abnormalities in the fetus is no more than that seen with assisted reproductive technologies such as in-vitro fertilization. In addition, tests would have to be developed to show that the embryos to be implanted are normal, and tests must be developed to monitor the fetus in utero for cloning-related defects. Groups that say they are working to clone a human now lack the fundamental biological knowledge to do so, the panel said. They also have not demonstrated the safety of animal cloning nor developed appropriate testing methods to assure safety.

C. EFFECT OF PROPOSED CHANGES:

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The bill defines "asexual reproduction" as "reproduction not initiated by the union of oocyte and sperm." "Oocyte" is defined as "an immature egg cell of the human ovary." "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 provides statutory construction to allow research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals.

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 by 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.

This 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.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Creates s. 877.27, F.S., 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., 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., 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.

III. 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.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

The bill does not require counties or municipalities to expend funds or to take any action requiring the expenditure of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

The bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

The bill does not reduce the percentage of state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

None.

C. OTHER COMMENTS:

None.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

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