SUBJECT: Prohibiting human cloning

COMMITTEE: Regulated Industries — committee substitute recommended

VOTE: 5 ayes — King, Baxter, Crabb, Guillen, Turner

0 nays

2 absent — Hunter, Wolens

WITNESSES: For — Richard Doerflinger, U.S. Conference of Catholic Bishops Secretariat for Pro-Life Activities; MerryLynn Gerstenschlager, Texas Eagle Forum; James Kelly; David Prentice, Do No Harm; *(Registered, but did not testify:)* Stacy Emick, Texas Right to Life Committee; Joe Kral, Texas Right to Life Committee; Andrea McWilliams, Baxter Healthcare; Terrance Moore, Texas Physicians Resource Council and Christian Medical Association; Joe Pojman, Texas Alliance for Life, Inc.; Beverly Nichals; Janelle Shepard

Against — Diana Gray, Juvenile Diabetes Research Foundation; Bettie Sue Masters, Federation of American Societies for Experimental Biology; Ellen Arnold; and nine others; *(Registered, but did not testify:)* Rebecca McCleery and Deborah Newsome, Juvenile Diabetes Research Foundation; Ann Wall; Harry Wall; Pamela Younts

BACKGROUND: Somatic cell nuclear transfer technology (SCNT), also referred to as research or therapeutic cloning, involves removing the nucleus of an unfertilized egg cell and replacing it with material from the nucleus of a body, or somatic, cell. The cell is then stimulated to divide into stem cells, which have the potential to form specialized tissues and organs that make up an organism in a laboratory environment. Reproductive cloning involves creating a baby that is genetically identical to a parent and implanted in a woman's womb to mature.

In 2001, President Bush authorized the use of federal funds for research using the approximately 60 existing lines of human stem cells donated from in vitro fertilization processes. In February 2003, the U.S. House of Representatives passed H.R. 534 that would ban human cloning, but the Senate has not yet approved the measure.

DIGEST:

CSHB 1175 would add subchapter R to Health and Safety Code, Ch. 161 to govern human cloning. It would prohibit human cloning by use of SCNT technology, but would not restrict other research that was not specifically prohibited by the subchapter. It also would not restrict research using nuclear transfer or other cloning techniques in producing molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans.

The bill would define terms associated with human cloning, including the definition of a human embryo as "a living organism with a full or nearly full human genetic composition in the earliest stages of development, including the one-cell stage."

A person who intentionally engaged in human cloning would commit a first-degree felony (life in prison or a sentence of five to 99 years and an optional fine of up to $10,000). The attorney general also could sue to collect a civil penalty of $5 million to $10 million per violation, with the amount of the penalty based on the seriousness of the violation, the person's history of previous violations, and the fine necessary to deter future violations. A person or entity licensed by a state agency as a health care practitioner or health care facility also would be liable for consequences, other than civil penalties, of violating any licensing requirements.

The bill would take effect September 1, 2003.

SUPPORTERS SAY:

Human cloning, whether for reproduction or research, degrades human life. Though it has the potential to yield advances in the treatment of debilitating diseases, this end does not justify the means. Creating and destroying human embryos violates the sanctity of life, the human conscience, and the principle of medical ethics to do no harm. Especially in light of the lack of federal prohibitions on human cloning, it is incumbent upon this Legislature to act decisively in preventing the further creation and destruction of cloned human embryos.

CSHB 1175 would not restrict any vital or viable medical research. Cloning and SCNT for any non-human organism would not be affected. Research on embryonic stem cells, including existing stem cell lines, still would be permitted. Matching an egg and sperm in a laboratory and then implanting the fertilized egg into a woman's uterus, as with in vitro fertilization, would be

allowed. Couples even could continue to donate frozen embryos that remained after in vitro fertilization, estimated to number about 400,000 nationwide, for embryonic stem cell research. The bill would prohibit exclusively SCNT of human embryos, for which there are no compelling scientific or ethical grounds to proceed.

There is no scientific evidence that embryonic stem cell research has resulted in any of the therapeutic benefits for disease that have been claimed. Further, stem cells can be obtained from umbilical cords and adult humans without destroying human embryos. Using adult stem cells is just as effective, and possibly more effective, than using embryonic stem cells, yet it avoids the ethical dilemmas of the latter. Current research solidly documents that adult stem cells are easy to isolate, can be grown in large quantities in culture, and, like embryonic stem cells, can specialize into all or most types of tissue present in the human organism. In experimental animals, transfers of adult stem cells have been more therapeutically beneficial than embryonic stem cells because they do not seem to be associated with tumors or transplant rejection in the patient. Embryonic stem cell research has been conducted for more than 20 years, but is still not as developed or effective, in most cases, as adult stem cell therapy.

There are several reasons why critics of this bill would prefer to continue working with human embryos. Many companies and laboratories wish to see returns on their investment in embryonic research and SCNT technology. Second, some researchers would like to clone human embryos for drug toxicology testing to determine how human tissue will respond to new drugs. While medical ethics clearly prohibit initial testing of drugs on living humans, the ethics of testing drugs on embryos in a lab are much less developed. Also, few scientists want their research limited. Philosophically, they want to keep the doors of investigation open. None of these reasons for continuing human embryonic SCNT has much to do with patients, treatments, and cures, despite all of the rhetoric to the contrary.

Any living cell that has a full complement of human genes is human life, in its very earliest stage. It has all of the genetic characteristics of *homo sapiens* and could be classified as no other type of organism. There is no difference between an egg that has fertilized by sperm and an egg that has undergone SCNT. The U.S. Department of Justice even has stated that it would be

impossible to enforce a law that allowed the cloning of human embryos yet forbade their implantation in a woman's uterus because, scientifically, it is impossible to distinguish between the two. The cell certainly has weeks of maturation to undergo before it is recognized as a fetus but it would, if given an environment in which to grow, become a viable human.

Using embryonic stem cells therapeutically for any significant number of patients is impractical because it would require millions or billions of donated eggs. There are not enough women of child bearing age in the United States to donate the number of eggs that would be required, and the hormone therapy that accompanies egg donation has serious risks that seriously could endanger donors. It would be detrimental to public health for government or private enterprise to encourage mass numbers of women to donate the eggs required to make embryonic stem cells a viable option for standard therapeutic uses.

Some have claimed that enactment of this bill would inhibit economic development and the biotechnology industry in Texas. Other states have similar laws, and their experiences do not support this allegation. For example, Pennsylvania has banned the destruction of human embryos, regardless of how they were produced, yet it ranks third nationally in biotechnology investment. In addition, Michigan bans destruction and cloning of human embryos, and it ranks 10th nationally in biotechnology investment. The experiences of these states indicates that Texas' economy likely would not be harmed by this bill.

Criminalizing human cloning as a first degree felony would be an appropriate punishment. It would be effective in deterring violations of the law, and rightly would equate cloning with murder. In both cases, human life is being destroyed.

OPPONENTS SAY:

The majority of Americans oppose reproductive cloning that would implant a human embryo genetically identical to a parent in a woman's womb. This bill would and should ban that variant of reproductive cloning. However, this bill would go much further and ban SCNT research for therapeutic purposes. In SCNT, the egg is never fertilized and is never implanted in a woman's uterus.

It is simply an egg whose DNA has been replaced with that from a somatic cell and could not properly be characterized as a human life.

The primary problem with this bill is that its definition of human embryo includes the one cell, or zygote, stage. A single cell organism is not viable human life. It has the potential to develop into human life if it multiplies and is implanted within a woman's uterus but, as a zygote in a petri dish, it is not human life. The term embryo has, in addition to its scientific meaning, a politically loaded connotation connected with the abortion debate. Calling a zygote an embryo might be legitimate scientifically, but it would be misleading. It would impute humanity to a single cell in a lab that indeed had a full complement of the human genome, but no viability as a human being. The definition of human embryo in the bill should be amended to reflect some measure of viability that would prohibit reproductive cloning while permitting much needed SCNT research to continue.

Embryonic cell research is an area in which knowledge is incomplete. For this reason, it should be kept open to investigation rather than closed off. Studies to date show conflicting evidence about its potential for therapeutic applications and should be allowed to continue until more solid conclusions can be drawn. Research shows promise for treating diseases like Parkinson's and Alzheimer's, juvenile diabetes, spinal cord injuries, and heart disease, among others. The results of research are never known in advance, but the prospect of this work leading to significant improvements in quality of life for individuals for whom existing treatments are ineffective is worth its continued investigation.

Legislation and regulation work very well for establishing guidelines within which scientific investigation will be conducted. The National Institutes of Health already have developed stringent guidelines for the ethical conduct of embryonic stem cell research. However, laws and regulations should not prohibit entire fields of scientific investigation, nor could they effectively do so. Most of the scientific community will police itself and follow federal guidelines concerning medical ethics. However, passing this or any other bill would not prevent those on the fringe from pursuing reproductive human cloning — they simply would do so outside of the system.

The sources of human embryos are existing stem cell lines, SCNT, and in vitro fertilization. This bill would prohibit SCNT, yet embryos from in vitro fertilization labs still would be available. The third option, existing stem cell lines, is insufficient for research needs for several reasons. First, the stem

cells are patented, and other researchers must pay to use them. The cost is prohibitive for many labs. Second, there are no more than about 70 lines that could be used, which is an extremely limited genetic pool. Third, almost all of them have been grown in a culture using mouse nutrients and are, thereby, unsuitable for human therapeutic use. Existing stem cell lines are useful scientifically, but they are insufficient. If this bill were enacted, the only source of human embryos available for research would be unused frozen embryos created through in vitro fertilization.

This bill also seriously could harm the biotechnology sector of the state's economy. Currently, biomedical research contributes more than $1 billion a year to the state's economy and employs thousands of people. This bill would send the message that leading edge biotechnology research was not welcome in Texas and could encourage companies and individual researchers to locate elsewhere. State lawmakers should try to encourage, not discourage, innovative scientists to work in Texas.

Criminalization of therapeutic cloning would be excessive. Intentionally murdering someone and aggravated kidnapping are other first-degree felonies. By contrast, rape is a second-degree felony, and kidnapping is a third-degree felony. Making cloning a crime comparable to murder would be inconsistent with the severity of the offense.

OTHER OPPONENTS SAY:

On the one hand, this bill would prohibit cloned embryos from being created so that they would not be destroyed or violated. On the other hand, it would allow other human embryos to be destroyed, such as those from in vitro fertilization. This is a double standard. State policy either should determine that the life of human embryo is protected or that it can be used and destroyed in research. However, the law should not discriminate between human embryos based on how they were produced.

NOTES:

The committee substitute would revise the definitions of human embryo and human somatic cell from those in the bill as introduced. It also would specify types of cloning research that are not prohibited by the bill.

The companion bill, SB 156 by Nelson, was referred to the Senate Jurisprudence Committee on January 30.