House
Legislative
Analysis
Section

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PROHIBIT CLONING OF HUMANS

House Bill 4846 as enrolled
Public Act 109 of 1998
Sponsor: Rep. Kirk Profit

House Bill 4962 as enrolled
Public Act 110 of 1998
Sponsor: Rep. Michelle McManus

House Bill 5475 as enrolled
Public Act 111 of 1998
Sponsor: Rep. George Mans

Senate Bill 864 as enrolled
Public Act 108 of 1998
Sponsor: Sen. Loren Bennett

House Committee: Health Policy
Senate Committee: Health Policy and Senior Citizens

Second Analysis (11-23-98)

THE APPARENT PROBLEM:

For years, the prospect of human cloning was the subject of science fiction. Then, in February of 1997, Scottish research biologists introduced Dolly to the world. Dolly was a sheep that was an exact genetic copy of another sheep, meaning that she had only one parent. In fact, Dolly is more accurately described as a younger twin of an adult sheep (see BACKGROUND INFORMATION), rather than a true offspring. Though cloning research involving microorganisms, plants, and animals has been progressing for over 40 years, the particular technique used to create Dolly suddenly brought the possibility of human cloning from the realm of the future into the here and now.

To create Dolly, Dr. Ian Wilmut and his colleagues at the Roslin Institute in Edinburgh, Scotland, used a technique known as somatic cell nuclear transfer to transfer the genetic material from an adult sheep's mammary cell into an egg from another sheep that had had the nucleus removed. A similar technique had been used by other researchers in cloning frogs, mice, and monkeys, but those experiments had been done using the cells from embryos. The Scottish researchers were the first to successfully use genetic material from a cell of an adult animal, thereby proving that cells beyond the early embryonic stage could be made to replicate an entire animal. It is this technology that many believe could be used to clone human beings.

President Clinton responded almost immediately by asking the National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues surrounding human cloning. The President also issued a directive barring the use of federal funds for cloning human beings. (A similar directive was issued by the president in December 1994 to prohibit the use of federal funds to create human embryos for research purposes.)

The 1997 NBAC report, entitled "Cloning Human Beings", contained recommendations that included the continuation on the current moratorium on the use of federal funds in creating a child by somatic cell nuclear transfer, a request to both private and public sector researchers and clinicians to comply with the intent of the moratorium on human cloning, and that

federal legislation be enacted to prohibit anyone from attempting to create a child through somatic cell nuclear transfer cloning. Though many feel that the possibility of cloning a human remains many years away, the recent announcement by a Chicago physicist, Dr. Richard Seed, of his intention to set up a clinic and clone children within the next two years has resulted in a public outcry for regulation. At the federal level, legislation has been introduced in both the House of Representatives and the Senate (H.R. 922, H.R. 923, S. 1602, and S. 1611) to ban the use of federal funds for research on cloning humans and to make it illegal to clone humans in the United States. In addition, several states have also introduced legislation to institute prohibitions at the state level. To date, only California has passed a cloning prohibition. Meanwhile, nineteen European countries recently signed an agreement to ban the cloning of humans. In an attempt to address public concern, legislation has been offered to prohibit the cloning of humans, to prohibit research to clone humans, and to create penalties for anyone attempting to clone a human being.

THE CONTENT OF THE BILLS:

The bills would prohibit human cloning and establish penalties for violations of the prohibition. "Human cloning" would be defined as "the use of human somatic cell nuclear transfer technology to produce a human embryo." The term "human embryo" would be defined as "a human egg cell with a full genetic composition capable of differentiation and maturing into a complete human being." A somatic cell would mean a human cell that was not and would not become a sperm or egg cell. "Human somatic cell nuclear transfer" refers to the procedure used in transferring the nucleus of a human somatic cell into an egg cell from which the nucleus has been removed or rendered inert. The bills specify that scientific research or cell-based therapies not specifically prohibited by the bills would be allowed. House Bills 4846 and 5475 and Senate Bill 864 would also state that they do not give a person a private right of action. Specifically, the bills, which are tie-barred to each other, would do the following:

House Bill 4846 would amend the Public Health Code (MCL 333.16221 et al.) to prohibit a person licensed or registered under the provisions of the code, or any individual, from engaging in or attempting to engage in human cloning. Under the bill, a licensee or registrant would have his or her license or registration revoked for a period of at least five years. In addition, the person who violated the ban on cloning would be subject to a civil penalty of $10 million. Fines collected for a violation of the ban would have to be distributed in the same manner as state penal fines. (Article 8, Section 9 of the Constitution the State of Michigan of 1963 requires fines collected under penal laws to be used for the support of public libraries and county law libraries.)

Further, the bill would add failure to comply with the child immunization reporting requirements instituted by Public Act 540 of 1996 to the list of activities constituting grounds for license and registration sanctions. Sanctions could include license or registration denial, revocation, restitution, probation, suspension, limitation, reprimand, or a fine. (For more information, see the House Legislative Analysis Section's analysis of House Bill 5477 dated 1-14-97.)

House Bill 4962 would amend the Michigan Penal Code (MCL 750.430a) to criminalize the cloning of human beings. Under the bill, a person who intentionally engaged in or attempted to engage in human cloning would be guilty of a felony and could face imprisonment for up to 10 years or a fine of up to $10 million, or both.

House Bill 5475 would create the Human Cloning Funding Prohibition Act to prohibit a person from using state funds to engage in or attempt to engage in human cloning. State funds could be used for scientific research or cell-based therapies that would not specifically be prohibited by the definition of cloning. A person who violated the ban would be subject to a fine of $10 million, and fines collected for a violation of the ban would have to be distributed in the same manner as state penal fines. (Article 8, Section 9 of the Constitution the State of Michigan of 1963 requires fines collected under penal laws to be used for the support of public libraries and county law libraries.)

Senate Bill 864 would amend the Public Health Code (MCL 333.16274, 333.20165, and 333.20197) to prohibit persons licensed or registered under the code to clone or attempt to clone human beings, and would require health facilities and agencies to ban such persons or any other person from such work in a facility owned or operated by the health facility or agency. A health professional violating the prohibition on human cloning would be subject to the civil and administrative penalties contained in House Bill 4846 (a civil fine of $10 million and license revocation for at least five years.) A health facility or agency found

in violation of the bill's provisions would be subject to license or registration sanctions and an administrative fine of $5 million.

BACKGROUND INFORMATION:

The news of a successful attempt to clone a sheep using cells from a mature animal has brought the prospect of successfully cloning a human being into the realm of the possible. It has also sparked many fears and concerns, as well as excitement about possible medical advances in fighting diseases and exploring tissue and organ regeneration. "Cloning" refers to making a genetic copy of a molecule, microorganism, cell, embryo, plant, or animal. Cloning is not unusual in nature, as some organisms replicate themselves through asexual reproduction, worms and a few other species can regenerate a whole being from just a part, other animal species can regenerate certain limbs, and many plants can be propagated from a slip or cutting from the "parent" plant. In humans, identical twins are a form of "natural" cloning.

Scientists have been researching cloning in plants and animals for several decades. Molecular cloning, an integral part of recombinant DNA technology, has been used to produce medicines to dissolve blood clots in heart attack patients, treat dialysis patients for anemia associated with kidney disease, and to produce insulin to treat diabetes. Cellular cloning, in which copies of cells from the body are made, is also used to test and occasionally make medicines. Another technique used to clone animals is to split an embryo shortly after fertilization. Each "split" then develops into a genetically identical animal.

In somatic cell nuclear transfer (the procedure used to create Dolly, the sheep), the nucleus of a somatic cell from one animal is removed and inserted into an egg from another animal. The nucleus of a cell contains the genetic material that directs an organism's development. A somatic cell is any cell of the body other than an egg or sperm cell. Before the nucleus of the somatic cell is inserted into the egg, the nucleus of the egg is removed and discarded. Therefore, the genetic material of the somatic cell is what directs the development of the fertilized (or fused) egg. Earlier attempts to clone an animal using somatic cells from older animals had failed, leaving scientists to conclude that after a certain point in the embryonic stage, a cell loses its ability to direct the development of cells that are different from itself. It was believed then that once a cell had "differentiated" (meaning that it had specialized into a specific type of cell such as a nerve or skin cell), it could only produce that same type of cell. The Scottish scientists speculated that the previous failures could be due to the older cell being out of sync, so to speak, with the younger egg. They devised a way to cause the genes in the older cell to revert to a state whereby the genes could direct the development of any type of cell. After 276 failed attempts, Dolly was born.

Dolly's significance lies in the fact that the scientists were able to get an older, already differentiated cell, to make all the cells needed to make another animal. This is considered to be more desirable than splitting embryos to get genetically identical animals, as there is a limited number of times an embryo can be split. Somatic cell nuclear transfer holds the possibility of making an unlimited number of genetically identical test subjects. Not only could this be an advancement in animal husbandry as far as developing a herd with desirable traits such as increased meat production or superior wool, research into human diseases could be speeded up by being able to clone herds that have a specific genetic makeup that scientists need to study. However, along with excitement over possible medical advances and better food production came concerns over possible abuses if the same technique were used to clone humans.

Within days of the announcement of Dolly's birth, President Clinton called for a ban on federal funding for cloning research and a moratorium on cloning by those in the public and private sector while the National Bioethics Advisory Committee (NBAC) studied the implications of cloning human beings. The NBAC report (available on the Internet) was released in June of 1997. Dr. Harold Shapiro, chairman of the commission and president of Princeton University, specified that the commission did not "revisit either the question of the cloning of humans by embryo-splitting or the issues surrounding embryo research", but restricted their focus to the use of somatic cell nuclear transfer with the intention of creating a child. (The advisability of embryo research and public policy recommendations were thoroughly explored previously by the Human Embryo Research Panel commissioned by the National Institutes of Health. A report was published in September of 1994.) In regards to cloning human beings, Dr. Shapiro wrote, "It seems clear to all of us, however, given the current stage of science in this area, that any attempt to clone human beings via somatic cell nuclear transfer techniques is uncertain in its prospects, is unacceptably dangerous to the fetus and, therefore, morally unacceptable."

The commission, among other things, called for a continuation of the ban on federal funding for human cloning research, that private sector researchers comply with the moratorium, and that professional and scientific societies communicate to their members "that any attempt to create a child by somatic cell nuclear transfer and implantation into a woman's body would at this time be an irresponsible, unethical, and unprofessional act."

The commission also recommended that federal legislation be enacted to prohibit a person from attempting to create a child through somatic cell nuclear transfer, but that any legislation (federal or state) include a sunset clause to ensure that the issue be reviewed at a future date to see if a ban continued to be needed. Further, the commission stated that any legislation should include a requirement that an oversight body, before the legislation expired, evaluate and report on the current status of somatic cell nuclear transfer technology, and on the ethical and social issues raised by human cloning in light of the understanding at that time. In regards to any regulatory or legislative actions undertaken to implement a ban on creating a child by somatic cell nuclear transfer, the commission concluded it "should be carefully written so as not to interfere with other important areas of scientific research." Should a legislative ban not be enacted, the commission called for the clinical use of somatic cell nuclear transfer techniques to create a child to be preceded by clinical trials governed by independent reviews and informed consent consistent with existing laws and standards that protect human subjects.

FISCAL IMPLICATIONS:

According to the Senate Fiscal Agency, the bill package to prohibit human cloning would have an indeterminate fiscal impact on state and local government. In fiscal notes on the three House bills, the agency reports that enforcement costs and fine revenue would depend on the number of violations. In a fiscal note on Senate Bill 864, the agency reports that it is not possible to determine the fiscal impact of the bill on the Department of Consumer and Industry Services without being able to predict the number of cloning violations or the extent to which the DCIS would choose to impose a fine instead of the existing punitive measures. (4-17-98)

ARGUMENTS:

For:

Though the possibility of using the somatic cell nuclear transfer technique to clone human beings now exists, it would be irresponsible to do so for many reasons. For starters, much animal research and testing would have to be conducted before human cloning should be attempted, as the technique has not even been perfected on animal subjects. Reportedly, only a few other animals have been cloned since Dolly was introduced to the world last year. Therefore, scientists are yet unclear as to the long-term health of cloned subjects. Also, the Roslin researchers had 276 unsuccessful cloning attempts before Dolly was born. Of the 277 eggs that were fused with the genetic material from an adult sheep's cells, only 29 of the eggs developed into embryos. Only 13 of the sheep that were implanted with the embryos became pregnant, and only one of the implanted embryos was carried to term and delivered live. For human subjects, such statistics are unacceptable. Assistive reproductive techniques, such as in vitro fertilization, have over four times the success rate, and were approved only after years of animal testing showed that such a technique could be done without an increased risk of harm to the baby. (Clinics and laboratories using assistive reproductive techniques are also closely regulated.)

Other health concerns for human clones have to do with changes that occur at the cellular level. For example, the National Bioethics Advisory Committee (NBAC) report raised the question of whether the phenomenon of imprinting (which refers to the fact that the genes inherited on the chromosomes from the father and those from the mother are not equivalent in their effects on the developing embryo) may affect the ability of the transferred genetic material to reprogram development. The genetic material in the nucleus that is transferred by the somatic cell nuclear transfer technique to the egg should not have an imbalance between the genes derived from the cell's donor's mother and father. According to the NBAC report, studies have shown that disturbances in imprinting have been associated with cancer and rare genetic conditions in children. Further, it is now known that as cells age, mutations are more likely to occur within the genetic material. Therefore, it is too early to predict what effect the accumulation of mutations in an

older cell may have if its genetic material is transferred to an egg for purposes of cloning a human. Questions are therefore raised such as whether the individual created by cloning would have an increased risk of cancer or other diseases in his or her lifespan.
The point is, there are too many unknowns as to the long-term safety and health of an individual born through the somatic cell nuclear transfer technique. Years of animal research and testing would have to be done before it would be known if this procedure is safe for human subjects. Though it is likely that the majority of doctors, researchers, and scientists both in the public and private sector will voluntarily comply with the presidential moratorium on human cloning, there is nothing to prevent or deter individual researchers in the private sector such as Dr. Seed, the Chicago physicist, from beginning human cloning research prematurely or attempting to produce a child through cloning.

The bills would create a strong deterrent for any attempt at cloning in Michigan at this time in the form of license revocation, imprisonment, and fines in excess of $10 million ($5 million under Senate Bill 864 for health facilities and agencies). Because of a variety of safety, legal, and ethical reasons, human cloning and cloning research involving embryos should not be allowed.

For:

A 1997 poll by Time/CNN found that 93 percent of Americans disapproved of cloning humans. Objections to human cloning are varied. Some feel strongly that cloning children is unethical and akin to playing God with one's own children, especially if cloning could be used to "design" desirable traits. Others feel that it represents a further moving away from having children within the context of marriage and family, placing it more in the hands of scientists to "manufacture" children in laboratories. To some it may violate religious beliefs, where others have concerns that cloning could lead parents of cloned children to think of the children as property.

However, many objections to cloning humans appear to revolve around the inherent uniqueness of the individual, and the psychological harm that could result in a child who learns that he or she is not unique, but more of a time-delayed twin who may be expected to think and behave like his or her genetic predecessor. The harm lies in the fact that issues of identity are extremely important to the mental health of an individual. Though studies of identical twins demonstrate that they are distinct and separate personalities who just happen to be exact genetic copies, peoples' tendencies are to believe that the same soul resides in a look-a-like body. In the NBAC report, the question is asked if there is a moral right to a unique identity, and if so, would cloning violate the person's right? If there is indeed a violation of a right to uniqueness, who would be violated -- the person cloned, or the clone of the person?

Similar questions are raised in regard to legal issues of ownership and privacy. Who retains the rights regarding an individual's genetic information, the parent or the child? What is the kinship relationship to the genetic precursor, younger twin sister or daughter? Other legal and ethical questions arise, including whether cloning technology could usher in a new wave of eugenics (the selection of advantageous inherited characteristics).

So, though there are many questions that should be answered before human cloning is permitted, there are no definitive state or federal laws to prohibit human cloning or cloning research, only a federal ban on using federal funds to create embryos for research or to clone humans. There is little or nothing to prevent those in the private sector from attempting to clone humans. Reportedly, about ten clinics or laboratories in the U.S. have the technological capabilities to begin using the somatic cell nuclear transfer technology on humans. Though reportedly the majority of professional and medical societies have indicated an intention to comply with the moratorium on cloning, there are no legal deterrents from conducting human cloning research or any mechanisms to prosecute someone who does.

Against:

There are no compelling reasons to rush into passing legislation at this time, and many compelling reasons to give the subject further study. First of all, it is apparent to researchers and medical personnel that the technology of somatic cell nuclear transfer is not ready to conduct human cloning experiments, and that it would be irresponsible to do so at this time. Further, many scientists also find the subject of human cloning to be repugnant. Just because a person, such as Dr. Seed, announces intentions to clone a human child within two years, does not mean that he or she would get the support or necessary financial and scientific backing needed from the research community. Besides, the Federal Drug Administration (FDA) announced that federal regulations require FDA approval for human cloning trials. Considering the

current five-year presidential moratorium on human cloning, it is unlikely that the agency would grant approval. In addition, President Clinton instituted a ban on federal funds for embryo research in December of 1994 prohibiting the use of federal funds for the creation of a human embryo for research purposes or for research in which a human embryo would be destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under current federal law. The prohibition was placed in federal statute in 1997 by Public Law 105-78, Section 513a, and included a definition of human embryo or embryos as being "any organism, not protected as a human subject under 45 CFR 46 . . . that is derived by fertilization, parthenogenesis, cloning (emphasis added), or any other means from one or more human gametes or human diploid cells." Reportedly, the same language was also placed in this year's recently signed federal appropriations bill for 1999. Therefore, sufficient prohibitions exist at the federal level to discourage human cloning research for the near future while the subject is looked into more closely.

Response:

Earlier this month, a medical technology company made public research conducted in 1995 and 1996 at the University of Massachusetts in which the nucleus of a human skin cell was fused with the egg of a cow. According to reports, the fused cell divided several times. This research was done well after the presidential ban on using federal funds for embryo research. Though the research was funded by corporate money, it was conducted on public university grounds using equipment that may have been purchased with federal funds: a clear violation of the federal ban. Yet, the research project went undetected by federal regulators. Under the bill package, this type of project would be prohibited in Michigan, and the company conducting such a project would be subject to a stiff penalty. Further, many pharmaceutical researchers feel they can continue to conduct important and potentially lifesaving research that involves the use of various cloning technologies within the parameters of the bill. The bill may not be a final answer, but it represents an important first step.

Against:

Many see cloning as an answer for infertile couples. Currently, available assistive reproductive techniques such as in vitro fertilization have about a one-in-five success rate. Cloning by somatic cell nuclear transfer may present a safer, more reliable method of enabling infertile couples to have their own offspring.

Additionally, some feel that a ban on cloning would violate an infertile couple's Constitutional reproductive rights. As to fears regarding horrendous abuses that cloning could bring, it is important to note that most of the fears surrounding the potential abuses of in vitro fertilization have proven to be unfounded. In vitro fertilization is tightly regulated, as, no doubt, cloning would be also.

Response:

The right to reproduce asexually may be beyond the scope of the Constitution, and therefore would not constitute a protected right.

Against:

The bills are problematic for several reasons. Most importantly, the advances in somatic cell nuclear transfer technique that have given rise to the successful cloning of mammals have happened so quickly, and since the research community had not considered human cloning with this technique possible for the foreseeable future, there has not been adequate time for those in the scientific and legal communities to adequately judge the legal, ethical, and scientific implications of state and federal legislation banning the use of the somatic cell nuclear transfer procedure in human cloning research.

At the national level, there has been much debate as to the advisability of embryo research, and currently, there is a Presidential and Congressional ban on using federal funds to support embryo research, although there is at present no regulation on research in the private sector. Many agree that the somatic cell nuclear transfer technique may unlock many medical advances in fighting diseases and developing methods to regenerate tissue and organs for transplants, but what may be difficult to determine at this time is whether all the answers can be supplied through animal research. Recently, a group of scientists at the Wisconsin Regional Primate Research Center in Madison announced the successful cultivation of cell lines from embryonic stem cells derived from human embryos. The study of human embryonic stem cells is seen as a major step forward in the development of technology to produce cell lines that can be stimulated to differentiate into specific types of tissues that in turn can be used to treat diseases or regenerate damaged tissues. However, this type of research, even if funded by private sources, would be prohibited within the state under the bill package. Therefore, the bills may have a chilling effect on research. In order to reach the goal of creating cells that could be used in transplants or to treat neurodegenerative disorders, diabetes, spinal cord injury, and diseases of the blood,

embryo research may have to come under further scrutiny and a definition of embryo be determined that would perhaps allow some initial research and yet still respect the developing form of human life that is represented after fertilization or fusion. Perhaps it is too soon to craft legislation precisely enough to prohibit that which is deemed to be objectionable and yet not impede medical advances that could benefit many.

Against:

A better approach might be to create stringent regulations as to what types of research might be allowed and what would be prohibited, rather than a broad, blanket prohibition that could have the effect of impeding legitimate medical research and discoveries that could improve the health and well-being of many. At the very least, any legislative ban on human cloning should contain a sunset provision, as the NBAC recommended, so that the subject of human cloning and cloning research could be reviewed after a closer study into the moral, ethical, legal, and scientific implications had been completed. Also, if there were a five-year ban (which would be in line with the presidential moratorium of five years on human cloning), the research gained from animal studies during that time should give significant information as to the feasibility or advisability of proceeding with human cloning research.

Against:

House Bill 4846 would amend the Public Health Code to prohibit a licensee or registrant or other individual from cloning or attempting to clone a human. However, the particular section of the code that the bill would amend is under the oversight of the Department of Consumer and Industry Services. According to departmental staff, the department only has jurisdiction over persons who are licensed or registered under the code, and not to the general public. Many professionals involved in cloning research, such as physicists, biologists, microbiologists, and so on are not licensed or registered under the code. Therefore, the question must be raised as to the authority that the department would have to bring a civil penalty against an unlicensed individual.

Analyst: S. Stutzky

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