House Legislative Analysis Section
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PROHIBIT CLONING OF HUMANS

House Bill 4846 (Substitute H-3)
Sponsor: Rep. Kirk Profit

House Bill 4962 (Substitute H-2)
Sponsor: Rep. Michelle McManus

House Bill 5475 (Substitute H-2)
Sponsor: Rep. George Mans

Committee: Health Policy

First Analysis (1-27-98)

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, HR 922 and HR 923 have been introduced 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. "Clone" or

"cloning" would be defined as "the use of human somatic cell nuclear transfer technology to produce an embryo." "Human somatic cell nuclear transfer" would mean the transferring of the nucleus of a human somatic cell into an oocyte (an egg that has not reached full development) from which the nucleus had been removed or rendered inert. "Somatic cell" would be defined as "a cell of an embryo, fetus, or a fully developed human being that is not and will not become a sperm or egg cell." The bills would specify that the prohibition on cloning human beings would not prohibit cloning or cloning research that did not produce an embryo. The bills are tie-barred to each other. (Note: The term "embryo" does not appear to be defined in Michigan law, and medical literature appears to offer different perspectives as to what is considered an embryo.) Specifically, the bills 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 cloning or attempting to clone a human being. Under the bill, a licensee, registrant, or other 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.)

In addition to the civil penalty, a licensee or registrant would also be subject to administrative penalties as prescribed in the code. Under the code, the boards governing the health professions appoint disciplinary subcommittees who have the authority to impose license sanctions and other penalties if certain grounds exist. The bill would add cloning or attempting to clone a human to the list of activities that constitute unprofessional conduct which in turn would be grounds for a disciplinary subcommittee to permanently revoke a health care professional's license or registration. Further, the bill would prohibit a board or task force from reinstating the license or registration of a person whose license or registration was revoked because of engaging in cloning activities. A person whose license or registration was revoked could not reapply for reinstatement, and so could not be granted a hearing to contest the revocation. The Department of Consumer and Industry Services would have to return any application for reinstatement from a person whose license or registration had been revoked for cloning.

Further, the bill would add failure to comply with the child immunization reporting requirements instituted by Public Act 540 of 1996 (for more information, see the House Legislative Analysis Sections' analysis of House Bill 5477 dated 1-14-97) 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.

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 cloned or attempted to clone a human being would be guilty of a felony and could face imprisonment of up to 10 years or a fine up to $5,000, or both.

House Bill 5475 would create the Human Cloning and Cloning Research Prohibition Act to prohibit a person from using state funds to clone a human being or to conduct research on human cloning. Like House Bill 4846, 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.)

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 nucleus of a somatic cell 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 would be reviewed 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 House Fiscal Agency, House Bills 4846 and 4962 may result in enforcement and legal costs to the state to implement and enforce the respective penalties contained in the bills (House Bill 4846 imposes a civil penalty of $10 million and administrative penalties for licensees and registrants; House Bill 4962 imposes a fine of up to $5,000 and ten years in jail.) Costs would be indeterminate at this time because it is not known to what extent cloning activities are occurring or the level of enforcement that would be necessary to implement the policy.

The agency reports that House Bill 5475, which prohibits the use of state funds to clone humans or to conduct research on human cloning, would not have a state or local fiscal impact. (1-20-98)

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 born 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 the effect that 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 permanent license revocation, imprisonment, and fines in excess of $10 million ($10 million under House Bills 4846 and 5475 and $5,000 under House Bill 4962). 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 to others it leads to concerns of parents of cloned children thinking 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 to 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.

Yet, many dismiss people's concerns about cloning as being unfounded and fed by fear. It is true that there are many misconceptions about cloning (no, neither Hitler nor Elvis can be cloned using the somatic cell nuclear transfer technique), but, today there are reports of researchers creating headless mice and tadpoles, and of the cross-breeding of animals using the somatic cell nuclear transfer technique. Today researchers are experimenting with using the somatic cell nuclear transfer technique in animals to genetically engineer cells to contain human genes to produce certain medicines in an animal's milk, or to experiment with genetically altering an animal's organs to be used in human transplant operations. Some of these paths may take us where we want to go, others may be opening doors best left closed. The point is, it is in the present that choices need to be made about what would be acceptable outcomes of this new cloning technique, as well as what would be unacceptable or even detrimental, both to individuals and to society. It is not enough to say today that cloning headless humans for organ harvesting won't happen because it is repugnant to do so. Policies regulating cloning research must be developed so that practices considered by many to be unacceptable will not come into being. While it is true that at this time many questions about the implications of cloning remain unanswered, public policy is needed to prevent potential abuses from developing. To simply say that as an advanced culture, scientists and political leaders would not engage in

dangerous, harmful, or unethical policies and practices is to ignore the lessons of history. Steps need to be taken today to shape the desired tomorrow.

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. 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 is 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. According to a National Institutes of Health, Office of Extramural Research posting on the Internet regarding contract proposals, "'human embryo or embryos' includes 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 form (sic) one or more human gametes." 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.

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 to ban the use of the somatic cell nuclear transfer procedure in human cloning research. For instance, the bills under consideration create very harsh penalties for anyone who used human somatic cell nuclear transfer technology to produce an embryo. Therefore, it would appear that the point at which someone broke the

law was when an embryo was produced. However, the bills do not define the term "embryo", nor is it defined under current Michigan law. This is likely to lead to long and costly litigation, as even in medical and scientific literature, the term "embryo" has various definitions ascribed to it. The NBAC report defines an embryo as an organism from the time of fertilization until the time it develops into a fetus. In Medicine of the FETUS & MOTHER by the J.B. Lippincott Company, a medical textbook used at university medical schools, the embryonic period is defined as extending "from the beginning of the fourth week to the end of the eighth week." Still other texts define an embryo as starting when the long axis develops, or at about the fourteenth day after fertilization. (Note: A search of Michigan law did not locate a definition of "embryo," and the only definition found in federal law was in a chapter governing the Nuclear Regulatory Commission, 10 CFR 20.1003(2), which reads "embryo/fetus means the developing human organism from conception until the time of birth.") Depending on the definition used, the bill could be interpreted to mean that as soon as the nucleus from a human somatic cell was injected into a donor egg cell a violation had occurred, or that the fused egg could be allowed to develop up to the fourteenth day but no more, or that research could be conducted up until the end of the third week, which some medical texts say is the beginning of the embryonic period. If physicians and other researchers are to face permanent license sanctions, fines in the millions of dollars, and imprisonment, a precise definition of embryo should be added to the bills so that it is clear to all when a violation of the proposed ban has occurred.

In fact, even defining "embryo" as beginning with fertilization could be problematic, as in somatic cell nuclear transfer, "fertilization" in the true sense is not taking place. Fertilization occurs when the egg and the sperm unite. In somatic cell nuclear transfer, a sperm is not used. Genetic material that had been fertilized long ago is used to spur new regeneration. So, it is unclear how this procedure would even fit into current definitions and understandings of human reproduction.

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, or if embryo research will have to come under further scrutiny and a definition of embryo be determined that would perhaps allow some

initial research and yet 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 what 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. The bills would ban the use of somatic cell nuclear transfer to produce an embryo. It is important to note that while federal laws regulate fetal research, no state or federal guidelines regulate embryo research for embryos that have not been implanted in a womb. However, according to a report by the Human Embryo Research Panel dated September 1994, guidelines for embryonic research have been developed by other countries and by professional and scientific societies in the United States. Though details of the guidelines adopted in the private sector for embryo research were not given in the report, reportedly research on embryos after the fourteenth day is discouraged. The panel concluded that from the perspective of public policy, "sufficient arguments exist to support the permissibility of certain areas of research involving the preimplantation human embryo within a framework of stringent guidelines" and that "[i]t is in the public interest that the availability of Federal funding and regulation should provide consistent ethical and scientific review for this area of research." Therefore, perhaps it would be more prudent to regulate the area of embryo research specifically as it relates to the use of human somatic cell nuclear transfer, rather than with broad legislative prohibitions that may be difficult to enforce.

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.

POSITIONS:

Representatives of the following organizations submitted written testimony to the committee in support of the bills (1-20-97):

- The Department of Community Health
- The Michigan Family Forum
- The Michigan Catholic Conference

A representative of Right to Life of Michigan testified in support of the bills. (1-20-97)

Analyst: S. Stutzky

■This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.