FOIA Number: 2013-0365-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: Domestic Policy Council

Series/Staff Member: Tom Freedman

Subseries:

OA/ID Number: 17542

FolderID:

Folder Title:
Cloning Bills and Acts

Stack:	Row:	Section:	Shelf:	Position:
S	99	4	1	3

SUBMITTED 6/9/97

A BILL

To prohibit any attempt to create a human being using somatic cell nuclear transfer, to provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.—This Act may be cited as the "Cloning Prohibition Act of 1997".

SECTION 2. FINDINGS.

(a) It has been reported that an adult sheep has been cloned using a technique called somatic cell nuclear transfer, a form of cloning.

(b) The National Bioethics Advisory Commission (NBAC) has reviewed the scientific and ethical implications of this technology's potential use to clone human beings.

(1) NBAC has found that:

(a) Somatic cell nuclear transfer technology may have many applications for biotechnology, livestock production, and new medical approaches including the production of pharmaceutical proteins and prospects for regeneration and repair of human tissues.

(b) However, the possibility of using somatic cell nuclear transfer for the purposes of creating a child entails significant scientific uncertainty and medical risk. Potential risks, known and unknown, could result in harm to a child.

(2) The NBAC concluded unanimously that at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning. The Commission's consensus is based on current scientific information indicating that this technique is not safe to use in humans at this point.

(3) Moreover, in addition to issues of safety, the Commission identified many additional serious ethical concerns which they agreed require a great deal more widespread and careful public deliberation before this technology may be used.

(4) NBAC recommended a continuation of the current moratorium on the use of Federal funds to support any attempt to create a child by somatic cell nuclear

transfer, and an immediate request to all firms, clinicians, investigators, and professional societies to comply voluntarily with the intent of the Federal moratorium.

(5) NBAC further recommended that Federal legislation be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning.

(6) NBAC also recommended that the United States cooperate with other countries to enforce mutually supported restrictions on this activity.

(7) NBAC specified that the legislation should include a sunset provision and that, prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use and recommend whether the prohibition should be continued.

(8) The Commission concluded that any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to interfere with other important areas of research, such as the cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that arise from the possible creation of children through somatic cell nuclear transfer techniques.

(9) The Commission also found that cloning animals by somatic cell nuclear transfer does not raise the same issues implicated in attempting to use the technique to create a child, and its continuation should only be subject to existing regulations regarding the humane use of animals.

(c) Biomedical research facilities, including those conducting cloning, and reproductive services facilities affect interstate commerce.

SECTION 3. PURPOSES.—The purposes of this Act are—

(a) To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and

(b) To provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in humans.

SECTION 4. DEFINITIONS.

(a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.

(b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).

(c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

SECTION 5. PROHIBITION.—It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being.

SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals.

SECTION 7. PENALTIES.—

(a) Any person who intentionally violates Section 5 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

(b) If a person is violating or about to violate Section 5, the Attorney General may commence a civil action in Federal district court to enjoin such violation.

(c) Any property, real or personal, derived from or used to commit a violation or attempted violation of Section 5, or any property traceable to such property, is subject to forfeiture to the United States in accordance with the procedure set forth in Chapter 46 of Title 18 of the United States Code.

(d) The Attorney General of the United States shall have exclusive enforcement authority under this Act.

SECTION 8. EFFECTIVE DATE.-This Act shall apply to somatic cell nuclear transfers performed within five years after the date of its enactment.

SECTION 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT.—No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 10. RIGHT OF ACTION.—Nothing in this Act shall be construed to give any individual or person a private right of action.

Draft3 1-13-98
ASRM

CLONING PROHIBITION AND RESEARCH PROTECTION ACT

SECTION 1. PROHIBITION. It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.

SECTION 2. DEFINITIONS. For the purposes of this section, the following definitions apply:

(a) "somatic cell nuclear transfer" means transferring the nucleus of a somatic cell of an existing or previously existing human child or adult into an oocyte from which the nucleus has been removed;
(b) "the creation of a human child" means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth;
(c) "somatic cell" means a mature, diploid cell;
(d) "oocyte" means the female germ cell, the egg;
(e) "nucleus" means cell structure that houses the chromosomes, and thus the genes; and
(f) "gestation" means the period during which an embryo develops, inside the uterus, into a fetus that is ready to be born.

SECTION 3. PREEMPTION OF STATE LAWS. This law shall preempt any state law that imposes on individuals or institutions any limitations with respect to nuclear transfer, human cloning, cloning of molecules, DNA, cells, and tissues, or the use of nuclear transfer techniques to develop animals, or to related research.

SECTION 4. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including but not limited to important and promising work that involves:

(a) the use of somatic cell nuclear transfer or other cloning technologies, to clone molecules, DNA, cells, and tissues; or
(b) the use of somatic cell nuclear transfer techniques to develop animals.

SECTION 5. EFFECTIVE DATE. This Act shall apply to somatic cell nuclear transfer performed after the date of its enactment.

SECTION 6. REAUTHORIZATION. The prohibition in this legislation shall expire five years from the effective date.

SECTION 7. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on

(a) the state of the science of somatic cell nuclear transfer;

(b) the ethical and social issues associated with the potential use of this technology in humans; and
(c) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 8. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.

SECTION 9. PENALTIES.

(a) Any person who intentionally violates Section 1 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

OUTLINE OF WHITE HOUSE STATEMENT

In fashioning a law to ban human cloning, we have to be extremely careful to ensure that we do not inadvertently ban research which is vital to developing cures and therapies for deadly diseases.

Let me outline the key principles which should guide us in drafting a law:

1. The law should ban the act of cloning of a human being. It should not ban "research" because that might chill scientists in the conduct of vital basic biomedical research.

2. The law should focus only on the issue addressed by the National Bioethics Advisory Commission (NBAC). NBAC did not review and made no recommendations regarding embryo research, which is already subject to a ban on federally funded research.

> "We do not revisit either the question of the cloning of humans by embryo-splitting or the issues surround embryo research. The latter issue has, of course, recently received careful attention by the National Institutes of Health panel, the Administration, and the Congress." Letter of Harold Shapiro, NBAC Chairman (June 9, 1997).

3. Violation of the ban would be determined based on objective activities, not the "intent" or "purpose" of the scientists. We need to give scientists objective standards to define the prohibited acts. Focusing on their "intent" or "purpose" is open to interpretation and misinterpretation and does not permit scientists to predict how the statute will be enforced.

4. We need a national ban on human cloning. The national law should govern and we need to avoid the enactment of multiple and different state laws. This was one of the recommendations of NBAC.

> "The advantage to federal legislation -- as opposed to state-by-state laws -- lies primarily in its comprehensive coverage and clarity....Besides ensuring interstate uniformity, a federal law would relieve the need to rely on the cooperation of diverse medical and scientific societies, or the actions of diverse IRBs, to achieve the policy objective. As an additional benefit, federal legislation could displace the varied state legislative efforts now ongoing, some of which suffer from ambiguous drafting that could inadvertently prohibit the important cellular and molecular cloning research described...in this report." NBAC report at 100.

5. We need to enact the law for a five year period with a mandatory review at that time to determine whether the ban should be extended.

> "It is notoriously difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science. Some mechanism, therefore, such as a sunset provision, is absolutely needed to ensure an opportunity to re-examine any judgment made today about the implications of somatic

cell nuclear transfer cloning of human beings. As scientific information accumulates and public discussion continues, a new judgment may develop and we, as a society, need to retain the flexibility to adjust our course in this manner. A sunset provision...ensures that the question of cloning will be revisited by the legislature in the future, when scientific and medical questions have been clarified, possible uses have been identified, and public discussion of the deeper moral concerns about this practice have matured." NBAC report at 101.

6. We need to make sure the bill sets penalties which will absolutely deter any violations. The penalties should be civil fines in large amounts and we should not threaten the existence of a entire research firm.

7. We need to include a findings section and a explicit list of protected medical research to help ensure that the law does not have unintended consequences in inhibiting biomedical research.

8. Finally, we need to ensure that the Department of Justice enforces the law, not private individuals. We need to prevent the filing of frivolous or harassment law suits.

KEY DRAFTING ISSUES

Ban act of cloning

-- No ban "research"

Do not ban embryo research

Violation should be determined based on objective facts, not "intent" or "purpose"

-- "intent" and "purpose" are criminal law concepts, unpredictable, subjective

Federal preemption -- NBAC recommendation

-- Florida bill would have banned cloning of cells and genes!

Sunset -- NBAC recommendation

Penalties -- fines vs. confiscation

Protected medical research -- findings

No private right of action -- Clinton bill

DEFINING WHEN LIFE BEGINS

BILL PROPOSED BY CLINTON ADMINISTRATION

SECTION 5. PROHIBITION. It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb **or in any other way creating a human being.**

-- **Implies that "introducing" = "creating a human being"**

MODEL LEGISLATIVE LANGUAGE REGARDING HUMAN CLONING

The following legislative language is technically accurate from a scientific point-of-view and focuses only on the cloning of a human being.

SECTION 1. TITLE. This act shall be called the "Human Cloning Prohibition Act of 1998."

SECTION 2. PROHIBITION. It shall be unlawful for any person to use federal funds to create a human child identical in terms of nuclear deoxyribonucleic acid (DNA) to an existing or previously existing individual using somatic cell nuclear transfer technology.

SECTION 3. DEFINITIONS. For the purposes of this section, the following definitions apply:

(a) "somatic cell nuclear transfer technology" means transferring the nucleus of a somatic cell of an existing or previously existing human child or adult into an oocyte from which the nucleus has been removed;

(b) "the creation of a human child" means implanting the product of somatic cell nuclear transfer technology for gestation and subsequent birth;

(c) "somatic cell" means a differentiated, diploid cell;

(d) "oocyte" means the mature female germ cell, the egg;

(e) "nucleus" means the cell structure that houses the chromosomes, and thus the genes; and

(f) "gestation" means the period during which an embryo develops into a fetus that is ready to be born.

SECTION 4. PREEMPTION OF STATE LAWS. This law shall preempt any state law which imposes on individuals or institutions using federal funds a prohibition or limitation with respect to research regarding somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, and tissues, to the use of somatic cell nuclear transfer techniques to develop animals, or to related research.

SECTION 5. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including but not limited to important and promising work that involves:

(a) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or

(b) the use of somatic cell nuclear transfer techniques to develop animals.

SECTION 6. EFFECTIVE DATE. This Act shall apply to somatic cell nuclear transfers performed after the date of its enactment.

SECTION 7. REAUTHORIZATION. The prohibition in this legislation shall expire five years from the effective date.

SECTION 8. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on

(a) the state of the science of somatic cell nuclear transfer;

(b) the ethical and social issues associated with the potential use of this technology in humans; and

(c) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 9. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.

Draft3 1-13-98
ASRM

CLONING PROHIBITION AND RESEARCH PROTECTION ACT

SECTION 1. PROHIBITION. It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.

SECTION 2. DEFINITIONS. For the purposes of this section, the following definitions apply:

(a) "somatic cell nuclear transfer" means transferring the nucleus of a somatic cell of an existing or previously existing human child or adult into an oocyte from which the nucleus has been removed;
(b) "the creation of a human child" means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth;
(c) "somatic cell" means a mature, diploid cell;
(d) "oocyte" means the female germ cell, the egg;
(e) "nucleus" means cell structure that houses the chromosomes, and thus the genes; and
(f) "gestation" means the period during which an embryo develops, inside the uterus, into a fetus that is ready to be born.

SECTION 3. PREEMPTION OF STATE LAWS. This law shall preempt any state law that imposes on individuals or institutions any limitations with respect to nuclear transfer, human cloning, cloning of molecules, DNA, cells, and tissues, or the use of nuclear transfer techniques to develop animals, or to related research.

SECTION 4. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including but not limited to important and promising work that involves:

(a) the use of somatic cell nuclear transfer or other cloning technologies, to clone molecules, DNA, cells, and tissues; or
(b) the use of somatic cell nuclear transfer techniques to develop animals.

SECTION 5. EFFECTIVE DATE. This Act shall apply to somatic cell nuclear transfer performed after the date of its enactment.

SECTION 6. REAUTHORIZATION. The prohibition in this legislation shall expire five years from the effective date.

SECTION 7. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on

(a) the state of the science of somatic cell nuclear transfer;

(b) the ethical and social issues associated with the potential use of this technology in humans; and
(c) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 8. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.

SECTION 9. PENALTIES.

(a) Any person who intentionally violates Section 1 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

California Law Penalties

(a) If the violator is a corporation, firm, clinic, hospital, laboratory, or research facility, by a civil penalty of not more than one million dollars ($1,000,000) or the applicable amount under subdivision (c), whichever is greater.

(b) If the violator is an individual, by a civil penalty of not more than two hundred fifty thousand dollars ($250,000) or the applicable amount under subdivision (c), whichever is greater.

(c) If any violator derives pecuniary gain from a violation of this section, the violator may be assessed a civil penalty of not more than an amount equal to the amount of the gross gain multiplied by two.

BIO
BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

News Release

1625 K Street, N.W. · Suite 1100 · Washington, D.C. 20006 · (202) 857-0244 · FAX: (202) 857-0237

FOR IMMEDIATE RELEASE

CONTACT:
Dan Eramian
Libby Mikesell
202-857-0244

BIO Calls For FDA To Assert Its Authority On Cloning

(WASHINGTON, D.C., January 13, 1998)...Carl B. Feldbaum, president of the Biotechnology Industry Organization (BIO) sent the attached letter to Health and Human Services Secretary Donna Shalala asking her to assert the Food and Drug Administration's (FDA) authority and jurisdiction over any possible attempts to clone a human being:

"It is clear that society is not ready for the cloning of a human being. We need to listen carefully, and analyze thoughtfully the ethical, moral and safety issues that have been raised.

"Recognition and assertion of the FDA's regulatory power over human cloning will protect biomedical advances and at the same time will give everybody some breathing room to debate this issue. Bioethics issues will occur with further advances in science. We need to be certain, before we move ahead, that advances will clearly benefit human kind and not set us back into some new age of uncertainty about our values and the quality of human life."

The Biotechnology Industry Organization (BIO) represents over 745 biotechnology companies, academic institutions, and state biotechnology centers in 46 states and more than 25 nations. BIO members are involved in the research and development of health care, agricultural and environmental biotechnology products.

###

BIO

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

January 13, 1998

The Honorable Donna E. Shalala, Ph.D.
Secretary,
Department of Health and Human Services
615F Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Dear Secretary Shalala:

The recent announcement from Dr. Richard Seed regarding his proposal to establish a clinic for the cloning of human beings has caused significant controversy. BIO supports President Clinton's and the National Bioethics Advisory Commission's (NBAC) moratorium on the cloning of a human being. Cloning a human being poses major ethical and moral questions, as well as deeply troubling medical safety issues. The experience with "Dolly," in which there were 276 unsuccessful attempts before an apparently healthy sheep was born, points to the experimental nature of this technology in animals. It is plainly inappropriate to attempt to apply this technology to human beings. While these questions remain unresolved, government and public opposition to the cloning of a human being remains strong. Society needs to be heard and respected on this issue.

Several members of Congress have recently expressed interest in legislation that would ban the cloning of human beings. They may not be aware that the Food and Drug Administration (FDA) has broad authority to regulate biological products. Last February, FDA published a regulatory framework for the regulation of cellular and tissue-based products. The level of FDA oversight is dictated by the degree of human manipulation of cells or tissues. Those products which are subject to a low level of oversight are those which are defined as 'minimal manipulation' when the processing does not alter the biological characteristics of the cells or tissue.

But in those cases where there is more than 'minimal manipulation,' FDA has stated its intent to subject such products to formal regulatory review including the investigational new drug (IND) regulations and license review regulations.

BIO believes that the Dr. Seed's proposal to clone humans using nuclear transfer technology is much more than minimal manipulation as the original function of the egg cell is unmistakably altered by the removal of the parental haploid DNA and insertion of DNA from a somatic cell from another person. Thus, any such research along these lines should be subject to the IND regulations that require patient informed consent, review by an institutional review board (IRB) where the research is being conducted, and FDA review under 21 CFR Part 312.

In addition to raising profound ethical issues, nuclear transfer technology has not been reliably proven to work in animal models and raises serious safety issues. We believe that for the foreseeable future, FDA should issue a clinical hold on any IND submission to proceed with such experiments.

A public statement by senior officials within HHS as to the regulatory status of nuclear transfer technology would be welcomed and useful as the public debate continues.

Sincerely,

Carl B. Feldbaum /ag

Carl B. Feldbaum
President

CBF:ag

cc: Michael Friedman, MD, Food and Drug Administration

President Clinton's proposal (not yet introduced)

POSITIVES:

- Focuses only on the act of cloning a human being using somatic cell nuclear transfer, not on "research."
- Includes a five year "sunset" provision to determine the science and public sentiment on the issue in the future. (Just as public and political views have changed about artificial insemination, heart transplants and test tube babies.)
- Includes "findings" section which describes value of biomedical research.
- Includes clause that describes areas of critical protected biomedical research.

NEGATIVES:

- Definition of violation is over broad. One example is that as written it would limit treatments for mitochondrial disease.
- Violations turn on "intent" of individual to clone. The concept of "intent" comes from the criminal law and has no meaning in the context of a statute with civil penalties. Implementing an "intent" test includes a complex assessment of the psychological state of mind of a researcher, opens up the possibility of abuse by prosecutors and other enforcers, and provides no predictability to researchers.
- Does not preempt state laws.
- Draconian penalties (fine plus confiscation of entire research property).

Bond (S. 368)
(Referred to Senate Labor Committee)

POSITIVE:

- Good intentions.

NEGATIVES:

- Outlaws "research" on cloning a human being, does not focus only on the act of cloning a human being using somatic cell nuclear transfer.

- Scientific terms need further definition or refinement.

    - For example, there is no definition of "replication" — does not require individuals to be genetically identical in terms of nuclear DNA and the bill appears to cover all "cells" taken from any source.
    - It does not appear to require taking of cells from an existing or previously existing human being.

- Definition of violation is over broad. For example it would limit treatments for mitochondrial disease.

- Does not preempt state laws.

- Does not include "findings" section which describes value of biomedical research.

- Does not include clause describing areas of "protected biomedical research."

- Does not bar private right of action to enforce prohibition

Elhers (HR 922)
(Substitute bill reported from House Science Committee: referred to House Commerce Committee).

POSITIVE:

- Includes clause describing areas of "protected biomedical research."

NEGATIVES:

- Focuses on 'research," not on the act of cloning a human being using somatic cell nuclear transfer technology.
- Focuses only on "creation of..an embryo," not on the act of cloning to produce a baby which, must include implementation and birth of clone.
- Does not include any "sunset" provision to mandate reconsideration.
- Does not preempt state laws (this could result in 51 separate cloning statutes — one federal and 50 state laws that confuse and inhibit valuable biomedical research.)
- Does not bar private right of action to enforce prohibition.

Ehlers (HR 923)
(referred to House Commerce Committee)

POSITIVE:

- Focuses on the act of cloning a human being using somatic cell nuclear transfer, not on "research" about cloning.

NEGATIVES:

- No definition of scientific terms.
- Does not include any "sunset" provision to reconsider legislation.
- Does not preempt state laws.
- Does not include "findings" section which describes value of biomedical research.
- Does not include clause describing areas of "protected biomedical research."
- Does not bar private right of action to enforce prohibition.

California Cloning Law

POSITIVES:

- Focuses only on the act of cloning a human being using somatic cell nuclear transfer, not vaguely on "research."
- Includes a five years "sunset" provision.
- Includes a "findings" section which describes value of biomedical research.

NEGATIVES:

- Piecemeal approach to national issue.
- Definition of violation is over broad — for example it would limit treatments for mitochondrial disease.
- Violations turn on "purpose" of individual to clone. The concept of "purpose" comes from the criminal law ans has no meaning in the context of a statute with civil penalties. Implementing a "purpose" test once again involves a complex assessment of the psychological state of mind of a researcher, opens up the possibility of abuse by prosecutors and the enforcers.
- Does not include a description of "protected biomedical research."
- Does not bar private right of action to enforce prohibition.

BILL PROPOSED BY CLINTON ADMINISTRATION

To prohibit any attempt to create a human being using somatic cell nuclear transfer, to provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE. This Act may be cited as the "Cloning Prohibition Act of 1997".

SECTION 2. FINDINGS.

(a) It has been reported that an adult sheep has been cloned using a technique called somatic cell nuclear transfer, a form of cloning.

(b) The National Bioethics Advisory Commission (NBAC) has reviewed the scientific and ethical implications of this technology's potential use to clone human beings.

(1) NBAC has found that:

(a) Somatic cell nuclear transfer technology may have many applications for biotechnology, livestock production, and new medical approaches including the production of pharmaceutical proteins and prospects for regeneration and repair of human tissues.

(b) However, the possibility of using somatic cell nuclear transfer for the purposes of creating a child entails significant scientific uncertainty and medical risk. Potential risks, known and unknown, could result in harm to a child.

(2) The NBAC concluded unanimously that at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning. The Commission's consensus is based on current scientific information indicating that this technique is not safe to use in humans at this point.

(3) Moreover, in addition to issues of safety, the Commission identified many additional serious ethical concerns which they agreed require a great deal more widespread and careful public deliberation before this technology may be used.

(4) NBAC recommended a continuation of the current moratorium on the use of Federal funds to support any attempt to create a child by somatic cell nuclear transfer, and an immediate request to all firms, clinicians, investigators, and professional societies to comply voluntarily with the intent of the Federal moratorium.

(5) NBAC further recommended that Federal legislation be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning.

(6) NBAC also recommended that the United States cooperate with other

countries to enforce mutually supported restrictions on this activity.

(7) NBAC specified that the legislation should include a sunset provision and that, prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use and recommend whether the prohibition should be continued.

(8) The Commission concluded that any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to interfere with other important areas of research, such as the cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that arise from the possible creation of children through somatic cell nuclear transfer techniques.

(9) The Commission also found that cloning animals by somatic cell nuclear transfer does not raise the same issues implicated in attempting to use the technique to create a child, and its continuation should only be subject to existing regulations regarding the humane use of animals.

© Biomedical research facilities, including those conducting cloning, and reproductive services facilities affect interstate commerce.

SECTION 3. PURPOSES. The purposes of this Act are

(a) To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and

(b) To provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in humans.

SECTION 4. DEFINITIONS.

(a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.

(b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).

© "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

SECTION 5. PROHIBITION. **It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being.**

SECTION 6. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals.

SECTION 7. PENALTIES.

(a) Any person who intentionally violates Section 5 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

(b) If a person is violating or about to violate Section 5, the Attorney General may

commence a civil action in Federal district court to enjoin such violation.

© Any property, real or personal, derived from or used to commit a violation or attempted violation of Section 5, or any property traceable to such property, is subject to forfeiture to the United States in accordance with the procedure set forth in Chapter 46 of Title 18 of the United States Code.

(d) The Attorney General of the United States shall have exclusive enforcement authority under this Act.

SECTION 8. EFFECTIVE DATE. This Act shall apply to somatic cell nuclear transfers performed within five years after the date of its enactment.

SECTION 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 10. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.

Ehlers Bill (H.R. 922) as Reported From House Science Committee

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Human Cloning Research Prohibition Act''.

SEC. 2. PROHIBITION AGAINST EXPENDITURE OF FEDERAL FUNDS FOR RESEARCH ON CLONING HUMANS.

(a) Prohibition.-- None of the funds made available in any Federal law may be obligated or expended to conduct or support any project of research that includes the use of human somatic cell nuclear transfer technology to produce an embryo.

(b) Definitions.-- For purposes of this section--

(1) the term ''human somatic cell nuclear transfer'' means transferring the nucleus of human somatic cell into an oocyte from which the nucleus has been removed or rendered inert; and

(2) the term ''somatic cell'' means a cell of an embryo, fetus, child, or adult which is not and will not become a sperm or egg cell.

SEC. 3. REVIEW. The Director of the National Science Foundation shall enter into an agreement with the National Research Council for a review of the implementation of this Act. Not later than 5 years after the date of the enactment of this Act, the Director shall transmit to the Congress a report containing the results of that review, including the conclusions of the National Research Council on--

(1) the impact that the implementation of this Act has had on research; and

(2) recommendations for any appropriate changes to this Act.

SEC. 4. PROTECTED SCIENTIFIC RESEARCH. Nothing in this Act shall restrict other areas of scientific research not specifically prohibited by this Act, including important and promising work that involves--

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells other than human embryo cells, or tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals other than humans.

HR 923 (EHLERS)
105th CONGRESS
1ST SESSION

To prohibit the cloning of humans.

IN THE HOUSE OF REPRESENTATIVES
March 5, 1997

Mr. EHLERS introduced the following bill; which was referred to the Committee on Commerce

A BILL

To prohibit the cloning of humans.

[Italic->] Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, [<-Italic]

SECTION 1. SHORT TITLE.

This Act may be cited as the 'Human Cloning Prohibition Act'.

SEC. 2. PROHIBITION AGAINST CLONING OF HUMANS.

(a) IN GENERAL- It shall be unlawful for any person to use a human somatic cell for the process of producing a human clone.

(b) CIVIL MONEY PENALTY- Any person who violates subsection (a) is liable to the United States for a civil money penalty in an amount not exceeding $5,000.

S 368 (BOND)
105th CONGRESS
1ST SESSION

To prohibit the use of Federal funds for human cloning research.

IN THE SENATE OF THE UNITED STATES
February 27, 1997

Mr. BOND (for himself and Mr. ASHCROFT) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To prohibit the use of Federal funds for human cloning research.

[Italic->] Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, [<-Italic]

SECTION 1. PROHIBITION ON CLONING RESEARCH.

(a) IN GENERAL- No Federal funds may be used for research with respect to the cloning of a human individual.

(b) DEFINITION- For purposes of this section, the term 'cloning' means the replication of a human individual by the taking of a cell with genetic material and the cultivation of the cell through the egg, embryo, fetal, and newborn stages into a new human individual.

CALIFORNIA LAW
BANNING HUMAN CLONING

BILL NUMBER: SB 1344 CHAPTERED
BILL TEXT

CHAPTER 688
FILED WITH SECRETARY OF STATE OCTOBER 6, 1997
APPROVED BY GOVERNOR OCTOBER 4, 1997
PASSED THE SENATE SEPTEMBER 10, 1997
PASSED THE ASSEMBLY SEPTEMBER 2, 1997
AMENDED IN ASSEMBLY AUGUST 25, 1997
AMENDED IN SENATE APRIL 21, 1997

INTRODUCED BY Senator Johnston and Assembly Member Battin

MARCH 11, 1997

An act to add and repeal Sections 2260.5, 16004, and 16105 to the Business and Professions Code, and to add and repeal Chapter 1.4 (commencing with Section 24185) to Division 20 of the Health and Safety Code, relating to human cloning.

LEGISLATIVE COUNSEL'S DIGEST

SB 1344, Johnston. Human cloning.
Existing law regulates medical experimentation on humans. **This bill would prohibit a person from cloning, as defined, a human being, and from purchasing or selling an ovum, zygote, embryo, or fetus for the purpose of cloning a human being.** The bill would authorize the State Director of Health Services to levy administrative penalties for violation of $1,000,000 on a corporation, firm, clinic, hospital, laboratory, or research facility and $250,000 on an individual, or twice the amount of pecuniary gain from the violation, if greater, to be paid into the General Fund. The bill would provide that violation of the prohibition constitutes unprofessional conduct for purposes of the Medical Practice Act. The bill would require city business licenses and county business licenses to be revoked for violation of the prohibition. The bill would repeal its provisions on January 1, 2003.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. **It is the intent of the Legislature to place a five-year moratorium on the cloning of an entire human being in order to evaluate the profound medical, ethical, and social implications that such a possibility raises. It is not the intent of the Legislature**

that this moratorium apply to the cloning of human cells, human tissue, or human organs that would not result in the replication of an entire human being. During this moratorium period, the State Director of Health Services should be called upon to establish a panel of representatives from the fields of medicine, religion, biotechnology, genetics, law, bioethics, and the general public to evaluate those implications, review public policy, and advise the Legislature and the Governor in this area.

SEC. 2. Section 2260.5 is added to the Business and Professions Code, to read:

2260.5. (a) A violation of Section 24185 of the Health and Safety Code, relating to human cloning, constitutes unprofessional conduct.

(b) This section shall remain in effect only until January 1, 2003, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2003, deletes or extends that date.

SEC. 3. Section 16004 is added to the Business and Professions Code, to read:

16004. (a) Any license issued to a business pursuant to this chapter shall be revoked for a violation of Section 24185 of the Health and Safety Code, relating to human cloning.

(b) This section shall remain in effect only until January 1, 2003, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2003, deletes or extends that date.

SEC. 4. Section 16105 is added to the Business and Professions Code, to read:

16105. (a) Any license issued to a business pursuant to this chapter shall be revoked for violation of Section 24185 of the Health and Safety Code, relating to human cloning.

(b) This section shall remain in effect only until January 1, 2003, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2003, deletes or extends that date.

SEC. 5. Chapter 1.4 (commencing with Section 24185) is added to Division 20 of the Health and Safety Code, to read:

CHAPTER 1.4. HUMAN CLONING

24185. (a) No person shall clone a human being.

(b) No person shall purchase or sell an ovum, zygote, embryo, or fetus for the purpose of cloning a human being.

© For purposes of this section, "clone" means the practice of creating or attempting to create a human being by transferring the nucleus from a human cell from whatever source into a human egg cell from which the nucleus has been removed for the purpose of, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being.

24187. For violations of Section 24185, the State Director of Health Services may, after appropriate notice and opportunity for hearing, by order, levy administrative penalties as follows:

(a) If the violator is a corporation, firm, clinic, hospital, laboratory, or research facility, by a civil penalty of not more than one million dollars ($1,000,000) or the applicable amount under subdivision (c), whichever is greater.

(b) If the violator is an individual, by a civil penalty of not more than two hundred fifty thousand dollars ($250,000) or the applicable amount under subdivision (c), whichever is greater.

(c) If any violator derives pecuniary gain from a violation of this section, the violator may be assessed a civil penalty of not more than an amount equal to the amount of the gross gain multiplied by two.

(d) The administrative penalties shall be paid to the General Fund.

24189. This chapter shall remain in effect only until January 1, 2003, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2003, deletes or extends that date.

APPENDIX C:
BIO ANALYSIS OF CLINTON ADMINISTRATION DRAFT BILL REGARDING CLONING OF HUMAN BEINGS

A copy of the bill proposed by the Clinton Administration is attached as Appendix D to this testimony. This analysis raises issues about the bill's unintended consequences and other issues.

1. "Cloning Prohibition Act"

The proposed short title for the draft bill -- "the Cloning Prohibition Act" -- is literally misleading. The draft bill would not, in fact, prohibit "cloning" and explicitly states that nothing in the bill should "interfere with other important areas of research, such as the cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that arise from the possible creation of children through somatic cell nuclear transfer techniques." Section 2 (b)(8). The draft also states that "cloning animals by somatic cell nuclear transfer does not raise the same issues implicated in attempting to use the technique to create a child, and its continuation should only be subject to existing regulations regarding the humane use of animals." Section 2(b)(9). The draft defines the term "cloning" to include many technologies other than somatic cell nuclear transfer.

To give the draft bill this title might well increase the possibilities that the bill would be interpreted or enforced in ways which do, in fact, inhibit the use of cloning technologies to produce medicines and other beneficial products to treat deadly and disabling diseases. It would be preferable to have no title for any such law or a title which reflects its substance.

2. Purposes Section

The purposes section, Section 3, does not include as one purpose the protection of vital biomedical research even though the bill as drafted includes -- in Section 6 -- such protections. Including this purpose in Section 3 would reduce the possibilities that the proposed bill would be interpreted and enforced in ways which would, in fact, inhibit the use of cloning technologies for beneficial purposes.

3. "Introducing" and "Creating a Human Being"

The proposed bill refers to "introducing" the product of somatic cell nuclear transfer

"into a woman's womb or in any other way creating a human being."

To begin with it is not clear whether this means that there are two possible violations or one. One violation might be "introducing" and the second might be "creating."

Another interpretation of this language is that "introducing" is equivalent to "creating a human being." It can be read that one way of "creating a human being" is to introduce the product of somatic cell nuclear transfer into a woman's womb. If this is a correct interpretation, this might be the first Federal statute which states or implies that a fertilized embryo in a woman's womb is already a "human being."

The ethical question of when a "human being" has been "created" is not an issue with respect to which our industry has expertise. These are not issues about technology; they are issues for society.

A further interpretation is that the draft bill contemplates that there are ways of "creating a human being" other than "introducing" an egg into a woman's womb. It might, for example, be interpreted to mean that a "human being" has already been created when an egg is fertilized outside the womb -- the standard practice with *in vitro* fertilization.

In addition, the word "introducing" is ambiguous. The term is not defined in the proposed bill and could refer to any number of different acts.

We are not aware of "any other way" of creating a human being other than birth. If the authors of the draft bill are aware of other ways, perhaps they should be specified. If there are no other ways, then this language is superfluous.

We only point out that this proposed bill has far reaching implications which go way beyond the issue of somatic cell nuclear transfer technology and go to the fundamental ethical question of what constitutes a "human being."

4. Acts vs. Intent

The proposed bill focuses on use of somatic cell nuclear transfer "with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being."

The use of the word "intent" here is quite confusing and troubling. Consider four possible scenarios:

(1) If an individual has no intent to "introduce" or otherwise create a human being, then there is no violation even if the cell is, in fact, later introduced into a woman's womb by that individual. In this sense the proposed language does not violate the act of introducing or creating as long as there is no intent.

(2) If an individual has no intent to "introduce" but a third party does, in fact, "introduce," then the first party is presumably not liable even if the introduction does, in fact, take place.

(3) If an individual has the requisite intent, but does nothing to actually "introduce" the cell into a woman's womb, then the individual may be found liable. Read carefully, the draft bill does not require the actual "introduction" of the cell into a woman's womb, but only the "intent" to do so.

(4) Finally, it is possible for an individual to "intend" to do something which is not only not done, but which is likely to be impossible to be done. If an individual announces that he "intends" to use nuclear transfer technology to create a human child, makes no attempts to do so, and then finds out that it is quite impossible to do so, he or she still might be liable.

None of these results makes sense.

The point is that the wording of the proposed bill does not focus solely on the final act of creating a human being. As a result, it is impossible to avoid the absurdity of prosecuting individuals even where no human being is created and not prosecuting individuals even though human beings have, in fact, been created.

If the gravamen of the violation is the act of using somatic cell nuclear transfer technology to create a human being, then intent should not be relevant. If no such act occurs, then there should be no violation no matter what the intent may be.

The only way to avoid these absurdities is to focus exclusively on the act of creating a human being. Any focus on intent will very likely lead to unintended results.

5. Implementation of "Intent" Requirement

We are concerned that a focus on "intent" would lead to unpredictable explorations of the psyche of researchers. What evidence would have to be produced to prove the "intent" of the individual? Would it be sufficient to demonstrate that the introduction or creation took place, or would additional evidence required to show that this was the specific "intent" of the researcher?

If "intent" is an element of the offense, would the individual be entitled to produce evidence to show that he or she has the equivalent of an insanity defense or is not able to recognize the consequences of the act?

It is particularly strange to focus on "intent" if the violation is that of a "legal entity" rather than a "person." There are many different legal entities -- universities, non-profit foundations, and companies. What evidence would be needed to prove that such an entity had the requisite "intent" to violate the prohibition? The concept of "intent" is not normally one

which is relevant to the conduct of a "legal entity." If the requisite "intent" is that of the "legal entity," would that require that the "intent" be that of an officer of the entity who had legal authority to bind the entity, rather than that of an employee with no legal authority to bind the entity?

We believe that these are not quibbles over semantics given the fact that one of the penalties is confiscation of the entire legal entity by the government when a violation has been proven.

6. Research vs. Somatic Cell Nuclear Transfer

As explained above, the draft bill focuses on the use of a specified technology with a specified intent. The gravamen of the violation is not, using the words of the draft bill, "creating a human being." Violations can occur even if a human being is not, in fact, created. This raises very serious issues about the potential chilling impact of the draft bill on biomedical research.

The fact that the bill is not confined to cases where a human being is created means that the draft bill is particularly likely to inhibit a broad spectrum of research, not just research which leads to certain end points. There are many intermediate points in the research process short of, say, infusing a drug into a human subject. Every one of the acts short of infusing the drug may be critical to the research and discovery process. This research can have totally different, non-controversial purposes, and involve no actual infusion of the drug. The reference to "intent" can give rise to fears that every act of research concerning somatic cell nuclear transfer is vulnerable to misinterpretation and that every researcher or institution involved with this technology is vulnerable to suit for research.

It may be that the authors of this proposed bill mean to prohibit unsuccessful as well as successful "attempts" to create a child. There are several other places in the draft bill which refer to the "attempt" to use this technology, rather than to the concept of "intent." (See Section 3, Purposes, where it refers to any "attempt" to create a human being.) The word "attempt" is quite different than the word "intent." "Attempts" involve specific acts, not mental states, and it would be easier to determine when a violation occurs. The determination would be less subjective.

Even if the proposed bill were to refer to "attempts" rather than "intent," it may still inhibit research. Every act of research might be characterized as an "attempt," just as it might be seen as evidence of "intent." Every act of research which might, after many additional steps, lead to creation of a human being could be questioned.

Again, the only way to avoid this unintended effect is to focus the proposed bill on the final and definitive act of creating a child using a specified technology, not on the intent or attempt to create a human being using the technology. Any statute which focuses on the technology, as distinct from the end use and application of the technology, inherently and necessarily inhibits research. The only way to avoid this result is to make the "creation of a

human child" using this technology the violation.

7. Definition of "somatic cell nuclear transfer"

The complexity of the issues raised by this draft bill are evident in the definitions of the key scientific terms it uses to specify the reach and impact of the prohibition and penalties. Some of the definitions are not correct from a scientific point of view. This creates ambiguity about the conduct which is subject to the prohibition and penalties and casts doubt on the wisdom of enacting this proposal. Ultimately this is a proposed bill which seeks to regulate scientists and, if it is not possible to draft it to include scientifically accurate terminology, it may well fail to deter conduct which is intended to be covered and deter conduct which is not controversial.

The draft bill would make it unlawful for a person or legal entity to "perform or use somatic cell nuclear transfer" for certain purposes. The draft bill's definition of a "somatic cell" excludes cells which are "germ cells (eggs or sperm)." Then the draft defines "somatic cell nuclear transfer" to mean the "transfer of a cell nucleus from a somatic cell to an egg from which the nucleus has been removed." The terms "germ cells, "eggs" and "sperm" are not defined in the draft bill.[1]

To add to the confusion the NBAC report glossary defines "somatic cells" as "any cell of an embryo, fetus, child or adult not destined to become a sperm or egg cell." The first footnote in the NBAC report defines "somatic cell" as "any cell of the embryo, fetus, child, or adult which contains a full complement of two sets of chromosomes; in contrast with a germ cell, i.e. an egg or a sperm, which contains only one set of chromosomes." And the text of the NBAC report provides a third definition. It recommends that the prohibition apply to "banning nuclear transfer using the nuclei derived from somatic cells other than those of an embryo or fetus" and defines this nuclear transplantation as "transplanting the genetic material from a differentiated somatic cell into an egg from which the nucleus had been removed." Thus, the somatic cell comes from a non-embryonic, non-fetal source.

At a minimum this means that the Administration's draft bill differs from the legislation which the NBAC report recommends be enacted.

It also means that we have three definitions of the critical term "somatic cell," one in the bill, and two in the NBAC report. (And two more definitions in the Ehlers and Bond bills.) This is hardly a reassuring situation. This is, after all, the term which defines the

---

The glossary in the appendix to the NBAC report defines an "egg" as "the mature female germ cell; also called ovum, or oocyte." The glossary provides other interrelated definitions: a "germ cell" is defined as "a sperm or egg (all other body cells are known as somatic cells)"; "sperm" as "mature male reproductive cells, an egg as the mature female germ cell"; and a "gamete" as a "mature sperm or egg."

violation and with respect to which extreme penalties are prescribed. The fact that there is such wide disagreement about how to define this term casts doubt on the wisdom of enacting the draft bill.

We believe that none of the three definitions is accurate. Our initial view was the definition in the NBAC glossary is closest to the mark -- with its reference to cells which are "not destined to become a sperm or egg cell." The other two definitions will cause confusion as they include a zygote as one type of somatic cell.[2] We need a definition which is more precise than the glossary definition and is less likely to jeopardize vital biomedical research.

In addition to these unsettling questions about the definition of a "somatic cell, " no mention is made in the draft bill of the cells which are destined to become gametes, which are not somatic cells (at least under two of the above definitions). These cells are not fully differentiated and therefore they are not gametes per se. Many researchers refer to the types of cells that will become eggs and sperms as "germ cells"; the terms "pre-meiotic germ cells," "primordial germ cells" or "progenitor germ cells" are also often used. These cells can be isolated from embryos which are only eight days old (in mice) and they are destined to become sperm or eggs when the diploid (double) cells split into haploid (single) cells. Thus, by these definitions diploid germ cells are present in adult animals.

We don't know if these pre-meiotic germ cells can be used for the purpose of nuclear transfer, but in mice it is possible to isolate these cells from fetuses, grow them *in vitro* (tissue culture) and maintain their totipotency, allowing them to contribute to all cell types in a new animal. The fact that the definitions of cell types mentioned in the draft bill are not scientifically precise and are defined differently by different scientists illustrates the extreme difficulty of drafting a bill on this subject.

The NBAC definition of an "egg" is not included in the draft bill although it appears to be correct from a scientific point of view. But there have been instances, in the murine and bovine systems, where two cell embryos, rather than eggs, have been enucleated and used as hosts for the donor nucleus. A "two cell embryo" is not an egg. An egg is an unfertilized, haploid gamete which when combined with a sperm forms a zygote. An embryo is created when the zygote divides for the first time. Although progenitor germ cells and two cell embryos were not mentioned in the Roblin Institute paper and are not covered in the draft bill, many different protocols and procedures could be adapted for use in this context. Again, we

---

The NBAC report includes the following interrelated definitions of "embryo," "fertilization," "oocyte," and "zygote": "embryo" is defined as "the developing organism from the time of fertilization until significant differentiation has occurred, when the organism becomes known as a fetus"; "fertilization" as "the process whereby male and female gametes unite [which] begins when a sperm contacts the outside of the egg cell and ends with the formation of a zygote"; "oocyte" as "the mature female germ cell, the egg"; and "zygote' as "the single-celled, fertilized egg." None of these definitions is included in the draft bill.

point out that the proposed bill is deficient from the point of view of science and that it is extremely difficult to draft a bill on this complex issue.

8. Penalties

The penalties proposed by the Administration for violation of the ban can only be described as draconian. This fact, combined with the vagueness of the description of the prohibited conduct, is likely to discourage research well beyond its explicit terms.

The penalties include a fine which is the greater of "$250,000 or two times the gross gain or loss from the offense" and confiscation of "any property, real or personal, derived from or used to commit a violation...or any property traceable to such property..."

If the violation occurs at a university, would the proposed bill permit confiscation of the entire university? If the violation were to occur at a company, would the proposed bill permit the confiscation of the entire company even if only one researcher were involved?

Researchers who are seeking grants from the National Science Foundation or other foundations would tend to avoid any research with any potential or possible connection, real or perceived, to this technology. No funding agency would dare to fund such research.

The draft bill refers also to penalties being imposed on "public" legal entities. By this we assume that the draft bill could refer to the National Institutes of Health or another public agency which performs biomedical research. We find it odd to contemplate the possibility of the Attorney General seeking to impose a fine on NIH or to confiscate its property.

It is obvious to us that the vagueness of the draft bill and the severity of the penalties could lead any prudent university or company or NIH institute to cease doing research even remotely connected to the type of technology covered by the statute.

Even if a company avoided this technology entirely, there is a danger that investors might misinterpret the company's research focus and be unwilling to put their capital at risk with that company. This is a clear case where the existence of even a narrowly crafted bill will have a chilling effect far beyond its specific terms.

In addition, the terms of the proposed penalties are vague. It appears that the proposed bill does not call for incarceration, but we are confused given the repeated use of the term "intent" in the proposed bill, a concept which is often associated with criminal law.

The penalty section provides for the payment of the greater of $250,000 or "two times the gross gain or loss from the offense." The concept of imposing a fine based on the "gross gain" of a firm, university, or institute presumably refers to its gross receipts or revenue and the concept of "gross...loss" presumably refers to its gross expenses. We know of no precedent for imposing a fine based on a multiple of the expenses incurred.

The concept of imposing fines based on gains and losses "from the offense" is also vague. Would it be a fine based on the receipts or expenses of the entire firm, university, or institute or a subset of that? The manner in which this provision might be implemented has potentially dire consequences.

The final ambiguity is how the proposed bill would be interpreted in the case of an individual researcher, acting without authorization. Would the firm, university, or Institute where the individual is employed or where he or she conducted the unauthorized research be fined or subject to confiscation? Would a failure to exercise reasonable supervision be evidence of "intent"?

9. Advisory Opinions

Were a law to be enacted, we recommend that a mechanism be established to enable scientists to secure advisory opinions regarding the scope, interpretation and possible enforcement of the law with regard to specific research projects.

This would require the Justice Department to establish sufficient expertise and staff to respond to requests for advisory opinions. It could defer to the expertise of the National Institutes of Health, Institute of Medicine, National Science Foundation, and other bodies which have expertise on these issues or experts in the private sector.

To the extent that it would not compromise the confidentiality of research projects, the privacy interests of patients, or the intellectual property rights of the researchers, these advisory opinions should be published so that other researchers could benefit from the information.

To be clear, we do not believe that such a mechanism would entirely eliminate the inevitable chilling impact of a law on this subject.

10. Exclusive Remedy

The proposed bill provides that the Attorney General will have "exclusive enforcement authority under this Act." We suggest that this clause be interpreted to mean that the authority to seek enforcement cannot be delegated by the Attorney General to another official.

The draft bill also provides that it shall not be "construed to give any individual or person a private right of action." We are concerned that this language is not parallel to language elsewhere in the draft bill referring to a "person or other legal entity." This section should use this same language to clarify that the draft bill cannot be construed to confer a right of action on any "legal entity," not just any "person or individual."

11. Preemption

The proposed bill fails to include a clause preempting state laws. We had thought that

one of the reasons why NBAC and the Administration have proposed enactment of a Federal statute was concern about the potential for many conflicting state laws on these complex issues. Given how difficult it is proving to be to craft any statute on this issue, if enactment of a law is considered to be necessary, we believe enactment of one Federal law is essential, as opposed to enactment of many different state laws. The possibilities for differential interpretation and enforcement of state laws would have a particularly chilling impact on vital biomedical research.

To be effective the preemption clause must refer to all types of laws on the subject of cloning, including the cloning of cells and genes, not just somatic cell nuclear transfer, so that it covers appropriate laws even if they do not use any of the terms in the proposed Federal statute.

12. Effective Date

We interpret the "effective date" section of the proposed bill to include both an effective date and a sunset provision. The proposed bill states that it "shall apply" to acts "performed within five years after the date of enactment." This implies that acts of this type performed thereafter would not be covered by the statue. It would be preferable and clearer if the effective date and sunset provisions were stated separately in distinct sections so there is no confusion.

If a statue is to be enacted, it should certainly include a sunset provision, as NBAC has emphasized. This area of science is new and we need to reevaluate the impact of any law on the subject. Enactment of a permanent law without a sunset provision will increase the likelihood that the law will chill vital biomedical research. A sunset provision will at least focus the attention of the researchers and others on a process towards the end of the five year period when all of these issues can again be reviewed.

Draft Letter Regarding Legislation to Ban Cloning of Human Beings

We are writing to express our concern about legislation pending in the Congress to ban the cloning of entire human beings.

Let us be clear. We oppose the cloning of a human being. We see no ethical or medical justification for the cloning of a human being and agree with the conclusions of the National Bioethics Advisory Commission (NBAC) that it is unacceptable at this time for anyone in the public or private sector, whether in a research or clinical setting, to create a human child using somatic cell nuclear transfer technology. We recognize that this application of the technology raises fundamental ethical and social issues. This technology is not currently safe to use in humans.

The American Society for Reproductive Medicine, the Biotechnology Industry Organization, and the Federation of American Societies of Experimental Biology have all pledged that their members will not seek to clone a human being. These three associations include essentially every researcher or practitioner in the United States who has the scientific capability to clone a human being.

We agree with NBAC in its report on cloning that: "It is notoriously difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science." Poorly crafted legislation to ban the cloning of human beings may put at risk biomedical research which is vital to finding the cures to the diseases and ailments which our organizations champion. Cancer, diabetes, (list specific disease of signatories here) and many others will benefit from the advances achieved by biomedical researchers.

We urge the Congress to proceed with extreme caution and adhere to the ethical standard for physicians, "first do no harm." We believe that there are two distinct issues here, cloning of a human being and the healing which comes from biomedical research. Congress must be sure that any legislation which it considers does no harm to biomedical research which can heal those with deadly and debilitating diseases.

Please keep patients' concerns in mind as you proceed in analyzing this very complicated issue.

Sincerely,

PATIENT ADVOCACY GROUPS
PROFESSIONAL MEDICAL SOCIETIES

CURRENT BAN ON FEDERAL FUNDING OF BOTH EMBRYO AND CLONING RESEARCH

The Fiscal Year 1996 and 1997 Labor, HHS Appropriations bills have included a broad ban on funding for **embryo** research. The text of this ban follows:

> (a) None of the funds made available in this Act may be used for -- (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero... (b) For purposes of this section, the term 'human embryo or embryos' include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning or any other means from one or more human gametes.

The Fiscal Year 1998 Labor, HHS Appropriations bill, H.R. 2264, as passed by the House and Senate, and signed into law, was **amended in both bodies to provide that this ban be extended to any embryo or embryos that is derived by "human diploid cells." Human diploid cells are precisely the type of cells used in the sheep cloning experiment which led to the human cloning debate.** The new language in both bills reads as follows:

> (a) None of the funds made available in this Act may be used for -- (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero... (b) For purposes of this section, the term 'human embryo or embryos' include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning or any other means from one or more human gametes **or human diploid cells.**[1]

Neither the National Bioethics Advisory Commission (NBAC) nor the President have reviewed or made any recommendations regarding enactment of any legislation regarding embryo and fetal tissue research.

> We do not revisit either the question of the cloning of humans by embryo-splitting or the issues surround embryo research. The latter issue has, of course, recently received

---

[1] This reference to "human diploid cells" may be over broad and prevent use of any human cell line -- say cancer cells lines -- in research, not just use of these cells for somatic cell nuclear transfer cloning.

careful attention by the National Institutes of Health panel, the Administration, and the Congress. Letter of Harold Shapiro, NBAC Chairman (June 9, 1997).

The bill reported in July by the House Science Committee, H.R. 922, focuses only on Federal funding of embryo research. The substitute amendment adopted by the Committee in reporting the bill provides that "None of the funds made available in any Federal law may be obligated or expended to conduct or support any project of research that includes the use of human somatic cell nuclear transfer technology to produce an embryo." This would, in effect, make the current ban on embryo research permanent.

The House Commerce Committee and Senate Labor Committees have jurisdiction over bills, H.R. 922 (Ehlers) and S. 368 (Bond), respectively, which could ban all embryo research, irrespective of Federal funding.

IMPORTANCE OF "CLONING" TECHNOLOGY TO MEDICAL RESEARCH

Introduction

"Cloning" is an essential tool in biomedical research. Cloning techniques -- the isolation of and duplication of genes or cell lines -- have proved to be a cornerstone of scientists' ability to use biotechnology to develop new drugs for previously intractable diseases. Scientists have used cloning as a standard laboratory technique for several decades. Scientifically, cloning animal and human cells and genes provides greater quantities of these identical materials for study.

Over the past 20 years, cloning has been an invaluable research tool leading to the production of breakthrough medicines, diagnostics and vaccines to treat heart attacks, various cancers, kidney disease, diabetes, hepatitis, multiple sclerosis, cystic fibrosis, and other diseases. More than 100 million people worldwide have already benefited from biotechnology medicines and vaccines. Cloning techniques are critical to the biomedical research that holds the promise of many more treatments to come.

The development of the sheep named Dolly has raised new questions about one specific type of cloning techniques and the implications of using this technology to clone entire human beings. Dolly is determined to be a "clone" because her genetic makeup duplicates almost entirely the genetic makeup of another sheep. We would like to distinguish the ways in which cloning can be used to create identical copies of genes and cells and the benefits these technologies are bringing to research and drug development.

Gene Cloning

Scientists routinely isolate and make copies of DNA (deoxyribonucleic acid), the molecular basis of genes; segments of DNA comprise genes. Genes are isolated, copied and inserted into bacteria where they are amplified. The gene is duplicated – or cloned -- when the bacteria reproduces.

Scientists developed ways to greatly amplify the DNA using "PCR" to improve the speed and efficiency with which DNA can be cloned in the lab, in effect "xeroxing" the DNA. PCR is valuable to researchers because it allows them to multiply unique regions of DNA. Many scientific experiments would not be possible without the availability of large quantities of identical copies of DNA.

Medical Benefits of Gene Cloning

Cloning genes is useful to develop diagnostic tests and eventually therapies for genetically-based disorders. The human genes that direct the production of factor VIII to treat hemophilia, of human insulin and of human growth hormone have each been incorporated into the DNA of certain bacteria. These bacteria are then used commercially to make sufficient quantities of these medicines to treat patients. The cloning of genes also has contributed to the development of important medicines, such as tissue plasminogen activator (tPA) to dissolve clots after a heart attack, and erythropoietin (EPO) to treat anemia associated with dialysis for kidney disease.

Cell Cloning

Cells can be cloned by isolating them from the body through a biopsy, and culturing them in a laboratory. The original cells start to grow and divide, producing new cells that are identical to the original cells. The genetic makeup of the resulting collection of cells, called a "cell line," is identical to that of the original cell. Cell cloning is a highly reliable procedure that is used to test and sometimes to develop new medicines.

Medical Benefits of Cell Cloning

Scientists are using cloning technology to study the regeneration of damaged or diseased tissues and organs. There are many areas where this technology would be invaluable, such as research focusing on: nerve cells to address spinal cord injuries or in diseases where nerves degenerate, muscle cells to address some types of heart disease or diseases in which the muscles are wasting, and skin cells to treat burn victims. Researchers are investigating transplantation of bone marrow stem cells to treat blood disorders and cancer, transplantation of pancreatic beta cells to treat diabetes and neurons to treat brain disorders. Other research is underway to develop cell lines that could help to generate cells for organ transplantation and tissue repair. For instance, one of our companies treats knee damage by taking a biopsy of the patient's knee cartilage, propagating additional cartilage cells and transplanting the new cells back into the patient's knee.

With a better understanding of early cell growth and specialization, scientists may be able to reverse the degenerative processes in conditions such as Alzheimer's, Parkinson's, and Huntington's diseases. Scientists may also learn more about the process by which cancerous tumors spread throughout the body, and examine ways to control and eliminate the growth of cancer cells. There are other types of research to help us learn more about genetic birth defects and infertility.

The Journey from Single Cell to Whole Organism

In normal development of a human being, a sperm containing DNA from the male, and an egg with DNA from the female, fuse to form a new cell, a zygote, with a full genetic complement from two parents. The zygote divides into many more cells, forming a cluster of identical cells. Then, the cells start to grow and differentiate into various types of cells, such as cells that will form the nervous system, or cells that will form the heart. The cells differentiate through genetic regulation with different genes switching off and on, depending on the type of cell they are becoming. As more cells divide and differentiate, the cell cluster grows into an embryo and eventually into a baby.

How Was "Dolly" Cloned?

The procedure used to produce "Dolly" is called "somatic cell nuclear transfer technology." This type of cloning technology involves transferring the nucleus containing DNA from a somatic cell (i.e., any cell of the body, except the egg or sperm) into an egg from which the nucleus has been removed and implanting the resultant embryo into a surrogate mother for gestation and birth.

This procedure resulted in the birth of a sheep whose genetic material is identical to the adult sheep who donated the nucleus, with the exception of the DNA in the mitochondria which is inherited through the cytoplasm with the enucleated egg. Dolly is a clone because her genes are identical to the genes in the first sheep, her mother. It is important to note that this process is extremely difficult and inefficient at this time. This experiment was carried out on 277 eggs before the one success that resulted in the birth of Dolly.

Bio

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

PLEDGE BY BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) TO SUPPORT MORATORIUM ON CLONING OF A HUMAN BEING

March 27, 1997

The Honorable William J. Clinton
President of the United States
The White House
Washington, D.C. 20500

Dear Mr. President:

The recent cloning of a sheep from the genetic material of an adult cell has riveted the world. Previously, researchers had reported using genetic material from animal embryos to create new organisms. But, as you observed, this latest development raises profound new issues. When two individuals are created from the same embryonic genetic material, identical twins result. We are quite familiar with identical twins in our everyday lives. However, "Dolly" raises new prospects for which we are not so adequately prepared. While our everyday lives may include identical twins of the same age, we have never experienced identical twins substantially different in age, indeed, perhaps alive during entirely different periods in history. In our everyday lives we may decide to procreate a child and wait in wonder and awe to see the unique individual he or she will turn out to be. We do not, on the other hand, have experience creating a child where part of that decision may include an evaluation of the life, health, character and accomplishments of an adult from whom we will take the genetic material that will become the child's entire genetic makeup.

These new prospects challenge some of the most fundamental concepts we hold about ourselves as social and spiritual beings. These concepts include what it means to be a parent, a brother or sister, a family. We believe that it was in response

1625 K STREET, N.W., SUITE 1100
WASHINGTON, D.C. 20006-1604

202-857-0244
FAX 202-857-0237
http://www.bio.org

to this moral and spiritual challenge that you requested the nation's biomedical research community to agree to a voluntary moratorium on the cloning of human beings until the National Bioethics Advisory Commission can review the meaning of this scientific breakthrough. We share your desire for a reflective examination of the moral issues raised by Dolly. We support this moratorium on cloning human beings.

In the days since the announcement of Dolly, the potential benefits to be derived from cloning procedures in agricultural and laboratory animal species have been widely discussed. Cloning, the duplication of specific genes and individual types of cells -- is an essential tool in biotechnology. The techniques involved are integral to the process used to produce breakthrough medicines, diagnostics and vaccines to treat heart attacks, various cancers, kidney disease, diabetes, hepatitis, multiple sclerosis, cystic fibrosis and other diseases. More than 100 million people worldwide have already benefited from biotechnology medicines and vaccines.

There is also valuable research into cloning human cells, organs and other tissue. This could produce replacement skin, cartilage and bone tissue for burn and accident victims. This avenue of study may produce cells for cancer therapy and result in ways to regenerate retinal or spinal cord tissue. Research is also under way to develop replacement internal organs in transgenic animals for human transplantation.

Perhaps even more important, human cells used in a subset of the cloning procedures -- that is, procedures that by themselves could not create a new human being -- could provide profound new insights into how genes control human development. These fundamental insights, in the decades ahead, will provide the basis for even greater biomedical advances in the service of humanity.

Mr. President, we are pleased to report that the Board of Directors of the Biotechnology Industry Organization fully supports your call for a moratorium on research efforts undertaken for the purpose of cloning a human being while the National Bioethics Advisory Commission considers the implications of Dolly. But we firmly believe that research involving duplication of cellular material has such enormous potential benefits for society that it should proceed without hindrance. Accordingly, we ask you to oppose, as we do, any hastily drafted laws to ban the cloning of human beings that may, however well intentioned, inadvertently also ban this valuable research.

Sincerely,

Henri A. Termeer
Chairman

Carl B. Feldbaum
President

PLEDGE BY AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM) TO SUPPORT MORATORIUM ON CLONING OF A HUMAN BEING

At its October 18, 1997 meeting, The Board of Directors of The American Society for Reproductive Medicine approved a voluntary moratorium on cloning human beings.

Resolved: The American Society for Reproductive Medicine declares a voluntary five-year moratorium on cloning human beings, where "cloning human beings" is defined as the duplication of an existing or previously existing human being by transferring the nucleus of a differentiated, somatic cell into an enucleated human oocyte, and implanting the resulting product for intrauterine gestation and subsequent birth.

In addition, the following statement was issued on June 5 (date of releaase of NBAC report)

FOR IMMEDIATE RELEASE: CONTACT: Heather E. Kowalski June 5, 1997
(202) 863-2439 Hkowalski@asrm.com

ASRM STATEMENT ON HUMAN CLONING THROUGH NUCLEAR TRANSPLANTATION

(Washington, DC) -- The American Society for Reproductive Medicine (ASRM) is issuing the following statement:

The American Society for Reproductive Medicine (ASRM) finds the practice of cloning an existing human being unacceptable. However, ASRM believes that the broader field of human embryo research is acceptable and important, and guidelines both promoting and limiting the research should be set on the national level. The current moratorium on federal funding of human embryo research should be overturned and oversight for such research should be given to the National Institutes of Health.

The American Society for Reproductive Medicine (ASRM)), founded in 1944, has more than 10,000 members who are devoted to advancing knowledge and expertise in reproductive medicine and biology, including obstetrician-gynecologists, urologists, endocrinologists, research scientists, medical technologists, and allied health professionals.

# # #

PLEDGE BY THE FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY (FASEB) TO SUPPORT MORATORIUM ON CLONING OF A HUMAN BEING

For more information, contact:
Howard Garrison, 301/571-0657

September 18, 1997

FASEB ENDORSES VOLUNTARY MORATORIUM ON CLONING HUMAN BEINGS

Bethesda, Md -- Federation of American Societies for Experimental Biology (FASEB) President Ralph G. Yount announced the adoption of a voluntary moratorium on cloning human beings. Members of FASEB's Public Affairs Executive Committee, representing the 14 member societies of the Federation, unanimously voted in favor of the following statement at a recent meeting:

> RESOLVED: The Federation of American Societies for Experimental Biology (FASEB) adopts a voluntary five year moratorium on cloning human beings, where "cloning human beings" is defined as the duplication of an existing or previously existing human being by transferring the nucleus of a differentiated, somatic cell into an enucleated human oocyte, and implanting the resulting product for intrauterine gestation and subsequent birth.

In accord with the recommendations by the National Bioethics Advisory Commission, this moratorium will be in effect for a period of five years, with subsequent reconsideration for possible extension.

Yount, a Professor of Biochemistry and Chemistry at Washington State University, noted that the Federation adopted this moratorium for several important reasons.

> "First and foremost," stated Yount, "we seek to reassure Americans that biologists have no intentions of cloning human beings. Indeed, we would regard cloning a human being as an unethical and reprehensible act. But, we have also recognized that there is a role for us -- as scientists -- to play in this debate. We need to ensure that imprecise or misused technical language is not included in legislation designed to prevent the cloning of human beings. If

enacted, such laws could hinder vital biomedical research that can lead to the repair of diseased and damaged human tissues and organs, and to possible cures for diabetes, cancer, Parkinson's Disease and other neurodegenerative diseases."

FAX Transmittal Sheet

DATE: January 27, 1998

TO: Tom Freedman

ORGANIZATION: DPC

TELEPHONE: 65587

FAX: 67431

FROM: RACHEL E. LEVINSON

TELEPHONE: (202) 456-6137

FAX: (202) 456-6027

NUMBER OF PAGES, INCLUDING COVER PAGE: 9

SPECIAL INSTRUCTIONS: Feinstein's bill for comment cob today. It is based on our's with a few modifications: It still has a 10-year sunset. It uses ASRM's defs and a hybrid prohibition.

O:\BAI\BAI98.097 S.L.C.

DRAFT

105TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mrs. FEINSTEIN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To prohibit any attempt to create a human being using somatic cell nuclear transfer, to provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.—

This Act may be cited as the "Prohibition on Cloning of Human Beings Act of 1998".

SEC. 2. FINDINGS.

Congress finds that—

(1) it has been reported that an adult sheep has been cloned using a technique called somatic cell nuclear transfer, a form of cloning;

(2) the National Bioethics Advisory Commission (referred to in this Act as the "NBAC") has reviewed the scientific and ethical implications of the potential use of such technology to clone human beings;

(3) the NBAC has determined that—

(A) somatic cell nuclear transfer technology may have many applications for biotechnology, livestock productions, and new medical approaches including the production of pharmaceutical proteins and prospects for regeneration and repair of human tissues; and

(B) the possibility of using somatic cell nuclear transfer for the purposes of creating a child entails significant scientific uncertainty and medical risk, which could result in harm to a child;

(4) the NBAC concluded unanimously that at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer-cloning;

(5) the consensus of the NBAC is based on current scientific information indicating that this technique is not safe to use in humans at this time;

(6) in addition to issues of safety, the NBAC identified many additional serious ethical concerns which they agreed require a great deal more widespread and careful public deliberation before this technology may be used;

(7) the NBAC recommended a continuation of the current moratorium on the use of Federal funds to support any attempt to create a child by somatic cell nuclear transfer, and an immediate request to all firms, clinicians, investigators, and professional societies to comply voluntarily with the intent of the Federal moratorium;

(8) the NBAC further recommended that Federal legislation be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning;

(9) the NBAC also recommended that the United States cooperate with other countries to enforce mutually supported restrictions on this activity;

(10) the NBAC specified that such Federal legislation should include a sunset provision and that,

prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use and recommend whether the prohibition should be continued;

(11) the NABC concluded that any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to interfere with other important areas of research, such as the cloning of human DNA sequences and cells, which raise neither the scientific nor the ethical issues that arise from the possible creation of children through somatic cell nuclear transfer techniques;

(12) the NABC also found that cloning animals by somatic cell nuclear transfer does not raise the same issues implicated in attempting to use the technique to create a child, and its continuation should only be subject to existing regulations regarding the humane use of animals; and

(13) biomedical research facilities, including those conducting cloning, and reproductive services facilities affect interstate commerce.

SEC. 3. PURPOSES.

It is the purpose of this Act to—

(1) prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and

(2) provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in humans.

SEC. 4. DEFINITIONS.

In this Act:

(1) CLONING.—The term "cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.

(2) NUCLEUS.—The term "nucleus" means the cell structure that houses the chromosomes, and thus the genes.

(3) OOCYTE.—The term "oocyte" means the female germ cell, the egg.

(4) SOMATIC CELL.—The term "somatic cell" means a mature, diploid cell.

(5) SOMATIC CELL NUCLEAR TRANSFER.—The term "somatic cell nuclear transfer" means transferring the nucleus of a somatic cell of an existing or previously existing human child or adult into an oocyte from which the nucleus has been removed.

SEC. 5. PROHIBITION.

It shall be unlawful for any person or other legal entity, public or private, to implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus.

SEC. 6. PROTECTED BIOMEDICAL RESEARCH

Nothing in this Act shall be construed to restrict areas of biomedical and agricultural research or practice not expressly prohibited in this Act, including research or practices that involve—

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals.

SEC. 7. PENALTIES.

(a) IN GENERAL.—Any person who intentionally violates the provisions of section 5 shall be fined the greater of $250,000 or 2 times the gross pecuniary gain or loss resulting from the violation.

(b) CIVIL ACTIONS.—If a person is violating or about to violate the provisions of section 5, the Attorney General may commence a civil action in an appropriate Federal district court to enjoin such violation.

(c) FORFEITURE.—Any property, real or personal, derived from or used to commit a violation or attempted

violation of the provisions of section 5, or any property traceable to such property, shall be subject to forfeiture to the United States in accordance with the procedures set forth in chapter 46 of title 18, United States Code.

(d) AUTHORITY.—The Attorney General shall have exclusive, nondelegable enforcement authority under this Act.

(e) ADVISORY OPINIONS.—The Attorney General shall, upon request, render binding advisory opinions regarding the scope, applicability, interpretation, and enforcement of this Act with regard to specific research projects or practices.

SEC. 8. COOPERATION WITH FOREIGN COUNTRIES.

It is the sense of Congress that the President should cooperate with foreign countries to enforce mutually supported restrictions on the activities prohibited under section 5.

SEC. 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT.

Not later than 4½ years after the date of enactment of this Act, the National Bioethics Advisory Commission shall prepare and submit to the President a report concerning—

(1) the state of the science of somatic cell nuclear transfer;

(2) the ethical and social issues associated with the potential use of this technology in humans; and

(3) the advisability of continuing the prohibition established under this Act.

The Commission is authorized to continue for the 10-year period described in section 12 to prepare such report and for other purposes as established in Executive Order 122975 and subsequent amendments to such Order.

SEC. 10. RIGHT OF ACTION.

Nothing in this Act shall be construed to give any individual or person a private right of action.

SEC. 11. PREEMPTION OF STATE LAW.

The provisions of this Act shall preempt any State law that prohibits or limits research or practices regarding somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, or tissues, the use of somatic cell nuclear transfer techniques to develop animals, or related research.

SEC. 12. EFFECTIVE DATE.

This Act shall be effective for the 10-year period beginning on the date of enactment of this Act. The prohibitions contained in this Act shall terminate at the expiration of such 10-year period.

O:\BAI\BAI98.156 S.L.C.

(Lowin Bond S.11 — ew

105TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. BOND (for himself, Mr. FRIST, Mr. GREGG, Mr. LOTT, Mrs. HUTCHISON, Mr. SHELBY, Mr. NICKLES, Mr. LUGAR, Mr. ABRAHAM, Mr. GRAMS, and Mr. HAGEL) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend title 18, United States Code, to prohibit the use of somatic cell nuclear transfer technology for purposes of human cloning.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Human Cloning Prohibition Act".

SEC. 2. FINDING.

Congress finds that in order to prevent the creation of a cloned human individual through human somatic cell nuclear transfer technology, it is right and proper to pro-

hibit the creation of cloned human embryos that would never have the opportunity for implantation and that would therefore be created solely for research that would ultimately lead to their destruction.

SEC. 3. PROHIBITION ON CLONING.

(a) IN GENERAL.—Title 18, United States Code, is amended by inserting after chapter 15, the following:

"CHAPTER 16—CLONING

"§ 301 Prohibition on cloning

"(a) IN GENERAL.—It shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, to use human somatic cell nuclear transfer technology.

"(b) IMPORTATION.—It shall be unlawful for any person or entity, public or private, to import an embryo produced through human somatic cell nuclear transfer technology.

"(c) PENALTIES.—

"(1) IN GENERAL.—Any person or entity who is convicted of violating any provision of this section shall be fined according to the provisions of this title or sentenced to up to 10 years in prison, or both.

"(2) CIVIL PENALTY.—Any person or entity who is convicted of violating any provision of this

section shall be subject to, in the case of a violation that involves the derivation of a pecuniary gain, a civil penalty of not more than an amount equal to the amount of the gross gain multiplied by 2.

"(d) DEFINITION.—The term 'human somatic cell nuclear transfer technology' means taking the nuclear material of a human somatic cell and incorporating it into an oocyte from which the nucleus has been removed or rendered inert and producing an embryo (including a preimplantation embryo).".

(b) CLERICAL AMENDMENT.—The table of chapters for part I of title 18, United States Code, is amended by inserting after the item relating to chapter 15, the following:

"16. Cloning § 301". .....

SEC. 4. COMMISSION TO PROMOTE A NATIONAL DIALOGUE ON BIOETHICS.

(a) ESTABLISHMENT.—There is established within the Institute of Medicine a commission to be known as the National Commission to Promote a National Dialogue on Bioethics (referred to in this section as the "Commission").

(b) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 25 members, of whom—

(A) 6 shall be appointed by the Majority Leader of the Senate;

(B) 6 shall be appointed by the Minority Leader of the Senate;

(C) 6 shall be appointed by the Speaker of the House of Representatives; and

(D) 6 shall be appointed by the Minority Leader of the House of Representatives; and

(E) 1, who shall serve as the Chairperson of the Commission, to be appointed jointly by the Majority Leader of the Senate, and the Speaker of the House of Representatives, in consultation with the Minority Leader of the Senate and the Minority Leader of the House of Representatives.

(2) REQUIREMENTS.—Each individual described in subparagraph (A) through (D) of paragraph (1) shall ensure that members appointed to the Commission are representative of the fields of law, theology, philosophy or ethics, medicine, science, and society.

(3) DEADLINE FOR APPOINTMENT.—Members of the Commission shall be appointed by not later than December 1, 1998.

(4) TERMS OF APPOINTMENT.—A member of the Commission appointed under paragraph (1) shall serve for a term of 3 years. Members may not serve consecutive terms.

(5) MEETINGS.—The Commission shall meet at the call of its Chairperson or a majority of its members.

(6) QUORUM.—A quorum shall consist of 13 members of the Commission.

(7) VACANCIES.—A vacancy on the Commission shall be filled in the same manner in which the original appointment was made not later than 30 days after the Commission is given notice of the vacancy and shall not affect the power of the remaining members to execute the duties of the Commission.

(8) COMPENSATION.—Members of the Commission shall receive no additional pay, allowances, or benefits by reason of their service on the Commission.

(9) EXPENSES.—Each member of the Commission shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

(c) DUTIES OF THE COMMISSION.—The Commission shall provide an independent forum for broad public par-

ticipation and discourse concerning important bioethical issues including cloning, and provide for a report to Congress concerning the findings, conclusions, and recommendations of the Commission concerning Federal policy and possible Congressional action.

(d) STAFF AND SUPPORT SERVICES.—

(1) STAFF.—With the approval of the Commission, the chairperson of the Commission may appoint such personnel as the chairperson considers appropriate.

(2) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the Commission shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

(3) EXPERTS AND CONSULTANTS.—With the approval of the Commission, the chairperson may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

(4) PHYSICAL FACILITIES.—The Administrator of the General Services Administration shall locate suitable office space for the operation of the Com-

mission. The facilities shall serve as the headquarters of the Commission and shall include all necessary equipment and incidentals required for the proper functioning of the Commission.

(e) POWERS OF COMMISSION.—

(1) HEARINGS AND OTHER ACTIVITIES.—For the purpose of carrying out its duties, the Commission may hold such public hearings and undertake such other activities as the Commission determines to be necessary to carry out its duties.

(2) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the Commission, the head of any Federal agency is authorized to detail, without reimbursement, any of the personnel of such agency to the Commission to assist the Commission in carrying out its duties. Any such detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

(3) TECHNICAL ASSISTANCE.—Upon the request of the Commission, the head of a Federal agency shall provide such technical assistance to the Commission as the Commission determines to be necessary to carry out its duties.

(4) USE OF MAILS.—The Commission may use the United States mails in the same manner and

under the same conditions as Federal agencies and shall, for purposes of the frank, be considered a commission of Congress as described in section 3215 of title 39, United States Code.

(5) OBTAINING INFORMATION.—The Commission may secure directly from any Federal agency information necessary to enable it to carry out its duties, if the information may be disclosed under section 552 of title 5, United States Code. Upon request of the Chairperson of the Commission, the head of such agency shall furnish such information to the Commission.

(6) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

(7) PRINTING.—For purposes of costs relating to printing and binding, including the cost of personnel detailed from the Government Printing Office, the Commission shall be deemed to be a committee of the Congress.

(f) SUBCOMMITTEES.—

(1) IN GENERAL.—The Commission shall establish 6 subcommittees, including—

(A) a subcommittee on legal issues;

(B) a subcommittee on theological issues;

(C) a subcommittee on philosophical and ethical issues;

(D) a subcommittee on medical issues;

(E) a subcommittee on scientific issues; and

(F) a subcommittee on social issues.

(2) MEMBERSHIP.—With respect to the issues for which each subcommittee has been established, each subcommittee shall be composed of—

(A) 1 expert to be appointed by the members of the Committee who were appointed under subparagraphs (A) and (C) of subsection (b)(1);

(B) 1 expert to be appointed by the members of the Committee who were appointed under subparagraphs (B) and (D) of subsection (b)(1);

(C) 1 individual operating in the private sector who is acquainted with the issues but who is not an expert to be appointed by the members of the Committee who were appointed under subparagraphs (A) and (C) of subsection (b)(1);

(D) 1 individual operating in the private sector who is acquainted with the issues but who is not an expert to be appointed by the members of the Committee who were appointed under subparagraphs (B) and (D) of subsection (b)(1); and

(E) 4 members of the Commission with relevant expertise.

(3) MEETINGS.—Meetings of the subcommittees shall be approved by the Commission.

(g) REPORT.—Not later than December 31, 1999, and annually thereafter, the Commission shall prepare and submit to the appropriate committees of Congress a report which shall contain a detailed statement of the recommendations, findings, and conclusions of the Commission.

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 5. UNRESTRICTED SCIENTIFIC RESEARCH.

Nothing in this Act (or an amendment made by this Act) shall be construed to restrict areas of scientific research that are not specifically prohibited by this Act (or amendments).

SEC. 6. SENSE OF CONGRESS.

It is the sense of Congress that the Federal Government should advocate for and join an international effort to prohibit the use of human somatic cell nuclear transfer technology to produce a human embryo.