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[Folder 2]: Human Cloning Acts & Bills State Legislation on Human Cloning] [2]

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prepared by BIO

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.

© 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.

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.

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(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.

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(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.

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. <u>Acts vs. Intent</u>

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

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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

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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?

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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.

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. <u>Acts vs. Intent</u>

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

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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"**

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ANALYSIS OF BOND/FRIST/GREGG
HUMAN CLONING BILL

First Issue: The Bond/Frist/Gregg human cloning bill bans the act of "producing an embryo (including a preimplantation embryo)" through the use of a specified technology (somatic cell nuclear transfer). It would ban the production of this embryo even if the production of such an embryo is for purposes completely unrelated to the cloning of a human being.

The bill, therefore, would effectively ban some research to generate stem cells for the following types of treatments:

cardiac muscle cells to treat heart attack victims and degenerative heart disease;

skin cells to treat burn victims;

spinal cord neuron cells for treatment of spinal cord trauma and paralysis;

neural cells for treating those suffering from neurodegenerative diseases;

pancreas cells to treat diabetes;

blood cells to treat cancer anemia, and immunodeficiencies;

neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS);

cells for use in genetic therapy to treat 5,000 genetic diseases, including Cystic Fibrosis,

Tay-Sachs Disease, schizophrenia, depression, and other diseases;
blood vessel endothelial cells for treating atherosclerosis;
liver cells for liver diseases including hepatitis and cirrhosis;
cartilage cells for treatment of osteoarthritis;
bone cells for treatment of osteoporosis;
myoblast cells for the treatment of Muscular Dystrophy;
respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer;
adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration;
modified cells for treatment of various genetic diseases; and
other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions.

To be precise, the bill would ban the generation of stem cells for these purposes where the stem cells have nuclear DNA from a "human somatic cell" -- see critical discussion below and somatic cell nuclear transfer technology was used.

It would not ban stem cell research where the stem cell is generated without the use of somatic cell nuclear transfer or does not involve nuclear DNA from a "human somatic cell" -- again, see the critical discussion below.

If the legislation is limited to somatic cells with nuclear DNA identical to that of an existing or previously exisiting human being -- again, see critical discussion below -- the specific type of stem cells research which is banned is "customized" stem cell research. A researcher or doctor might want to create a human zygote with DNA identical to that of an existing or previously existing person through the use of somatic cell nuclear transfer -- the act prohibited in the Bond/Frist/Gregg bill -- in order to create a customized stem cell line to treat the individual from whom the DNA was extracted. By using the same DNA the stem cell would be more likely to be compatible and not rejected by the person when the stem cell is transferred (back) to the person for the treatment.

The statement released by Senators Bond/Frist/Gregg about the impact of their bill on biomedical research is technically accurate but highly misleading. The title of the document is "CURRENT RESEARCH UNTOUCHED BY THE BOND/FRIST/GREGG LEGISLATION" and it is followed by a list of such research, including "In Vitro Fertilization," "Stem Cell Research," "Gene Therapy," "Cloning of Cells, Tissues, Animals and Plants," "Cancer," "Diabetes," "Birth Defects," "Arthritis," "Organ Failure," "Genetic Disease," "Severe Skin Burns," "Multiple Sclerosis," "Muscular Dystrophy," "Spinal Cord Injuries," "Alzheimer's Disease," "Parkinson's Disease," and "Lou Gehrig's Disease." The title to this document includes a critical qualification -- an asterisk. The asterisk qualification states, "The Bond/Frist/Gregg bill would not prohibit any of this research, even embryo research, as long as it did not involve the use of a very specific technique (somatic cell nuclear transfer) to create a live cloned human embryo."

This qualification swallows the list. It acknowledges that the bill would, in fact, ban some types of stem cell research and other research, as explained above. Given the importance of the asterisk, the title to the document and the list of protected research are highly misleading.

The statement of Senators Bond/Frist/Gregg is a challenge to patient disease groups to seek to include in the legislation a specific guarantee that research on the diseases they list is not, in fact, stifled. Such an exemption might read as follows:

"NOTHING IN THIS ACT shall apply where the acts or research are for the purpose of producing or generating stem cells to treat or diagnose deadly or disabling diseases and other medical conditions including the following: cardiac muscle cells to treat heart attack victims and degenerative heart disease; skin cells to treat burn victims; spinal cord neuron cells for treatment of spinal cord trauma and paralysis; neural cells for treating those suffering from neurodegenerative diseases; pancreas cells to treat diabetes; blood cells to treat anemia, immunodeficiencies, and cancer; neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS); cells for use in genetic therapy to treat 5,000 genetic diseases, including Cystic Fibrosis, Tay-Sachs Disease, schizophrenia, depression, and other diseases; blood cells for use in treating patients with cancer, anemia, or immunodeficiency diseases; blood vessel endothelial cells for treating atherosclerosis; liver cells for liver diseases including hepatitis and cirrhosis; cartilage cells for treatment of osteoarthritis; bone cells for treatment of osteoporosis; myoblast cells for the treatment of Muscular Dystrophy; respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer; adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration; modified cells for treatment of various genetic diseases; and other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions; or for the purpose of conducting scientific research into the mechanisms of interaction between the genes and their intracellular and extracellular environments in order to control and redirect the specialization of somatic cells into novel treatments or diagnostic products for deadly or disabling diseases and other medical conditions."

If Senators Bond/Frist/Gregg are, in fact, determined to protect this research, they could not object to including this explicit guarantee in their bill.

The stem cell technology is exciting and potentially revolutionary. Scientists are developing an entirely new approach for treating human diseases that depend not on drugs like antibiotics but on living cells that can differentiate into blood, skin, heart, or brain cells and potentially treat cancers, spinal cord injuries, or heart disease. This research -- called stem cell research -- holds the potential to develop and improve cancer treatments by gaining a more complete understanding of cell division and growth and the process of metastasis. This could also lead to a variety of cancer treatment advances.

The kinds of cells that make up most of the human body are differentiated, meaning that they have already achieved some sort of specialized function such as blood, skin, heart or brain cells. The precursor cells that led to differentiated cells come from the embryo. They are called stem cells because functions stem from them like the growth of a plant. Stem cells have the capacity for self-renewal, meaning that they can produce more of themselves, and differentiation, meaning that they can specialize into a variety of cell types with different functions. In the last decade, scientists studying mice and other laboratory animals have discovered powerful new approaches involving cultured stem cells. Studies of such cells obtained from mouse stem cells show that they are capable of differentiating in vitro or in vivo into a wide variety of specialized cell types. Stem cells have been derived by culturing cells of non-human primates and promising efforts to obtain human stem cells have also recently been reported.

Stem cell research has been hailed as the "[m]ost tantalizing of all" research in this field. The reason for this is because adults do not have many stem cells. Most cells are fully differentiated into their proper functions. When differentiated cells are damaged, such as cardiac muscle when someone suffers a heart attack, the adult cells do not have the ability to regenerate. If stem cells could be derived from human sources and induced to

differentiate in vitro, they could potentially be used for transplantation and tissue repair.

Using the heart attack sufferer as an example, we might be able to replace damaged cardiac cells with healthy stem cells that could differentiate into cardiac muscle. Research with these stem cells could lead to the development of "universal donor cells" of invaluable benefit to patients. Stem cell therapy could make it possible to store tissue reserves that would give health care providers a wholly new and virtually endless supply of the cells listed above. The use of stem cells to create these therapies would lead to great medical advances. We have to be sure that nothing we do in this legislation concerning human cloning would obstruct in any way this vital research.

Second Issue: The bill bans the use of somatic cell nuclear to transfer a "human somatic cell" but it does not state that this is limited to somatic cell which contains nuclear DNA identical to that of an existing or previously existing person. This means that the bill is not limited to cloning (creating a person or embryo with nuclear DNA identical to that of someone else), but would also apply to the use of somatic cell nuclear transfer of nuclear DNA which is not identical. It would, in fact, prohibit the use of somatic cell nuclear transfer where the nuclear DNA is the product of normal, sexual reproduction -- that is the opposite of cloning. It would also prohibit the use of somatic cell nuclear transfer where the somatic cell had been modified in some way prior to the use of somatic cell nuclear transfer. In short, the bill prohibits a broad range of uses of somatic cell nuclear transfer having nothing whatever to do with cloning, such as use of this technology to treat mitochondrial disease.

Message Sent To:

Toby Donenfeld/OVP @ OVP
Wendy A. Taylor/OMB/EOP
gips_d @ a1.eop.gov @ inet
Clifford J. Gabriel/OSTP/EOP
Jeffrey M. Smith/OSTP/EOP
Lucia A. Wyman/WHO/EOP
Thomas L. Freedman/OPD/EOP
Jerold R. Mande/OSTP/EOP
William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

DRAFT – NOT FOR RELEASE

February 4, 1998
(Senate)

S. 1601 - Human Cloning Prohibition Act
(Sen. Lott (R) MS)

On June 9, 1997, the President transmitted to Congress legislation making it illegal for anyone to clone a human being. The President believes that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. The Administration, however, opposes enactment of S. 1601 because it would have the ill-advised effect of permanently impeding significant scientific research in critical areas such as finding cures for diseases, enhancing treatments for infertility, and transplanting tissue and organs.

Instead, the Administration strongly supports enactment of the Feinstein/Kennedy amendment that will be offered as a substitue for S. 1601. The Feinstein/Kennedy amendment, which is based on the President's proposal, would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research.

Pay-As-You-Go Scoring

S.1601 could affect receipts; therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990. OMB's preliminary scoring estimate of this bill is zero.

* * * * * * * * * *

Rachel E. Levinson 02/04/98 01:23:21 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: draft cloning letter for discussion at 4 today

I commend you on your introduction of S. 1602 the "Prohibition on Cloning of Human Beings Act of 1998." If enacted, this bill would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research. The bill, which closely parallels the bill I submitted last June, also follows the findings and recommendations presented to me by my National Bioethics Advisory Commission. I said then and reaffirmed this belief in my January 10 radio address that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. I called on Congress to enact legislation making it illegal for anyone to clone a human being at this time. I am pleased to see your response to my challenge.

Trying to draft a bill that walks the fine line between defining the unacceptable act of producing a child that is the genetic replica of another person, while protecting biomedical and agricultural research is a formidable task. My bill offered one way to achieve those dual goals; your bill clearly reaches for the same result. In this case, imprecise wording carries the threat of impeding research that might one day offer hope to those suffering from spinal cord injury, Parkinson's disease, diabetes or AIDS. We must not make such a mistake in our haste to close the doors to those who would subvert this promising new technology by using it for unethical purposes.

I am also pleased that you have heeded my proposal to put a time limit on this prohibition. The sunset provision ensures a continuing examination of the risks and benefits of this technology, while we are free from worry that someone will use it prematurely.

Society shouldn't make decisions about the application of a specific technology without first understanding its full potential, both good and bad. Asking the National Bioethics Advisory Commission to return to this complex issue in four and one-half years will promote a deeper awareness of the power we hold to alleviate the burden of human illness and a broader debate on the ethical and moral limits we ought to impose on exercising that power. We are not ready to answer these enormously challenging questions today.

That is why we must act now to reassure the public that this government will not tolerate anyone using somatic cell nuclear transfer to create a child. I thank you for your efforts on

behalf of the American people and look forward to signing this bill.

Message Sent To:

Toby Donenfeld/OVP @ OVP
Wendy A. Taylor/OMB/EOP
gips_d @ a1.eop.gov @ inet
Clifford J. Gabriel/OSTP/EOP
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Total Pages: 3

LRM ID: RJP187

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Thursday, February 5, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148
SUBJECT: **Statement of Administration Policy on S1601 Human Cloning Prohibition Act**

DEADLINE: **10:00 a.m. Friday, February 6, 1998**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: ***REVISED*** **Statement of Administration Policy - incorporates changes received to date and has been reviewed and approved by HHS. HHS advises that the SAP should be held pending tonight's meeting on the cloning ban bill.**
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LRM ID: RJP187 **SUBJECT:** Statement of Administration Policy on S1601 Human Cloning Prohibition Act

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: **Robert J. Pellicci Phone: 395-4871 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

_____ **(Name)**

_____ **(Agency)**

_____ **(Telephone)**

The following is the response of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** _____ **pages, attached to this response sheet**

DRAFT -- NOT FOR RELEASE

DRAFT

February 5, 1998
(Senate)

S. 1601 - Human Cloning Prohibition Act
(Sen. Lott (R) MS)

On June 9, 1997, the President transmitted to Congress legislation making it illegal for anyone to clone a human being. The President believes that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. The Administration, however, believes S. 1601 poses a significant threat to important biomedical research and, therefore, has concerns regarding passage of the bill in its current form. The Administration looks forward to working with the Congress to address these concerns. Specifically, the Administration supports amendments to S. 1601 that would:

-- Include a five year sunset on the prohibition on human somatic cell nuclear transfer technology. The sunset provision ensures a continuing examination of the risks and benefits of this technology, while being free from the worry that someone will use it prematurely.

-- Permit somatic cell nuclear transfer using human cells for the purpose of developing stem cell (unspecialized cells capable of giving rise to specific cells and tissue) technology to treat or diagnose deadly or disabling diseases and other medical conditions, including the treatment of cancer, diabetes, genetic diseases, and spinal cord injuries and for basic research that could lead to such treatments.

-- Repeal the bill's criminal penalties and instead make any property, real or personal, derived from or used to commit violations of the Act subject to forfeiture to the United States.

-- Repeal the bill's provisions establishing a new Commission to Promote a National Dialogue on Bioethics. The new Commission would unnecessarily duplicate the mission of the President's National Bioethics Advisory Commission.

The President's proposal, which in many ways is reflected in S. 1602 sponsored by Senators Feinstein and Kennedy, would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research.

* * * * * * * * * * *

DRAFT -- NOT FOR RELEASE

DRAFT

February 5, 1998
(Senate)

S. 1601 - Human Cloning Prohibition Act
(Sen. Lott (R) MS)

On June 9, 1997, the President transmitted to Congress legislation making it illegal for anyone to clone a human being. The President believes that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. The Administration, however, has a number of concerns about S. 1601 and looks forward to working with the Congress to address these concerns. Specifically, the Administration supports amendments to S. 1601 that would:

-- Include a five year sunset on the prohibition on human somatic cell nuclear transfer technology. The sunset provision ensures a continuing examination of the risks and benefits of this technology, while being free from the worry that someone will use it prematurely.

-- Permit the creation of an embryo for the purpose of producing or generating stem cells to treat or diagnose deadly or disabling diseases and other medical conditions, including the treatment of cancer, diabetes, genetic diseases, and spinal cord injuries.

-- Repeal the bill's criminal penalties and instead make any property, real or personal, derived from or used to commit violations of the Act subject to forfeiture to the United States.

-- Repeal the bill's provisions establishing a new Commission to Promote a National Dialogue on Bioethics. The new Commission would unnecessarily duplicate the mission of the President's National Bioethics Advisory Commission.

The President's proposal, which in many ways is reflected in S. 1602 sponsored by Senators Feinstein and Kennedy, would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research.

Pay-As-You-Go Scoring

S.1601 could affect receipts; therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990. OMB's preliminary scoring estimate of this bill is zero.

* * * * * * * * * *

Total Pages: ____

LRM ID: RJP187

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Thursday, February 5, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference

OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148

SUBJECT: **Statement of Administration Policy on S1601 Human Cloning Prohibition Act**

DEADLINE: **2:00 p.m. Thursday, February 5, 1998**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: Senate floor consideration of S. 1601 is scheduled to begin today. **DEADLINE IS FIRM.**

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LRM ID: RJP187 **SUBJECT:** Statement of Administration Policy on S1601 Human Cloning Prohibition Act

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

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Please include the LRM number shown above, and the subject shown below.

TO: Robert J. Pellicci Phone: 395-4871 Fax: 395-6148
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7382

FROM:

_____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet