NLWJC - Kagan

DPC - Box 006 - Folder 019

Cloning [2]

1/14/98

FOR EK -

Cloning materials from meeting today. The bills drafted by WH, The Reproductive Society, & Biotech industry are on top. I sent you a short e-mail on the meeting.

TOM

Cloning

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"

Reproductive Society

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.

BIOTECH INDUSTRY

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.

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.

Elhers (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

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[1] 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?

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

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[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

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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.

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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."

Fil-cloning

THE WHITE HOUSE

WASHINGTON

March 3, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Jack Gibbons
Assistant to the President for Science and Technology

Bruce Reed
Assistant to the President for Domestic Policy

SUBJECT: Background and Suggested Presidential Statement on Cloning

As you know, the February 27 issue of *Nature*, a renowned scientific journal, contains an account of the first successful cloning of an adult sheep. Hypothetically, similar techniques could be used to clone humans. Because of the ethical concerns human cloning would present, on February 24 you asked your National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues involved and to report back within 90 days on possible federal actions.

We recommend that you: (1) issue a statement on cloning to assure the public that federal funds will not be used to clone humans; and (2) call on the scientific community to voluntarily refrain from human cloning while NBAC and the nation distinguish the facts from the hype and consider its ethical implications.

Background

Most scientists believe that human cloning faces major scientific barriers. For complicated scientific reasons, sheep may be more easily cloned than humans and other animals, and all attempts to clone other mammals such as mice starting with cells from mature animals have failed. The majority of experts believe that any prospect of successfully applying this new cloning method to human beings in the near future is extremely remote.

Human cloning research also faces funding barriers. On December 2, 1994, you issued a statement barring the use of federal funds to create human embryos for research purposes. Appropriations bills for FY96 and FY97 codified this policy and expanded it to cover HHS research in which human embryos are "destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." (The Administration has opposed addressing the issue through legislation and has supported repealing this provision). Senator Bond (R-MO) has begun to draft legislation making permanent the current ban on federal funding for human embryo research.

News reports have indicated that the Congressional ban prohibits using federal funds for human cloning, and no one in Congress has taken issue with this understanding. But the language is not as tight as it could be. It does not explicitly bar federally-supported scientists from creating human

embryos they intend to implant -- it only prohibits them from creating embryos they will discard. In addition, the Congressional ban only covers HHS-funded research.

Privately funded facilities are free to engage in human cloning research under current law. There is a booming business in all forms of reproduction technology to assist infertile couples. Human cloning is not likely to be pursued in this context -- at least until it has a chance of competing successfully against existing technology -- but it cannot be definitively ruled out.

Congress has scheduled fact-finding hearings on human cloning March 5 (Technology Subcommittee, House Science Committee) and March 12 (Senate Subcommittee on Science, Technology and Space). NIH Director Harold Varmus has been asked to testify at both upcoming hearings. On February 26, in testimony before the House Appropriations Subcommittee on Labor and Health and Human Services, Dr. Varmus stated that the idea of human cloning was "repugnant." He went on to say that he "would be concerned about a rush to legislate" a prohibition since legislation could also restrict related work that offers important medical, economic, and scientific benefits.

Rushed attempts to ban cloning could easily result in unintended harmful effects on important research. For example, Dr. Varmus has noted that sheep cloning might inform new methods for producing human proteins, creating model organisms to study human diseases, and possibly reprogramming human cells for treatment of cancer, burns, and other disorders. Therefore, any restraints on human cloning should be worded carefully to avoid unintended consequences on a broader sphere of biomedical and agricultural research.

A consensus is emerging, however, that researchers should not pursue human cloning at least until the nation has more thoroughly considered the ethical implications of the technology. The current restrictions do not assure this outcome for two reasons. First, as noted above, the current ban on using federal funds to create embryos for research does not explicitly prohibit all human cloning -- it only covers cloning of embryos that will be discarded (not implanted), and only covers HHS-funded research. Second, the restrictions apply to federally-supported human embryo research only, not privately-funded activities.

You could urge the non-federally funded scientific community to declare a self-imposed moratorium on human cloning. Some in science will question the need for this approach because they do not believe our ability to clone humans is imminent.. Some also believe that it would be inappropriate for you to take action before NBAC reports back to you with recommendations (your referral of the issue to NBAC received enthusiastic, bipartisan support at NIH's February 26 appropriations hearing). On the other hand, your calling for a moratorium might deter restrictive, ill-advised legislation, reassure the public, and strengthen the nation's resolve to consider ethical questions carefully before advancing human cloning. The scientific community favors a voluntary moratorium over a Congressional ban, and key scientists including Dr. Varmus would understand your calling for it.

Suggested Presidential Statement

We recommend that you issue a statement to:

- Affirm the scientific promise of the new cloning technique and its concurrent ethical challenges;
- Argue that ethical concerns must be confronted before people try to use the technology to clone humans;
- Restate that you have referred the issue to NBAC;
- Clarify that federal dollars cannot be used for human cloning and that you are signing a memorandum to that effect; and
- Call on the scientific community to refrain from human cloning at least until NBAC and the nation have carefully considered the issue.

Cloning

THE PRESIDENT HAS SEEN
6-4-97

THE WHITE HOUSE
WASHINGTON

Copied to:
Kagan
Gibbons
Emanuel
Bowles

June 3, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: TODD STERN
PHIL CAPLAN

SUBJECT: Cloning Policy Options -- Report of National Bioethics Advisory Committee

The attached Gibbons/Kagan memo (Bruce Reed is recused) urges you to follow the recommendation of the NBAC to submit legislation banning human cloning but permitting cloning of human tissue, including embryos. NBAC's cloning report is to be released Saturday, though the Washington Post reported on a leaked draft today. Jack/Elena also recommend that the U.S. support a modified version of a French proposal for a cloning paragraph in the G-8 communique.

NBAC Report/Legislation. NBAC concludes that it is morally unacceptable for anyone to try to create a child using the cloning technology that created Dolly. But NBAC finds that other forms of "human cloning" -- e.g., of DNA sequences, cell lines, tissues, embryos -- are appropriate and scientifically important, as is animal cloning. Therefore, NBAC calls for narrowly worded legislation barring anyone from trying to create a child through somatic cell nuclear transfer techniques. The legislation would sunset and, prior to the sunset, an oversight body would report on the state of the technology and social/ethical issues.

Likely Reaction. While there is a broad consensus emerging (including AMA and World Medical Association) that cloning humans is wrong, biotech and pharmaceutical industries will strongly oppose legislation as they fear it will impede research. The right-to-life community will oppose on the ground that the ban should extend further -- to the cloning of human embryos for research. *This issue, incidentally -- whether to allow the cloning of embryos for research -- is exactly what the Post honed in on this morning.* (Currently, the Administration bars the creation of embryos for federally funded research only, and has opposed legislation on the subject.)

Jack/Elena recommend that you announce your support for NBAC-type legislation and that you propose specific legislative language. (A possible event where you could accept the NBAC report and announce your position is under consideration for Monday, June 9.) *Rahm concurs.*

Approve ✓ Disapprove___ Discuss___

G-8 Communique. France proposes a paragraph embracing national and international bans on reproductive cloning. Jack/Elena recommend that we support this proposal, but with critical modifications along the lines of the NBAC proposal. If you approve, Dan Tarullo will seek to negotiate specific language, but cautions that agreement by all eight countries may be difficult.

Approve ✓ Disapprove___ Discuss___

THE WHITE HOUSE

WASHINGTON

'97 JUN 3 AM8:28

May 29, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: JACK GIBBONS
Assistant to the President for Science and Technology

ELENA KAGAN
Deputy Assistant to the President for Domestic Policy

SUBJECT: CLONING POLICY OPTIONS

Two upcoming events create the need to develop a position on legislation banning the cloning of human beings. First, the National Bioethics Advisory Commission (NBAC) is about to complete the review you requested of the ethical and legal issues associated with cloning human beings. On Saturday, June 7, at its final public meeting, NBAC is expected to vote in favor of a legislative ban. Second, France has proposed that the Denver Summit communique include a paragraph urging countries to pass domestic legislative bans and to work together toward a global ban.

We recommend: (1) that you support domestic legislation banning human cloning, and that you announce specific legislation at the top of your June 10th press conference; and (2) that the U.S. support the gist of France's proposed cloning paragraph while insisting on critical modifications.

NBAC's Findings and Recommendations

In its draft final report, NBAC unanimously concludes that "it is morally unacceptable for anyone . . . to attempt to create a child" using the technology that created Dolly the sheep: somatic cell nuclear transfer -- that is, the transfer of the nucleus from an adult somatic (non egg or sperm) cell into an enucleated egg. NBAC bases this conclusion on safety concerns, finding that the technology is "likely to involve substantial risk to the potential child." The report also states that "serious ethical concerns... require a great deal more widespread and careful thought and public deliberation before this technology should be used."

NBAC also concludes, however, that other forms of "human cloning" -- such as the cloning of DNA sequences, cell lines, and tissues (which do not involve the creation of entire human beings) -- are scientifically important and not ethically problematic. Moreover, NBAC finds that animal cloning is ethically acceptable and promises important benefits. The Commission thus cautions that restrictions on cloning not impede these activities.

The Commission notes that current restrictions effectively prohibit federally funded and regulated entities from attempting to clone a human being through somatic cell nuclear transfer. However, fertility clinics and other privately-funded clinical and research establishments face no prohibition on human cloning, and NBAC questions whether some of these organizations will adhere to a voluntary moratorium.

Accordingly, NBAC's draft final report calls for carefully-worded national legislation prohibiting anyone from "attempting to create a child through somatic cell nuclear transfer techniques." The Commission specifies 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 in humans. NBAC also recommends that the U.S. cooperate with other countries to enforce mutually-supported cloning restrictions.

National Legislation

We recommend that you embrace NBAC's proposal to establish a narrowly crafted time-limited legislative moratorium. Legislation is the only way to establish a comprehensive, enforceable prohibition on cloning entire human beings in all publicly and privately funded research and clinical activities. If carefully written, the ban will not preclude important research.

Reaction to proposed legislation will be mixed. A national and international consensus is emerging that attempting to apply the technology used to clone Dolly to humans is morally wrong. The American Medical Association has conveyed this view to NBAC, and the World Medical Association has issued a similar statement. Given NBAC's recommendation, we expect many in the scientific and ethics communities to accept a legislative moratorium.

But some who agree that cloning a human being using somatic cell nuclear transfer is morally unacceptable will oppose a legislated moratorium. In particular, the biotechnology and pharmaceutical industries strongly oppose legislation. These two industries are deeply concerned that a legislative debate will produce broadly drawn language that impairs critical research. Some academic researchers may share this view. Fertility clinics also may oppose legislation, but to date have not signaled a position.

Finally, some in the right-to-life community will argue from the other side that NBAC's proposed approach does not go far enough. This community will push for a comprehensive ban on the creation of embryos, through any means, for research purposes (i.e., not for the purposes of creating a child). The Administration has applied this restriction to federally-funded research, but opposed legislation on the subject. This is an issue NBAC declined to review, and we do not recommend revisiting it in this context.

We recommend that you announce your support for legislation and propose specific legislative language on June 10, at your scheduled press conference, three days after NBAC's

recommendation will become public. We anticipate that the release of NBAC's report will prompt Congressional hearings and legislative proposals. By acting quickly you can maintain your leadership on the issue and carefully frame the legislative debate, making clear the value of biotechnology research and the danger of overly broad regulation, while calling for the prohibition of an unethical use of a specific technology.

Approve ___ Disapprove ___

Group of Eight Statement on Cloning

France has proposed a paragraph for inclusion in the G-8 communique embracing national and international bans on "reproductive human cloning." Germany will support the statement; Canada will support it with some modification.

The U.S. biotechnology and pharmaceutical industries strongly oppose including any paragraph on cloning in the communique. They fear that it will not be carefully drafted and may inadvertently extend to the cloning of DNA, cells, and tissues as well as entire human beings. Further, industry is concerned that a statement on cloning ultimately could provide cover for protectionist efforts to restrict U.S. biotechnology products and activities.

Nevertheless, we recommend that the Administration support the French proposal with critical modifications. Specifically, we suggest that the U.S. insist on changes to: (1) affirm the potential medical and agricultural benefits of cloning technology; (2) limit the prohibition to the use of somatic cell nuclear transfer technology; and (3) propose a time-limited moratorium instead of a ban. USDA and HHS support this position.

Approve ___ Disapprove ___

copied
Kagan
Gibbons
COS

Cloning

THE WHITE HOUSE

WASHINGTON

June 8, 1997

Bruce –
FYI. What we gave to the President this weekend.
Elena

THE PRESIDENT HAS SEEN
6/8/97

MEMORANDUM FOR THE PRESIDENT

FROM: TODD STERN

SUBJECT: Proposed Cloning Legislation

At your cloning event tomorrow, you will receive the report of the National Bioethics Advisory Commission and announce legislation along the lines of NBAC's proposal. Elena Kagan and Jack Gibbons seek your views on two issues -- embryo research, which has already been run by you once, in the memo you received last week, and a sunset provision. *It would be desirable for you to reconfirm your views on the embryo issue before the event tomorrow, since you are likely to be asked about it. If you are comfortable deciding the sunset issue as well, you will be able to submit the legislation tomorrow. Alternatively, if you need more time, you can announce at the event tomorrow that you will be submitting legislation in the near future.* ***It would be very helpful for planning purposes if you could return this memo to our office today.***

Embryo research. In a nutshell, NBAC would ban the cloning of embryos for implanting in a woman's uterus (i.e., cloning humans), but take care not to inhibit cloning of human cells or tissues or the cloning of animals. NBAC's proposed legislation would *not* ban the cloning of embryos for research purposes, regarding that as ethically no different from the creation of research embryos through other techniques. You have banned the use of federal funds to create embryos for research, but have not supported a broader prohibition. The pro-life community will criticize any failure to ban the cloning of research embryos, but a ban on cloning for research would be strongly opposed by the scientific and fertility communities, since such a ban could halt research on infertility and possibly other conditions. **The attached Kagan/Gibbons memo recommends that you follow NBAC in *not* banning the cloning of embryos for research.**

Agree ✓ Disagree___ Discuss___

Sunset. Your proposed legislation currently includes a 5-year sunset provision and directs NBAC to report to the President in 4 ½ years on whether to continue the ban. This follows NBAC's strong recommendation. Some will criticize a sunset provision, however, saying that if you are banning cloning for ethical reasons (as opposed to, say, safety), then nothing will change in 5 years and there is no reason for a sunset. But even some who see cloning as ethically wrong think it would be a good idea to renew the national debate in a few years, see whether the legislative language needs adjustment, etc. And the biotech and pharmaceutical industries will very likely oppose cloning legislation *unless* there is a sunset. The Vice President favors NBAC review after 4 ½ years, but no built-in sunset; the biotech and pharmaceutical communities, as well as Gibbons and Varmus (NIH), oppose this approach.

5-year sunset ✓ No sunset/but review (VP idea)___ No sunset or review___ Discuss___

THE WHITE HOUSE

WASHINGTON

'97 JUN 8 PM12:47

June 8, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Jack Gibbons
Assistant to the President for Science and Technology

Elena Kagan
Deputy Assistant to the President for Domestic Policy

SUBJECT: Cloning Policy Decisions

This memo summarizes (1) the final version of the National Bioethics Advisory Commission (NBAC) cloning report completed yesterday, and (2) the cloning legislation we have prepared for you to submit to Congress on Monday. The memo addresses two issues about the legislation we would like you to focus on: (1) whether to prohibit the production of embryos (as well as human beings) through cloning; and (2) whether to sunset the prohibition on cloning after 5 years.

NBAC's Findings and Recommendations

In its final report NBAC states that at this time it is morally unacceptable for anyone to attempt to create a child using the technology that created Dolly the sheep (so-called somatic cell nuclear transfer technology). NBAC also concludes that the cloning of DNA, cells, and tissues, and the cloning of animals, are scientifically important and not ethically problematic. NBAC chose not to address at all the cloning of embryos for research purposes. NBAC calls for:

- Carefully-worded legislation that prohibits somatic cell nuclear transfer to create a child (without impeding important cloning research on DNA, cells, and animals), sunsets in 3-5 years, and provides for further review by an advisory body prior to the sunset date;
- Continuing your moratorium on the use of federal funds for cloning human beings while the proposed legislation is pending;
- Calling on all scientists and clinicians to adhere to the voluntary moratorium while the proposed legislation is pending; and
- Working with other countries to enforce common aspects of cloning restrictions.

Proposed Legislation

The legislation you will announce tomorrow, as currently written:

- Prohibits the use of somatic cell nuclear transfer with the intent of introducing the product into a woman's womb or in any other way creating a human being;
- Gives the Attorney General authority to seek injunctive relief, impose civil fines up to $250,000 or twice the profit from a violation of the Act (whichever is greater), and seize any and all property used in violating the Act (including entire laboratories);
- Sunsets the prohibition on cloning 5 years from the date of enactment; and
- Directs the National Bioethics Advisory Commission to report to you prior to the sunset date on the advisability of continuing the prohibition.

Key Legislative Issues

1. Embryo Research

NBAC's proposed legislation --and, as currently drafted, your bill --would not ban the creation of cloned embryos for research purposes. NBAC simply did not evaluate the ethics or scientific benefits of this activity; it focused exclusively on the use of cloning techniques to create an embryo that would then be implanted in a woman's uterus and brought to term. NBAC reasoned that other entities (including a 1994 NIH panel) already have discussed extensively the creation of embryos for research purposes and that the use of cloning technology in this context raises no distinct ethical issues. By contrast, the use of somatic cell nuclear transfer technology to create a child raises a host of new and different ethical issues relating to safety, individuality, and family integrity.

You took action in 1994 to restrict embryo research by banning the use of NIH funds to create embryos for research purposes. (The NIH panel had recommended permitting the funding of research on embryos in very limited circumstances.) You also signed a spending bill that included a prohibition on the use of HHS funds for embryo research. But your budget submissions for FY97 and FY98 stated in a footnote that the Administration did not support addressing this issue in legislation. Nor have you ever indicated support for extending the current restriction to privately funded embryo research.

The right-to-life community already has criticized NBAC for not recommending a ban on creating cloned embryos. But there are good reasons for not going so far. There is no moral rationale for treating embryos created through cloning differently from embryos developed through other means (e.g. in vitro fertilization) when embryos are used solely for research. Prohibiting the creation of embryos for research using private funds could halt important research on infertility and possibly other medical conditions and would provoke strong opposition from the scientific and fertility communities. In short, it is a controversial step that merits further consideration. We therefore recommend that you limit the scope of the legislation you submit to Congress on Monday to the issue the Commission addressed. If asked about your position on embryo research, you should note that it is an important but

separate question and reiterate your position that no federal funds should be used to create embryos for research purposes.

2. Sunset Provision

NBAC recommends strongly that any legislative prohibition on cloning include a sunset clause to ensure that Congress review the issue after a specified period of time.

Whether a sunset provision makes sense depends in part on why a cloning ban is appropriate. For those who believe cloning is unethical primarily because of safety concerns, a sunset is necessary because time may mitigate those concerns. But for those who believe that cloning is inherently immoral, a sunset provision may seem wrong because time cannot lessen the problem. If you propose a sunset provision, you will subject yourself to criticism on this score.

It is important to understand, however, that some who share your view that cloning is inherently wrong nonetheless favor a sunset provision. They reason that: (1) a sunset provision provides a strong incentive for Congress and the Administration to renew the national debate on cloning within several years, ensuring continued attention to the ethical questions; (2) there has been little time to fully consider the moral issues, and it is possible that convictions may evolve; and (3) there is a high probability that Congress will simply get the legislative language wrong the first time around, given our limited understanding of the science, the difficulty of defining terms, and the vagaries of the legislative process.

As an alternative to proposing a sunset provision, you could propose legislation that provides for review by NBAC in 4 ½ years but does not sunset the ban. This approach would shift the burden of proof to those who want to lift the ban, since Congress would have to act affirmatively to effect change. Jack Gibbons, Harold Varmus, and the scientific and biotechnology communities oppose this modification to your draft legislation. The Vice President prefers this modified approach.

Unions

JOSHUA
GOTBAUM
01/12/98 10:56:35 PM

Record Type: Non-Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP, Susanne Bachtel/OSTP/EOP

cc: Christopher C. Jennings/OPD/EOP
Subject: URGENT: CONCURRENCE REQUESTED ON EMBRYOS/CLONING POLICY FOR BUDGET

In the FY99 budget, the Administration includes language concerning a number of sensitive issues. OMB staff have solicited comments from the various EOP agencies and HHS and would like to propose the following position. **If you disagree and we need to meet, please contact me at 395-9188 no later than 2:00 pm Tuesday.**

We propose to repeat the FY 1998 enacted language that prohibits the use of funds for the creation of human embryos or the use of embryos for research. The FY97 and FY99 Budgets proposed to delete this language (explaining in a footnote that "the Administration does not support addressing this issue in legislation"), but given the Administration's emphatic opposition to human cloning, leaving the language intact seems the better course this year. The language would appear as follows:

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 under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(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.

Cloning

Sarah A. Bianchi 01/09/98 12:00:38 PM

Record Type: Record

To: Jordan Tamagni/WHO/EOP
cc: Elena Kagan/OPD/EOP, Jeffrey M. Smith/OSTP/EOP
bcc:
Subject: Re: Cloning

Jordan Tamagni
This one is actually not me. I believe it is you Jeff right? However, Melissa Skolfield did call me about this yesterday. She has thoughts on how we talk about this, particularly with regard to FDA's role (she's at 690-7850). (FDA does have jurisdication, and I believe they do not want to say much new on this). Also, Bill Hubbard at FDA usually answers my FDA questions. (call 301-827-3370 and they can tell you how to reach him).

sb

Jordan Tamagni
01/09/98 11:38:19 AM

Record Type: Record

To: Sarah A. Bianchi/OPD/EOP
cc: Elena Kagan/OPD/EOP, Jeffrey M. Smith/OSTP/EOP
Subject: Cloning

Questions: first, are you the right person to ask about this stuff; if not you, who?

Second, FDA has jurisdiction over gene therapies -- does cloning come under this jurisdiction? Are there any plans for regulatory control of such techniques in advance of legislation? Did FDA made a public statement regarding regulations after we issued moratorium? Since the news about Dr. Seed broke? Has any administration official other than McCurry?

Third, what is the status of legislation on the Hill (I'll ask Forbes, as well). Are there competing, more conservative bills out there that somehow limit reproductive freedom?

I need to know this stuff double asap. Thanks.

Drugs - Needle exchange (and) Market - budget (and) Cloning

CLICK ON THE SECTIONS BELOW FOR BACKGROUND ON NEEDLES AND CLONING

NEEDLE EXCHANGE

Statutory Restrictions on the Use of Federal Funds for NEPs:

Since 1988, US Appropriations or Authorization law has placed a conditional prohibition on the use of Federal funds for the operation of needle exchange programs.

Currently, there are three statutory restrictions on the use of Federal funds for the operation of needle exchange programs:

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992, prohibits the use of Substance Abuse and Mental Health Services Administration Block grant funds for needle exchange programs unless the Surgeon General determines that they are effective in reducing the spread of HIV and the use of illegal drugs. The statute does, however, allow Federal research and evaluation of existing needle exchange programs.

Section 422 of the 1996 Ryan White CARE Act reauthorization places a flat prohibition on the use of Ryan White funds for needle exchange.

Sections 505 & 506 of the FY 1998 L/HHS / Ed Appropriations bill read:

505: Not withstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

506: Section 505 is subject to the condition that after March 31, 1998, a program for exchanging such needles and syringes (referred to in this section as an "exchange project") may be carried out in a community if (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by such Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

This limitation has been in Labor/ H appropriations language in some form since 1990. In the FY 1998 Appropriations bill, the Appropriators split the provision into two provisions and added the six-month moratorium on certification and the language requiring that the exchange programs must be operated in accordance with criteria established by the Secretary.

In the past, the Administration has worked to avoid an outright ban on the use of Federal funds for NEPs (like the current Section 505) and maintain the authority of the Secretary to certify that Federal funds can be used for such programs.

RECOMMENDATION:

There have been several studies done on the efficacy of NEPs in recent years, and there is current data available to meet the first requirement in this language (e.g. that NEPs are successful in preventing the spread of HIV), but HHS maintains that the data on the second provision (that NEPs do not encourage the use of illegal drugs) is still inconclusive. HHS is expecting the results of additional studies on NEPs in the coming year and wants to maintain the Secretary's authority to continue to evaluate the evolving scientific data on this issue and to certify that Federal funds can

be used for NEPs.

To maintain maximum flexibility for the Secretary, we recommend bracketing (deleting) Section 506 and modifying Section 505 by re-proposing the language that was proposed in the FY 1998 Budget on this issue:

505: Not withstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug unless the Surgeon General determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs.

[Note: The words "or syringes" were added in FY 1998 enacted language -- they were not proposed in the 98 Budget. Our recommendation would repeat "or syringes" in the FY 1999 Budget.]

ALTERNATE RECOMMENDATION:

In addition to bracketing section 506, we could add a footnote similar to that placed on the Hyde language deletions: *The Administration proposes to delete this provision and will work with Congress to address this issue.*

Also, rather than repeat the language in the FY 1998 Budget that gave the authority to certify NEPs to the Surgeon General to the Secretary of Health and Human Services, we could maintain the language that was made by Congress in the FY 1997 Labor/HHS/Ed Appropriations bill that gave such authority to the Secretary of Health and Human Services. This may be something the Administration wants to consider given the upcoming confirmation hearings for Surgeon General nominee David Satcher.

Background on Human Embryos/Cloning

Both the House and Senate L/HHS bills for FY 1998 extended the FY 1996 and FY 1997 appropriations Act ban on using Federal funds on human embryo research, and modified it to include research involving "human diploid cells." NIH staff advise that in practice, this extension does not differ from the original ban on human embryo research and would have no effect on NIH's present research efforts. The words "human diploid cells" were apparently added in an attempt to address cloning.

A diploid cell is produced after fertilization occurs in humans -- it is one stage of a developing embryo. Diploid cells could theoretically be produced via somatic cell nuclear transfer, which is more commonly referred to as "cloning." The FY 1996 and FY 1997 L/HHS Acts barred Federal funding for the creation of human embryos for research purposes or performing research on human embryos that subjects them to significant risk. The prohibition on creating embryos for research purposes would, de facto, prohibit creating a human embryo through cloning technology. This is why including diploid cells in the embryo research ban does not differ practically from banning the creation of human embryos.

The FY 1998 Budget proposed to delete the embryo research ban, stating that the Administration "does not support addressing this issue in legislation." In December 1994, the President had issued a statement barring the use of Federal funds for creating human embryos for research purposes. On June 9, 1997, the President announced that he was sending proposed legislation to the Congress, the "Cloning Prohibition Act of 1997," which would prohibit any attempt to create a

human being using somatic cell nuclear transfer. The Administration did not oppose the language in the FY 1998 bill in its letters or SAP's.

Observations: Last year's budget's proposal to delete this provision came before the cloning debate of last spring (e.g., Dolly).

Given the President's proposed legislation on prohibiting cloning, and the fact that SAP's did not oppose the language during the FY 1998 appropriations process, the Administration may not want to bracket the language again, even with the footnote that says the Administration does not support addressing this issue in legislation.

Message Sent To:

Bruce N. Reed/OPD/EOP@EOP
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Message Copied To:

L/HHS/Ed. General Provisions for FY 1999 Budget
"Side-by-Side" Comparison for Selected Provisions
Titles II and V of L/HHS Bill

FY 1998 Enacted Section No./ Provision	FY 97 Enacted	FY 98 President's Budget	FY 98 Enacted	Recommended FY 99 Language
Sec. 505. Needle Exchange	SEC. 505. Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles for the hypodermic injection of any illegal drug unless the Secretary of Health and Human Services determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs.	SEC. 505. Proposed transfer of authority from the "Secretary of Health and Human Services" to the "Surgeon General".	Sec. 505. Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.	**OMB Staff:** Repeat FY 98 Budget language. **HHS:** No position yet. Alternatives: (1) Give authority to Secretary as opposed to Surgeon General; (2) use footnote approach, i.e., delete provision and say the Administration will work with Congress to resolve.
Sec. 506. Condition on Needle Exchange			Sec. 506. Section 505 is subject to the condition that after March 31, 1998, a program for exchanging such needles and syringes for used hypodermic needles and syringes (referred to in this section as an "exchange project") may be carried out in a community if - (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by such Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.	**OMB Staff:** Delete. Alternative: Footnote saying we will work with Congress. **HHS:** No position yet.

FY 1998 Enacted Section No./ Provision	FY 97 Enacted	FY 98 President's Budget	FY 98 Enacted	Recommended FY 99 Language
Sec. 513. Use of funds for embryo research--limitations	SEC. 512. (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 under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). (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.	Proposed deletion with a footnote that states that the Administration does not support addressing this issue in legislation.	Sec. 513. Same as FY 97 enacted except end of last sentence changed to "...or more human gametes or human diploid cells."	**OMB Staff and HHS:** Repeat FY 98 Budget, i.e., propose deletion with the same footnote: "The Administration proposes to delete this provision and does not support addressing this issue in legislation."
Sec. 509. Appropriation limitations for abortion procedures (Hyde language)	SEC. 508. None of the funds appropriated under this Act shall be expended for any abortion except when it is made known to the Federal entity or official to which funds are appropriated under this Act that such procedure is necessary to save the life of the mother or that the pregnancy is the result of an act of rape or incest.	Proposed deletion with footnote that the Administration will work with Congress to address this issue.	Sec. 509. (a) None of the funds appropriated under this Act shall be expended for any abortion. (b) None of the funds appropriated under this Act shall be expended for health benefits coverage that includes coverage of abortion. (c) The term "health benefits coverage" means the package of services covered by managed care provider or organization pursuant to a contract or other arrangement.	**OMB Staff and HHS**: Repeat FY 98 Budget, i.e., propose deletion, and add footnote:"The Administration proposes to delete this provision and will work with Congress to address this issue."

FY 1998 Enacted Section No./ Provision	FY 97 Enacted	FY 98 President's Budget	FY 98 Enacted	Recommended FY 99 Language
Sec. 510. Appropriation limitations for abortion procedures (Hyde language)			(New provision) Sec. 510. (a) The limitations established in the preceding section shall not apply to an abortion - (1) if the pregnancy is the result of an act of rape or incest; or (2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed. (b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State locality, entity, or private person of State, local, or private funds (other than a State's or locality's contribution of Medicaid matching funds). Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State's or locality's contribution of Medicaid matching funds).	**OMB Staff and HHS:** Delete provision and add footnote: "The Administration proposes to delete this provision and will work with Congress to address this issue."

FY 1998 Enacted Section No./ Provision	FY 97 Enacted	FY 98 President's Budget	FY 98 Enacted	Recommended FY 99 Language
Sec. 212. Appropriation of funds for entities under title X of the Public Health Service Act	SEC. 518. None of the funds appropriated in this Act may be made available to any entity under title X of the Public Health Service Act unless it is made known to the Federal official having authority to obligate or expend such funds that the applicant for the award certifies to the Secretary that it encourages family participation in the decision of the minor to seek family planning services.	SEC. 513 . Same as FY 97 Enacted.	Sec. 212. None of the funds appropriated in the Act may be made available to any entity under title X of the Public Health Service Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services and that it provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.	**OMB Staff**: Repeat FY 98 enacted. **HHS**: No position yet.
Sec. 514. Use of funds for promotions of controlled substances--limitations	SEC. 513. (a) LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES.—None of the funds made available in this Act may be used for any activity when it is made known to the Federal official having authority to obligate or expend such funds that the activity promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812). (b) EXCEPTIONS.—The limitation in subsection (a) shall not apply when it is made known to the Federal official having authority to obligate or expend such funds that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that Federally-sponsored clinical trials are being conducted to determine therapeutic advantage.	SEC. 511. Same as FY 97 enacted.	Sec. 514. Same as FY 97 enacted and FY 98 President's Budget.	**OMB Staff**: Repeat FY 98 Budget language. Same as enacted.

Cloning

Cathy R. Mays 01/09/98 04:59:15 PM

Record Type: Record

To: Laura Emmett/WHO/EOP

cc:
Subject: Slight revisions in bold

---------- Forwarded by Cathy R. Mays/OPD/EOP on 01/09/98 04:59 PM ----------

Jordan Tamagni
01/09/98 04:57:50 PM

Record Type: Record

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

cc: Sara M. Latham/WHO/EOP, Ruby Shamir/WHO/EOP, Cathy R. Mays/OPD/EOP
Subject: Slight revisions in bold

Draft 1/9/98 5:00pm

PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS ON CLONING
January 10, 1998

Good morning. This week, like many Americans, I learned the profoundly troubling news that a member of the scientific community is laying plans to clone a human life. Today, I want to talk about the reasons why we, as a nation, must condemn this plan as a violation of our deepest values.

Last year, news that scientists had successfully cloned a sheep astonished the world. We knew then that this remarkable breakthrough had the potential to yield enormous agricultural and medical benefits. But we also knew that with this great potential came the troubling possibility that these new techniques could be used to clone human life.

I said then and I believe just as strongly today that any discovery that touches upon human creation requires us to move with caution, care, and deep concern about the impact of our actions. That is why I banned the use of federal funds for cloning human beings while we study the risks and responsibilities of such a possibility. And that is why I asked the National Bioethics Advisory Commission to conduct a thorough review of the scientific, moral, and spiritual dimensions of cloning human life. The commission spent three months speaking to families, physicians, religious leaders, and researchers, all of whom agreed unanimously that

attempting to clone a human being is unacceptably dangerous to the child and morally unacceptable to our society.

In response to this overwhelming consensus, I sent legislation to Congress that would ban human cloning for five years, while preserving our ability to study the morally and medically acceptable uses of cloning technology. Unfortunately, Congress has not yet acted on this legislation.

This week, we learned why we need it. While the vast majority of scientists and physicians in the private sector have refrained from using these techniques improperly -- and risen up to condemn any plan to do so -- we know now that there will be those who ignore the consensus of their countrymen and proceed without regard for our common values. So today, I call again on Congress to act now to prevent the use of these techniques to clone a human life. It is untested, it is unsafe, and it is morally wrong.

Let me be very clear about this. I am firmly and fully committed to supporting scientific research and development, because I believe it is essential to our progress as we go forward into the 21st Century. The balanced budget that I submit in just a few weeks to Congress will reflect that commitment. And in my upcoming State of the Union address, I will talk more about what we are doing to keep America on the cutting edge of the scientific and technological advances that are driving the global economy. **But science divorced from values will not bring us one step closer to meeting the challenges or reaping the benefits of of the 21st Century.**

Because ultimately, it is our values that drive our vision for the future -- and our commitment to carry those enduring ideals with us, and to renew their promise in a new century and a new millennium. We must never lose touch with that, no matter the reason, or we will lose touch with ourselves as a people. Thanks for listening.

Message Sent To:

John Podesta/WHO/EOP
Ann F. Lewis/WHO/EOP
John H. Gibbons/OSTP/EOP
Elena Kagan/OPD/EOP
Jeffrey M. Smith/OSTP/EOP

Cloning

Elizabeth Drye
06/12/97 05:23:04 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, William P. Marshall/WHO/EOP, Toby Donenfeld/OVP @ OVP

cc: Sherman G. Boone/OPD/EOP, Rachel E. Levinson/OSTP/EOP
Subject: Cloning g-8 language

Other countries have softened the cloning paragraph so that it no longer calls for legislation or an international ban. That gives us room, I think, to back off of our strict adherance to "somatic cell nuclear transfer." Here's what we've put together trying to use other countries' words where possible at NEC's request; I've sent this to HHS for clearance. Any thoughts?

We have taken note of the recent successful cloning of an adult sheep, which could open the way to the use of cloning for the replication of human individuals. While recognizing the considerable benefits for basic research, agriculture, and human health from cloning technology, we regard the deliberate cloning of human beings as ethically unacceptable. We are encouraged by the serious attention being given to the ethical implications of this technology by both national and international bodies. This will enable a measured approach to the debate on which uses of this technique are, and which are not, unacceptable. We support international cooperation to enforce common aspects of national policies on the use of cloning to create human beings.

Cloning

Elizabeth Drye
06/09/97 05:17:19 PM

Record Type: Record

To: Joshua Silverman/WHO/EOP

cc: Elena Kagan/OPD/EOP, Laura Emmett/WHO/EOP
Subject: unofficial Q&A

Q. Why is the Federal government getting involved? Shouldn't that be left to the states?

A. The federal government has the experience and expertise to evaluate emerging technologies -- particularly biomedical technologies -- and ensure that the public is not put at risk. This is why, for example, the Federal government has responsibility for ensuring the safety and development of pharmaceuticals and medical devices.

Q. But does the Constitution give the Federal government authority to ban cloning?

A. Under the Commerce Clause of the Constitution it is clear we have authority to act. Cloning facilities, like reproductive health facilities and biomedical research centers, would likely affect interstate commerce in a number of ways -- for example, by acquiring equipment and medical products from other states; by serving clients from other states; by advertising accross state lines, and by sharing information and research findings in a national arena.

Cloning

Genentech, Inc.

JUN 9 1997

Elena/Michael W.
Podesta wanted you to see this, he thought it was an impt. message

808 17th Street, NW, Suite 250
Washington, DC 20006
Tel: (202) 296-7272
Fax: (202) 296-7290

June 6, 1997

John Podesta
Deputy Chief of Staff
Office of the President
White House
Washington, DC 20500

Dear John:

Just a short note to call to your attention the political risks of proceeding with legislation of banning the cloning of human beings unless there is a clear Congressional game plan. If the National Bioethics Advisory Commission (NBAC) recommends legislation --- as appears likely --- it will quickly get sidetracked into an abortion/ embryo research issue (see the Wall Street Journal article, attached, with the views of "right to life" and Senator Bond).

Equally problematic for the biotech industry and the science community would be the lack of a clear statement from the President that pursuing legislation to ban the cloning of entire human beings can not include any provisions that will interfere with research that is necessary for biomedical, agricultural or other valid purposes. Without such a strong Presidential statement from the beginning of the debate, the risk of mischievous amendments is real.

We have communicated these views to others within the White House family including Chris Jennings, Don Gips and others. Please let us know if we can help thread this needle. Even though the industry would strongly prefer legislation, we have informally communicated suggested language that would limit the scope of the problem to the NBAC and its staff.

Thanks for all that you do everyday to help preserve, protect and defend.

Sincerely,

David Beier
Vice President, Government Affairs

DB/drw

The Wall Street Journal June 5, 1997

U.S. Panel May Urge Legislative Ban On the Creation of Humans by Cloning

By Laurie McGinley
Staff Reporter of The Wall Street Journal

WASHINGTON — A federal advisory board is considering recommending a legislative ban on the creation of humans by cloning, but antiabortion groups complain such an action would fall short because it wouldn't bar cloning experiments for research only.

President Clinton asked the 18-member panel, called the National Bioethics Advisory Commission, for guidance on how to deal with cloning issues after Scottish scientists in February cloned a sheep named Dolly from a cell of another adult sheep. The group has had several meetings on the topic and is expected to wrap up its work this weekend.

In a draft report dated May 16, the panel recommends:

- A continuation of the current federal funding ban for research related to human cloning.
- An immediate request to scientists and businesses in the private sector "to voluntarily comply with the intent of the federal moratorium."
- Narrowly focused legislation to prohibit, in both the public and private sectors, the attempt to create a child using the technique used to create Dolly, called the adult nuclear transfer technique. This technique, which has never been tried on humans but remains at least a theoretical possibility, calls for producing an embryo by inserting adult cells in an egg whose nucleus has been removed.

A copy of the draft was obtained by The Wall Street Journal. It was reported in the Washington Post. People knowledgeable about the group's deliberations say that some questions remain in dispute and that some recommendations may be changed before the report goes to the president.

The draft says that allowing attempts to produce a child by cloning is "unethical at this time because of lack of evidence that it is effective and safe."

The draft recommendations don't address the issue of human cloning experiments for research only, and thus wouldn't change the status quo. Under current law, such experiments can't be funded by the federal government because they involve human embryos. But they may be conducted by the private sector, as may other types of human embryo research.

Antiabortion groups oppose experiments on human embryos, including those involving cloning, because the embryos are discarded when the research is finished. "We see cloning as a grave evil, but once a child's life begins, that embryonic child has a right to life," said John Cavanaugh-O'Keefe, a spokesman for the American Life League, an antiabortion group based in Stafford, Va. The group plans to press Congress for a complete prohibition on human cloning work, including private experimentation for research only.

Sen. Christopher Bond (R., Mo.) expressed sympathy for Mr. Cavanaugh-O'Keefe's view, saying that the draft recommendations appear "unacceptable" and would prompt him to "continue to fight to have Congress go further toward banning these practices."

Cloning

June 8, 1997

PRESENTATION OF THE CLONING REPORT

DATE:	June 9, 1997
LOCATION:	Rose Garden
BRIEFING TIME:	11:00 am -11:30 am
EVENT TIME:	11:30 am -12:10 am
FROM:	Jack Gibbons, Elena Kagan

I. PURPOSE

To receive the National Bioethics Advisory Commission (NBAC) report on the possible cloning of human beings, and to announce your response to the NBAC recommendations.

II. BACKGROUND

In February, following reports of the first successful cloning of an adult sheep, you asked NBAC to review the profound ethical issues raised by the possible cloning of human beings. At this event, Dr. Harold Shapiro, the Chair of the Commission and President of Princeton University, will formally present you with its report.

NBAC unanimously concluded that it is morally unacceptable at this time to create a child by using the technology that created Dolly the sheep. The Commission also found that the cloning of DNA, cells, tissues, and animals using somatic cell nuclear transfer and other cloning techniques is not ethically problematic, may have many agricultural and medical benefits, and should not be banned. The Commission chose not to address at all issues related to embryo research, including the cloning of embryos for research purposes. The legislation recommended by the Commission bans the "Dolly" technology only when used for the purposes of creating human beings.

You will be making the following announcements to respond to the NBAC recommendations:

- Propose legislation prohibiting the use of somatic cell nuclear transfer to create a human being. The legislation also directs NBAC to report back in 4 ½ years on whether to continue the ban.
- Keep in effect the moratorium you put in place in March so that while legislation is pending no federal funds will be used to clone human beings,
- Urge privately-funded scientists and clinicians to adhere to the voluntary moratorium you called for in March while legislation is pending.

III. PARTICIPANTS

Briefing Participants:
Erskine Bowles
Jack Gibbons
Elena Kagan
Secretary Shalala
Harold Varmus
John Hilley
Michael Waldman

Event Participants:
The Vice President
Dr. Harold Shapiro, NBAC Chair

Also Seated on Stage:
Secretary Shalala
Harold Varmus

Members of the National Bioethics Advisory Commission, the President's Committee of Advisors on Science and Technology, and Members of Congress will be seated in the audience.

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- You will meet briefly with the members of the National Bioethics Advisory Commission in the Oval Office prior to event. (*This is the first time you will have met with NBAC.)
- You will be announced into the Rose Garden accompanied by the Vice President, Dr. Harold Shapiro, Secretary Shalala, and Harold Varmus.
- The Vice President will make welcoming remarks.
- Dr. Harold Shapiro will makes remarks and present the NBAC report to you.
- You will accept the report and make remarks.
- Following remarks, you will depart the Rose Garden and meet with Members of the President's Committee of Advisors on Science and Technology in the Roosevelt Room.

VI. REMARKS

Remarks Provided by Jordan Tamagni in Speechwriting.

Meet and Greet with National Bioethics Advisory Commission

Harold T. Shapiro, Chair of the National Bioethics Advisory Commission, is the President and Professor of Economics and Public Affairs, Princeton University and is a world-renowned educator and economist. He is a member of numerous honorary professional societies including the Institute of Medicine and has been awarded many honorary degrees. Dr. Shapiro serves on advisory boards to several public organizations and corporations and is a past member of the President's Committee of Advisors on Science and Technology (1990-1993). He earned a B-Comm. from McGill University, and an M.A. and Ph.D. in economics from Princeton University.

Members of the National Bioethics Advisory Commission

Patricia Backlar, of Oregon, Senior Scholar at the Center for Ethics in Health Care, Oregon Health Sciences University.
Arturo Brito, M.D., of Florida, Assistant Professor of Clinical Pediatrics at the University of Miami School of Medicine.
Alexander M. Capron, L.L.B., of California, co-director of the Pacific Center for Health Policy and Ethics at the University of Southern California.
Eric J. Cassell, M.D., F.A.C.P., of New York, Physician to In-Patients at The New York Hospital-Cornell Medical Center.
R. Alta Charo, J.D., of Wisconsin, Assistant Professor in the University of Wisconsin Medical and Law Schools.
James F. Childress, Ph.D., of Virginia, Edwin B. Kyle Professor of Religious Studies and Professor of Medical Education at the University of Virginia, and co-director of the Virginia Health Policy Research Center.
David R. Cox, M.D., Ph.D., of California, Professor of Genetics and Pediatrics at the Stanford University School of Medicine.
Rhetaugh Graves Dumas, Ph.D., of Michigan, Vice Provost for Health Affairs, The University of Michigan.
Ezekiel J. Emanuel, M.D., Ph.D., of Massachusetts, Assistant Professor of Medicine, Social Medicine and Clinical Epidemiology at the Dana-Farber Cancer Institute, Harvard Medical School. ***He is Rahm Emanuel's brother.***
Laurie M. Flynn of Virginia, Executive Director of the National Alliance for the Mentally Ill.
Carol W. Greider, Ph.D., of New York, Senior Staff Scientist, Cold Spring Harbor Lab.
Steven H. Holtzman of Massachusetts,Chief Business Officer, Millenium Pharmaceuticals,Inc.
Bette O. Kramer of Virginia, President of the Richmond Bioethics Consortium.
Bernard Lo, M.D., of California, Professor of Medicine and Director of the Program in Medical Ethics at the University of California, San Francisco.
Lawrence H. Miike, J.D., M.D., of Hawaii, Director of the Dept. of Health, State of Hawaii.
Thomas H. Murray, Ph.D., of Ohio, Professor of Biomedical Ethics and Director of the Center for Biomedical Ethics at the Case Western Reserve University School of Medicine.
Diane Scott-Jones, Ph.D., of Pennsylvania, Associate Professor in the Department of Psychology, Temple University.

Cloning

Qs and As on Cloning
June 9, 1997

Q. What did the Commission recommend?

A. The Commission recommends legislation to prohibit anyone in either the public or private sector from attempting to create a child using the cloning technology that made possible the creation of "Dolly" -- so-called "somatic cell nuclear transfer" technology. The Commission also supports a continuation of the current moratorium on federal funding of creating a child by cloning while the legislation is pending. NBAC is also asking the private sector to comply with the voluntary moratorium President Clinton called for in March, pending the legislative prohibition. Finally, NBAC also called for continuing public dialogue on these issues to further understand the ethical and social implications of this technology.

Q. What exactly does the President's legislation ban?

A. The President's legislation prohibits the use of somatic cell nuclear transfer to create a human being (specifically, "with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being").

Q. How will the prohibition be enforced?

A. The legislation gives the Attorney General authority to seek injunctive relief, impose civil fines up to $250,000 or twice the profit from a violation of the Act (whichever is greater), and seize any and all property used in violating the Act (including entire laboratories).

Q. Why doesn't it make cloning a criminal act and impose jail time?

A. We think the penalties in the bill provide an effective deterrent. In particular, they make it clear no one will profit from this activity. It is appropriate to be cautious about criminalizing any activity, and at this point we don't have any indication that we need the threat of criminal sanctions to deter this activity.

Q. But what if Congress wants to impose criminal sanctions?

A. We have seriously considered this option and would be willing to look at it again.

Q. Why is there need for a "sunset" provision?

NBAC recommends -- and the President supports -- a sunset provision, combined

with review by an advisory body prior to the sunset date. There are several reasons to take this approach. First, a sunset provision provides a strong incentive for Congress and the Administration to renew the national debate on cloning within several years, ensuring continued attention to the ethical questions; second, there is a possibility that we will get the precise legislative language wrong the first time around, given our limited understanding of the science, the difficulty of defining terms, and the vagaries of the legislative process; and third, there has been little time to fully consider the moral issues, and it is possible that convictions may evolve.

follow-up

Q. But if you think cloning is morally wrong now, won't it be morally wrong for all time?

Even if one thinks cloning is morally wrong, a sunset provision still makes sense. As I just noted, it will force a renewed national debate within several years and will keep the ethical issues squarely in view. A sunset provision will also make sure we revisit how we've defined the ban and ensure we have done it exactly right.

Q. Why ban the cloning of humans?

A. It is morally unacceptable for anyone in either the public or private sector to attempt this type of cloning. NBAC found it is simply unsafe; knowing that "Dolly" was the only successful case in 277 attempts, there is no doubt that there would be substantial risk to the potential child. And the possibility of replicating ourselves raises other ethical and religious concerns about the implications of this technology for our society. These issues need further discussion before the technology is used.

Q. Why not ban all cloning? What are the potential benefits of cloning research?

A. There are legitimate and beneficial applications of cloning cells, DNA, tissues, and animals: including the development of medicines, and therapies for diseases such as cancer, cystic fibrosis, and diabetes. Cloning also furthers our knowledge about developmental biology that may one day lead to such advances as regeneration of tissue in severe burns and spinal cord injuries.

Q. Why is any additional legislation necessary? Why not extend the President's moratorium?

A. The President's moratorium covers only federally funded activities. In March, President Clinton called for a voluntary ban on privately funded activities. Legislation is necessary, however, to ensure that the privately funded research and clinical centers comply with the proposed prohibition on cloning of human beings using the somatic cell nuclear transfer technique.

Q. With the proposed legislation, are we interfering with people's reproductive freedom?

A. No. We don't think people should have the "freedom" to do this activity. It's unsafe and ethically objectionable.

Q. How will the recommendations and legislation affect research?

A. NBAC found that a ban on human cloning will not impede any important research at this time. Basic research in such areas as animal husbandry and drug development will continue. Similarly, basic research using somatic cell nuclear transfer technology to study, for instance, the potential for regenerating tissues and organs will continue. However, under current federal restrictions, human embryo research using federal funds will remain prohibited.

Q. Why would you (or the Commission) support a total ban on cloning people, but not on creating embryos using cloning technology for research?

A. The issue of embryo research is an important but separate question. NBAC found that the technology that created Dolly doesn't raise new questions related to embryo research. By contrast, the use of somatic cell nuclear transfer technology to create a child raises a host of new and different ethical issues relating to safety, individuality, and family integrity. The President's legislation is directed at these concerns. Further, the President has prohibited the use of federal research funds to create an embryo for research purposes -- whether through cloning or any other means.

Q. If human embryo research is bad, why not ban it in the private sector as well?

A. Whether to ban privately-funded embryo research is a question that needs careful deliberation, as such research may offer medical benefit, particularly with respect to treating infertility. We simply need further discussion about regulation of this activity in the private sector before pursuing legislation.

Q. Does the Federal Government have any jurisdiction over privately funded research with human embryos?

A. If the research is part of an effort to develop a drug, biologic, or medical device, the research is subject to regulation by the Food and Drug Administration. Otherwise, it is unregulated.

Q. What happens to human embryos created for research? If they are not implanted, isn't that tantamount to abortion, or even murder?

A. Creation of human embryos for research is a prohibited use of Federal funds. The extent of such research under private sponsorship is unknown; therefore, we have no reliable information on the fate of human embryos used in this way.

Q. How will this affect childless couples who see cloning as their only chance to have genetically related offspring?

A. Prohibiting this technology will have little practical effect on such couples. Currently neither the science base nor safety considerations make it possible to produce a child by somatic cell nuclear transfer.

Q. Is the United States acting unilaterally on this issue? Are we treating this issue any differently than other countries?

A. Some European countries have already established legal prohibitions on the cloning of humans. To the extent that there are common aspects to our respective policies, we will certainly cooperate with these nations regarding enforcement.

Cloning

"CLONING PROHIBITION ACT OF 1997"

FACT SHEET

The President today transmitted to the Congress the "Cloning Prohibition Act of 1997." This legislative proposal would implement the key recommendation of the National Bioethics Advisory Commission for legislation to prohibit any attempt to create a human being using somatic cell nuclear transfer technology.

The National Bioethics Advisory Commission (NBAC) Report

President Clinton today accepted the NBAC's report on the possible cloning of human beings. In February, following reports of the successful cloning of a sheep, the President asked the NBAC to review the profound ethical issues raised by the possible cloning of human beings. Today, Dr. Harold Shapiro, Chair of the Commission and President of Princeton University, formally presented the report to the President.

The Commission found unanimously that it is morally unacceptable for anyone to attempt to create a child with the technology used to create Dolly the sheep. The NBAC reported that attempting to create a child using so-called somatic cell nuclear transfer cloning would pose great risks to the child and raise other ethical issues needing further discussion. The NBAC called for a moratorium on the use of the technique in humans.

The Commission also found that the new technology may have many agricultural and medical benefits, including the development of medicines, therapies for diseases such as cancer, cystic fibrosis, and diabetes, and prospects for repair and regeneration of human tissues. The NBAC concluded that the cloning of DNA, cells, tissues, and non-human animals --using somatic cell nuclear transfer and other cloning techniques --is not ethically problematic when conducted in compliance with existing regulations and guidelines.

Cloning Prohibition Act of 1997

Acting on the Commission's key recommendation, President Clinton announced legislation banning the use of the new technology to clone human beings. Consistent with the NBAC's recommendation, the President's legislative proposal prohibits for five years the use of somatic cell nuclear transfer to create a human being and directs the NBAC to report to the President in four and a half years on whether to continue the ban. The proposal is carefully worded to ensure that it will not interfere with beneficial biomedical and agricultural activities.

Further Actions By The President

As recommended by the NBAC, President Clinton today also:

- **Reaffirmed that no Federal funds will be used to clone human beings.** The President stated that the prohibition he put in place in March will remain in effect while his proposed legislation is pending.

- **Urged privately funded scientists and clinicians to adhere to the voluntary moratorium he called for in March.** The President asked these professionals to work through their societies and associations to ensure that all adhere to the current voluntary ban while his proposed legislation is pending.

- **Pledged to work with other countries to enforce the prohibition.** Several other countries, including Great Britain, Denmark, Germany, Australia, and Spain, have banned human cloning.

Cloning

TO THE CONGRESS OF THE UNITED STATES:

I am pleased to transmit today for immediate consideration and prompt enactment the "Cloning Prohibition Act of 1997." This legislative proposal would prohibit any attempt to create a human being using somatic cell nuclear transfer technology, the method that was used to create Dolly the sheep. This proposal will also provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings.

Following the February report that a sheep had been successfully cloned using a new technique, I requested my National Bioethics Advisory Commission to examine the ethical and legal implications of applying the same cloning technology to human beings. The Commission concluded 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" and recommended that Federal legislation be enacted to prohibit such activities. I agree with the Commission's conclusion and am transmitting this legislative proposal to implement its recommendation.

Various forms of cloning technology have been used for decades resulting in important biomedical and agricultural advances. Genes, cells, tissues, and even whole plants and animals have been cloned to develop new therapies for treating such disorders as cancer, diabetes, and cystic fibrosis. Cloning technology also holds promise for producing replacement skin, cartilage, or bone tissue for burn or accident victims, and nerve tissue to treat spinal cord injury. Therefore, nothing in the "Cloning Prohibition Act of 1997" restricts activities in other areas of biomedical and agricultural research 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.

The Commission recommended that such legislation provide for further review of the state of somatic cell nuclear transfer technology and the ethical and social issues attendant to its potential use to create human beings. My legislative proposal would implement this recommendation and assign responsibility for the review, to be completed in the fifth year after passage of the legislation, to the National Bioethics Advisory Commission.

I urge the Congress to give this legislation prompt and favorable consideration.

WILLIAM J. CLINTON

THE WHITE HOUSE
June 9, 1997

Cloning

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.

Cloning

EXECUTIVE SUMMARY

The idea that humans might someday be cloned—created from a single somatic cell without sexual reproduction—moved further away from science fiction and closer to a genuine scientific possibility on February 23, 1997. On that date, *The Observer* broke the news that Ian Wilmut, a Scottish scientist, and his colleagues at the Roslin Institute were about to announce the successful cloning of a sheep by a new technique which had never before been fully successful in mammals. The technique involved transplanting the genetic material of an adult sheep, apparently obtained from a differentiated somatic cell, into an egg from which the nucleus had been removed. The resulting birth of the sheep, named Dolly, on July 5, 1996, was different from prior attempts to create identical offspring since Dolly contained the genetic material of only one parent, and was, therefore, a "delayed" genetic twin of a single adult sheep.

This cloning technique is an extension of research that had been ongoing for over 40 years using nuclei derived from non-human embryonic and fetal cells. The demonstration that nuclei from cells derived from an adult animal could be "reprogrammed," or that the full genetic complement of such a cell could be reactivated well into the chronological life of the cell, is what sets the results of this experiment apart from prior work. In this report we refer to the technique, first reported by Wilmut, of nuclear transplantation using nuclei derived from somatic cells other than those of an embryo or fetus as "somatic cell nuclear transfer."

Within days of the published report of Dolly, President Clinton instituted a ban on federal funding related to attempts to clone human beings in this manner. In addition, the President asked the recently appointed National Bioethics Advisory Commission (NBAC) to address within ninety days the ethical and legal issues that surround the subject of cloning human beings. This provided a welcome opportunity for initiating a thoughtful analysis of the many dimensions of the issue, including a careful consideration of the potential risks and benefits. It also presented an occasion to review the current legal status of cloning and the potential constitutional challenges that might be raised if new legislation were enacted to restrict the creation of a child through somatic cell nuclear transfer cloning.

The Commission began its discussions fully recognizing that any effort in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term. Ethical concerns surrounding issues of embryo research have recently received extensive analysis and deliberation in our country. Indeed, federal funding for human embryo research is severely restricted, although there are few restrictions on human embryo research carried out in the private sector. Thus, under current law, the use of somatic cell nuclear transfer to create an embryo solely for research purposes is already restricted in cases involving federal funds. There are, however, no current federal regulations on the use of private funds for this purpose.

The unique prospect, vividly raised by Dolly, is the creation of a new individual

genetically identical to an existing (or previously existing) individual—a "delayed" genetic twin. This prospect has been the source of the overwhelming public concern about such cloning. The Commission recognizes that any creation of embryos for research purposes alone raises serious ethical issues. However, these ethical issues have already been extensively discussed, and the use of somatic cell nuclear transfer to create embryos raises no new issues in this respect. The unique and distinctive ethical issues raised by the use of somatic cell nuclear transfer to create children relate to, for example, serious safety concerns, individuality, family integrity, and treating children as objects. Consequently, the Commission focused its attention on the use of such techniques for the purpose of creating an embryo which would then be implanted in a woman's uterus and brought to term. It also expanded its analysis of this issue to encompass activities in both the public and private sector.

In its deliberations, NBAC reviewed the scientific developments which preceded the Roslin announcement, as well as those likely to follow in its path. It also considered the many moral concerns raised by the possibility that this technique could be used to clone human beings. Much of the initial reaction to this possibility was negative. Careful assessment of that response revealed fears about harms to the children who may be created in this manner, particularly psychological harms associated with a possibly diminished sense of individuality and personal autonomy. Others expressed concern about a degradation in the quality of parenting and family life.

In addition to concerns about specific harms to children, people have frequently expressed fears that a widespread practice of somatic cell nuclear transfer cloning would undermine important social values by opening the door to a form of eugenics or by tempting some to manipulate others as if they were objects instead of persons. Arrayed against these concerns are other important social values, such as protecting the widest possible sphere of personal choice, particularly in matters pertaining to procreation and child rearing, maintaining privacy, and the freedom of scientific inquiry, and encouraging the possible development of new biomedical breakthroughs.

To arrive at its recommendations concerning the use of somatic cell nuclear transfer techniques to create children, NBAC also examined long-standing religious traditions that guide many citizens' responses to new technologies and found that religious positions on human cloning are pluralistic in their premises, modes of argument, and conclusions about human cloning. Some religious thinkers argue that the use of somatic cell nuclear transfer cloning to create a child would be intrinsically immoral and thus could never be morally justified. Other religious thinkers contend that human cloning to create a child could be morally justified under some circumstances, but hold that it should be strictly regulated in order to prevent abuses.

The public policies recommended with respect to the creation of a child using somatic cell nuclear transfer reflect the Commission's best judgments about both the ethics of attempting such an experiment and our view of traditions regarding limitations on individual actions in the name of the common good. At present, the use of this technique to create a child would be a

premature experiment that would expose the fetus and the developing child to unacceptable risks. This in itself is sufficient to justify a prohibition on cloning human beings at this time, even if such efforts were to be characterized as the exercise of a fundamental right to attempt to procreate.

Beyond the issue of the safety of the procedure, however, NBAC found that concerns relating to the potential psychological harms to children and effects on the moral, religious, and cultural values of society merited further reflection and deliberation. Whether upon such further deliberation our nation will conclude that the use of cloning techniques to create children should be allowed or permanently banned is, for the moment, an open question. Time is an ally in this regard, allowing for the accrual of further data from animal experimentation, enabling an assessment of the prospective safety and efficacy of the procedure in humans, as well as granting a period of fuller national debate on ethical and social concerns. The Commission therefore concluded that there should be imposed a period of time in which no attempt is made to create a child using somatic cell nuclear transfer.[1]

Within this overall framework the Commission came to the following conclusions and recommendations.

I. The Commission concludes 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. We have reached a consensus on this point because of insufficient information on the safety and effectiveness of this method in humans. Indeed, we believe it would violate important ethical obligations were clinicians or researchers to attempt to create a child using these particular technologies, which are likely to involve substantial risks to the fetus and/or potential child. Moreover, in addition to safety concerns, many other serious ethical concerns have been identified, which require much more widespread and careful public deliberation before this technology may be used.

The Commission, therefore, recommends the following for immediate action:

- A continuation of the current moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer.

- An immediate request to all firms, clinicians, investigators, and professional societies in the private and non-federally funded sectors to comply voluntarily with the intent of the federal moratorium. Professional and scientific societies should make clear that any attempt to create a child by somatic cell nuclear transfer and implantation into a woman's

[1] The Commission also observes that the use of any other technique to create a child genetically identical to an existing (or previously existing) individual would raise many, if not all, of the same non-safety-related ethical concerns raised by the creation of a child by somatic cell nuclear transfer.

body would at this time be an irresponsible, unethical, and unprofessional act.

II. The Commission further recommends that:

- Federal legislation should be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning. It is critical, however, that such legislation include a sunset clause to ensure that Congress will review the issue after a specified time period (three to five years) in order to decide whether the prohibition continues to be needed. If state legislation is enacted, it should also contain such a sunset provision. Any such legislation or associated regulation also ought to require that at some point prior to the expiration of the sunset period, an appropriate oversight body will evaluate and report on the current status of somatic cell nuclear transfer technology and on the ethical and social issues that its potential use to create human beings would raise in light of public understandings at that time.

III. The Commission also concludes that:

- Any regulatory or legislative actions undertaken to effect the foregoing prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere with other important areas of scientific research. In particular, no new regulations are required regarding the cloning of human DNA sequences and cell lines, since neither activity raises the scientific and ethical issues that arise from the attempt to create children through somatic cell nuclear transfer, and these fields of research have already provided important scientific and biomedical advances. Likewise, research on cloning animals by somatic cell nuclear transfer does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees.

- If a legislative ban is not enacted, or if a legislative ban is ever lifted, clinical use of somatic cell nuclear transfer technique to create a child should be preceded by research trials that are governed by the twin protections of independent review and informed consent, consistent with existing norms of human subjects protection.

- The United States Government should cooperate with other nations and international organizations to enforce any common aspects of their respective policies on the cloning of human beings.

IV. The Commission also concludes that different ethical and religious perspectives and traditions are divided on many of the important moral issues that surround any attempt to create a child using somatic cell nuclear transfer techniques. Therefore, we recommend that:

- The federal government, and all interested and concerned parties, encourage widespread

and continuing deliberation on these issues in order to further our understanding of the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding this technology should the time come when present concerns about safety have been addressed.

V. Finally, because scientific knowledge is essential for all citizens to participate in a full and informed fashion in the governance of our complex society, the Commission recommends that:

- Federal departments and agencies concerned with science should cooperate in seeking out and supporting opportunities to provide information and education to the public in the area of genetics, and on other developments in the biomedical sciences, especially where these affect important cultural practices, values, and beliefs.

RECOMMENDATIONS

I. The Commission concludes 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 the somatic cell nuclear transfer technique. We have reached a unanimous consensus on this point because of the total lack of information on the safety and effectiveness of this method in humans. Indeed, we believe it would violate important ethical obligations were clinicians or researchers to attempt to create a child using these particular technologies, which are likely to involve substantial risk to the potential child. Moreover, in addition to safety concerns many additional serious ethical concerns have been identified which require a great deal more widespread and careful thought and public deliberation before this technology should be used.

The Commission, therefore, recommends the following for immediate action:

X A continuation of the current moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer.

X An immediate request to all firms, clinicians, investigators, and professional societies in the private sector to voluntarily comply with the intent of the federal moratorium. Professional and scientific societies should make clear that any attempt to create a child by somatic cell nuclear transfer and implantation into a woman's body would at this time be an irresponsible, unethical, and unprofessional act.

II. The Commission further recommends that:

X Federal legislation should be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer techniques. It is critical, however, that such legislation include a sunset clause to ensure that Congress will review the issue after a specified time period in order to decide whether the prohibition continues to be needed. If state legislation is enacted it should also contain such a sunset provision. Any such legislation or associated regulation ought also to require that at a specified point prior to the expiration of the sunset period an appropriate oversight body would be responsible for evaluating and reporting on the

current status of somatic cell nuclear technology and on the ethical and social issues that its potential use with human beings would raise in light of public attitudes at that time.

III. The Commission also concludes that:

X Any regulatory or legislative actions undertaken to effect the foregoing prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere inadvertently and unnecessarily with other important areas of scientific research. In particular, the cloning of human DNA sequences and cell lines raises neither the scientific nor the ethical issues that arise from the possible creation of children through somatic cell nuclear transfer, and these fields of research have already provided some scientific and biomedical advances. Likewise, research on cloning of animals by somatic cell nuclear transfer does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees.

X If a legislative ban is not enacted, or if a legislative ban is ever lifted, then any effort to use the somatic cell nuclear transfer technique to create a child should be governed by the twin protections of independent review and appropriate human subjects protections, including informed consent.

X The United States Government should cooperate with other nations and international organizations to enforce any common aspects of their respective policies on the cloning of human beings.

IV. The Commission also concludes that different ethical and religious perspectives and traditions are divided on many of the important ethical issues that surround any attempt to create a child using somatic cell nuclear transfer techniques. Therefore, we recommend that:

X The federal government and all interested and concerned parties encourage widespread and continuing deliberation and thought on these issues in order to further our understanding of the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding this technology should the time come when present concerns about safety have been met.

V. Finally, since scientific knowledge is essential for all citizens to participate in a full and informed fashion in the governance of our ever more complex society, federal departments and agencies concerned with science should cooperate in seeking out and supporting opportunities to provide information and education to the public in the area of genetics and on other developments in the biomedical sciences where these affect important cultural practices and commitments.

INTRODUCTION

The idea that humans might someday be cloned—created from a single cell without sexual reproduction—moved further away from science fiction and closer to a genuine scientific possibility on February 23, 1997. On that date, *The Observer* broke the news that Ian Wilmut, a Scottish scientist, and his colleagues at the Roslin Institute were about to announce the successful cloning of a sheep by a new technique. The technique involved transplanting the genetic material of an adult sheep, apparently obtained from a fully differentiated somatic[1] cell into an egg from which the nucleus had been removed. The resulting birth of the sheep, named Dolly, on July 5, 1996 appears to mark yet another milestone in our ability to control, refine, and amplify the forces of nature.

The Scottish sheep experiment was different from prior attempts to create identical offspring from a single pair of adult animals. It used a cloning technique, referred to in this report as "somatic cell nuclear transfer," to produce an animal that was a genetic twin of an adult sheep. Put another way, Dolly contained the genetic material of only one parent. This technique of transferring a nucleus from a somatic cell into an egg is an extension of experiments that had been ongoing for over 40 years. The fact that somatic cells could be "reprogrammed," or that the genetic complement of the cell could be reactivated well into the chronological life of the cell, is what sets this experiment apart from prior work.

For some time, scientific evidence has suggested that the genetic material contained in differentiated somatic cells still has the potential to direct the development of healthy fertile adult animals, but its capacity to do so remained unproved (DiBernadino, 1997). The Roslin experiment, therefore, was a significant scientific event with potentially profound implications since it brings us closer to the possibility of developing a capacity to clone human beings in an asexual manner. Although for the past ten years scientists have routinely cloned sheep and cows from embryo cells, this was the first successful experiment using the nucleus of a somatic cell to clone an animal that matured to a fully developed state.

The issues surrounding the cloning of human beings have long been the subject of

[1] A somatic cell is any cell of the body other than those destined to become germ cells, i.e., eggs or sperm.

periodic concern and debate among philosophers, scientists, ethicists, and others, particularly following the publication of Joshua Lederberg's 1966 article on cloning in the *American Naturalist* (Lederberg, 1966). Nevertheless, the impact of these most recent developments on our national psyche has been quite remarkable. Some commentators have suggested that the furor aroused by the new possibility for cloning is out of proportion to most of the ethical, legal, and moral issues it raises, since these same issues have been raised by previous developments and are simply emerging again in a novel and striking form. At the same time it is important to acknowledge that the possibilities raised by this new technique would be certainly unprecedented and some would consider its use to be a truly radical step. This type of cloning involves human procreation by asexual means with a predetermined genetic profile and the capacity to create many genetically identical offspring. Perhaps these events also have captured our imaginations as symbols of a much older and deeper narrative that speaks to our concerns regarding the impact of science and technology on our moral lives and on long established cultural values.

Some scientists were surprised that the technical barriers of cell differentiation and development seemingly could be so easily overcome when using somatic cells as the source for nuclear transfer. The public—including many members of the scientific community—responded to Dolly with a combination of fascination, hope for useful new understandings of human biology, and profound concern—even alarm—about the prospect of being able to create whole humans from a single somatic cell via nuclear transfer cloning techniques. Although much of the initial public reaction was one of fear, concern, and serious moral reservations about the potential use or abuse of this new technological capacity, a few voices were heard cautiously suggesting that a better understanding of cell dynamics in humans and animals might enable us to develop new cures for various diseases. Thus, it is important that we reflect not only on the dangers and ethical reservations but also on the potential human benefits from the use of this type of cloning that might arise in such areas as treating particular infertility problems, transplanting cells or tissues, or preventing certain genetically transmitted harms to offspring.

A few of the initial objections to this new type of cloning were either speculative or based on simple misunderstanding, for example, that cloning would allow for the instantaneous creation of a fully grown adult from the cells of an individual. Other fears stemmed from the incorrect idea that an exact copy, although much younger, of an existing person could be made. This fear reflects an erroneous belief that one's genes bear a simple relationship to the physical and psychological traits that make up a person. Although genes provide the building blocks for

each individual, it is the interactions between a person's genetic inheritance, the environment, and the process of learning that result in the uniqueness of each individual human. Thus the idea that nuclear transplantation cloning could be used to re-create exemplary or evil people has no scientific basis and is simply false.

Other objections to nuclear transplantation cloning, however, are based on carefully articulated philosophical ideals, deep cultural commitments, or religious beliefs, and these deserve continuing and careful consideration. These objections reflect deeply held beliefs about the value of human individuality and personal autonomy, the meaning of family and the value of a child, respect for human life and the natural world, and the preservation of the integrity of the human species.

Many public leaders in the United States responded to the announcement about Dolly with immediate and strong condemnation of any attempt to clone human beings in this new manner. The reasons ranged from frightening science fiction imagery to the judgment that cloning of human beings is a serious violation of basic human rights and human dignity. The reaction abroad was similar, with many nations seemingly ready—indirectly or directly—to prohibit cloning human beings in this fashion. Indeed, many international organizations such as UNESCO and the Council of Europe have a long-established and well-articulated concern that research and clinical applications in biology and genetics remain consistent with a fundamental commitment to human dignity and human rights. To date, Australia, Great Britain, Denmark, Germany, and Spain have enacted laws banning cloning human beings. Unfortunately, some of the deep concerns supporting such views and associated legislation are stated in vague or overly broad terms. The widespread public discomfort, even revulsion, about cloning human beings deserves the best articulation possible, a task which takes time and requires the considered reflections of diverse groups within American society and abroad.

Within days of the published report of the apparently successful cloning of a sheep in this new manner, President Clinton instituted a ban on federal funding for research related to cloning of human beings. In addition, the President asked the recently appointed National Bioethics Advisory Commission (NBAC) to address within ninety days the ethical and legal issues that surround the subject of cloning human beings. This provided a welcome opportunity for initiating a thoughtful analysis of the many dimensions of the issue, including a careful consideration of the potential risks and benefits. It also presented an occasion to review the current legal status of cloning and the potential constitutional challenges that might be raised if

new legislation were enacted to restrict the creation of a child through somatic cell nuclear transfer.

Controlling Nature

Humankind's efforts to control nature date back as far as recorded history. In particular, domesticated plants and animals have been the mainstay of our agricultural heritage. Over time human mastery over nature often has been met, quite understandably, with opposition and concern, and frequently has been considered by some to be an affront to the natural order of things or by others to be at odds with interpretations of God's revealed word. Indeed many myths and legends, ancient as well as modern, deal directly with humankind's on-going struggle to ensure that the benefits of our new technological capacities clearly outweigh the harms—both expected and unexpected. The idea that our growing technological mastery is filled with moral ambiguity and capable of both vast good and catastrophic evil is deeply embedded in many cultural traditions.

A prime example is the mythology of the Argo, the first ship, in classical Greek culture. The Greeks see the initial act of shipbuilding as both the origin of culture and the origin of decline. While sailing enables one to encounter other persons and other possibilities, it also brings marauders and war, and its very existence bespeaks the danger of unlimited human desire. Thus, the ability to build and sail boats is both a boon and a curse. Euripides' Medea starts with a lament about the trees that were cut down to build the Argo and the other troubles that followed.

> Would that the Argo had never winged its way to the land of Colchis....
> Would that pine trees had never been felled in the glens of Mount Pelion and
> furnished oars for the hands of the heroes who at Pelias' command set forth in
> quest of the Golden Fleece.

Concern about our tools and technology has been greatly accelerated with the coming of modern industrialized societies. Is it possible, some now wonder, that our confidence in human competence and technology may be just another myth? How, some are now asking, can we find some moral compass or moral limit to our desire to master everything and possess all? Only such limits, many would say, can save us from the moral ambiguity of our own cleverness.

In recent years, concern about humankind's control over nature has been particularly acute

in relation to the new moral choices created by the stunning developments in the biomedical sciences, especially in the area of human reproduction. Although personal reproductive health is considered to be, in most cases, a private matter, ongoing controversies regarding the moral standing of human genetic material and particular human interventions in procreation have focused public attention on the ethical and legal implications of new reproductive techniques. In many cases, initial fears give way to cautious acceptance, but a wariness lingers that is easily reawakened with each new advance.

Artificial insemination by donor, for example, was considered a form of adultery when first introduced in the 1940s. It is now a widely used and accepted practice in the treatment of infertility, although some continue to have serious reservations. When prenatal diagnosis was introduced in the late 1960s, the public simultaneously welcomed the opportunity to prevent lethal disease in newborns but worried about the use of such techniques to select "vanity" characteristics or nonmedical traits in offspring. The birth of Louise Brown, conceived via *in vitro* fertilization, in 1978 was another dramatic event, providing a new and controversial means to parenthood. With all of these technical advances, there has been a continuing debate about safety, legality, ethical acceptability, and the government's right to intervene in private matters.

Research itself, not just its clinical application, has often sparked debate. For example, research involving human fetuses has been a subject of intense national debate and disagreement for over two decades (Institute of Medicine, 1994). Federal research in this area continues to be restricted to that which has potential therapeutic benefit to the fetus, or involves no more than minimum risk to the fetus even if potential benefit to the mother can be demonstrated. Restrictions also remain regarding embryo research. Despite the cautious recommendations of the National Institutes of Health Human Embryo Research Panel (1994), that certain targeted and carefully regulated research using early human embryos be eligible for federal funds, in December 1994 the President directed NIH not to allocate federal funds for research programs that involved the creation of human embryos for research purposes. This issue was also addressed by Congress, which inserted language in the FY96 and FY97 appropriations bills that widened the presidential ban to prohibit virtually all human embryo research conducted with federal funds. Work in this area continues in the United States, but it is largely limited to the private sector and takes place without any federal regulation.

PNR

Recombinant DNA research represents another example of controversy and intense debate. In the 1970s concerns about the safety of unintended release of recombinant organisms

led to a voluntary research moratorium in the scientific community and the development of guidelines (Fredrickson, 1991). Similarly, until recently all experiments involving gene therapy (treatment of specific diseases by inserting human genes into human patients) have been subject to guidelines and review by a federal body.

As segments of human DNA or human cells became the focus of study and the objects of manipulation, their use as research materials raised increasingly important ethical issues about how these materials are obtained, transformed, and, in some cases, used to develop commercial products (Office of Technology Assessment, 1987). Such research with human genetic material generates questions about respect for persons and the human body, and the value and moral status to be placed on cells and tissues.

Genetic and reproductive technologies also cause concern because of the specter of eugenics and of real or imagined social control through manipulation of human genes. Genetic control suggests broken taboos, and, in the words of Henry David Thoreau, implies that "men have become the tools of their tools"(Blank, 1981). While these concerns are often set against and partly attributable to a backdrop of fiction, fantasy, and misunderstanding, they are, more importantly, related to profound concerns regarding the nature of humankind and its relationship to other aspects of the natural world.[2] When the bizarre and fantastic scenarios are removed, we are left with a myriad of reactions: sincere expressions of opposition; serious moral concerns; new hope for a better understanding of human biology and the prospect of combating currently untreatable afflictions; calls for more study; and guarded statements about the need for some measure of control (Macklin, 1994; 1997).

Controlling Science

With some notable exceptions, the scientific community has enjoyed for centuries a great deal of autonomy in directing and regulating its research agenda. Since mid century, however, demands for external regulation have increased, in part because much research, particularly in the biological sciences, is publicly funded and therefore requires some additional measure of

[2] With respect to interesting fiction consider Aldous Huxley's Brave New World (1932), David Rorvik's unsubstantiated claim of successful human cloning in In His Image (1978), and popular films such as The Boys from Brazil (1978) and Jurassic Park (1993) in which cloning leads to dire, doomsday consequences.

accountability. More importantly, society has become more sensitive to concerns about the dangers—particularly to human participants—of the research itself and its future consequences. Further, our evolving moral sensibilities, together with the spectacular advances in biomedical science have generated new ethical concerns. As Bernard Davis of Harvard Medical School and others have noted, society sometimes seeks to regulate or restrict research when it poses the specters of dangerous or unfamiliar products, powers, or ideas (Davis, 1980).

The regulation of science has thus become part of the landscape, particularly for those who receive federal funds (Office of Technology Assessment, 1986). In addition to environmental, health, occupational, and safety regulations, scientists must also comply with animal welfare and human subjects protections and abide by restrictions and moratoria on specific types of research. Because science is both a public and social enterprise and its application can have profound impact, society recognizes that the freedom of scientific inquiry is not an absolute right. There are times when limits must be imposed, even if such limits are perceived as an impediment by an individual scientist. Limits on freedom of inquiry, however, must be justified, and impositions on such freedom should satisfy certain conditions—for example, that the limits are not arbitrary, that they emerge from the thoughtful balancing of costs and benefits, that they are not unnecessarily oppressive, that they do not lightly impinge on long established rights and freedoms, that there is some continuing public discourse with those affected by the ban, and that such limitations be open to reconsideration in the light of new information and new understanding.

Consideration of Ethical and Religious Perspectives

When the President asked NBAC to take up the issue of the cloning of human beings he admonished that "any discovery that touches upon human creation is not simply a matter of scientific inquiry, it is a matter of morality and spirituality as well." Although well aware that the United States Constitution prohibits the establishment of policies that are *solely* motivated by religious beliefs, NBAC shared the President's concern and sought out testimony about the cloning of human beings from leading scholars from a variety of religious traditions. In the same spirit NBAC also commissioned a background paper on the positions a number of religious traditions have taken or are considering on the cloning of human beings.

NBAC felt this was especially important because religious traditions influence and shape the moral views of many U.S. citizens and religious teachings over the centuries have provided

an important source of ideas and inspiration. Although in a pluralistic society particular religious views cannot be determinative for public policy decisions that bind everyone, policy makers should understand and show respect for diverse moral ideas regarding the acceptability of cloning of human beings in this new manner.

Although some religious responses to the cloning of human beings through somatic cell nuclear transfer are tied tightly to particular scriptural texts or other faith commitments, often these ideas can be stated forcefully in terms understandable and persuasive to all persons, irrespective of specific religious beliefs. For example, appeal may be made to a view of human nature or of human reason, rather than exclusively to a religious source of knowledge such as scripture or revelation.

NBAC also wanted to determine whether various religious traditions, despite their distinctive sources of authority and argumentation, reach similar conclusions about this type of human cloning. A convergence of views across these traditions, as well as across secular traditions, would be instructive, even if not necessarily determinative, for public policy.

While many Americans look to their religious faiths for moral guidance on issues, other sources of moral knowledge and insight are also important. Many moral considerations that would be widely acknowledged as legitimate do not depend for their force on particular religious commitments or a specific philosophical outlook. For example, the conviction that it is wrong to harm a child is broadly shared among Americans. If you inquire why it is wrong to harm a child, people may give different answers. Some may refer to their religious convictions that a child is a gift from God. Others may say that it is always wrong to harm an innocent person without some compelling reason. To many people, this is a bedrock principle of ethics, even if it has no single, universally acknowledged foundation in a specific religious or philosophical tradition. Rather, it finds its foundation in many different understandings of morality, some religious, some secular. Moral ideas such as the obligation not to inflict harm on others are accessible to all Americans and, therefore, can provide a robust foundation for public policy.

America has a vibrant tradition of ethical dialogue in which all are invited to participate. What moral considerations deserve our attention and which are the most important in responding to a particular issue? These are questions that arise with every new controversy. Whether one's ethical beliefs come from theological commitments, philosophical arguments, or from hard-won life experience, all voices should be welcome to the conversation, and all thoughtful views are

entitled to a respectful hearing.

Policy makers need to consider a range of moral views when they try to determine whether a particular policy is ethically justifiable as well as politically feasible. A particular policy may not be politically feasible, for instance, if it evokes thoughtful, widespread and vigorous moral opposition. In such circumstances its social costs may outweigh its putative benefits, and additional education and deliberation may be required before new policies are put in place.

Consideration of Law and Public Policy

The public policy chosen with respect to the cloning of human beings via somatic cell nuclear transfer should reflect a keen knowledge of the science, our best judgments about the ethics of attempting such an experiment, and our traditions regarding limitations on individual actions in the name of the common good. Americans in this era, relative to earlier generations, have a wide interest in and substantial knowledge of science. Nevertheless, in the weeks following the report of Dolly both the public, the media, and even some scientists demonstrated a surprising lack of understanding of the science involved in cloning. NBAC believes that public debate about issues such as human cloning requires an even more educated populace. Science policy has become public policy, which can only be wisely decided by an informed nation.

American tradition has been to avoid prohibiting or regulating personal activities, absent a compelling reason related to effects on others or society as a whole. Where the individual actions are expressions of fundamental rights, such as the right to free speech or the right to privacy, the reasons for limitation must be compelling, and the limitations made as minimal as possible.

The possibility of cloning human beings in this new fashion appears to raise concerns about direct physical harms to the children who may result. This in itself is sufficient to justify a prohibition on such attempts at this time, even if such efforts were to be characterized as the exercise of a fundamental right to procreate. More speculative psychological harms to the child, and effects on the moral, religious, and cultural values of society may be enough to justify prohibitions in the future, but more time is needed for discussion of these concerns.

In its discussion of potential policy options, the Commission considered the relative

benefits of achieving an immediate prohibition through federal legislation on cloning human beings using somatic cell nuclear transfer techniques. It also considered more indirect means to deter such experiments.

Indirect, non-legislative options considered by the Commission include cooperation by the private sector, both research and clinical, in a moratorium on such experiments and/or clinical practice, and the continued prohibition of the use of federal funds to support such experiments. The American Medical Association and the World Medical Association, for example, have already called for such a moratorium on clinical activities.

The Commission also weighed, in terms of nuclear transplantation cloning, the potential impact of a possible legislative measure to extend basic human subjects protections to all research conducted in the United States. This would insure that any research efforts to clone a human in this manner would, along with all other research using human subjects, be covered by the twin protections of informed consent and appropriate scientific review to insure an ethically acceptable balance between risks and benefits. In light of the early state of animal research in this area, such protections should prevent such cloning research from going forward at this time.

Finally, NBAC recognized that cooperation with our foreign counterparts in the enforcement of any common elements of our respective policies could strengthen any of the measures adopted by the United States. Since science is a global endeavor, cooperation with our foreign counterparts would ensure consistency across borders and enhance public confidence in scientific research generally.

Process of NBAC and Organization of the Report

The results of NBAC's 90-day analysis are presented in this report. In its deliberations, NBAC focused its discussion on the science of the cloning of human beings using the somatic cell nuclear transfer technique, and the ethical, religious, legal, and regulatory implications of cloning human beings in this manner. To aid in these tasks the Commission invited testimony from an array of scientists, scientific societies, ethicists, theologians, and legal experts, and heard from a wide variety of interested parties during the public comment session at each meeting. In addition, it commissioned numerous background papers from recognized experts to inform its work.

This report consists of five chapters in addition to this one. Chapter Two describes the scientific developments which preceded and made possible the cloning of Dolly and speculates on potential applications of this and related technologies. Chapter Three presents some of the key themes in religious interpretations and evaluations of human cloning. Chapter Four outlines the numerous ethical concerns raised by the prospect of cloning human beings via somatic cell nuclear transfer. Chapter Five discusses the legal and policy issues considered by the Commission as it pondered various recommendations. The final section, Chapter Six, presents the recommendations made by the Commission in response to the President's request.

In many instances, the Commission found itself moving at a rapid pace in only partly charted waters. In those times it relied on its individual and collective wisdom, judgment, and moral foundations, and the advice of others. The Commission argued and debated the issues as it searched for appropriate formulations of the problem and the wisdom to suggest useful policy options. While the members of the Commission learned a great deal during its deliberations, we could not reach a resolution on all of the issues before us. Nevertheless, it was able to accomplish two things. First, it developed a set of recommendations, which are set out in Chapter Six. Second, it agreed that it was important to take a number of steps to ensure the continuation of an informed national discussion of these issues and other developments in the biomedical sciences and clinical practices that have an impact on our moral lives and cultural traditions.

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LEGAL AND POLICY CONSIDERATIONS

The public policies chosen with respect to the creation of a child using somatic cell nuclear transfer should reflect both our best judgments about the ethics of attempting such an experiment and our traditions regarding limitations on individual actions in the name of the common good. At present, the use of this technique to create a child would be a premature experiment that exposes the developing child to unacceptable risks. This in itself is sufficient to justify a prohibition on cloning human beings at this time, even if such efforts were to be characterized as the exercise of a fundamental right to attempt to procreate. More speculative psychological harms to the child, and effects on the moral, religious, and cultural values of society may be enough to justify prohibitions in the future, but more time is needed for discussion of these concerns. The prohibition on cloning human beings via somatic cell nuclear transfer could be effectuated directly, through federal legislation, or indirectly, by way of a collection of efforts aimed at deterring such experiments. These efforts include voluntary cooperation by the private sector, both research and clinical, in a moratorium on such experiments, and a continued prohibition of the use of federal funds to support such experiments. Enhancement of protections for human subjects of medical research and cooperation with our foreign counterparts in the enforcement of any common elements of our respective policies could strengthen any of these measures.

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This chapter briefly reviews existing and proposed laws and policies that would affect efforts to clone human beings via somatic cell nuclear transfer, as well as the potential constitutional challenges that might be raised if such efforts are restricted.[1]

Almost immediately after the announcement of Dolly's birth, legislation was introduced in the Congress and in approximately a dozen states, aimed at prohibiting all or some research on human cloning (see Table 1). Some of the bills would prohibit the use of somatic cell nuclear transfer cloning to create a child; others would also, either deliberately or inadvertently, prohibit

[1] To support the Commission's review, a commissioned paper, "The Current and Future Legal Status of Cloning" was prepared by Lori Andrews, Chicago-Kent College of Law. In addition, NBAC commissioned a review of research moratoria, "Do Research Moratoria Work?" prepared by Robert M. Cook-Deegan, and a review of international responses, "Cloning: An International Comparative Perspective," prepared by Bartha Knoppers, University of Montreal.

research on cloning DNA sequences or cell lines. The current moratorium on the use of federal funds for the cloning human beings in this manner has provided an opportunity for additional analysis of the potential risks and benefits of human cloning, its current legal status, and the potential constitutional challenges that might be raised if new legislation is enacted to restrict such acts.

Laws Affecting Efforts to Clone a Human Being

At present, there is no law in the United States directly addressing attempts to create a child through somatic cell nuclear transfer. A variety of state and federal laws or policies, however, do have some application.

At the federal level, there is a law that requires monitoring of clinics that use assisted reproduction techniques, such as *in vitro* fertilization, which would appear to apply to efforts to use somatic cell nuclear transfer cloning to create a child. This statute, the Fertility Clinic Success Rate and Certification Act of 1992 (42 U.S.C.A. Sec. 263a-1 et seq), covers all laboratories and treatments that involve manipulation of human eggs and embryos, and requires that rates of success at achieving pregnancies be reported to the Department of Health and Human Services (DHHS) for publication in a consumer guide. It also directs DHHS to develop a model program for inspection and certification of laboratories that use human embryos, to be implemented by the states.

Implementation of this law would mean that any clinic or laboratory involved in attempts to initiate pregnancies by somatic cell nuclear transfer cloning would be identifiable to the federal government, and the outcomes of its efforts known to the public. As states move to implement the inspection and certification aspects of the law, it would also mean that a mechanism would exist to prevent attempts to use the technology, if it is shown to be ineffective or dangerous for the tissue donor or resulting child.

Federal law also exists that will have an impact on the conduct or funding of any research aimed at cloning human beings. Research that is conducted with federal funds or at institutions that have executed an agreement with the federal government is subject to the regulatory provisions aimed at ensuring that the human subjects are not exposed to unreasonably risky experiments and are enrolled in research only after giving informed consent (45 C.F.R. Part 46).

Enforcement of these protections lies primarily in the hands of "Institutional Review Boards," which are committees that review experiments before people can be enrolled. To the extent that efforts to clone human beings take place at institutions subject to these regulations or in experiments funded by the federal government, concerns about the physical harms that might result would make it difficult for such experimentation to be approved.

With regard to research funding, President Clinton announced in 1994 that the National Institutes of Health (NIH) should not finance any research that involves the creation of embryos that would be used solely for research that would result in their destruction.[2] Furthermore, Congress has passed prohibitions on the use of FY96 and FY97 funds appropriated to the Departments of Labor, Education, and HHS for any research that involves exposing embryos to risk of destruction for non-therapeutic research.[3] The net effect of these policies is to eliminate virtually all federal funding for research on cloning human beings, as even research aimed at initiating a pregnancy would probably involve the destruction of many embryos that fail to develop normally.

While this does not mean that privately financed research could not continue, there are a number of state laws regarding the management of embryos that arguably could restrict even private research.[4] By and large, however, states do not have legislation directly regulating assisted reproduction techniques, leaving state law covering medical malpractice as the primary means for regulating clinical application of the technology.[5]

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[2]"Statement of the President on NIH Recommendations Regarding Human Embryo Research," U.S. Newswire (Dec. 2, 1994).

[3]P.L. 104-91 and P.L. 104-208.

[4]Add cite listing embryo statutes from lori andrews' contract

[5]If cloning is considered to be a form of fertilization, questions arise regarding whether state laws setting standards for who may perform *in vitro* fertilization will cover the practice. Certain laws governing reporting, the qualifications of personnel, and so forth, will be applicable to researchers. A New Hampshire law, for example, requires counseling in advance of *in vitro* fertilization and limits the procedure to participants over age 21 (which, if applied to cloning, might prohibit the use of DNA from a minor child). Pennsylvania has a reporting requirement which mandates that anyone performing *in vitro* fertilization file quarterly reports with the Department of Health describing such facts as the number of embryos destroyed and discarded and the number of women in whom embryos are implanted. Louisiana's law requires that *in vitro* fertilization shall only be undertaken by practitioners and facilities meeting the

State laws governing family relationships would also be applicable if efforts to clone human beings were successful. But paternity acts, surrogacy statutes, and egg donation statutes are not necessarily broad enough to address the kinship relationships involved in cloning human beings. The use of this technique would result in a child having as many as four individuals with claims to parental status based on some aspect of genetic connection: the person from whom the cell nucleus was derived, that individual's genetic parents, and the woman contributing the enucleated egg cell which contains a small fraction of DNA in the cytoplasmic mitochondria. In addition, if the egg with the transferred nucleic material is implanted in a surrogate gestational mother, the child will have two other potential parents—the gestational mother[6], and if she is married, her husband.[7] There may also be intended rearing parents unrelated to the individual who is cloned. The contributors to such cloning arrangements will have various legal rights and responsibilities with respect to the resulting child.

Overall, existing law would severely restrict public funding for efforts to clone human beings; would monitor most efforts to clone human beings for safety and efficacy; and would discourage premature experimentation. It would not, however, prohibit all such efforts. Further, if an attempt to clone a human being were successful, then existing law would struggle to characterize the family relationships that ensue.

Policy Considerations

Although the potential ability to clone human beings via somatic cell nuclear transfer

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standards of the American College of Obstetricians and Gynecologists (ACOG) and the American Fertility Society (AFS) (currently, the American Society for Reproductive Medicine). La. Rev. Stat. Ann. § 9:128 (West 1991).

[6]In many states, the woman who gives birth is considered to be the legal mother and her husband the legal father of any resulting child. Under statutes in Arizona and Utah, this holds true even when the surrogate is gestating an embryo with no genetic relationship to her. Only in Florida, New Hampshire, North Dakota and Virginia do court-approved gestational surrogacy arrangements result in the intended parents—not the surrogate— being viewed as the legal parents.

[7]The latter will have rights (even though he has no biological connection to the child) based on the common law presumption that if a woman gives birth within marriage, her husband is the child's legal father, or in some states, based on specific statutes holding that the surrogate and her husband are the legal parents of a child she has gestated regardless of their genetic contribution. See, e.g., Ariz. Rev. Stat. § 25-218 (1996).

engendered a great deal of discussion,[8] the formation of appropriate public policy with respect to cloning of human beings in this manner depends on more than the particular views of individuals or groups regarding the rights and wrongs of cloning itself. It also depends on the traditions, customs, and principles of constitutional law that guide public policy making in the United States. These bear repeating and include such important factors as:

a) a presumption in favor of individual freedom of action, absent compelling arguments to the contrary based on the common good and the need to protect others from harm;

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[8]See, e.g., *Los Angeles Times*, February 25, 1997, page 6, "Next, Really Prolific Cows: Scientists Clone a Sheep, but We Needn't Fret the Doomsday Scenarios"; *The New York Times*, February 25, 1997, Section A; page 26; "Cloning for Good or Evil"; *The Houston Chronicle*, February 25, 1997, Outlook; page 19, "Dolly's birth is father to some worrying musings," Otis Pike; *The Record*, February 25, 1997, page L10, "Of Sheep and Men; Before Building a Better Beast, Think Twice; *The San Diego Union-Tribune*, February 25, 1997, page B-6, "Amazing breakthrough: Cloning of sheep has remarkable implications"; *Wall Street Journal*, February 25, 1997, Section A; page 22, "Review & Outlook: Listening to the Lamb"; *The Arizona Republic*, February 26, 1997, page B4, "Cloning Question; The Mysteries of Life"; *The Florida Times-Union*, February 26, 1997, page A10, "No need for panic"; *Miami Herald*, February 26, 1997, Section A; page 16, *"God's Work; Man's Hands"*; *The Morning Call*, February 26, 1997, page A16, "'Dolly' Opens New Vistas For Mankind"; *St. Petersburg Times*, February 26, 1997, page 14A, "Rules for cloning needed"; *The Buffalo News*, February 27, 1997, page 2B, "Ready or Not, Cloning Has Arrived; Don't Lose Time Banning it in Humans; *Dayton Daily News*, February 27, 1997, page 1a, "Animal Cloning Calls for Human Restraint"; *Philadelphia Inquirer*, February 27, 1997, page 19, "Don't Be Too Hasty With Laws on Cloning," by James K Glassman; *The San Francisco Examiner*, February 27, 1997, page A20, "Hello Dolly: The cloning of a lamb from a sheep cell opens up a new era of nervous jokes, profound questions and athletic opportunity"; *The Augusta (Ga.) Chronicle*, February 28, 1997, page A4, "Ban Human Cloning"; *The State Journal-Register* (Springfield, IL), March 2, 1997, page 16, "Cloning of sheep holds remarkable implications"; *The Baltimore Sun*, March 3, 1997, page 8A, "More of you and me?; Hello, Dolly: Replicating a sheep raises concerns about cloning humans"; *The Indianapolis News*, March 4, 1997, page A6, "Wolves in sheep's cloning"; *The Spokesman-Review* (Spokane, WA), March 7, 1997, page B6, "Cloning Tempts Our Darker Sides; Ban Research; We Won't Resist the Urge to Turn Humans into Instruments," D.F. Oliveria; *The Spokesman-Review* (Spokane, WA), March 7, 1997, page B6, "Cloning Offers Hope, Not Evil; Don't Be Afraid; Cloning Research Offers Hope to Solve Genetic Mysteries," Rebecca Nappi; *The Times-Picayune*, March 10, 1997, page B6, "Cloning Begets Questions"; *Dayton Daily News*, March 10, 1997, page 6A, "Fear of Clones Itself a Threat;" *The Orange County Register*, March 10, 1997, page B06, "Vital questions"; *Los Angeles Times*, March 13, 1997, page 8, "Don't Rush Anti-cloning Laws; Concerns Are Real, but Legislation Needs Expert Input;" *The Nashville Banner*, March 19, 1997, page A8, "Frist's note of caution; Don't be too hasty, he says, to pass law on cloning"; *The Nation*, March 24, 1997, No. 11, Vol. 264; Pg. 4; ISSN, "Irreplaceable ewe; cloning of a sheep;" Editorial, Hubbard, Ruth; *The New York Times*, April 1, 1997, page 22, "Cloning as an Anticlimax," Philip M. Boffey; Information Bank Abstracts, *Wall Street Journal*, May 2, 1997, page 14, "Will Cloning Beget Disaster?"

b) the requirement that arguments against individual freedom of action be made in terms as convincing and understandable as possible to all those who will be affected, recognizing that U.S. citizens are of various religious faiths and cultural traditions;

c) the requirement that liberty be constrained as little as needed while serving the public interest;

d) allowing individual deviation from the applicable public policy when a compelling need is shown, whenever possible;

e) restraint in the exercise of federal powers with regard to areas traditionally governed by diverse state laws and policies; and

f) coordination with common policies set in other nations, where appropriate.

The presumption in favor of individual freedom of action is not without its critics in America. Legal scholar Mary Ann Glendon, for example, has noted that an overly narrow approach that maintains a focus on rights to the exclusion of responsibility leaves us in a situation where "we can barely find the words to speak of indirect harms, cumulative injury, or damages that appear only long after the acts that precipitated them" (Glendon, 1991). Nonetheless, from the writings of Locke to the writings of the United States Supreme Court, the American tradition has been to assume the freedom to act absent a specific, justifiable prohibition. This tradition is enshrined in the constitutional language of liberty used in case law, ranging from freedom from unreasonable searches and seizures to freedom to refuse medical treatment.

Despite this presumption, however, many things are prohibited in the name, for example, of the common good. The liberty enshrined in American tradition and constitutional law is not, therefore, an unfettered liberty, but rather the ordered liberty of a social compact. To ensure the good order of society frequently one person's liberty is limited when its exercise would serve to limit the liberty of another, or would otherwise undermine important social values.

It is for this reason that an individual's actions may be limited when they would directly harm another. This principle can be applied even when the harm will not be experienced by a currently living person. Thus, on occasion, American courts have recognized that even actions

taken prior to the conception of a child might lead to legal responsibility for that child's health costs, if the actions were unreasonable and avoidable.[9]

On this basis alone, efforts at this time to create a child via somatic cell nuclear transfer may well be inappropriate, since there is widespread consensus that such a step would be dangerous and premature before a great deal of further animal research is conducted for the following reasons: the potential for unacceptably high rates of developmental abnormalities in the resulting embryos and fetuses; uncertainty regarding the "age" or "genetic clock" of the child created through cloning; and the uncertain impact of hidden mutations in the somatic cell used in the procedure.

Public and Private Values

In addition to the concerns about safety, of course, are the potential psychological harms to the resulting child and systematic affronts to public values and morale. These latter concerns (as discussed in Chapter 3) include issues surrounding the undermining of self-identity, human dignity, privacy, autonomy, and kinship relations of the child created through somatic cell cloning.

Concerns about the potential impact of cloning human beings through somatic cell nuclear transfer on public and private values and morale are quite real, but nonetheless difficult to articulate with precision.

Americans share some but not all of their ethical and cultural traditions, and no single set of approaches that balances conflicting values in particular ways enjoys universal acceptance (Brock, 1995). Some theological analyses provide answers, as we have noted several times, but these are incapable of serving as the sole basis for policy making in a religiously diverse nation committed to separation of church and state.[10] Further, the absence of an agreed upon

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[9]See, e.g., Curlender v. Bio-Science Laboratories, 165 Cal. Rptr. 477 (Ct. App. 1980).

[10]"[I]n order to be legitimate, the State's interest [in prenatal life] must be secular; consistent with the First Amendment the State may not promote a theological or sectarian interest. Planned Parenthood of Southeastern Pennsylvania v. Casey, 112 S. Ct. 2791, 120 L.Ed 2d 674, 739 (1992) (Stevens, J. concurring in part and dissenting in part). See also Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747, 778 (1986) (Stevens, J. concurring); see generally Webster v. Reproductive Health Services, 492 U.S. 490, 563-572 (1989) (Stevens, J., concurring in part and dissenting in part).

When applied to ethical decision making, one philosopher notes: "Morality's ambition is, or at

methodology in moral philosophy or bioethics for resolving disputes among competing ethical theories and conflicting values means that no analytical argument can be persuasive to every person (Brock, 1995).

Finally, the instinctive distrust with which much of the American public greeted the prospect of cloning is necessarily a significant factor. No suggested public policy can hope to gather support and compliance in the absence of either consensus or persuasive argumentation.

Many of the objections described above are, to a large extent, based upon predictions of the widespread effects on society should this type of cloning become a frequent practice. Thus, they are arguments not only about the morality of cloning itself, but also about the need to avoid it even in arguably compelling cases, lest the accumulation of such individual cases lead to widespread practice that could undermine—as many who testified before NBAC have put it—the very meaning of being human.

Members of the Commission could not come to a common evaluation of each of these objections, as they are partly speculative, partly theological, and partly based on particular values or world views that are commonly, but nonetheless not universally, shared by all Americans. On the other hand, the collective force of these objections makes a strong *prima facie* case for a political judgment that creating a child in this manner would violate the deeply held views of many Americans.

But while such arguments may make a strong political case for prohibiting this type of cloning, American law occasionally demands more. Specifically, while any rational reason will suffice for government limitation of ordinary individual liberties, such as the right to drive or to go to school, sometimes the law demands a more compelling reason, as well as proof that the prohibition has been written as narrowly as possible so as to infringe upon individuals as little as is necessary in order to accomplish the compelling state purpose.

This is the case when fundamental liberties are at stake. Fundamental liberties have been

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least ought to be, to provide a system of conduct under which everyone can live with a sense of mutual justifiability. This follows from the conditions of political legitimacy. We do not live in a theocracy, where some people are thought to have a privileged and direct line to moral truth." Thomas Nagel, "Moral Epistemology," in Institute of Medicine, [Ruth Bulger, Elizabeth Bobby, Harvey Feinberg, eds.] Society's Choices: Social and Ethical Decision Making in Biomedicine 201, 212 (1995).

defined by the Supreme Court as those that are specifically mentioned in the Constitution, for example, the right to free speech, as well as those so grounded in our culture and history as to be assumed by the public as beyond casual governmental interference.

Thus, to determine if the arguments put forth are sufficient to justify a prohibition legally, as well as politically, it is necessary to examine whether the choice to create a child via somatic cell nuclear transfer cloning would be viewed as a fundamental liberty. Since such cloning, if successful, would involve bringing children into the world, it is quite possible that one could characterize it as a form of procreation, for which the courts have carved out large areas of special protection since the "bearing and begetting" of children has been characterized as a fundamental right.

Rights and Procreation

The right to make decisions about whether or not to bear children is constitutionally protected under the constitutional right to privacy[11] and the constitutional right to liberty.[12] The U.S. Supreme Court in 1992 reaffirmed the "recognized protection accorded to liberty relating to intimate relationships, the family, and decisions about whether to bear and beget a child,"[13] and a federal district court has indicated that this right to make procreative decisions encompasses the right of an infertile couple to undergo medically assisted reproduction, including *in vitro* fertilization and the use of a donated embryo, stating:

> It takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure

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[11] See, e.g., Griswold v. Connecticut, 381 U.S. 379 (1965); Eisenstadt v. Baird, 405 U.S. 438 (1972).

[12] Planned Parenthood v. Casey, 505 U.S. 833, 112 S.Ct. 2791 (1992).

[13] Planned Parenthood v. Casey, 505 U.S. 833, 112 S.Ct. 2791, 2810 (1992). Early decisions protected the married couples' right to privacy to make procreative decisions, but later decisions focused on individuals' rights as well. The U.S. Supreme Court, in Eisenstadt v. Baird, stated, "[i]f the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child." Eisenstadt v. Baird, 405 U.S. 438, 453 (1972).

that may bring about, rather than prevent, pregnancy.[14]

Some commentators argue that the Constitution could similarly protect the right to create a child through this method of cloning, as it is not qualitatively different from the practice of medically assisted reproduction. Others disagree, deeming cloning via somatic cell nuclear transfer to represent a radical new step and to be classified as "replication," rather than "reproduction" (Annas, 1997; Kass; 1997; Macklin, 1997; Robertson, 1997).

To the extent that cloning invokes the choice to generate a child, it is indeed procreative. On the other hand, cases discussing procreative rights have always been premised on underlying assumptions about the meaning of procreation. Among those has been the assumption that it is interdependent, i.e., it involves the reproductive cooperation of a male and a female, at least on the biological level. Another assumption has been that it involves the transmission of genes vertically across a generation, that is, between a parent and child. Cloning via somatic cell nuclear transfer represents a form of genetic duplication within the existing generation.

Whether cloning is best characterized as procreation or as something entirely new and different is a matter of debate, or at best, prediction regarding future decisions by the U.S. Supreme Court. Thus, it is impossible to say with certainty whether it would be treated in law as a fundamental right. All that can be said at this time is that, if it were to be treated as a fundamental right, then arguments against the practice based on speculative psychological and social harms would be tested against the strictest scrutiny of the judicial system.

Policy Options

It is against this backdrop that the Commission developed the following policy options:

X To continue the existing moratorium on federal funding of research on the creation of a child through somatic cell nuclear transfer, and to extend the intent of that moratorium to cover any effort to use federal funds for this technology in a clinical, i.e. non-research, setting (e.g., reimbursement for medical care).

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[14] Lifchez v. Hartigan, 735 F.Supp. 1361 (N.D. Ill.), aff'd without opinion, sub nom., Scholberg v. Lifchez, 914 F.2d 260 (7th Cir. 1990), cert. denied, 111 S.Ct. 787 (1991)

X To obtain the agreement of the private sector to abide by the spirit of the federal moratorium.

X To extend to all participants in research protocols the human subjects protections already in place for those enrolled in federally funded protocols.

X To legislatively prohibit efforts to clone human beings.

X To facilitate public education and debate, in preparation for possible legislative action, if any, and to carry on a national discussion about the uses of somatic cell nuclear transfer cloning technology.

X To cooperate with our counterparts in other nations to enforce any common elements of our respective policies regarding efforts to clone human beings.

OPTION: Continue the Moratorium on the Use of Federal Funding for the Creation of a Child Using Somatic Cell Nuclear Transfer

The first, and simplest, of the policy options is to call for a continuation and expansion of the March 4 Presidential ban on the use of federal funds for cloning of human beings via somatic cell nuclear transfer. The continuation of this moratorium could encompass both federal research funds, such as those made available by the Department of Health and Human Services, as well as other federal payments. Thus, for example, Medicaid and Medicare could make clear what is already widely assumed, to wit, that they will not pay for any efforts to attempt to create a child via somatic cell nuclear transfer because, among other things, they do not pay for experimental procedures.[15]

It may be worth exploring, as well, the feasibility of attaching conditions to the receipt of certain federal funds so as to extend the prohibition on cloning of human beings via nuclear transplantation. For example, the federal government provides large block grants for maternal and child health services. In light of the significant risks to the child's health posed by this

[15]The applicability of Medicare funds may not be apparent, but with the advent of post-menopausal pregnancy via hormonal maintenance, Medicare unexpectedly became a public insurer with at least theoretical obligations to pay for pregnancy care.

technology, it might be appropriate to condition receipt of federal funds on the promise to prohibit attempts within a specific institution. In the past, such an approach has been used with regard to prospects for human gene therapy. Thus, in the 1980s institutions were told that they could receive federal funds for work on recombinant DNA therapy on the condition that no one would attempt to use it in people until the specific application had been reviewed for its safety and ethical acceptability by a specially created review body. Compliance with these conditions has been excellent.

OPTION: Appeal to the Private Sector for Adherence to the Intent of the Federal Moratorium on the Cloning of Human Beings

An appeal can be made immediately to all portions of the private sector, and to all relevant societies of clinicians and researchers, urging them to forego any attempt to use nuclear transfer to create a child. Compliance is likely to be high, especially within the research community, which has a history of successfully invoking voluntary moratoria even on exciting and appealing innovations such as gene therapy.

The closest analogy to a moratorium on cloning human beings may well be found in the existing moratorium on the use of germ line gene therapy, i.e., deliberate changes in human DNA intended to be inherited. A decade ago, the consensus was that no one could do gene therapy safely and reliably. Opinion split about the prudence of banning it. On the one hand, there seemed little harm in banning it, with some prospect of public assurance as a benefit. On the other hand, some voices pointed out that if the technology evolved sufficiently, one might imagine clinical scenarios, however rare, where it could be useful. Policy on deliberate germ-line intervention now varies from barely permissive to explicitly proscriptive. In the United States, "the [Recombinant DNA Advisory Committee] RAC will not *at present* entertain proposals for germ line alterations" [emphasis added]. This turn of phrase says the door is closed but RAC might open it in response to an appropriate knock. This was a deliberate decision, as an outright ban was urged by the Council for Responsible Genetics (CRG) in 1985, but the RAC subcommittee elected to stick with its language. German and Danish laws, by contrast, say that such germ-line intervention is a criminal act.

For ten years, RAC has had a *de facto* ban on germ line gene therapy. If a concrete, clinically defensible proposal is ever made, RAC can simply choose to review the protocol if need be.

Many scientific societies have already indicated to NBAC their support for such a moratorium; of 32 societies contacted, the majority stated that they take the position that it is wrong at this time to attempt to clone human beings.[16] The World Medical Association, representing clinicians around the world, has also endorsed a moratorium.[17] Historically, moratoria have garnered less resistance than governmentally imposed prohibitions. In addition, such moratoria avoid governmental intrusion into the freedom of scientific inquiry via legislative fiat. Finally, and perhaps counter-intuitively, a self-imposed moratorium may be more durable, as it is largely immune from the constitutional challenges, as they are most often relevant when individuals challenge governmental—as opposed to private—limitations on personal choices.

On the other hand, a voluntary moratorium may not be sufficient to deter the occasional use of somatic cell nuclear transfer cloning. The history of infertility treatment—especially that of in vitro fertilization—demonstrates that where there is a sizeable and well financed demand for a novel service, there will be professionals willing to try to provide it. Sanctions against those who try to provide the service prematurely are weak. State medical licensing authorities, for example, are not as vigorous in their prosecution of medical violations as they could be.[18]

No one has offered NBAC a good estimate of the number of laboratories that might be capable of attempting to somatic cell nuclear transfer to create a child, but W. Bruce Currie, a biologist at Cornell University, estimates that at least ten fertility clinics in the United States have the technology.[19]

As mentioned previously, if somatic cell nuclear transfer cloning were attempted, the only federal legislation clearly on point would be the Fertility Clinic Success Rate and Certification

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[16]To receive input on scientific and professional society views about cloning of human beings, NBAC commissioned the Critical Technologies Institute of RAND to request informal input from relevant organizations, of which 32 responded. "Views of Scientific Societies and Professional Associations on Human Nuclear Transfer Cloning Research," by Elisa Eiseman, May 1997.

[17]"Global Group Urges a Voluntary Ban on Human Cloning," *Chicago Tribune*, May 12, 1997, p. 16.

[18]Hogan, "The Effectiveness of Licensing: History, Evidence, and Recommendations," *7 Law and Human Behavior* 117 (1983); F. Grad and G. Marti, *Physician Licensure and Discipline: the Legal and Professional Regulation of Medical Practice* (1979).

[19]Sharon Begley, "Little Lamb, Who Made Thee?" *Newsweek*, March 10, 1997, pp. 53-57.

Act of 1992 which regulates assisted reproductive technology programs. But despite this and arguably applicable state statutes, there is no comprehensive protection at the federal or state legislative levels against dangerous applications of technology that could be used to try to clone a human being in this manner.

The threat of medical malpractice litigation does provide some protection against premature application of a risky technology, but it too is lacking. Since the very people who request the service most urgently are the ones who would hold the privilege of suing for malpractice, it is unlikely that many suits would be brought, even if the technology were to prove tragically flawed for human application. And even though the child himself or herself would hold an independent right to sue for injuries incurred through premature use of the technique, the limited range of legal actions and the need for someone other than the parents to be motivated to obtain authority to sue on the child's behalf makes this, too, an inadequate means of policing the clinical application of the technology.

Nonetheless, in order to bolster the effectiveness of a self-imposed moratorium on cloning human beings, state authorities should be called on to tell their licensed practitioners that this technology is not ripe for human application. Relevant clinical societies should be urged to do the same.

Professional societies can set voluntary, informal standards for professional behavior, require members to participate in continuing professional education to maintain active membership status, or require periodic examination. They can have codes of ethics governing general behavior, as do the American Medical Association and the National Society of Genetic Counselors. A professional organization can also survey its members and gather data on new techniques. Membership in professional societies is voluntary, as is members' adherence to an organization's code of conduct and standards and participation in membership surveys. Moreover, no professional organization that represents *in vitro* fertilization clinicians and scientists has publicly expressed its opposition to such cloning attempts.

The American Medical Association has already stated to NBAC that it is not an acceptable form of medical practice to attempt to clone human beings through somatic cell nuclear transfer, and the World Medical Association has issued a similar statement. The result should be to deter efforts to use the technology, and to make redress against those who do use it somewhat easier, should there be public or private efforts to prove malpractice. Not only do such

statements provide guidance to practitioners directly, they also provide guidance to courts, which have increasingly become arbiters of whether a health care provider has met his or her professional obligations to a patient.

OPTION: Legislate Extended Human Subjects Protections

A third action that could be taken to prevent dangerous uses of cloning would be to extend human subjects protections, currently spelled out in regulations at 45 CFR Part 46, to all persons in the United States. At the moment, these protections extend only to those persons enrolled in research trials at institutions that have executed a multiple project assurance with the government; those in trials using Food and Drug Administration (FDA)-regulated investigational drugs, devices, and biologics; and those enrolled in trials sponsored by one of the 17 federal agencies that have adopted the common rule for subject protection. This still leaves some number of research subjects unprotected by federal law, as documented by the Office for Protection from Research Risks in its presentation to NBAC at the first commission meeting, and, more recently, in its April 10, 1997 letter to the NBAC subcommittee on human subjects protections.

By extending protection to encompass all research settings any person attempting to use nuclear transfer cloning to produce a human child within the context of a systematic investigation (the federal definition of research) would be subject to Institutional Review Board (IRB) review and a basic risk/benefit balancing test. In light of the significant physical harms that are expected based on current data, such research could not easily be approved until some compelling benefits have been shown.

An advantage to extending human subjects protection via this type of legislation rather than relying on a voluntary ban is its flexibility over time should information from studies in other animals indicate that physical risks to humans are less than expected. More importantly, this approach represents a robust response to new and unanticipated response to technological innovations. Rather than addressing cloning alone, it sets the stage for review of any new technology that has application in humans by taking full advantage of the existing system of decentralized IRB-review. In addition, it accomplishes other NBAC goals regarding the extension of basic human subjects protections.

This particular legislative option does, however, suffer from several disadvantages. First,

because it requires legislative action it cannot be implemented immediately. Further, it depends on the decentralized IRB-review system, which itself has been subject to much criticism as inadequate to the task, due to overwork, conflicts of interest, and the absence of sufficient expertise, particularly with regard to novel technologies.[20] Finally, because the protections it offers extend only to those enrolled in research protocols, it does not address experimental use of this technology that is offered in a therapeutic or other non-research guise; for that setting, the protections outlined above regarding voluntary moratoria and professional society or disciplinary body statements must be used.

OPTION: Legislative Ban on the Use of Somatic Cell Nuclear Transfer to Create a Child

If the foregoing options do not suffice to deter dangerous or premature efforts at cloning, or if the more general societal harms are viewed as sufficiently alarming as to require more dramatic attention, then a legislative prohibition can be considered. Indeed, such prohibitions are already being considered by a number of state legislatures and will probably be adopted by a number of other countries or international bodies as well (Knoppers, 1997).

The advantages to federal legislation as opposed to state-by-state laws lie primarily in its comprehensive coverage and clarity, as it would cover both private and public work in both research and clinical settings. By relying on a single statement of principle, there is no need to rely on the cooperation of diverse medical and scientific societies, or the actions of diverse IRBs, to accomplish one's goal. In addition, legislative prohibitions offer the opportunity to draft significant penalties for violation, thus increasing the deterrent effect enormously as compared to that offered by the other measures outlined above. Indeed, one of the strongest deterrent effects might be to inhibit incipient commercial interest in the use of the technology for infertility relief, thus removing a structural force that could otherwise lead to intense and possibly premature pressure to attempt clinical application even before necessary research in animals has been completed. Finally, a clear prohibition on efforts to create a child through nuclear transfer could help to quell anxieties with regard to the purely molecular and cellular techniques, called "cloning," that form the basis of much of contemporary biomedical science, and that continue to hold such promise for medical and scientific advance without raising the same ethical issues as those associated with creating a child.

[20]See transcripts of NBAC Human Subjects Subcommittee meeting, December 16, 1996.

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 cellular and molecular cloning that is so important, as we have noted, for contemporary biomedical science (see science chapter). Further, by unifying law at the national level, federal legislation could prevent "forum shopping," in which motivated researchers or clinicians are enticed to relocate to states where protections against dangerous uses of cloning are fewer.

On the other hand, drawbacks to federal legislation exist. There is a tradition in the United States of foregoing federal legislation in areas traditionally reserved to the states. Direct regulation of family affairs and of medical practice—both of which would be implicated in a legislative prohibition—represents two such areas. Thus, federal action could stifle the diverse policy responses of the states, should some states wish to be more liberal in permitting nuclear transfer to create a child. It would also hinder experimentation with different legal regimes governing the technology, thus perhaps obscuring lessons that might be learned from long term observation of the experiences in states with diverse legislative responses to this technique.

A legislative ban also would represent a strong obstacle to changes in policy as scientific information develops. While it is true that a ban could always be removed by a vote to repeal the prohibition, such an effort would take a strong interest group lobbying for change. Since the applications of cloning for procreation are likely to be few, and the numbers of persons with a compelling interest in pursuing this option similarly small, a legislative ban might leave some small number of persons with compelling needs nonetheless unable to pursue their interests.

It is for this reason that one should consider a legislative ban that includes a sunset provision. It is notoriously difficult to draft legislation at any particular moment that can serve to govern the rapid and unpredictably advances of science in the future. Some mechanism, such as a sunset provision, is needed to ensure an opportunity to re-visit early judgement about the effects of somatic cell nuclear transfer cloning. A sunset provision would dictate that the prohibition expire, either automatically after a certain period of years, or upon declaration by some sort of review body set up for this purpose. While the inclusion of a sunset provision risks losing some of the advantages—in terms of enhanced public confidence—that are gained by a legislative prohibition, it ensures that the question of cloning will be revisited 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.

A sunset provision, however, would have to include details explaining how and when the legislative ban would expire. An alternative to simply choosing an arbitrary number of years, which may or may not coincide with a moment at which significant new information about the technology has emerged, would be the creation of a body, either immediately, or at a specific time (e.g., one year) prior to the date of the sunset, that is charged with identifying the moment, if ever, when the ban ought to be repealed. The details of who should set up such a body, how its members should be appointed, the criteria by which it would render its decisions, and the tasks it should undertake in order to monitor the technology are crucial for the design of this sort of sunset provision. One advantage to the creation of such a body, however, is its availability to serve as a forum for ongoing public education about the technology, as it develops, in order to deepen and widen the discussions about the ethics of its use.

OPTION: Cooperate With Other Nations in the Enforcement of Common Elements of Our Policies Regarding Human Cloning

On December 15-18, 1996, in Strasbourg, France, at the Third Symposium on Bioethics of the Council of Europe on "Medically-Assisted Procreation and the Protection of the Human Embryo," the renowned biologist Dr. Anne McLaren of the United Kingdom stated in her report on "Research on Embryos in Vitro: The Various Types of Research" that "[a]reas of research that are widely regarded as ethically unacceptable and often prohibited by law include the following: . . . 3) cloning by nuclear substitution." (Convention, 1996). At the same meeting, J. Egozcue, the Spanish expert, in his report on "Research in Human Conceptuses" reiterated that "[o]ther lines of research are forbidden or even penalized, although in some cases they may correspond to extremely useful models for the study of some special situations, that do not carry with them any danger, menace or unethical load. Among them are cloning, parthenogenesis, the production of chimeras, interspecies fertilization (with the exemption of the human-hamster system), any modification of the genome (or of the non-pathological genome, as in the Spanish law) and germ-cell therapy" (Convention, 1996).

Recently, two international ethics committees, one governmental (UNESCO), and the other a committee of the non-governmental Human Genome Organization (HUGO) were deliberately created for the study of the ethical, legal and social issues surrounding human genetics. Neither has an explicit statement on cloning, but the UNESCO International Bioethics Committee has as its mandate, "the preparation of an international instrument on the protection of the human genome" (1993).

The preamble of UNESCO's proposed *Universal Declaration on the Human Genome and the Protection of Human Rights* recalls the universal principles of human rights as found in the international instruments and recognizes that: "research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but emphasiz[es] that such research should fully respect human dignity and individual rights . . ."

The International Ethics Committee of HUGO in its *Statement on the Principled Conduct of Genetic Research* was also concerned with research under the Human Genome Project and Human Genome Diversity Project generally, and not with any particular form of research. However, the *Statement* in its background principles refers to the "acceptance and upholding of human dignity and freedom."

While easily dismissed as too broad and vague, these international approaches, which are necessarily the result of compromise, may prove to be more inclusive than the narrow, scientific definitions often found under national legislation. To the extent that cloning human beings via somatic cell nuclear transfer is viewed by these nations and international organizations as incompatible with human dignity, prohibitions under domestic law of the signatory countries will follow. Indeed, plans for such prohibitions have already been announced by Germany and France,[21] and the United Kingdom is examining its own existing law to ensure that efforts to clone a human being would be clearly prohibited. Indeed, European opinion seems unanimous on this point, and 20 countries associated with the Council of Europe have called for such a ban,[22] an idea endorsed by the World Health Organization.[23]

Since science and medicine are now transnational endeavors, the U.S. government could look for ways to cooperate with its foreign counterparts to enforce any common policies aimed to deter efforts to clone a human being. These could include agreement to enforce one another's prohibitory legislation where appropriate, as well as for the United States to affirm its

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[21]Emma Thompson, "Germans and French Press for Worldwide Ban on Human Cloning," *The Herald* (Glasgow), April 30, 1997, p. 14.

[22]Gile Tremlett, "Twenty European Countries Sign International Convention," *The Times* (U.K.), April 5, 1997.

[23]"Health Agency Says Cloning of Humans Unacceptable," *Chicago Tribune*, May 15, 1997.

commitment to some of the international documents being prepared.

Clinton

Draft 6/8/97 6:30pm

PRESIDENT WILLIAM J. CLINTON
ANNOUNCEMENT OF CLONING LEGISLATION
THE ROSE GARDEN
JUNE 9, 1997

Acknowledgments: Vice President Gore; Secretary Shalala; Dr. Harold Varmus, Dir., NIH; Dr. Jack Gibbons, the President's Advisor on Science and Technology; President's Committee of Advisors of Science and Technology.

I want to express my deep gratitude to Dr. Shapiro and the National Bioethics Advisory Commission for preparing this report. As Dr. Shapiro described, the time was short, the topic was difficult, and the area of inquiry was wide. I thank each of you for your commitment and your courage to break new ground in public policy making.

As the remarkable breakthrough in cloning we are here to address makes so clear, we are living in a breathtaking era of scientific discovery. More and more, America's future -- and the world's future -- depend on science and technology. And more and more, the scientific community can influence the course of that future, and the lives our children will lead in the 21st century. As I said in my commencement address at Morgan State University last month, our scientific explorations must be guided by our commitment to human values, the good of society, and our basic sense of right and wrong.

Nothing makes the necessity of that moral obligation more clear than the troubling possibility that these new animal cloning techniques could be used to create a child. That is why I acted quickly in March to ban the use of federal funds for cloning human beings -- and to urge the private sector to observe this ban voluntarily -- while we initiated a national dialogue on the risks and responsibilities of such a possibility. And that is why I asked the National Bioethics Advisory Commission to prepare this report.

For three months, the Commission has rigorously explored the scientific, moral and spiritual dimensions of human cloning. You have talked to leading scientists and religious leaders; philosophers and concerned families; patient advocates and the general public. And from many opinions and beliefs, one unanimous conclusion has emerged: attempting to clone a human being is unacceptably dangerous to the child and is morally unacceptable to society.

I believe strongly that this conclusion reflects a national consensus . . . and I believe personally that it is right. Today, I am sending legislation to Congress that

prohibits anyone -- in either the private or the public sector -- from using these techniques to create a child *[for the next five years]*. Until the day I sign that legislation into law, the ban on federal funding I declared in March will remain in effect. And once again, I call on the private sector to refrain voluntarily from using this technology to attempt to clone a human being -- it is untested, it is unsafe, and it is wrong.

I want to make clear that there is nothing inherently immoral or wrong with these new techniques if they are used for proper purposes. In fact, these techniques hold out the promise of revolutionary new medical treatments and life-saving cures to diseases like cystic fibrosis, diabetes, and cancer; of better crops and stronger livestock. That is why this legislation will not prohibit the use of these techniques to clone DNA and cells, and it will not ban the cloning of animals.

What this legislation will do is reaffirm our most cherished beliefs about the miracle of human life, and the God-given individuality that each person possesses. It will ensure that we do not fall prey to the temptation to replicate ourselves at the expense of those beliefs . . . and the lives of the innocent children we would produce. Finally, this legislation will ensure that we continue the national dialogue we began three months ago.

To make sure that all of our voices are heard as we explore the morality of human cloning, this legislation specifically requires the National Bioethics Advisory Commission to continue its study, and report back to me within four-and-a-half years. At that time, based on all of the available information, we will decide how to proceed.

Banning human cloning reflects our humanity; it is the right thing to do. Creating a child through this new method calls into question our most fundamental beliefs about what it means to be human. It has the potential to threaten the sacred family bonds that are at the very core of our ideals. And at its worst, this technology could lead to misguided and even malevolent attempts to select certain traits and create certain kinds of children.

We are still a long way from understanding all of the implications of this discovery. But it is our moral obligation to confront the issues it raises, and to act now to prevent its abuse. Once again, I thank the National Bioethics Advisory Commission for the work you have done and will continue to do in the coming years.

Thank you and God bless you.

Cloning

Sherman G. Boone
06/14/97 11:03:28 AM

Record Type: Record

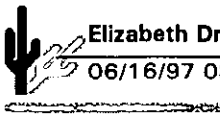
To: Elena Kagan/OPD/EOP, William P. Marshall/WHO/EOP

cc: Elizabeth Drye/OPD/EOP, Rachel E. Levinson/OSTP/EOP
Subject:

The following is revised (by Tarullo) language for the Denver Summit of the Eight Communique as agreed to by Rachel and Elizabeth. I will run it by Dan once again; we plan to transmit the communique early this afternoon.

Human Cloning

We have taken note of recent scientific experiments which could open the way to creating a child by cloning an existing person. While recognizing the considerable benefits for basic research, agriculture and human health from cloning technology, we agree on the need for appropriate domestic legislation and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child, while countries explore ethical and scientific implications in greater depth. We are encouraged by the reflections underway within national ethics committees, as well as in various regional and international fora, which will enable a measured approach in deciding which uses of this technique are, and which are not unacceptable. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at an appropriate universal moratorium.



Elizabeth Drye
06/16/97 08:55:46 AM

Record Type: Record

To: Elena Kagan/OPD/EOP, William P. Marshall/WHO/EOP

cc:
Subject: G-8 on Cloning, revised again

FYI-- Dan wanted to get call for universal moratorium in, so here is new language.
---------- Forwarded by Elizabeth Drye/OPD/EOP on 06/16/97 08:55 AM ----------

Sherman G. Boone
06/14/97 11:03:28 AM

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Science: cloning

Elizabeth Drye
05/19/97 11:26:01 AM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP

cc:
Subject: Clinton's Panel Backs Moratorium on Human Clones

FYI -- I assume you saw attached in yesterday's NYTs. Accurate characterization of debate at Saturday's meeting. Also, Shapiro told me Saturday that he's fine with the week of June 9th (is checking specifically on the 10th), but would very much like to have POTUS meet commissioners. Publicly he told his troops that the Commission will need another meeting before finishing and that he would have to check with the WH about any change in 90-day deadline.

---------- Forwarded by Elizabeth Drye/OPD/EOP on 05/19/97 11:14 AM ----------

May 18, 1997

Clinton's Panel Backs Moratorium on Human Clones

Related Articles
* Cloning Index

By GINA KOLATA

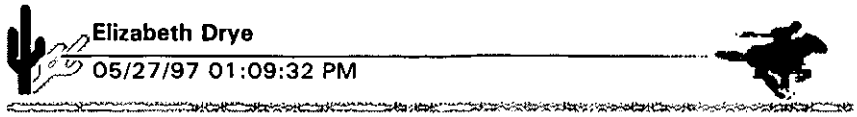
[A] RLINGTON, Va. -- Trying to tread a fine line between encouraging scientific progress and preventing horrendous abuses of a new technology, a presidential advisory committee agreed Saturday that there should be a moratorium on the cloning of human beings by public or private institutions.

The group said efforts to clone a person would not be safe now because they would be too likely to result in malformed fetuses.

The 18-member group was charged by President Clinton with making a recommendation on human cloning by the end of the month. Among the issues it faces is whether the cloning of humans should be prohibited, and, if so, how a ban should be enforced.

Even though the group reached a limited agreement, the struggle to complete its report shows how difficult it can be, even for a group with no obvious factions, to decide the issue.

~~clon~~ cloning



Elizabeth Drye
05/27/97 01:09:32 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: cloning

The French put forth a cloning paragraph for the Summit of the Eight on Friday. NEC has asked us to vet it and recommend any changes by Thursday COB. I will work with OSTP and HHS over the next two days to respond and also to draft preliminary national legislative language. The biotech and pharmaceutical industries have expressed concern about legislation and the Summit proposal; OSTP, NBAC's exec director and I are meeting with industry this afternoon to get their input. I'm pulling in VP's office as well. Given the industry's interest, other WH offices may get calls -- so I'll keep you posted.

Science-cloning

Elizabeth Drye
05/20/97 02:35:51 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Bruce N. Reed/OPD/EOP

cc: Cathy R. Mays/OPD/EOP, Laura Emmett/WHO/EOP, Jonathan Prince/WHO/EOP
Subject: PLEASE RESPOND TODAY -- HHS giving Wash. Post. draft cloning report

The Post has requested a copy of the draft cloning report under FACA. HHS doesn't think it can legally say no. Shapiro doesn't want a fight and doesn't mind giving it out. Unless we have immediate concerns, HHS will send the report over later today or tomorrow. NBAC discussed its policy recommendations publicly last Saturday, so these won't create news, but the report's interesting and detailed discussion of ethical, religious, legal and scientific issues may be newsworthy. Given HHS's legal position, I'm assuming we have to let the draft out.

Can we give HHS the go ahead to give report to Washington Post? Do I need to prepare anything for press office?

Additionally, NBAC has decided to hold its last meeting on cloning Saturday, June 7, 8:30-11:30 am in Crystal City. The Post has also asked for copies of materials for the June 7 meeting at or before the meeting. We should think about how to do POTUS announcement given these developments. Ideas?

Cloning

Elizabeth Drye
05/22/97 03:19:23 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Christa Robinson/OPD/EOP, Elena Kagan/OPD/EOP

cc: Christopher C. Jennings/OPD/EOP
Subject: Release of Cloning Rpt.

HHS/WH Counsel concur that Shapiro has to make the revised draft report available to the pubic at the Commission's Saturday, 7:30-11:30 am June 7 mtg. Shapiro does not think the report will have any surprises so we'll know it's basic content in advance. The Commission will vote at the meeting on whether to recommend legislation -- Shapiro expects a yes. Given that, shouldn't we revisit 6/10 date for POTUS remarks? Any lessons from the mammography announcement on how to coordinate commission findings/POTUS response?

~~Science~~ Cloning

Elizabeth Drye
05/13/97 04:04:20 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: Elena Kagan/OPD/EOP
Subject: NBAC report release

I talked to Shapiro today re. week of June 9th. He of course could delay the report until then and notes that there are some benefits to delay, but would need our help explaining the delay in a way that doesn't reflect poorly on the Commissioners since he has pushed them incredibly hard to meet the deadline. Any ideas on how we can communicate the delay in a way that works for both him and us? FYI the Commission meets this Saturday to wrap up cloning and meets Saturday, June 7 to get back to business on their other issues. [OSTP lawyers tell me once NBAC sends the report to POTUS it's public, so White House can't simply get it at 90-day mark and sit on it until June 9th.]

File: cloning

Elizabeth Drye
04/23/97 04:21:54 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Jonathan Prince/WHO/EOP

cc: Rachel E. Levinson/OSTP/EOP, Elena Kagan/OPD/EOP
Subject: Cloning

Rachael Levinson (OSTP) and I had a good but inconclusive discussion with Shapiro. He's not sure where NBAC will be in its public deliberations by the May 17th meeting. It's possible the members will vote on positions that day and that the meeting will generate news, but the Commission's main conclusions could become public before or after that weekend. He apologized for not being more helpful, said he thought he'd know more after the May 2nd meeting, and understands our need to know as much as possible as soon as possible given the possible Morgan State address.

He did give me a better sense of where the Commission's going. He expects the Commission to recommend that the moratorium continue and to make some effort to better define the moratorium's scope. Specifically, the Commission is likely to differentiate among "human cloning" activities -- sanctioning the cloning of human cells and human molecules but not of human beings. The Commission may also comment on the appropriateness of creating embryos for research purposes (which POTUS has opposed), or may duck this thorny question altogether.

Given where the Commission's headed, POTUS could affirm his commitment to considering the ethics of scientific advances; restate his reasons for the cloning moratorium; illustrate some of the questions cloning raises quoting from the Commission's public deliberations (some of the ethical questions may be particularly troubling to minorities, however); and state his commitment to act on the Commission's findings.

I will stay in touch with him. Let me know if you need more.

Fil-cloning

March 3, 1997

CLONING MEETING AND STATEMENT

DATE: March 4, 1997
LOCATION: Oval Office
TIME: 9:00 A.M.
FROM: Tim Newell

I. PURPOSE

You will meet with Administration officials in the area of research and ethics to 1) issue a statement on cloning to assure the public that federal funds will not be used to clone humans; and (2) call on the scientific community to voluntarily refrain from human cloning until the ethical issues can be considered.

II. BACKGROUND

The recent announcement that Scottish researchers have successfully cloned an adult sheep has received widespread attention, since, hypothetically, similar techniques could be used to clone humans. Because of the ethical concerns human cloning would present, on February 24 you asked your National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues involved and to report back within 90 days on possible federal actions (see attached letter to Dr. Shapiro, NBAC Chair).

Most scientists believe that human cloning faces major scientific barriers, and the majority of experts believe that any prospect of successfully applying this new cloning method to human beings in the near future is remote.

Human cloning research also faces federal funding barriers. On December 2, 1994, you issued a statement barring the use of federal funds to create human embryos for research purposes. Appropriations bills for FY96 and FY97 codified this policy and expanded it to cover HHS research in which human embryos are "destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." (The Administration has opposed addressing the issue through legislation and has supported repealing this provision)

There is some fear, however, that public concern over this issue could erode support for important genetic research programs, and/or result in

overly-restrictive legislation. On February 26, testifying before the House Appropriations Subcom. on Labor, Health and Human Services, Dr. Varmus stated that while the idea of human cloning was "repugnant," he "would be concerned about a rush to legislate" a prohibition since legislation could also restrict related work that offers important medical, economic, and scientific benefits.

A consensus is emerging that researchers should not pursue the cloning of human beings at least until the nation has more thoroughly considered the ethical implications of the technology. The current restrictions do not assure this outcome for two reasons.

First, the current ban on using federal funds to create embryos for research does not explicitly prohibit all human cloning -- it only covers cloning of embryos that will be discarded (not implanted), and only covers HHS-funded research.

Second, the restrictions apply to federally-supported human embryo research only, not privately-funded activities. Privately funded facilities are free to engage in human cloning research under current law. There is a booming business in all forms of reproduction technology to assist infertile couples. Human cloning is not likely to be pursued in this context -- at least until it has a chance of competing successfully against existing technology -- but it cannot be definitively ruled out.

Congress has scheduled fact-finding hearings on human cloning March 5 (Technology Subcommittee, House Science Committee) and March 12 (Senate Subcommittee on Science, Technology and Space). NIH Director Harold Varmus has been asked to testify at both upcoming hearings.

Your statement at this time is intended to reassure the public; deter restrictive, ill-advised legislation; and strengthen the nation's resolve to consider ethical questions carefully before advancing human cloning by 1) clarifying that federal dollars cannot be used for human cloning and that you are signing a memorandum to that effect; 2) calling on the scientific community to refrain from human cloning at least until NBAC and the nation have carefully considered the issue.

III. PARTICIPANTS

Meeting Participants
The President
The Vice President
Secretary Shalala

Harold Varmus, Director of NIH
Harold Shapiro, President of Princeton University/Chair, Natl Bioethics Advisory Comm
Jack Gibbons
Bruce Reed
John Podesta
Tim Newell

Oval Office Event Participants
The Vice President
Secretary Shalala
Harold Varmus, Director of NIH
Harold Shapiro, President of Princeton University/Chair, Natl Bioethics Advisory Comm.
Jack Gibbons
Bruce Reed
John Podesta
Tim Newell
Elena Kagan
Elizabeth Dryer
Cliff Gabriel
Rachel Levinson

IV. PRESS PLAN

Press Pool

V. SEQUENCE OF EVENTS

- At 9:00 AM, you will meet briefly in the Presidential Dining Room with the Vice President, Sec. Shalala, Dr. Varmus, Dr. Shapiro, Jack Gibbons, and Bruce Reed to discuss the Administration's response to the recent advances in cloning technology.

  -- Dr. Varmus will brief the Vice President and you on the biomedical implications of the new cloning technology.
  -- Dr. Shapiro will discuss how NBAC will respond to your request for a review of the ethical and legal implications related to cloning humans.

- At 9:10 AM, you will proceed into the Oval Office to the podium, accompanied by the Vice President, Sec. Shalala, Dr. Varmus, Dr. Shapiro, and Jack Gibbons.

- You will make a statement on cloning to the Press Pool.

- You will take questions from assembled press.

- You will depart the Oval Office.

VI. REMARKS

To be provided by Speechwriters

VII. ATTACHMENTS

24 Feb 97 letter to NBAC/Shapiro

Cloning

Human Cloning
Possible Q's & A's

Question:

Why have you issued a directive prohibiting the use of Federal funds for cloning of human beings?

Answer:

I believe we need to make it absolutely clear that Federal funds will not be used in this manner, and the current prohibitions left room for other interpretations.

In 1994, I directed NIH not to support the creation of human embryos for research purposes, and Congression extended this ban to cover other forms of human embryo research. However, neither of these prohibitions would clearly cover the creation of human embryos, using cloning technology, that are intended to be actually implanted in a womb and carried to term.

My directive today will make it clear that federal funds are not to be used for cloning humans.

Question:

Would you support legislation to ban the cloning of humans?

Answer:

I think that legislation is premature at this time. Frankly, I believe that the broader Congressional prohibition on human embryo research risked cutting off sound research that has great medical importance. I think that we need a serious, public discussion-- which I have asked NBAC to lead -- rather than hasty legislation.

Question:

What are the next steps?

Answer:

I have asked the National Bioethics Advisory Commission (NBAC) to report back to me in 90 days with recommendations for possible federal action. They will review the ethical and legal implications as the basis for their deliberations, which will take

place in open, public meetings. Each meeting will provide an opportunity for public input and education, which are crucial for reaching agreement on what we should do next. I will take NBAC's recommendations and develop proposals that will also require public comment before they become final.

Question:

What impact does the directive have on the private sector?

Answer:

The directive only covers work done by government scientists or in a federally funded laboratory. Therefore, I am also asking the scientific and medical communities to also refrain from cloning human beings at this time, until NBAC has had time for its deliberations. But, let me be clear, the majority of scientific experts believe that any prospect of successfully applying this cloning method to human beings in the near future if extremely remote.

Question:

Is animal research like the sheep experiment affected by the directive?

Answer:

No. The directive refers to the cloning of humans. The legislative ban also covers only human research. There is no ban, nor should there be any ban on animal cloning. There is very important scientific work that can be accomplished using animals. This work will have significant benefits for agriculture, medicine and veterinary medicine. It could also lead to improvements in organ transplantation and better treatments for burn victims or cancer patients. Also, by creating genetically identical animals, scientists testing drugs could use far fewer animals than they now need.

Document No. Cloning

WHITE HOUSE STAFFING MEMORANDUM

DATE: 3/3/97 ACTION/CONCURRENCE/COMMENT DUE BY: 3/3/97 7:00 p.m.

SUBJECT: Remarks on Human Cloning

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☑	☐	McCURRY	☐	☑
BOWLES	☑	☐	McGINTY	☐	☐
McLARTY	☐	☐	NASH	☐	☐
PODESTA	☑	☐	RUFF	☑	☐
MATHEWS	☑	☐	SMITH	☐	☐
RAINES	☐	☐	REED	☑	☐
BAER	☑	☐	SOSNIK	☑	☐
ECHAVESTE	☐	☐	LEWIS	☑	☐
EMANUEL	☑	☐	YELLEN	☐	☐
GIBBONS	☑	☐	STREETT	☐	☐
HALE	☐	☐	SPERLING	☐	☐
HERMAN	☐	☐	HAWLEY	☐	☐
HIGGINS	☑	☐	WILLIAMS	☐	☐
HILLEY	☐	☐	RADD	☐	☐
KLAIN	☑	☐	Waldman	☑	☐
BERGER	☐	☐	Kagan	☑	☐
LINDSEY	☐	☐	Newell	☑	☐

REMARKS:

Comments to Eli Attie.

RESPONSE:

Staff Secretary
Ext. 6-2702

draft 2/2 2pm

PRESIDENT WILLIAM J. CLINTON
REMARKS ON HUMAN CLONING
Tuesday, March 3, 1997

'97 MAR 3 PM3:00

In recent days, all Americans were startled to learn of the successful cloning of a sheep by Scottish researchers. There is no question that this is a breakthrough of enormous consequence for science, medicine, and agriculture -- one that could yield important benefits in the years to come.

It also raises a very troubling prospect -- that it might someday be possible to use these techniques to clone human beings from our own genetic material.

There is much about this discovery and its applications that we still do not know. But this much we do know: any discovery that touches upon human creation is not simply a matter of scientific inquiry. It is a matter of human morality and human decency as well.

My own deeply-held view is that the prospect of human cloning is morally repugnant. It violates our most cherished concepts of faith and humanity. Each human life is unique -- blessed by the spirit of a mother and a father, born of a miracle that reaches beyond laboratory science. I believe that we must respect this profound gift, and resist the temptation to become our own creators.

That is why, one week ago today, I asked our National Bioethics Advisory Commission, headed by Princeton University President Harold Shapiro, to conduct a thorough review of the moral and ethical issues raised by this new cloning technology, and to recommend possible actions to prevent its abuse. Their report, due back in 90 days, will give us a better understanding of the scope and implications of this scientific breakthrough.

But there are steps we can take right now to prevent the possibility of human cloning. After reviewing the current restrictions on the use of federal funds for research involving human embryos, we found loopholes that could allow human cloning. Today, I am issuing a directive that bans the use of <u>any</u> federal funds for human cloning. Effective immediately, no federal agency may support, fund, or undertake such activity.

Of course, a great deal of research and activity in this area is supported by private funds. That is why I am urging the entire scientific community -- and every foundation, university, and industry that supports work in this area -- to heed the federal government's example. I am asking for a voluntary moratorium on all efforts to pursue or undertake human cloning, until our Bioethics Advisory Commission and our entire nation have had a chance to understand and debate the profound ethical implications.

Until we learn more about the potential uses and abuses of cloning, the sensible course is to proceed not just with caution, but with <u>conscience</u> as well. By insisting that not a single taxpayers' dollar supports human cloning -- and by urging a moratorium on all private efforts to pursue human cloning -- we can ensure that as we move forward on this issue, we weigh the concerns of faith and family, and not just of laboratory science alone.

File-cloning

Document No. _____

WHITE HOUSE STAFFING MEMORANDUM

DATE: 3/3 ACTION/CONCURRENCE/COMMENT DUE BY: —

SUBJECT: Cloning

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	☐	☑	McCURRY	☐	☑
BOWLES	☐	☑	McGINTY	☐	☐
McLARTY	☐	☐	NASH	☐	☐
PODESTA	☐	☑	RUFF	☐	☑
MATHEWS	☐	☐	SMITH	☐	☐
RAINES	☐	☑	REED	☐	☐
BAER	☐	☑	SOSNIK	☐	☑
ECHAVESTE	☐	☑	LEWIS	☐	☑
EMANUEL	☐	☑	YELLEN	☐	☐
GIBBONS	☐	☐	STREETT	☐	☐
HALE	☐	☐	SPERLING	☐	☐
HERMAN	☐	☐	HAWLEY	☐	☐
HIGGINS	☐	☑	WILLIAMS	☐	☐
HILLEY	☐	☑	RADD	☐	☐
KLAIN	☐	☐	Kagan	☐	☑
BERGER	☐	☐	Waldman	☐	☑
LINDSEY	☐	☐	Marshall Bill	☐	☑

REMARKS:

This has been forwarded to the President

RESPONSE:

Staff Secretary
Ext. 6-2702

THE WHITE HOUSE

WASHINGTON

March 3, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Jack Gibbons
Assistant to the President for Science and Technology

Bruce Reed
Assistant to the President for Domestic Policy

SUBJECT: Background and Suggested Presidential Statement on Cloning

As you know, the February 27 issue of *Nature*, a renowned scientific journal, contains an account of the first successful cloning of an adult sheep. Hypothetically, similar techniques could be used to clone humans. Because of the ethical concerns human cloning would present, on February 24 you asked your National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues involved and to report back within 90 days on possible federal actions.

We recommend that you: (1) issue a statement on cloning to assure the public that federal funds will not be used to clone humans; and (2) call on the scientific community to voluntarily refrain from human cloning while NBAC and the nation distinguish the facts from the hype and consider its ethical implications.

Background

Most scientists believe that human cloning faces major scientific barriers. For complicated scientific reasons, sheep may be more easily cloned than humans and other animals, and all attempts to clone other mammals such as mice starting with cells from mature animals have failed. The majority of experts believe that any prospect of successfully applying this new cloning method to human beings in the near future is extremely remote.

Human cloning research also faces funding barriers. On December 2, 1994, you issued a statement barring the use of federal funds to create human embryos for research purposes. Appropriations bills for FY96 and FY97 codified this policy and expanded it to cover HHS research in which human embryos are "destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." (The Administration has opposed addressing the issue through legislation and has supported repealing this provision). Senator Bond (R-MO) has begun to draft legislation making permanent the current ban on federal funding for human embryo research.

News reports have indicated that the Congressional ban prohibits using federal funds for human cloning, and no one in Congress has taken issue with this understanding. But the language is not as tight as it could be. It does not explicitly bar federally-supported scientists from creating human

embryos they intend to implant -- it only prohibits them from creating embryos they will discard. In addition, the Congressional ban only covers HHS-funded research.

Privately funded facilities are free to engage in human cloning research under current law. There is a booming business in all forms of reproduction technology to assist infertile couples. Human cloning is not likely to be pursued in this context -- at least until it has a chance of competing successfully against existing technology -- but it cannot be definitively ruled out.

Congress has scheduled fact-finding hearings on human cloning March 5 (Technology Subcommittee, House Science Committee) and March 12 (Senate Subcommittee on Science, Technology and Space). NIH Director Harold Varmus has been asked to testify at both upcoming hearings. On February 26, in testimony before the House Appropriations Subcommittee on Labor and Health and Human Services, Dr. Varmus stated that the idea of human cloning was "repugnant." He went on to say that he "would be concerned about a rush to legislate" a prohibition since legislation could also restrict related work that offers important medical, economic, and scientific benefits.

Rushed attempts to ban cloning could easily result in unintended harmful effects on important research. For example, Dr. Varmus has noted that sheep cloning might inform new methods for producing human proteins, creating model organisms to study human diseases, and possibly reprogramming human cells for treatment of cancer, burns, and other disorders. Therefore, any restraints on human cloning should be worded carefully to avoid unintended consequences on a broader sphere of biomedical and agricultural research.

A consensus is emerging, however, that researchers should not pursue human cloning at least until the nation has more thoroughly considered the ethical implications of the technology. The current restrictions do not assure this outcome for two reasons. First, as noted above, the current ban on using federal funds to create embryos for research does not explicitly prohibit all human cloning -- it only covers cloning of embryos that will be discarded (not implanted), and only covers HHS-funded research. Second, the restrictions apply to federally-supported human embryo research only, not privately-funded activities.

You could urge the non-federally funded scientific community to declare a self-imposed moratorium on human cloning. Some in science will question the need for this approach because they do not believe our ability to clone humans is imminent.. Some also believe that it would be inappropriate for you to take action before NBAC reports back to you with recommendations (your referral of the issue to NBAC received enthusiastic, bipartisan support at NIH's February 26 appropriations hearing). On the other hand, your calling for a moratorium might deter restrictive, ill-advised legislation, reassure the public, and strengthen the nation's resolve to consider ethical questions carefully before advancing human cloning. The scientific community favors a voluntary moratorium over a Congressional ban, and key scientists including Dr. Varmus would understand your calling for it.

Suggested Presidential Statement

We recommend that you issue a statement to:

- Affirm the scientific promise of the new cloning technique and its concurrent ethical challenges;
- Argue that ethical concerns must be confronted before people try to use the technology to clone humans;
- Restate that you have referred the issue to NBAC;
- Clarify that federal dollars cannot be used for human cloning and that you are signing a memorandum to that effect; and
- Call on the scientific community to refrain from human cloning at least until NBAC and the nation have carefully considered the issue.

Cloning

Date: 06/04/97 Time: 15:45
HCloning proposals draw outcry from anti-abortion groups

WASHINGTON (AP) A proposal to allow lab experiments on human cloning but forbid the actual replication of a person drew immediate outcries Wednesday from anti-abortion groups, who say that would permit ''grave evils.''

However, the partial-cloning recommendation from a federal advisory panel brought praise from biotechnology groups, who say it would allow valuable research while essentially calling a timeout on efforts to actually make cloned humans.

The panel, the National Bioethics Advisory Commission, meets Saturday to draw up final recommendations for President Clinton on the stance the federal government should take on human cloning.

Despite a basic consensus, members still disagree on many details of their recommendations, said one member of the advisory group, who spoke on condition of anonymity. He said those differences may not be resolved until Saturday.

At the White House, the Clinton administration declined comment until the commission issues its final report. ''Let's wait and see what actually comes to the White House,'' said spokesman Mike McCurry.

Cloning became an issue of government concern after a Scottish scientist cloned a sheep, named Dolly, from cells taken from adult sheep. The experiment was the first to successfully clone a genetic duplicate individual from an adult mammal. The effort's success prompted a call for legislation to forbid human cloning.

Clinton asked Congress to wait on considering cloning laws until the group of scientists and ethicists could study the issue.

Although final points remain unresolved, a consensus of the 18-member group will call for laws to forbid human replication through cloning, but to not address experimentation with cloned human cells that go no further than a laboratory dish, said the panel member.

He said there is fundamental agreement on these points:

Human cloning that leads to the birth of a child should be strictly forbidden in all U.S. labs, both private and public.

Human embryo research, including cloning research, that stops short of producing a child should not be addressed by federal law. But the moratorium on federal money for such embryo research would continue.

The group's position means that research could continue on the ''Dolly technique,'' the panel member said research in which a human embryo is made from the nucleus of a mature cell joined in a lab dish with a human egg without its nucleus. However, such embryos could not then be placed into a woman's womb for development into a baby.

Such a recommendation by the commission permits ''two separate grave evils,'' said John Cavanaugh-O'Keefe, director of the American Bioethics Advisory Commission, a part of the American Life League Inc. anti-abortion group.

The first, he said, was the creation in a lab of a cloned human embryo; the second was to prohibit implantation and development of the embryo, which eventually would be killed.

''This means it is OK to clone as long as you kill,'' he said. His group considers any human embryo to be a human, he said.

But Carl Feldbaum, president of the Biotechnology Industry Organization, which includes 700 companies, applauded the proposed recommendation.

''What we had hoped is that the commission will draw a bright line distinguishing between whole human research and research which uses only tissue that has been cloned,'' he said.

Such research could help science learn how to make ''spare parts,'' tissue that could replaced diseased organs or burned skin.

Feldbaum said his industry is opposed to cloning whole humans because ''the technique is imperfectly understood. There are also ethical and moral questions. We are not intellectually or emotionally prepared.''

A commission member said the group probably will recommend that any law restricting human cloning include a ''sunset clause'' causing the law to expire at some point.

That would force Congress to re-evaluate the issue if scientific advances make cloning ''not as fraught with risks as in the Dolly technique.''

Although Dolly was successfully cloned, Scottish researchers reported more than 100 failures, some of which involved monstrous birth defects in lambs that quickly died. Such a result would not be tolerated in humans.

If science finds a way to correct safety issues, said the commissioner, then society will need to consider human cloning again. The government then would have to determine what level of safety should be required for human cloning to be considered and then to address, once more, the basic issue of whether it should be permitted, he said.

The commission, he added, is nowhere near resolving those issues.

APNP-06-04-97 1600EDT

Cloning

Talking Points on Cloning

Background

On Saturday, June 7, the National Bioethics Advisory Commission (NBAC) is expected to complete its review of cloning issues. In its draft final report, NBAC concludes that it is morally unacceptable for anyone to attempt to create a child using the technology that created Dolly the sheep. NBAC also concludes, however, that the cloning of DNA sequences, cell lines, and tissues (which do not involve the creation of entire human beings) are scientifically important and not ethically problematic. NBAC chose not to address the creation of embryos; its draft report neither sanctions nor condemns the cloning of embryos.

NBAC's draft final report calls for carefully-worded legislation prohibiting anyone from "attempting to create a child through somatic cell nuclear transfer techniques." The Commission recommends a sunset provision and further review of the issues by an oversight body prior to the sunset date. The Commission will vote on this recommendation at its public meeting Saturday, and the President is scheduled to announce legislation implementing NBAC's proposal in a White House ceremony Monday, June 9th.

TALKING POINTS

o On Saturday, the National Bioethics Advisory Commission is scheduled to conclude its review of the ethical and scientific issues raised by possible human cloning. The President expects to receive NBAC's final report soon. We look forward to receiving and reviewing the Commissions recommendations.

Q. The Washington Post reported Wednesday that NBAC will recommend a legislative ban on creating a child through cloning but that the proposed ban won't cover the creation of embryos using this technology. Where does the President stand? Does he think we should allow cloned embryos?

A. The President is very concerned about using this new technology to clone human beings. He is deeply troubled by the prospect that it might someday be possible to create a child from one's own genetic material. That is why he asked NBAC to review the issue.

The question of creating embryos for research -- as opposed to creating a child -- is a separate question that raises distinct scientific and ethical issues. The President has already acted in this area. In 1994 he directed the National Institutes of Health not to fund the creation of human embryos for research purposes. Congress has also placed restrictions on the use of

federal funds for embryo research.

As you know, NBAC has not issued its final report, and the President has not yet reviewed their recommendations. We will have more to say about it after he has reviewed it.

Cloning

Toby Donenfeld @ OVP
06/06/97 06:31:10 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: VP on sunset of cloning

---------- Forwarded by Toby Donenfeld/OVP on 06/06/97 06:24 PM ----------

Toby Donenfeld
06/06/97 06:27 PM

To: Elizabeth Drye/OPD/EOP @ EOP
cc:
Subject: VP on sunset of cloning

The VP responded that he supports that the ban continues unless Congress acts to discontinue the ban and that there should be something written into the legislation that call for a general review (after 5 years) to explore the safety and moral issues. The VP said "a review, not a sunset or expiration."

Hope that's helpful. Thanks.