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Folder Title:
Human Cloning: Cloning-Somatic Cell Nuclear Transfer (SCNT)

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DRAFT 11/25/98
RTP U+A

105TH CONGRESS
2D SESSION

S. _____

Feinstein
Kennedy

IN THE SENATE OF THE UNITED STATES

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.—**

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

6 **SEC. 2. FINDINGS.**

7 Congress finds that:—

1 (1) it has been reported that an adult sheep has
2 been cloned using a technique called somatic cell nu-
3 clear transfer, ~~a form of cloning,~~

4 (2) the National Bioethics Advisory Commission
5 (referred to in this Act as the "NBAC") has re-
6 viewed the scientific and ethical implications of the
7 potential use of such technology to clone human
8 beings;

9 (3) the NBAC has determined that—

10 (A) somatic cell nuclear transfer tech-
11 nology may have many applications for bio-
12 technology, livestock productions, and new med-
13 ical approaches including the production of
14 pharmaceutical proteins and prospects for re-
15 generation and repair ^{or replacement} of human tissues; and

16 (B) the possibility of using somatic cell nu- ^{or organs}
17 clear transfer for the purposes of creating a
18 child entails significant scientific uncertainty
19 and medical risk, which could result in harm to
20 a child;

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

1 (5) the consensus of the NBAC is based on cur-
2 rent scientific information indicating that this tech-
3 nique is not safe to use in humans at this time;

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

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

16 (8) the NBAC further recommended that Fed-
17 eral legislation be enacted to prohibit anyone from
18 attempting, whether in a research or clinical setting,
19 to create a child through somatic cell nuclear trans-
20 fer cloning;

21 (9) the NBAC also recommended that the Unit-
22 ed States cooperate with other countries to enforce
23 mutually supported restrictions on this activity;

24 (10) the NBAC specified that such Federal leg-
25 islation should include a sunset provision and that,

1 prior to the sunset date, an oversight body should
2 review and report on the status of somatic cell nu-
3 clear transfer technology and the ethical and social
4 issues associated with its use and recommend wheth-
5 er the prohibition should be continued;

✓ 6 (11) the NABC concluded that any regulatory
7 or legislative actions undertaken to effect the fore-
8 going prohibition should be carefully written so as
9 not to interfere with other important areas of re-
10 search, such as the cloning of human DNA se-
11 quences and cells, which raise neither the scientific
12 nor the ethical issues that arise from the possible
13 creation of children through somatic cell nuclear
14 transfer techniques;

✓ 15 (12) the NABC also found that cloning animals
16 by somatic cell nuclear transfer does not raise the
17 same issues implicated in attempting to use the
18 technique to create a child, and its continuation
19 should only be subject to existing regulations regard-
20 ing the humane use of animals; and

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

24 **SEC. 3. PURPOSES.**

25 It is the purpose of this Act to—

✓ 1 (1) prohibit any attempt to ^{clone} ~~create~~ a human
 2 being, using ^{that is, to use} somatic cell nuclear transfer ~~cloning~~,
 3 and ^{to create a human being genetically identical}
 4 ^{to an existing or deceased human being.}
 5 (2) provide for further review of the ethical and
 6 scientific issues associated with the use of somatic
 7 cell nuclear transfer in humans.

7 SEC. 4. DEFINITIONS.

8 In this Act:

✓ 9 (1) CLONING.—The term “cloning” means the
 10 production of a precise genetic copy of a molecule
 11 (including DNA), cell, ^{organ} tissue, plant, animal, or
 12 human.

13 (2) NUCLEUS.—The term “nucleus” means the
 14 cell structure that houses the chromosomes, and
 15 thus the genes.

16 (3) OOCYTE.—The term “oocyte” means the fe-
 17 male germ cell, the egg.

18 (4) SOMATIC CELL.—The term “somatic cell”
 19 means a mature, diploid cell.

✓ 20 (5) SOMATIC CELL NUCLEAR TRANSFER.—The
 21 term “somatic cell nuclear transfer” means transfer-
 22 ring the nucleus of a somatic cell of an existing or
 23 ~~previously existing~~ ^{deceased} human child or adult into an oo-
 24 cyte from which the nucleus has been removed.

↑ or ~~inactivated~~
 nuclear insert

6 SEC. 3. PROTECTED BIOMEDICAL RESEARCH

11 (1) ~~the use of~~ somatic cell nuclear transfer or

14 (3) ~~the use of~~ somatic cell nuclear transfer
15 techniques to create ^{non-human} animals.

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

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

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

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

8 (e) **ADVISORY OPINIONS.**—The Attorney General
9 shall, upon request, render binding advisory opinions re-
10 garding the scope, applicability, interpretation, and en-
11 forcement of this Act with regard to specific research
12 projects or practices.

13 **SEC. 8. COOPERATION WITH FOREIGN COUNTRIES.**

14 It is the sense of Congress that the President should
15 cooperate with foreign countries to enforce mutually sup-
16 ported restrictions on the activities prohibited under sec-
17 tion 5.

18 **SEC. 9. NATIONAL BIOETHICS ADVISORY COMMISSION RE-**
19 **PORT.**

20 Not later than 4½ years after the date of enactment
21 of this Act, the National Bioethics Advisory Commission
22 shall prepare and submit to the President a report con-
23 cerning—

24 (1) the state of the science of ~~somatic cell nu-~~
25 ~~clear transfer~~ *cloning + cell biology*

and Congress

relevant developments in

✓ 1 (2) the ^{safety} ethical and social issues associated with
2 the potential use of this technology in humans; and
3 (3) the advisability of continuing the prohibition
4 established under this Act.

✓ 5 The Commission is authorized to continue for the ⁵~~10~~-year
6 period described in section 12 to prepare such report and
7 for other purposes as established in Executive Order
✓ 8 ~~122~~975 and subsequent amendments to such Order.

9 SEC. 10. RIGHT OF ACTION.

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

12 SEC. 11. PREEMPTION OF STATE LAW.

13 The provisions of this Act shall preempt any State
14 law that prohibits or limits research or practices regarding
15 somatic cell nuclear transfer, human cloning, cloning of
✓ 16 molecules, DNA, cells, or tissues, ^{or organs,} the use of somatic cell
17 nuclear transfer techniques to develop animals ~~or related~~
✓ 18 ~~research.~~

19 SEC. 12. EFFECTIVE DATE.

✓ 20 This Act shall be effective for the ⁵~~10~~-year period be-
21 ginning on the date of enactment of this Act. The prohibi-
22 tions contained in this Act shall terminate at the expira-
23 tion of such 10-year period.

CLONING FACT SHEET

- Cloning means making a identical copy of a molecule like DNA, a cell, a tissue, a plant, an animal, or a human.

- Ethics aside, It is unsafe to clone an entire human being at this time because the technology isn't good enough to ensure that abnormal children wouldn't be born. The Kennedy-Feinstein bill would ban this type of cloning with a 5 year sunset.

- To clone an adult human being would require taking the adult's DNA (genes) and putting it into an egg cell. If the egg is grown under certain conditions, an embryo will develop and become a whole person. However, the egg cell can be grown under other conditions to develop instead into a specific kind of tissue like muscle, skin, nerves, or bone. (We can already do this in mice, humans are the next step.) This technology would revolutionize tissue transplantation for all kinds of medical conditions: cancers, burns, spinal cord injuries, diabetes, heart attacks, Parkinson's, etc. There would be little danger of the rejection that occurs when you use tissue from another human, and doesn't carry the threat of viral diseases that we have now using baboon or pig tissue. Theoretically, this could lead to making organs for transplantation too. The Kennedy-Feinstein bill would not ban using cloning technology to grow compatible tissues and organs.

- Cloning an entire human being is a category of embryo research. Creating compatible tissue from a human being using cloning techniques is also a category of embryo research since it uses an egg cell.

- If we don't do embryo research we won't fully understand or can't do:

- causes and treatments of infertility
- tissue/organ transplants customized for the patient
- treatment of cancer, especially childhood cancers
- better methods of birth control
- cause and treatments of birth defects
- gene therapy to correct diseases in embryos

The Kennedy-Feinstein bill would not prohibit these kinds of embryo research.

- In vitro fertilization requires making lots of embryos, because many are defective. We can screen embryos for specific genetic diseases and only implant the ones that are OK. In vitro fertilization is very expensive and inefficient and to develop better methods will require research on embryos. Most research is on embryos less than 5 days old. Those embryos are a ball of identical cells at that stage and wouldn't have implanted in a womb yet. A 1994 panel at the NIH decided that most research (excluding cloning) was ethical on embryos less than 14 days old. However, an executive order and appropriation bans over the last 3 years have limited embryo research to companies or universities using private funds.

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To prohibit the use of Federal funds for human cloning research. (Introduced in the Senate)

S 368 IS

105th CONGRESS

1st Session

S. 368

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.

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

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.

Op-Ed**The New York Times**
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January 28, 1998

Why The Rush To Ban Cloning?



By ARTHUR L. CAPLAN

PHILADELPHIA -- Richard Seed, the retired physicist who scared the nation to death earlier this month with his talk of creating a brave new biological world, has inadvertently become the poster boy for regulating cloning. It does not seem to matter that Dr. Seed, who has none of the laboratories, technical skills, money or other tools requisite to harness this powerful and dangerous technology, will never clone anyone.

Regulation is all but an inevitability. This situation should make people like me, who think human cloning should proceed at a snail's pace, ecstatic. But I am not ecstatic. Before the President, Congress, the Food and Drug Administration or anyone else rushes to ban anything, we need to be sure that laws and regulations do not control human cloning at the cost of forgoing the huge benefits that animal and cell cloning will bring.

If cloning can be perfected, which is by no means a certainty, it will permit the easier mass production of animals with particular traits.

The same will be true for cells and many types of tissues. That means more food at less cost, a cornucopia of biologically valuable substances available in huge quantities, and the ability to preserve species on the verge of extinction.

The benefits of rushing to attempt human cloning are far harder to see. So it is clear what the goal of regulation and legislation ought to be: to buy us the time to insure the safety and proper oversight of human cloning work. Put a moratorium of a few years on any effort to create a human being by means of cloning.

But therein lies the problem. Can legislation be written with the requisite precision? The early signs are not good. The torrent of legislative and regulatory ideas now being floated are not limited to human cloning. Most troubling, some legislators are tempted to use anti-cloning measures to try to ban or limit abortion and embryo research.

The latest to offer a regulatory response to the cloning question is the F.D.A. The agency says anyone who wants to clone will have to answer to it.

What is not at all clear, however, is whether a regulatory body charged with insuring the safety of drugs and medical devices intended for commercial sale has the standing to say anything about human cloning. Nor is it clear from the agency's statements what the F.D.A. thinks its authority and enforcement powers are. Even if the regulatory net of the F.D.A. is extended to human cloning, the way to debate the pros and cons and fine points of the subject is not through the filter of a bureaucracy whose mandate does not include metaphysics.

Some state legislators are also getting into the act. In Minnesota, Alabama and many other states, bills are pending that would ban or limit cloning, and California has already imposed a ban. But cloning is not an activity that should be handled at the state level, since having 50 sets of rules would make little sense. Moreover, such local efforts -- which have included proposals to ban all forms of cloning, to make any manipulation of human embryos illegal and to ban any use of human genes in genetic engineering -- are a cure far worse than the disease.

In Congress, pro-life forces are eager to use anti-cloning legislation to outlaw abortion, fetal tissue research and embryo research. When Representative Vernon Ehlers, a Michigan Republican, introduced a bill in the House last year to ban Federal financing for human cloning, he soon found himself hauling around a proposal that banned human embryo research as well. If human cloning becomes just another pawn in the ongoing abortion wars, we risk living with a law that covers too much for reasons having nothing to do with cloning. Or we risk having no legislation at all.

What we need is a political agreement to keep the focus squarely on human cloning. Talk of outright bans should stop. Efforts at regulating cloning at the state level should cease. Regulatory agencies should stand aside and let the American people ask for a breather through Federal legislation.

A moratorium would give us the time we need to decide where to go next when and if cloning technology has been shown safe and reliable in animals. We should not let the likes of a Dr. Seed or abortion politics make us do anything that will make the benefits of cloning impossible to obtain.

Arthur L. Caplan, the director of the Center for Bioethics at the University of Pennsylvania Health System, is the author of "Am I My Brother's Keeper: The Ethical Frontiers of Biomedicine."

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S.L.C.

DRAFT

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1 (1) it has been reported that an adult sheep has
2 been cloned using a technique called somatic cell nu-
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4 (2) the National Bioethics Advisory Commission
5 (referred to in this Act as the "NBAC") has re-
6 viewed the scientific and ethical implications of the
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8 beings;

9 (3) the NBAC has determined that—

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12 technology, livestock productions, and new med-
13 ical approaches including the production of
14 pharmaceutical proteins and prospects for re-
15 generation and repair of human tissues; and

16 (B) the possibility of using somatic cell nu-
17 clear transfer for the purposes of creating a
18 child entails significant scientific uncertainty
19 and medical risk, which could result in harm to
20 a child;

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

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3

1 (5) the consensus of the NBAC is based on cur-
2 rent scientific information indicating that this tech-
3 nique is not safe to use in humans at this time;

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5 identified many additional serious ethical concerns
6 which they agreed require a great deal more wide-
7 spread and careful public deliberation before this
8 technology may be used;

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

16 (8) the NBAC further recommended that Fed-
17 eral legislation be enacted to prohibit anyone from
18 attempting, whether in a research or clinical setting,
19 to create a child through somatic cell nuclear trans-
20 fer cloning;

21 (9) the NBAC also recommended that the Unit-
22 ed States cooperate with other countries to enforce
23 mutually supported restrictions on this activity;

24 (10) the NBAC specified that such Federal leg-
25 islation should include a sunset provision and that,

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S.L.C.

4

1 prior to the sunset date, an oversight body should
2 review and report on the status of somatic cell nu-
3 clear transfer technology and the ethical and social
4 issues associated with its use and recommend wheth-
5 er the prohibition should be continued;

6 (11) the NABO concluded that any regulatory
7 or legislative actions undertaken to effect the fore-
8 going prohibition should be carefully written so as
9 not to interfere with other important areas of re-
10 search, such as the cloning of human DNA se-
11 quences and cells, which raise neither the scientific
12 nor the ethical issues that arise from the possible
13 creation of children through somatic cell nuclear
14 transfer techniques;

15 (12) the NABO also found that cloning animals
16 by somatic cell nuclear transfer does not raise the
17 same issues implicated in attempting to use the
18 technique to create a child, and its continuation
19 should only be subject to existing regulations regard-
20 ing the humane use of animals; and

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

24 **SEC. 3. PURPOSES.**

25 It is the purpose of this Act to—

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S.L.C.

5

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

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

7 **SEC. 4. DEFINITIONS.**

8 In this Act:

9 (1) **CLONING.**—The term “cloning” means the
10 production of a precise genetic copy of a molecule
11 (including DNA), cell, tissue, plant, animal, or
12 human.

13 (2) **NUCLEUS.**—The term “nucleus” means the
14 cell structure that houses the chromosomes, and
15 thus the genes.

16 (3) **OOCYTE.**—The term “oocyte” means the fe-
17 male germ cell, the egg.

18 (4) **SOMATIC CELL.**—The term “somatic cell”
19 means a mature, diploid cell.

20 (5) **SOMATIC CELL NUCLEAR TRANSFER.**—The
21 term “somatic cell nuclear transfer” means transfer-
22 ring the nucleus of a somatic cell of an existing or
23 previously existing human child or adult into an oo-
24 cyte from which the nucleus has been removed.

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S.L.C.

6

1 **SEC. 5. PROHIBITION.**

2 It shall be unlawful for any person or other legal en-
3 tity, public or private, to implant or attempt to implant
4 the product of somatic cell nuclear transfer into a woman's
5 uterus.

6 **SEC. 6. PROTECTED BIOMEDICAL RESEARCH**

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

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

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

16 **SEC. 7. PENALTIES.**

17 (a) **IN GENERAL.**—Any person who intentionally vio-
18 lates the provisions of section 5 shall be fined the greater
19 of \$250,000 or 2 times the gross pecuniary gain or loss
20 resulting from the violation.

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

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

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S.L.C.

7

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

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

8 (e) **ADVISORY OPINIONS.**—The Attorney General
9 shall, upon request, render binding advisory opinions re-
10 garding the scope, applicability, interpretation, and en-
11 forcement of this Act with regard to specific research
12 projects or practices.

13 **SEC. 8. COOPERATION WITH FOREIGN COUNTRIES.**

14 It is the sense of Congress that the President should
15 cooperate with foreign countries to enforce mutually sup-
16 ported restrictions on the activities prohibited under sec-
17 tion 5.

18 **SEC. 9. NATIONAL BIOETHICS ADVISORY COMMISSION RE-**
19 **PORT.**

20 Not later than 4½ years after the date of enactment
21 of this Act, the National Bioethics Advisory Commission
22 shall prepare and submit to the President a report con-
23 cerning—

24 (1) the state of the science of somatic cell nu-
25 clear transfer;

1 (2) the ethical and social issues associated with
2 the potential use of this technology in humans; and
3 (3) the advisability of continuing the prohibition
4 established under this Act.

5 The Commission is authorized to continue for the 10-year
6 period described in section 12 to prepare such report and
7 for other purposes as established in Executive Order
8 122975 and subsequent amendments to such Order.

9 **SEC. 10. RIGHT OF ACTION.**

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

12 **SEC. 11. PREEMPTION OF STATE LAW.**

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

19 **SEC. 12. EFFECTIVE DATE.**

20 This Act shall be effective for the 10-year period be-
21 ginning on the date of enactment of this Act. The prohibi-
22 tions contained in this Act shall terminate at the expira-
23 tion of such 10-year period.

DRAFT

MEMORANDUM FOR THE PRESIDENT

FROM:

SUBJECT: Cloning Legislative Options

Interest in cloning legislation was renewed by reports that a Chicago physicist plans to attempt to use this technology to create a child. Your January 10 radio address challenged Congress to enact a ban on private sector activities like the one you have imposed on the public sector. This issue is likely to appear in both the House and Senate very soon after they return. Based on bills introduced in the fall, and the difficulties inherent in trying to craft a bill of appropriate scope, there is a strong possibility that Congressional measures may deviate from the principles outlined in your draft bill.

This memorandum summarizes the following options with respect to a legislative strategy on cloning: (A.) continue to support the principles and language in your June 9, 1997 draft bill; (B.) support the principles but refine the current language; (C.) change the scope of prohibited activities to respond to criticism; or (D.) adopt a prohibition with a more general focus.

The memorandum also presents the pros and cons associated with a clause pre-empting state legislation of human cloning.

I. Substantive Prohibition

A. Support existing language without changes

Your bill has been praised by industry and professional societies for its narrow focus on the act of creating a human being through somatic cell nuclear transfer (SCNT), the technology used to create Dolly the sheep, and the absence of mention of embryo research. These groups also applaud your protection of noncontroversial biomedical research and the 5-year sunset provision. Current language maintains the status quo with respect to freedom to carry out embryo research in the private sector under existing (albeit limited) Federal oversight. The Federal ban on creation of human embryos for research purposes is unaffected by any of the options in this memorandum.

B. Refine current language

Continue to hold to the principles expressed in your draft bill but make the following changes to clarify the prohibition:

Current language:

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.

Suggested modification:

It shall be unlawful for any person or other legal entity, public or private, to introduce the product of somatic cell nuclear transfer into a woman's womb in order to create a child.

Rationale

- There is greater agreement on the definition of a child than there is on a human being, thus avoiding some, but not all of the embryo research and abortion debate.
- The term "or in any other way" created unnecessary confusion.
- "Intent" was included as protection for a defendant, but industry and medical practitioners suggested deleting it.

C. Continue to support the principles in the existing bill but broaden its scope

We would like you to focus on pros and cons of including the phrase "in order to create a child" as it appears in Option B.

You have been sensitive to the need to be very cautious in setting a boundary around permissible biomedical research through this bill; hence its narrow focus. The phrase "in order to create a child" maintains that view with its implied intent. However, it suggests two potentially troubling scenarios of which you should be aware. First, it may be interpreted to encourage abortion because transfer of the product of cloning would be prohibited only if it was done so as to create a child, not if it was done with intent to abort. Second, someone caught in the act of attempting to create a child using this method could avoid liability simply by aborting the cloned embryo or fetus.

Therefore, we would suggest that the prohibition be modified to read as follows:
It shall be unlawful for any person or other legal entity, public or private, to introduce the product of somatic cell nuclear transfer into a woman's womb.

This clear language means that during the time this law is in effect, no one in the public or private sectors may perform somatic cell nuclear transfer and implant the resulting product in a woman's uterus. Today, this is legal in the private sector, although it may be possible to exert some regulatory oversight, as discussed in the background attachment. Some fertility research would be precluded under this option, although it is difficult to determine how much because efforts are generally made to sustain a pregnancy after implantation; not to perform experiments with the intention of aborting.

The right-to-life community criticized your bill for allowing the creation of embryos for research purposes using private funds, as long as those embryos were aborted subsequently. This modification still permits the creation of embryos but removes the incentive for abortion. While the scientific and medical communities supported your earlier version, it is likely that you will retain their support even with this change in view of the larger threats to research emanating from

Congress. However, it does make the sunset clause all the more crucial. We have been told that the fertility research community would not object to this approach.

D. Adopt a more general prohibition

Your bill is intended to prevent anyone from creating a child who is a genetically identical copy of an existing or previously existing person. Somatic cell nuclear transfer is one way of accomplishing this feat and you endorsed the recommendation of your National Bioethics Advisory Commission in limiting the scope of your bill to the use of this technology to create a child. Another option would be to construct a more general, non-technology specific ban such as the following:

It shall be unlawful to create a child who is genetically identical to an existing or previously existing child or adult.

Violation of this ban will depend on one's definition of the point at which life begins. Some people believe that an embryo is a child, hence, creating identical embryos would be in violation of the law. Under this definition, an existing reproductive technology known as blastomere or blastocyst splitting would be prohibited. This method is used to treat women with reduced fertility, particularly those who are older and wish to have more than one child but are unable or unwilling to undergo the drug treatments necessary to stimulate hyperovulation. It may also be used with donor eggs. What is done, in essence, is to fertilize one egg and after just a few cell divisions, split the early embryo. This mimics the occurrence in nature of identical twins. However, the mother has the option of implanting both embryos, or freezing one and implanting it at a later date, thus creating non-contemporaneous twins.

If one believes that life begins at birth, then it would be permissible to create a cloned embryo, implant that embryo in a woman's uterus, and abort it at any point prior to birth. This course has the same shortcomings as Option 2 in that it may be interpreted to encourage abortion.

Recommendation:

We propose that you select Option C. so as to: maintain as narrow a prohibition as possible, thus protecting a wide range of biomedical research, and preserve the status quo with respect to incentives for abortion.

Approve: _____ Disapprove: _____ Discuss: _____

II. Federal Pre-emption of State Regulation

The industry is strongly advocating that the Administration use this bill to pre-empt state laws restricting cloning research. The industry cites the California Bill as an example of the type

of provision that would prohibit appropriate biomedical research on cloning and they fear that the political climate would likely pressure states to adopt unduly restrictive measures.

There are also a number of reasons arguing against pre-emption at this time. For example, federalism concerns would normally militate against preemption unless it could be shown that such action is necessary (e.g. when there is a need for national standards). In this case, although the industry might be inconvenienced by the existence of differing laws, there is no clear reason why uniform standards are required. Indeed, in the area of biomedical research, there is a strong argument in favor of allowing the states to experiment with a wide range of options because no single correct approach to this issue is immediately obvious. Moreover, the industry's fears that the states would act in concert to preclude important biomedical research, beyond the use of cloning to create a child, seem unwarranted. It is not likely that every state would choose to ban all research because the states that elect to forego restrictive regulation would be likely, on that account, to attract new industry. Finally, using this particular bill to preclude all state regulation of biomedical research is inconsistent with our position that this bill is designed to address only the limited issue of cloning and is not an attempt to address broader research issues.

Recommendation:

We recommend against adding a pre-emption clause.

Approve: _____ Disapprove: _____ Discuss: _____

Attachments:

A. Discussion of Impact of FDA Regulatory Authority on Legislative Strategy

B. H.R. 922 - Bill Introduced By Rep. Vernon Ehlers to prohibit the expenditure of Federal funds to conduct or support research on the cloning of humans.

copied
Kagan
Gibbons
cos

Cloning

THE WHITE HOUSE

WASHINGTON

June 8, 1997

Bruce -

FYI. What we gave to the President This weekend.

Elena

MEMORANDUM FOR THE PRESIDENT

THE PRESIDENT HAS SEEN

6/8/97

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.

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 described 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) person—a "delayed" genetic twin. This prospect

has been the source of the overwhelming public concern about such cloning.

While the creation of embryos for research purposes alone always raises serious ethical questions, 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 particular 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 the 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. 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 might be 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 current scientific information indicates that this technique is not safe to use in humans at this point. 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 unacceptable 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 body would at this time be an irresponsible, unethical, and unprofessional act.

II. The Commission further recommends that:

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.

- 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 techniques 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.

June 9, 1997

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On February 24, 1997, in the wake of the announcement that scientists in Scotland apparently had succeeded in cloning an adult sheep, you asked the National Bioethics Advisory Commission to review the legal and ethical issues associated with the use of this technology and to report back within ninety days with recommendations. A week later you instructed the heads of executive departments and agencies that "no federal funds shall be allocated for cloning of human beings" thereby ensuring that precipitous steps would not be taken while the Commission was studying the subject.

In this short interval, we have made every effort to consult with ethicists, theologians, scientists, physicians, and other citizens with interests and concerns in this area. Moreover, we have invited inputs for the Commission's consideration from as broad a cross-section of the community as time allowed. Further, recognizing that science and medicine are international activities with outstanding investigators and facilities in many nations, we have attempted to review relevant policies and proposals with respect to human cloning in other countries. However, we do not view it as essential to follow others in this area unless we find their proposals compelling, since we have different political and cultural traditions.

In this report, we address a very specific aspect of cloning namely where genetic material would be transferred from the nucleus of a somatic cell of an existing human being to an enucleated human egg with the intention of creating a child. We do not revisit either the question of the cloning of humans by embryo-splitting or the issues surrounding embryo research. The latter issue has, of course, recently received careful attention by a National Institutes of Health panel, the Administration, and Congress.

Not surprisingly, we have discovered that the potential ability to clone human beings through the somatic cell nuclear transfer techniques raises a whole host of complex and difficult scientific, religious, legal and ethical issues--both new and old. Indeed, the Commission itself is unable to agree at this time on all the ethical issues that surround the issue of cloning human beings in this manner. It seems clear to all of us, however, given the current stage of science in this area, that any attempt to clone human beings via somatic cell nuclear transfer techniques is uncertain in its prospects, is unacceptably dangerous to the fetus and, therefore, morally unacceptable. At present, moral consensus on this issue should be easily achieved. Furthermore, the continuing

controversy over the social and ethical issues raised by this new development require more time for deliberation and the accumulation of new scientific data. We therefore recommend that the current moratorium on attempts to create children in this manner be continued and that you immediately ask for voluntary compliance in the private sector while federal legislation banning the use of these techniques for creating children is formulated and considered.

While we have been able to agree on this and certain other recommended actions, we feel quite strongly that most of the legal and moral issues raised can only be resolved, even temporarily, by a great deal more widespread deliberation and education. This type of national discussion is especially necessary in our democratic and pluralistic society for the following reasons: there is no universally accepted ethical theory; Americans hold various religious and moral perspectives on these issues; conflicting values are at stake; Americans differ on the importance and meaning of particular traditions; tolerance (agreeing to disagree) governs wide areas of our national life; and given our historical traditions, we are strongly inclined to leave to the individual conscience those acts that do not harm others and on which there is no moral consensus.

As a result, we must continue to build our understanding of the widespread public concern that has been generated by these recent developments. Some of this concern can be explained by an inadequate understanding of the issues--sometimes even confusing science and science fiction. This matter, however, can be addressed over time through further public education. Other concerns, however, run much deeper and range from the implications for particular faith commitments, to views regarding the appropriate sphere for human action, to concerns regarding the future of the family, to cumulative apprehensions about the real net benefit of a rapidly advancing technology that some believe is too aggressively pushing aside important social and moral values. As we move ahead to the next stage of our national discussion, these are among the many issues that need to be thoughtfully addressed.

Finally, while our specific recommendations include continuing the moratorium you announced in February of this year, and a call for a specific federal legislation, the report also includes important sections outlining the scientific, religious, ethical and legal issues that are raised by these new scientific developments. It is our hope that these materials, by clarifying certain issues and highlighting others, will form a useful initial basis for the ongoing deliberations and educational dialogues that we believe are so essential. We have been impressed by the difficulties caused by the lack of knowledge about genetics and the science involved in cloning revealed in the public and media responses to the cloning of Dolly the sheep. We believe, therefore, that the federal government should continue to actively encourage public education in this area of science so that as public deliberation takes place it is as informed as possible.

I would like to take this opportunity to thank all the Commissioners and our very dedicated staff for the intensity and depth of their commitment to the task that you assigned to us.

Sincerely,

Harold T. Shapiro
THE WHITE HOUSE

Cloning
THE PRESIDENT HAS SEEN
6-4-97

THE WHITE HOUSE
WASHINGTON

June 3, 1997

Copied to:
Kagan
Gibbons
Emanuel
Bowles

MEMORANDUM FOR THE PRESIDENT

FROM: TODD STERN *TS*
PHIL CAPLAN *PC*

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 ____

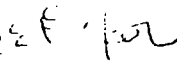
File-cloning

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:

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

shall be ineligible to receive any contract or subcontract made with funds made available in this Act, pursuant to the debarment, suspension, and ineligibility procedures described in sections 9.400 through 9.409 of title 48, code of Federal Regulations.

SEC. 507. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

[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.]¹

SEC. [509] 508. Notwithstanding any other provision of law—

(1) no amount may be transferred from an appropriation account for the Departments of Labor, Health and Human Services, and Education except as authorized in this or any subsequent appropriation Act, or in the Act establishing the program or activity for which funds are contained in this Act;

(2) no department, agency, or other entity, other than the one responsible for administering the program or activity for which an appropriation is made in this Act, may exercise authority for the timing of the obligation and expenditure of such appropriation, or for the purpose for which it is obligated and expended, except to the extent and in the manner otherwise provided in sections 1512 and 1513 of title 31, United States Code; and

(3) no funds provided under this Act shall be available for the salary (or any part thereof) of an employee who is reassigned on a temporary detail basis to another position in the employing agency or department or in any other agency or department, unless the detail is independently approved by the head of the employing department [of] or agency.

[SEC. 510. None of the funds made available in this Act may be used for the expenses of an electronic benefit transfer (EBT) task force.]

SEC. [510] 509. Not to exceed 1 percent of any discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act, as amended) which are appropriated for the current fiscal year for titles I, II, and III of this Act may be transferred between appropriations, but no such appropriation shall be increased by more than 3 percent by any such transfer: Provided, That such transfers may be made only between appropriations within each title: Provided further, That the Public Health and Social Services Emergency Fund appropriation under title II of this Act shall not be subject to the 3 percent limitation of this section.

SEC. [511] 510. None of the funds made available in this Act may be used to enforce the requirements of section 428(b)(1)(X)(iii) of the Higher Education Act of 1965 with respect to any lender when it is made known to the Federal official having authority to obligate or expend such funds that the lender has a loan portfolio under part B of title IV of such Act that is equal to or less than \$5,000,000.

[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.]²

SEC. [513] 511. (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. 514. (a) DENIAL OF FUNDS FOR PREVENTING ROTC ACCESS TO CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps (in accordance with section 654 of title 10, United States Code, and other applicable Federal laws) at the covered educational entity; or

(2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

(b) DENIAL OF FUNDS FOR PREVENTING FEDERAL MILITARY RECRUITING ON CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or

(2) access by military recruiters for purposes of Federal military recruiting to the following information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity:

(A) student names, addresses, and telephone listings; and

(B) if known, student ages, levels of education, and majors.

(c) EXCEPTIONS.—The limitation established in subsection (a) or (b) shall not apply to a covered educational entity if the Secretary of Defense determines that—

(1) the covered educational entity has ceased the policy or practice described in such subsection;

(2) the institution of higher education involved has a longstanding policy of pacifism based on historical religious affiliation; or

(3) the institution of higher education involved is prohibited by the law of any State, or by the order of any State court, from allowing Senior Reserve Officer Training Corps activities or Federal military recruiting on campus, except that this paragraph shall apply only during the one-year period beginning on the effective date of this section.

(d) NOTICE OF DETERMINATIONS.—Whenever the Secretary of Defense makes a determination under subsection (a), (b), or (c), the Secretary—

(1) shall transmit a notice of the determination to the Secretary of Education and to the Congress; and

(2) shall publish in the Federal Register a notice of the determination and the effect of the determination on the eligibility of the covered educational entity for contracts and grants.

(e) SEMIANNUAL NOTICE IN FEDERAL REGISTER.—The Secretary of Defense shall publish in the Federal Register once every 6 months a list of each covered educational entity that is currently ineligible for contracts and grants by reason of a determination of the Secretary under subsection (a) or (b).

(f) COVERED EDUCATIONAL ENTITY.—For purposes of this section, the term "covered educational entity" means an institution of higher education, or a subelement of an institution of higher education.

(g) EFFECTIVE DATE.—This section shall take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act, by which date the Secretary of Defense shall have published final regulations in consultation with the Secretary of Education to carry out this section.]

² The Administration proposes to delete this provision and does not support addressing this issue in legislation.

Human Embryo Research

Continuing Resolution 9 (P.L. 104-91) prohibited Federal funding for the "creation of a human embryo or embryos for research purposes..." and "for research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." The C.R. applied to funding for the entire FY 96. Identical language was placed in FY 97 DHHS Appropriations language (P.L.104-208). The President's FY 97 and 98 budgets proposed deleting the the second provision and did not support addressing this issue in legislation. The first section codifies the President's directive of Dec. 2, 1994. The second section addresses research on all human embryos, regardless of source. The second part goes substantially further in prohibiting a much larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

The second provision applies to embryos the same standards that are currently in place for research involving human fetuses. Research involving human fetuses is governed under DHEW 45 CFR part 46.208(a), "No fetus in utero may be involved as a subject in any activity covered by this subpart unless: (2) The risk to the fetus imposed by the research is minimal, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means." Minimal risk is defined as, "The probability and magnitude of harm or discomfort expected in the research is no greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." **Therefore, research that would involve manipulation of the preimplantation embryo that might result in its death, injury, or harm, is precluded under the Congressional ban, regardless of the source of the embryo.** This includes six of nine applications for funds for research on human in vitro fertilization that might have received NIH funding, in compliance with the President's directive of Dec. 1994.

Taken in sum, both phrases prohibit virtually all human embryo research that might be conducted with Federal funds under other circumstances. Due to the large demand for in vitro fertilization to circumvent certain male and female causes of infertility, there is considerable work under way in this area in the private sector, funded by patients. There are no standards in place governing such procedures, other than FDA requirements for approval of the component drugs and devices.

A preimplantation human embryo exists from a few days after conception until about 3 weeks, at which time implantation occurs. The NIH Human Embryo Research Panel highlighted research involving up to 14-day old embryos because it is at this time that the "primitive streak" appears; a line of cells that will eventually form the nervous system. Prior to development of the primitive streak, the embryo is a disc-shaped collection of cells that have yet to develop specific functions. This multi-function potential makes them especially valuable in the development of a wide range of therapeutic agents for leukemia, sickle cell anemia, Parkinson's disease, diabetes, and spinal cord injury. This field is emerging as one with significant potential to understand human biology and address illness and disease affecting millions of Americans.

CHRISTOPHER S. BOND
MISSOURI
COMMITTEE
APPROPRIATIONS
SMALL BUSINESS
BUDGET
ENVIRONMENT AND
PUBLIC WORKS

United States Senate

WASHINGTON, DC 20510-2503

January 9, 1998

Dear Colleague:

Please join me as a cosponsor of the "Human Cloning Prohibition Act". I intend to introduce the measure when the Senate reconvenes at the end of this month.

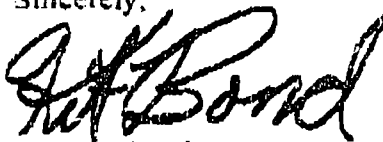
Reports this week that a Chicago-based scientist is prepared to move forward with human cloning experimentation forces an immediate debate on how far out on the moral cliff we are willing to let science proceed before we as a nation insist on some meaningful constraints. My legislation will send a strong message that this type of research is clearly unethical and unacceptable by placing an emergency ban on human cloning research.

Plant and animal cloning, and research taking place at the Human Genome Center offer great hope in addressing how to prevent, diagnose, and treat many devastating diseases. However, we must draw the line at human cloning. The belief that all human beings are unique and created by God is shared by billions of us around the world. Human cloning, or man's attempt to play God, would change the very meaning of life, of what it is to be human. Are we ready for that? Hardly.

The United States should show the moral courage and follow the example of several other countries by banning and criminalizing all human cloning research, whether public or private. Recent news accounts show that we no longer have the luxury of waiting for this morally reprehensible act to occur.

If you would like to join me, or if you have any questions, please call me or have your staff contact Joe Pierle of my staff at 4-5721.

Sincerely,



Christopher S. Bond

⑫ MO

Health

DIANNE FEINSTEIN
CALIFORNIACOMMITTEE ON FOREIGN RELATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

United States Senate

WASHINGTON, DC 20510-0504

Health

January 15, 1998

Dear Colleague:

I am writing to invite you to join me in cosponsoring legislation to prohibit human cloning, whether funded publicly or privately.

According to recent press reports, Dr. G. Richard Seed, a Chicago-area physicist, announced that he intends to clone a human being and that eight people have already volunteered to be cloned.

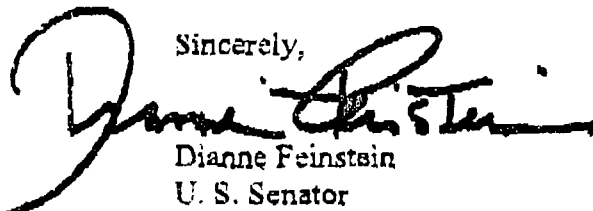
I agree with the recommendation of the National Bioethics Advisory Commission, that "... at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning." The Commission concluded that this technique is not safe to use in humans and that it raises "serious ethical concerns . . . which require much more widespread and careful public deliberation before this technology may be used."

Commendably, President Clinton on March 4, 1997, directed federal agencies not to use federal funds for the cloning of human beings. This prohibition, however, does not extend to privately-funded research and on June 10, the President proposed the Cloning Prohibition Act to cover both the public and private sector.

The legislation I will introduce will make it unlawful, for ten years, for any person or other legal entity, public or private, to use cloning to create human beings. It will also require the National Bioethics Advisory Commission to report to the President and the Congress on the (1) state of the science of somatic cell nuclear transfer and (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 the bill.

I hope you will join me in cosponsoring this bill and working for its prompt enactment. If you have any questions, please feel free to call me or Glenda Booth or Richard Pfohl at 4-3841 on my staff.

Sincerely,


Dianne Feinstein
U. S. Senator

D-CA

DF:gb

JUDD GREGG
NEW HAMPSHIRE

CHIEF DEPUTY WHIP

COMMITTEES:

BUDGET

APPROPRIATIONS

LABOR AND HUMAN RESOURCES

United States Senate

WASHINGTON, DC 20510-2904

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Health

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99 PEASE BOULEVARD
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January 14, 1998

Dear Colleague:

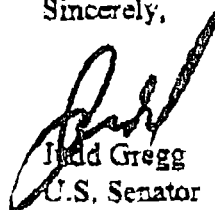
When we return for the second session of the 105th Congress, there is an issue that will require our immediate action: the cloning of human beings. I firmly believe that there needs to be an outright prohibition on the possible development of this procedure. Current law prohibits federal funds going toward human embryo research, but we must clearly now extend the ban to private activities as well. That is why I will be introducing legislation upon our return to ban human embryo creation by the process of cloning.

It has been almost 12 months since the world learned that, after 276 unsuccessful attempts, Dr. Ian Wilmut of the Roslin Institute in Scotland had actually managed to clone a sheep that became known as "Dolly." Since that time, the debate has gone from the theoretical to the possible implications of this ability to clone living beings. However, the overwhelming consensus has been that while cloning may hold some important scientific promise for producing therapies where they may not exist -- such as growing skin from skin cells for burn victims -- as well as potential for important agricultural and botanical advances, there is little tolerance for those who entertain the notion of reproducing human "carbon copies."

My legislation is modeled on a law that was enacted last year in the State of California, that became effective January 1, 1998. Similar to the California law, my bill makes the cloning of a human being unlawful. My bill differs from the California law, however, in that it outlaws human embryo creation even for the purpose of research. My proposal does allow certain genetic research that does not involve cloning human embryos to continue. This legislation sets up a system of penalties for the violation of this law that will serve as a deterrent for such activities in either the public or the private sector.

I hope that you will join me as a cosponsor of this legislation, which I will circulate shortly. I do not believe that we here in the Senate have the luxury of time on this issue. I hope to see this legislation considered expediently upon our return. If you are interested in being a cosponsor, please contact Kimberly Spaulding or Alan Gilbert of my staff at 4-0136.

Sincerely,


Judd Gregg
U.S. Senator

(R) 104

Prohibitions, Part 1

Prohibition	Administration	possible revision 1
wording	Administration Bill (June 9, 1997) 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.	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 in order to create a child.
discussion	"Or in any other way creating a human being"—The meaning of this phrase is unclear. It can be interpreted to mean creating a human being in any way other than by using SCNT, or, as we intended, creating a human being through extra-uterine gestation, a technology that is unlikely to become available prior to significant development of SCNT.	"intent"—Questions for the legal scholars — is intent a term associated only with criminal statutes? Would its inclusion make this language more difficult to enforce? What does it add? Does it make sense in reference to a legal entity? Is "other legal entity" necessary?
discussion	"human being"—We have not and probably would prefer not to attempt to define: a human being, the means for creating a human being, nor the definitive act that results in the creation of a human being. Therefore, one option is to substitute "child" in place of "human being," as the National Bioethics Advisory Commission chose to do. While this leaves open the question of when a fetus becomes a child, there is greater agreement on this point, i.e., at birth, than on when life begins.	
implication		
implication		
implication		

Prohibitions, part 2

possible revision II	ASRM	Council of Europe
It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer when the product of that transfer is introduced into a woman's womb [in order to create a child].	It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.	Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
	This is a very straightforward statement but is burdened by implications regarding abortion.	Does not mention any specific type of cloning technology, which may be desirable. Invites definitional issue of when a human being is created.
Violation begins at time of introduction of the product of SCNT into a woman's uterus.	Violation occurs at the time of birth (unless one believes that a child is created before birth) and so allows anything up to that point including creating an embryo via SCNT and introducing it into a woman's uterus	The word "seeking" is vague leaving open possibility of inhibiting a range of research involving other forms of cloning.
Would allow creation of an embryo (only with private funding) using SCNT, as long as transfer to woman's uterus does not occur.	Would require abortion at some point before birth	Similar to ASRM prohibition above.
Would maintain status quo for private sector IVF research	Would allow embryo research (using private funds), regardless of whether or not the embryo was transferred to a woman for gestation, thus permitting fertility and other biomedical research	Could be used to proscribe a broad range of research involving other forms of cloning.
Would be consistent with current public sector ban on embryo research, precluding opportunity to capitalize on SCNT for research into treatment for spinal cord and other nerve cell regeneration, AIDS, skin grafts, and replacement organs.		May prohibit blastomere or embryo splitting; a reproductive technique currently in use in this country, depending on definition of human being.

Definitions	Administration	ASRM	ASRM
wording	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:	"somatic cell means a mature, diploid cell."	"the creation of a human child" means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth."
discussion	"Somatic cell" – See alternative definition below. While ours differs from others, it is a reasonable, accurate lay language definition of a technical term. The goal of groups such as ASRM and BIO is to create a more narrow set of definitions in order to protect a rather broad class of research. Ours is not so encumbered, leaving out any oblique references to embryo research.	"Diploid" corresponds to our definition; mature is an addition intended to permit certain types of infertility or other biomedical research. For example, under this definition research might be carried out to improve the efficiency of in vitro fertilization and other treatments for infertility using cells taken from an embryo.	ASRM's intent is to prohibit the birth of a child created using SCNT technology but their definition is unclear with respect to the act of implantation.
		Research of more general interest might be done using cells not yet deemed to be mature, or so-called stem cells, cells which have not yet differentiated into their final form. Embryonic stem cells are cells from an early embryo that can go on to form any cell of the organism. Embryonal stem cells from mice have been grown in culture and can be stimulated to form precursors of blood, nerve and muscle cells. Human embryonal stem cells could be cultured similarly and engineered to prevent transplant rejection.	

OTHER	Administration	possible revision (suggested by Sen. Feinstein's staff)
wording	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:	SECTION 6. PROTECTED BIOMEDICAL RESEARCH AND MEDICAL PRACTICE.—Nothing in this Act shall restrict other areas of biomedical and agricultural research and medical practice, including important and promising work that involves:
discussion		Includes reference to medical practice.

CLONING

LEGISLATIVE OPTIONS

BACKGROUND

Cloning

Cloning means making a precise copy of a molecule (such as a gene), a cell, or an individual plant or animal. It is done routinely in laboratories and clinics around the world in order to understand how proteins work in an organism, to construct new drugs with fewer side effects, to engineer foods with better nutritional characteristics, or to produce animals as models for human disease. Forensic experts clone DNA to identify crime perpetrators, cartilage cells are cloned to repair damaged knees and a few of the more than 5,000 genetic defects are being treated by inserting properly functioning cloned genes into the patient's cells.

Dolly reviewed

Dolly was news because she is thought to be a replica of an adult sheep. We already have human replicas, or twins, which occur naturally and through assisted reproductive technology known as blastomere splitting. However, identical twins are born at the same time and have no identical forebears. Dolly was the product of somatic cell nuclear transfer (SCNT), a technique that may have applications ranging from reconstituting an AIDS patient's own immune system or producing skin cells for burn victims, bone marrow cells for cancer patients, insulin-producing cells to treat diabetes, leukemia and liver damage. Much of this research is prohibited at its earliest stages under the Federal ban on creating embryos for research purposes.

Embryo research

Federal funding for the creation of human embryos for research purposes is banned under a December 2, 1994 Presidential directive and other embryo research is also prohibited via restrictions on DHHS appropriations. (See Attachment A for further discussion.) Embryo research in support of improvements in assisted reproductive medicine is carried out in the private sector with virtually no Federal regulation.

We must assess the need to engage in the issue of embryo research in the context of a cloning bill and follow closely other legislative initiatives.

LEGISLATION

The issues of greatest concern [to scientists and industry] are what is prohibited and how the prohibited act(s) is(are) defined. (See Attachment B for discussion of options)

IMPACT OF FDA AUTHORITY ON CLONING OPTIONS

Recent reports notwithstanding, FDA is still in the process of developing a determination of its authority to regulate the use of somatic cell nuclear transfer (SCNT) for the purpose

of creating a child. Assuming for the moment that FDA **does** have this authority, how would that effect our strategy with respect to legislation?

The Food, Drug and Cosmetic Act gives FDA authority to regulate products and procedures on the basis of safety and efficacy—not ethics. Our bill would prohibit any attempt to create a child using SCNT and provide for further review of the ethical and scientific. FDA's likely authority takes care of the former, for some period of time, but does not address the need for public discourse. Therefore, there is still a need to pursue legislative options.