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COMPARISON OF PROPOSED CLONING LEGISLATION

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Title	Cloning Prohibition Act of 1997	Prohibition on Cloning of Human Beings Act of 1998	Human Cloning Research Prohibition Act	Human Cloning Prohibition Act	Human Cloning Prohibition Act of 1998	Human Cloning Prohibition Act
Sponsor	William Clinton (Not yet sponsored)	Dianne Feinstein (D-CA)	Vernon Ehlers (R-MI)	Vernon Ehlers (R-MI)	Christopher (Kit) Bond (R-MO)	Ben Nighthorse Campbell (R-CO)
Findings	NBAC Report	NBAC Report	none	none	none	Congress finds that the Federal Govt has a moral obligation to the nation to prohibit the cloning of humans.
Purposes	To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and to provide for further review of the ethical and scientific issues associated with its use.	To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and to provide for further review of the ethical and scientific issues associated with its use.	To prohibit the obligation or expenditure of Federal funds to conduct or support any project of research that includes the use of a human somatic cell nuclear transfer technology to produce an embryo.	To prohibit the cloning of humans.	To prohibit any attempt to create an embryo using human somatic cell nuclear transfer, protect research	To prohibit the cloning of humans.
Definitions	Cloning ¹ ; Somatic cell ² ; Somatic cell nuclear transfer ³	Cloning ⁴ , Nucleus ⁵ , Oocyte ⁶ , Somatic cell ⁷ , Somatic cell nuclear transfer ⁸	Human somatic cell nuclear transfer ⁹ , Somatic cell ¹⁰	none	Embryo ¹¹ , Human somatic cell nuclear transfer ¹² , Oocyte ¹³ , Somatic cell ¹⁴	Clone & Cloning ¹⁵

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Prohibitions	Unlawful for any public or private individual or entity to perform or use 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.	Unlawful for any person or other legal entity, public or private, to implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus.	Prohibition against obligation or expenditure of Federal funds to conduct or support any project of research that includes the use of a human somatic cell nuclear transfer technology to produce an embryo.	Prohibition against the use of a human somatic cell for the process of producing a human clone.	Unlawful for any person or entity, public or private, to knowingly use human somatic cell nuclear transfer to produce an embryo or to knowingly purchase or sell an ovum, embryo, or fetus for that purpose, or obligate or expend Federal funds on research that includes that purpose.	Unlawful for any person to clone a human being or conduct research for the purpose of cloning a human being or otherwise creating a human embryo; no Federal funds may be obligated or expended to knowingly conduct or support any project of research for the above purposes.
Protected Research	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or the use of somatic cell nuclear transfer techniques to create animals.	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or the use of somatic cell nuclear transfer techniques to create animals.	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, other than human embryo cells, or tissues; or the use of somatic cell nuclear transfer techniques to create animals other than humans.	none	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, other than human embryo cells, or tissues; or the use of somatic cell nuclear transfer techniques to create animals other than humans.	none

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Preemption of State Laws	none	Preempt any state law which prohibits or limits research or practices regarding somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, or tissues, the use of somatic cell nuclear transfer techniques to develop animals, or related research.	none	none	none	none
Penalties Specified	Fines (the greater of \$250,00 or 2X gross gain or loss), Civil Action by the AG, forfeiture of property derived from or used to commit act.	Fines (the greater of \$250,00 or 2X gross gain or loss), Civil Action by the AG, forfeiture of property derived from or used to commit act.	none	Civil money penalty not to exceed \$5,000.	Fines, up to 5 years in prison, forfeiture of property from or used to commit violation.	Civil money penalty not to exceed \$5,000 for each violation; ineligibility for Federal funds for 5 years after violation.
Effective Date	Date of Enactment--Applies to acts performed within 5 years after that date.	Act is effective for the 10 year period after the its enactment and will terminate at the expiration of 10 years.	none mentioned	none mentioned	none mentioned	none mentioned

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Provisions for Review	Review by NBAC 4 ½ years after enactment, on the state of the science of somatic cell nuclear transfer, the ethical and social issues associated with the potential use of this technology in humans, and advisability of continuing the prohibition established in the Act.	Review by NBAC 4 ½ years after enactment, on the state of the science of somatic cell nuclear transfer, the ethical and social issues associated with the potential use of this technology in humans, and advisability of continuing the prohibition established in the Act.	Review by NRC in agreement with the Director of NSF, not later than 5 years after the date of enactment, on the impact that the implementation of the Act has had on research and recommendations for any appropriate changes to the Act.	none	Review by Directors of NSF and NIH in agreement with NRC, not later than 5 years after enactment, on the impact that the implementation of the Act has had on research and recommendations for any appropriate changes to the Act.	None
Status	Legislative package was transmitted to Congress on June 9, 1997.		The bill was introduced on March 5, 1997, and jointly referred to the House Committees on Commerce, and Science. Hearings on substitution held July 22, 1997. Marked-up and passed out of the House Science Committee July 29, 1997.	The bill was introduced on March 5, 1997, and jointly referred to the House Committees on Commerce, and Science.		The bill was introduced on January 27, 1998 and referred to the Senate Committee on Labor and Human Resources.

PREPARED BY OSP

1. Cloning--the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal or human.
2. Somatic cell--any cell of the body other than germ cells (eggs or sperm.)
3. Somatic cell nuclear transfer--the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.
4. Cloning--the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal or human.
5. Nucleus--the cell structure that houses the chromosomes, and thus the genes.

6.Oocyte—the female germ cell, the egg.

7.Somatic cell—a mature, diploid cell.

8.Somatic cell nuclear transfer—transferring the nucleus of a somatic cell of an existing or previously existing human child or adult into an oocyte from which the nucleus has been removed.

9. Human somatic cell nuclear transfer-- transferring the nucleus of a human somatic cell into an oocyte from which the nucleus has been removed or rendered inert.

10. Somatic cell--a cell of an embryo, fetus, child, or adult which is not and will not become a sperm or egg cell.

11. Embryo—The developing organism from the time of fertilization, or from the time of the single cell stage at the inception of growth and development of an organism, until significant differentiation has occurred.

12.Human somatic cell nuclear transfer—transferring the nucleus of a human somatic cell into an oocyte from which the nucleus has been removed or rendered inert.

13.Oocyte—the mature female germ cell, the egg.

14.Somatic cell—any cell of an embryo, fetus, child, or adult that is not a germ cell or is not destined to become a germ cell.

15.Clone & Cloning—the practice of creating or attempting to create a human being by transferring the nucleus from a human cell from whatever source into a human cell from which the nucleus has been removed for the purpose of, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being.

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105TH CONGRESS
1ST SESSION**S.** _____

IN THE SENATE OF THE UNITED STATES

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

A BILL

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

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 "Human Cloning Prohi-
5 bition Act".

6 **SEC. 2. FINDING.**

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

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

5 **SEC. 3. PROHIBITION ON CLONING.**

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

8 **“CHAPTER 16—CLONING**

“Sec.

“301. Prohibition on cloning.

9 **“§ 301 Prohibition on cloning**

10 “(a) IN GENERAL.—It shall be unlawful for any per-
11 son or entity, public or private, in or affecting interstate
12 commerce, to use human somatic cell nuclear transfer
13 technology.

14 “(b) IMPORTATION.—It shall be unlawful for any per-
15 son or entity, public or private, to import an embryo pro-
16 duced through human somatic cell nuclear transfer tech-
17 nology.

18 “(c) PENALTIES.—

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

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

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

5 “(d) DEFINITION.—The term ‘human somatic cell
6 nuclear transfer technology’ means taking the nuclear ma-
7 terial of a human somatic cell and incorporating it into
8 an oocyte from which the nucleus has been removed or
9 rendered inert and producing an embryo (including a
10 preimplantation embryo).”.

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

“16. Cloning § 301”

15 **SEC. 4. COMMISSION TO PROMOTE A NATIONAL DIALOGUE**
16 **ON BIOETHICS.**

17 (a) ESTABLISHMENT.—There is established within
18 the Institute of Medicine a commission to be known as
19 the National Commission to Promote a National Dialogue
20 on Bioethics (referred to in this section as the “Commis-
21 sion”).

22 (b) MEMBERSHIP.—

23 (1) NUMBER AND APPOINTMENT.—The Com-
24 mission shall be composed of 25 members, of
25 whom—

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

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

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

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

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

16 (2) REQUIREMENTS.—Each individual de-
17 scribed in subparagraph (A) through (D) of para-
18 graph (1) shall ensure that members appointed to
19 the Commission are representative of the fields of
20 law, theology, philosophy or ethics, medicine, science,
21 and society.

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

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

5 (5) MEETINGS.—The Commission shall meet at
6 the call of its Chairperson or a majority of its mem-
7 bers.

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

10 (7) VACANCIES.—A vacancy on the Commission
11 shall be filled in the same manner in which the origi-
12 nal appointment was made not later than 30 days
13 after the Commission is given notice of the vacancy
14 and shall not affect the power of the remaining
15 members to execute the duties of the Commission.

16 (8) COMPENSATION.—Members of the Commis-
17 sion shall receive no additional pay, allowances, or
18 benefits by reason of their service on the Commis-
19 sion.

20 (9) EXPENSES.—Each member of the Commis-
21 sion shall receive travel expenses and per diem in
22 lieu of subsistence in accordance with sections 5702
23 and 5708 of title 5, United States Code.

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

1 ticipation and discourse concerning important bioethical
2 issues including cloning, and provide for a report to Con-
3 gress concerning the findings, conclusions, and rec-
4 ommendations of the Commission concerning Federal pol-
5 icy and possible Congressional action.

6 (d) STAFF AND SUPPORT SERVICES.—

7 (1) STAFF.—With the approval of the Commis-
8 sion, the chairperson of the Commission may ap-
9 point such personnel as the chairperson considers
10 appropriate.

11 (2) APPLICABILITY OF CIVIL SERVICE LAWS.—

12 The staff of the Commission shall be appointed with-
13 out regard to the provisions of title 5, United States
14 Code, governing appointments in the competitive
15 service, and shall be paid without regard to the pro-
16 visions of chapter 51 and subchapter III of chapter
17 53 of such title (relating to classification and Gen-
18 eral Schedule pay rates).

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

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

1 mission. The facilities shall serve as the head-
2 quarters of the Commission and shall include all
3 necessary equipment and incidentals required for the
4 proper functioning of the Commission.

5 (e) POWERS OF COMMISSION.—

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

11 (2) DETAIL OF FEDERAL EMPLOYEES.—Upon
12 the request of the Commission, the head of any Fed-
13 eral agency is authorized to detail, without reim-
14 bursément, any of the personnel of such agency to
15 the Commission to assist the Commission in carry-
16 ing out its duties. Any such detail shall not interrupt
17 or otherwise affect the civil service status or privi-
18 leges of the Federal employee.

19 (3) TECHNICAL ASSISTANCE.—Upon the re-
20 quest of the Commission, the head of a Federal
21 agency shall provide such technical assistance to the
22 Commission as the Commission determines to be
23 necessary to carry out its duties.

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

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

5 (5) OBTAINING INFORMATION.—The Commis-
6 sion may secure directly from any Federal agency
7 information necessary to enable it to carry out its
8 duties, if the information may be disclosed under
9 section 552 of title 5, United States Code. Upon re-
10 quest of the Chairperson of the Commission, the
11 head of such agency shall furnish such information
12 to the Commission.

13 (6) ADMINISTRATIVE SUPPORT SERVICES.—
14 Upon the request of the Commission, the Adminis-
15 trator of General Services shall provide to the Com-
16 mission on a reimbursable basis such administrative
17 support services as the Commission may request.

18 (7) PRINTING.—For purposes of costs relating
19 to printing and binding, including the cost of per-
20 sonnel detailed from the Government Printing Of-
21 fice, the Commission shall be deemed to be a com-
22 mittee of the Congress.

23 (f) SUBCOMMITTEES.—

24 (1) IN GENERAL.—The Commission shall estab-
25 lish 6 subcommittees, including—

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- 1 (A) a subcommittee on legal issues;
2 (B) a subcommittee on theological issues;
3 (C) a subcommittee on philosophical and
4 ethical issues;
5 (D) a subcommittee on medical issues;
6 (E) a subcommittee on scientific issues;
7 and
8 (F) a subcommittee on social issues.

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

12 (A) 1 expert to be appointed by the mem-
13 bers of the Committee who were appointed
14 under subparagraphs (A) and (C) of subsection
15 (b)(1);

16 (B) 1 expert to be appointed by the mem-
17 bers of the Committee who were appointed
18 under subparagraphs (B) and (D) of subsection
19 (b)(1);

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

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

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

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

11 (g) REPORT.—Not later than December 31, 1999,
12 and annually thereafter, the Commission shall prepare and
13 submit to the appropriate committees of Congress a report
14 which shall contain a detailed statement of the rec-
15 ommendations, findings, and conclusions of the Commis-
16 sion.

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

20 **SEC. 5. UNRESTRICTED SCIENTIFIC RESEARCH.**

21 Nothing in this Act (or an amendment made by this
22 Act) shall be construed to restrict areas of scientific re-
23 search that are not specifically prohibited by this Act (or
24 amendments).

11

1 SEC. 6. SENSE OF CONGRESS.

2 It is the sense of Congress that the Federal Govern-
3 ment should advocate for and join an international effort
4 to prohibit the use of human somatic cell nuclear transfer
5 technology to produce a human embryo.



White House Press Release

REMARKS BY THE PRESIDENT AT ANNOUNCEMENT OF CLONING LEGISLATION

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

June 9, 1997

REMARKS BY THE PRESIDENT AT ANNOUNCEMENT OF **CLONING** LEGISLATION

The Rose Garden

11:56 P.M. EDT

THE PRESIDENT: Thank you very much, Dr. Shapiro, for that fine set of remarks and for your report. I thank all the members of the President's Committee of Advisors. I'd also like to thank Secretary Shalala and Dr. Varmus for being here today, along with the President's Advisor on Science and Technology, Dr. Jack Gibbons. And I thank Congressman Brown and Congresswoman Morella for being here and for their interest in this important issue.

But mostly let me say again, I am profoundly grateful to the National Bioethics Advisory Commission and to Dr. Harold Shapiro for preparing this report on a difficult topic in a short period of time, requiring an extensive inquiry. Your commitment and your courage in breaking new ground in policy is deeply appreciated.

As the Vice President has said and all of us know, we live in an era of breath-taking scientific discovery. More and more, our future in the world depends upon advances in science and technology. And more and more, the scientific community will influence the course of the future and the lives that our children will lead in the new century that is upon us.

As I said in my commencement address at Morgan State University last month, our scientific explorations must be guided by our

commitment to human values, to the good of society, to our basic sense of right and wrong. Nothing makes the necessity of that moral obligation more clear than the troubling possibility that these new animal-**cloning** techniques could be used to create a child. That is why I acted in March to ban the use of federal funds for **cloning** human beings and to urge the private sector to observe the ban voluntarily while we initiated a national dialogue on the risks and the responsibilities of such a possibility, and why I asked this commission to issue this report.

For three months, the commission has rigorously explored the scientific, moral, and spiritual dimensions of human **cloning**. It has talked to leading scientists and religious leaders, to philosophers and families, to patient advocates and to the general public. From many opinions and beliefs, as Dr. Shapiro said, one unanimous conclusion has emerged: Attempting to **clone** a human being is unacceptably dangerous to the child and morally unacceptable to our society.

I believe strongly that this conclusion reflects a national consensus, and I believe personally that it is the right thing to do. Today I am sending legislation to the Congress that prohibits anyone in either public or private sectors from using these techniques to create a child. Until the day I sign the legislation into law, the ban on federal funding I declared in March will remain in effect. And once again, I call upon the private sector to refrain voluntarily from using this technology to attempt to **clone** a human being.

I want to make clear that there is nothing inherently immoral or wrong with these new techniques -- used for proper purposes. In fact, they hold the promise of revolutionary new medical treatments and life-saving cures to diseases like cystic fibrosis, diabetes and cancer, to better crops and stronger livestock.

This legislation, therefore, will not prohibit the use of these techniques to **clone** DNA in cells and it will not ban the **cloning** of animals. What the legislation will do is to reaffirm our most cherished belief about the miracle of human life and the God-given individuality each person possesses. It will ensure that we do not fall prey to the temptation to replicate ourselves at the expense of those beliefs and the lives of innocent children we would produce.

Finally, the legislation will ensure that we continue the national dialogue we began three months ago and will provide the nation and the Congress another opportunity to take a look at this issue in five years.

To make sure that all our voices are heard as we explore human **cloning**, the legislation specifically requires the National Bioethics Advisory Commission to continue its study and report back in four and a half years. At that time, we will decide how to proceed based on what has been accomplished and agreed upon and debated and discovered in the intervening period.

Banning human **cloning** reflects our humanity. It is the right thing to do. Creating a child through this new method calls into question our most fundamental beliefs. It has the potential to threaten the sacred family bonds at the very core of our ideals and our society. At its worst, it could lead to misguided and malevolent attempts to select certain traits, even to create certain kind of children -- to make our children objects rather than cherished individuals.

We are still a long way from understanding all the implications of the present discoveries, but it is our moral obligation

to confront these issues as they arise and to act now to prevent abuse. Today, I hope other countries will see what we are doing and do the same. And I pledge to work with them to enforce similar bans around the world that reflect these values.

Once again, let me say a heartfelt thank you on behalf of our entire nation to the National Bioethics Advisory Commission for the remarkable work you have done and the work you have agreed to continue doing in the coming years. Thank you very much. (Applause.)

END

12:02 P.M. EDT



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White House Press Release

PRESIDENT CLINTON ANNOUNCES CLONING PROHIBITION ACT OF 1997

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

June 9, 1997

PRESIDENT CLINTON ANNOUNCES **CLONING** PROHIBITION ACT OF 1997

June 9, 1997

Today at the White House, President Clinton will receive the National Bioethics Advisory Commission's report on human **cloning** and transmit to Congress the "**Cloning** Prohibition Act of 1997." This legislative proposal would implement the Commission's key recommendation for legislation to prohibit any attempt to create a human being using somatic cell nuclear transfer technology. The President will be joined in the Rose Garden by the Vice President and Commission Chairman Dr. Harold Shapiro.

The National Bioethics Advisory Commission (NBAC) Report

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

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

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

Cloning Prohibition Act of 1997

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

Further Actions By The President

As recommended by the NBAC, President Clinton today also:

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

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

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

MEMBERS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION

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

Patricia Backlar of Oregon, is Senior Scholar at the Center for Ethics in Health Care, Oregon Health Sciences University, where Ms. Backlar specializes in issues concerning individuals with severe and persistent mental disorders. She attended Vassar College, McGill University and Yale University, and holds a certificate in health care ethics from the University of Washington School of Medicine. Senator Hatfield supported Ms. Backlar's candidacy.

Arturo Brito of Florida, is Assistant Professor of Clinical Pediatrics at the University of Miami School of Medicine. Dr. Brito is also the Medical Director of the Pediatric Mobile Clinic of Miami. Dr. Brito earned his M.D. at the University of South Florida and interned at Emory University in pediatrics.

Alexander M. Capron of California, is co-director of the Pacific Center for Health Policy and Ethics at the University of Southern California. Professor Capron specializes in legal-medical issues and biomedical ethics. He is a member of the Institute of Medicine, a founding Fellow of the Hastings Center and a past member of the Human Gene Therapy Subcommittee of the NIH Recombinant DNA Advisory Committee. Professor Capron received his B.A. with high honors from Swarthmore College and his LL.B. from Yale University.

Eric J. Cassell of New York, is Physician to In-Patients at The New York Hospital-Cornell Medical Center. For five years, Dr. Cassell directed the Cornell University Medical College Program for the Study of Ethics and Values in Medicine. Dr. Cassell received a B.A. from Queens College, an M.A. from Columbia University, an M.D. from New York University School of Medicine and is board certified in internal medicine. Dr. Cassell's candidacy was supported by Senator Moynihan.

R. Alta Charo of Wisconsin, holds joint assistant professorships in the University of Wisconsin Medical and Law Schools. A Fellow of the Hastings Center, Ms. Charo has also held government appointments in the Office of Technology Assessment and the U.S. Agency for International Development. Ms. Charo earned an A.B. in biology, cum laude, from Harvard-Radcliffe College and a J.D. from Columbia University School of Law.

James F. Childress of Virginia, is the Edwin B. Kyle Professor of Religious Studies and Professor of Medical Education at the University of Virginia, where he is also the co-director of the Virginia Health Policy Research Center. Dr. Childress is the author of numerous articles and several books on biomedical ethics and is former vice-chairman of the National Task Force on Organ Transplantation. He received his B.A. from Guilford College, B.D. from Yale Divinity School and M.A. and Ph.D. from Yale University.

David R. Cox of California, is Professor of Genetics and Pediatrics at the Stanford University School of Medicine. Dr. Cox is a world-renowned expert on genetic diseases associated with defects in chromosome 21, including Down Syndrome and ataxia-telangiectasia. He is a member of the American Society of Human Genetics, the American Academy of Pediatrics, the American Federation for Clinical Research and the Human Genome Organization. Board certified in both pediatrics and human genetics, Dr. Cox received his A.B. from Brown University, and M.D. and Ph.D. in genetics from the University of Washington.

White House Press Releases Database: PR...NOUNCES CLONING PROHIBITION WITHHOLD 1997/cgi-bin/w...+%23<+19970419+19980127%29%29&use_hyp=
Rhetaugh Graves Dumas of Michigan, is the Vice Provost for Health Affairs, the University of Michigan. Formerly Dean of The University of Michigan School of Nursing, and Deputy Director of the National Institute of Mental Health, Dr. Dumas is known for her clinical research in the area of psychiatric nursing. She is a member of the American Nurses Association and a past president of the American Academy of Nursing. Dr. Dumas earned a B.S.N. at Dillard University, an M.S. from the Yale University School of Nursing and a Ph.D. in Social Psychology from the Union Institute, Cincinnati, Ohio.

Ezekiel J. Emanuel of Massachusetts, is Assistant Professor of Medicine, Social Medicine and Clinical Epidemiology at the Dana-Farber Cancer Institute, Harvard Medical School. A member of the Ethics Group under the President's Health Care Task Force, Dr. Emanuel is the author of many articles on medical ethics, focusing particularly on decisionmaking in terminal care. He holds a B.A. from Amherst College, M.Sc. from Oxford University, M.D. from Harvard Medical School and Ph.D. from Harvard University and is board certified in internal medicine and medical oncology.

Laurie M. Flynn of Virginia, is the Executive Director of the National Alliance for the Mentally Ill. A consultant to child welfare organizations, federal, state, and county governments, Ms. Flynn is also the author of numerous publications on family mental health services. She earned a B.A. in philosophy from the University of Virginia.

Carol W. Greider of New York, is Senior Staff Scientist at the Cold Spring Harbor Laboratory. Dr. Greider is an internationally known expert in molecular biology whose research focuses on the structure and function of telomeres, chromosomal components whose role in aging and cancer development is just beginning to become clear. In addition to studies at the George-August Universitat in Gottigen, West Germany, she was awarded a B.A. in biology from U.C. Santa Barbara and a Ph.D. in molecular biology from U.C. Berkeley.

Steven H. Holtzman of Massachusetts, is Chief Business Officer of Millenium Pharmaceuticals, Inc., a company using genetics, genomics and bioinformatics to identify genes responsible for common major diseases and in their work on human biology directed toward drug development. Mr. Holtzman's academic background includes a Rhodes Scholarship leading to a B.Phil., in addition to a B.A. in philosophy from Michigan State University. Mr. Holtzman chairs the Ethics Panel of the Biotechnology Industry Organization, who submitted his nomination as a representative of the biotechnology industry.

Bette O. Kramer of Virginia, is the founder and first president of the Richmond Bioethics Consortium, a community-based organization providing education and development support to institutional ethics committees, and educational opportunities to the general public. Active in a variety of health-related activities, such as the Blue Cross/Blue Shield Critical Care Task Force, Ms. Kramer also has professional experience as a security analyst. Ms. Kramer earned a B.A. in economics at Wellesley College.

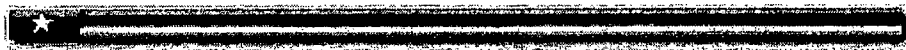
Bernard Lo of California, is Professor of Medicine and Director of the Program in Medical Ethics at the University of California, San Francisco, where he teaches a required course on medical ethics, law and

economics. Dr. Lo has served as a member of a number of public advisory committees including an OTA project on Life Sustaining Technologies in the Elderly. He received an A.B., summa cum laude, in physics from Harvard College; a M.A. from the University of Sussex in comparative literature; an A.M. from Harvard University in the history of science and an M.D. from Stanford University.

Lawrence H. Miike of Hawaii, is the Director of the Department of Health, State of Hawaii, which includes the Nation's 3rd largest public hospital system. Previously, Dr. Miike worked for the U.S. Congress. His studies led to the National Childhood Vaccine Injury Compensation Act, AIDS policies, and action on health care for American Indians and Alaska Natives. Dr. Miike holds a B.A. from Amherst College, a degree in medicine from U.C. San Francisco, and a law degree from U.C.L.A..

Thomas H. Murray of Ohio, is Professor of Biomedical Ethics and Director of the Center for Biomedical Ethics at the Case Western Reserve University School of Medicine. Dr. Murray's research focuses on ethics in medicine and science, including ethical aspects of health policy; the care of newborns and children, occupational health, and genetic engineering. Dr. Murray earned a B.A. at Temple University in psychology and a Ph.D. in social psychology from Princeton University.

Diane Scott-Jones of Pennsylvania, is Associate Professor in the Department of Psychology, Temple University. Dr. Scott-Jones is a Fellow of the American Psychological Association, who submitted her nomination, and a co-author of the Association's ethics guidelines. She is also a member and past chair of the Ethics Committee of the Society for Research in Child Development. Her research involves the role of family in supporting children's scholastic achievement. Dr. Scott-Jones holds a B.S. and M.A. in psychology from Appalachian State University, and a Ph.D. in development psychology from the University of North Carolina, Chapel Hill.



To comment on this service: feedback@www.whitehouse.gov

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

March 4, 1997

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Prohibition on Federal Funding
for **Cloning** of Human Beings

Recent accounts of advances in **cloning** technology, including the first successful **cloning** of an adult sheep, raise important questions. They potentially represent enormous scientific breakthroughs that could offer benefits in such areas as medicine and agriculture. But the new technology also raises profound ethical issues, particularly with respect to its possible use to **clone** humans. That is why last week I asked our National Bioethics Advisory Commission to thoroughly review the legal and ethical issues associated with the use of this technology and report back to me in 90 days.

Federal funds should not be used for **cloning** of human beings. The current restrictions on the use of Federal funds for research involving human embryos do not fully assure this result. In December 1994, I directed the National Institutes of Health not to fund the creation of human embryos for research purposes. The Congress extended this prohibition in FY 1996 and FY 1997 appropriations bills, barring the Department of Health and Human Services from supporting certain human embryo research. However, these restrictions do not explicitly cover human embryos created for implantation and do not cover all Federal agencies. I want to make it absolutely clear that no Federal funds will be used for human **cloning**. Therefore, I hereby direct that no Federal funds shall be allocated for **cloning** of human beings.

WILLIAM J. CLINTON

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To comment on this service: feedback@www.whitehouse.gov

1-23-97

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.

*Last sentence - FDA (see attachment)
import of FDA cell*

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

*since language there
has come out, problems*

A. Support existing language without changes

start out with caveat the problem w/ this approach

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.]

*face w/ distinct language
acc some principles*

DRAFT

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

is limiting some research

DRAFT

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

option C does limit a certain type of research

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.

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 ____

Cloning
THE PRESIDENT HAS SEEN

6-4-97

THE WHITE HOUSE
WASHINGTON

June 3, 1997

Copied to:
Kagan
Gibbons
Emanuel
Bowles

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PHIL CAPLAN *Phl*

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Approve ☒

Disapprove ☐

Discuss ☐

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THE WHITE HOUSE
WASHINGTON

'97 JUN 3 AM8:28

May 29, 1997

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Assistant to the President for Science and Technology

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Approve ____ Disapprove ____

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Approve ____ Disapprove ____

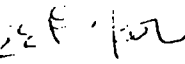
File-cloning

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.

Cloning Without Human Clones

By MEREDITH WADMAN

Maverick Chicago physicist Richard Seed received a great deal of attention recently when he announced plans to produce a human baby by cloning within the next two years. Over the weekend, University of Wisconsin scientists reported that they had successfully cloned five species—including primates—using cows' eggs as "incubators"; all resulted in miscarriages. The procedure, if ever perfected, could be another tool for the likes of Mr. Seed: If you can clone monkeys from a cow's eggs—which are far more readily available than human ova—why not human beings?

These developments will only increase the pressure already building on Congress to stop all human cloning as soon as it reconvenes next week. And Congress should act: Even if an experiment like Mr. Seed's is one day successful—and the physical risks are now grave—there are significant unresolved moral and ethical questions surrounding the creation of a human who is the genetic duplicate of another. But Congress should be careful to go after cloning with a surgeon's scalpel, and not a chain saw. Otherwise, the politicians risk stifling highly promising medical advances, from improved repairs of battered organs to better infertility treatments that don't involve duplication of any adult.

The states are already learning the perils of careless cloning bans. Last spring in Florida, a bill introduced and then swiftly withdrawn would have banned the cloning not only of people, but of DNA—virtually destroying that state's biotechnology industry. California lawmakers, in the rush to get out of Sacramento last September, passed a cloning ban that also outlawed oocyte nuclear transfer, a promising potential treatment for infertile mothers. This procedure, pioneered by New York University's John Zhang and Jamie A. Grifo,

would produce ordinary children, not clones.

Infertility isn't the only malady for which cloning technology shows promise. The cloning experiment that created the famous lamb Dolly opened up remarkable prospects in the area of repairing devastated tissues and organs, because it proved that an adult cell that has become specialized to do a particular job—say, to be liver or blood—can "unlearn" its role and be reprogrammed to do something quite different.

The applications are breathtaking. Imagine a day when a patient with severe liver disease might see another cell of his body—skin, hair, whatever—reprogrammed to act as a healthy liver cell, without the risk of immune rejection inherent in receiving a donated liver. Or a cancer patient whose bone marrow has been wiped out by radiation could be treated with bone marrow grown from another cell of his own body.

To get from here to there, scientists will need to use cloning techniques to study the biological processes at work in days-old embryos. They need to answer questions such as how the DNA and its cellular surroundings interact in the early embryo to direct cells to take their very first steps toward ultimately becoming, say, liver or blood cells.

Much of this work can now be done in animals, but not all. And with time, if human treatments are sought, work will need to be done with human embryos. These are microscopic clusters of eight to 100 cells—

embryos confined to petri dishes, not bound for baby buggies.

Congress each year bans federal funding for such work. But this research is legal if financed privately. The worry among scientists is that Congress, when it considers banning cloning for baby making, will not be able to resist banning its use in private embryo research as well.

Indeed, that tendency showed up in the House last summer. Rep. Vernon Ehlers (R., Mich.), a physicist by training, was forced by Science Committee colleagues to rewrite a bill banning federal funding for the cloning of babies to extend the ban to cloning's use in embryo research. The committee passed the bill, which has since languished.

Physicians and scientists were not pleased. "We are very worried that this bill... has become a permanent embryo research ban," Sean Tipton of the American Society for Reproductive Medicine said at the time.

This group—composed mainly of infertility doctors—isn't alone. Harold Var-mus, director of the National Institutes of Health, told Congress last March: "When I hear about research on human cloning as something that ought to be taken away, I shiver." The great majority of scientific societies responding last year to a poll by a presidential bioethics commission said that they opposed restricting the use of cloning technology for basic developmental-biology research, or for making specific human cell types. Trying to protect that research, scientists are backing the approach President Clinton took in a bill he sent to Congress last June. It would ban cloning for baby making, and not meddle with research.

Honorable people certainly can differ on the ethics of embryo research. So far, Congress has held off banning such work when it's not financed by taxpayers. When the politicians take up cloning, they will serve the public best if they show similar restraint.

Dr. Wadman covers biomedical research policy for the British journal Nature.



Notable & Quotable

From an interview with George Stephanopoulos in the New York Times Magazine, Jan. 11:

I regret working on the investigation in 1990 of the October Surprise. Because it was trying to take away by investigation what you didn't win by ballot box. If I had known then how it would have been carried forward, I like to think I wouldn't have done it. But I probably would have.

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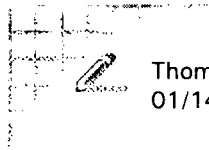


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Thomas L. Freedman
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To: Elena Kagan/OPD/EOP
cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP
Subject: Cloning

I went to the meeting you forwarded the invite to on cloning where the Biotech industry laid out its concerns on proposed cloning legislation; they are worried it will inadvertently ban embryo research etc..

The WH has a proposed formulation I think Bill Marshall put together, the bio tech industry has another and the Reproductive doctors society has a third. I am forwarding them to you.

Everyone, including Bill, felt more info was required on the effects of the different approaches. Rachel Levinson from OSTP will circulate a draft options memo on the scientific approaches and their implications for research, and right to life issues.

The basic issue centers on: how do you define what type of research is banned? The WH version bans all entities from using "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." That would seem to not ban experimentation with cloned embryos and would have right to life implications. The Biotech industry language: "it shall be unlawful for any person to use federal funds to create a human child identical in terms of DNA to an existing or previously existing individual using somatic cell nuclear transfer technology." Doesn't effect private sector, doesn't deal with experimentation and right to life. The reproductive society says "It shall be unlawful for any person to create a human child using somatic cell nuclear transfer." (applies to all, protects research specifically in separate section).

There is also a preemption issue.