

NLWJC - KAGAN

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[06/07/1997 - 06/08/1997]

Withdrawal/Redaction Sheet

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. email	Phone No. (Partial) (1 page)	06/07/1997	P6/b(6)

COLLECTION:

Clinton Presidential Records
Automated Records Management System [Email]
OPD ([Kagan])
OA/Box Number: 250000

FOLDER TITLE:

[06/07/1997-06/08/1997]

2009-1006-F

bm34

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

"CLONING PROHIBITION ACT OF 1997"

FACT SHEET

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

The National Bioethics Advisory Commission (NBAC) Report

President Clinton today accepted the NBAC's report on the possible cloning of human beings and acted on the report's recommendations. 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 at this time 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 that ethical issues need 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 and is governed adequately by existing regulations and guidelines.

Cloning Prohibition Act of 1997

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

Further Actions By The President

As recommended by the NBAC, President Clinton today also:

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

- **Urged privately funded scientists and clinicians to adhere to the voluntary moratorium he called for in March.** Since these groups will not face legal restrictions on cloning until the President's legislative proposal is enacted, the President asked these professionals to work through their societies and associations to ensure that all adhere to the current voluntary ban.
- **Pledged to work with other countries to enforce the prohibition.** Several other countries, including Great Britain, Denmark, Germany, Australia, and Spain, have banned human cloning.

Withdrawal/Redaction Marker

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Draft 6/7/97 7:00pm

**PRESIDENT WILLIAM J. CLINTON
REMARKS FOR CLONING EVENT
THE ROSE GARDEN
JUNE 9, 1997**

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

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

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

The possibility of creating a child through these new techniques mandates that we proceed with caution, and with conscience. That is why I acted immediately to ban the use of any federal funds for the cloning of human beings, and I urged the private sector to do the right thing and observe this ban voluntarily. And that is why I asked the National Bioethics Advisory Commission to prepare this report.

For three months, you have explored the scientific, moral and spiritual dimensions of human cloning. You have talked to leading scientists and religious leaders; philosophers and concerned families; patient advocates and the general public. And you have reached the following conclusion: cloning a human being is unacceptably dangerous and morally unacceptable, and we must act to prevent anyone -- for any reason -- from doing so.

I agree with the Commission's conclusions, and I accept your recommendation. Today, I will send legislation to Congress that prohibits the cloning of human beings for the next 5 years, and protects our fundamental human values. I am confident that Congress will act soon to pass this legislation, but until that time, the moratorium I declared in March will remain in effect. Once again, I call upon the private sector to refrain from using these techniques to attempt to clone a human being. There is still too much that we do not know -- and too much that we do not agree on -- to take the risk of creating innocent children in this untested way.

I want to make clear that there is nothing inherently immoral or wrong with the new cloning techniques. In fact, these techniques hold out the promise of revolutionary new medical treatments and life-saving cures; of better crops and stronger livestock. Cloning human tissues and cells is already helping to improve the lives of millions of people, and this legislation will not prohibit the use of the new techniques to do it. And it will not ban the cloning of animals for agricultural or veterinary purposes.

What it will do is give us time to continue the national dialogue we began three months ago. It will give the scientific community time to investigate the viability and the safety of these new techniques. It will give us time to reaffirm our most cherished beliefs about the miracle of human life, and the God-given individuality that each person possesses. Or, it will give us time to broaden those beliefs to include a new mystery, if to do so harms none and benefits all.

To make sure that all of our voices are heard as we explore the possibility of human cloning, the legislation specifically requires the National Bioethics Advisory Commission to continue to study the issue and report back to Congress after four and a half years. At that time, we will decide whether the ban will continue, or whether we will enter a new chapter of human life.

We are still a long way from understanding all of the implications of this remarkable breakthrough. But it is our obligation and our honor to confront the issues it raises, as a people. I am confident that the step we are taking today will continue that process. Once again, I thank the National Bioethics Advisory Commission for the work you have done and will continue to do in the coming years.

Thank you and God bless you.

RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP [OSTP])

CREATION DATE/TIME: 8-JUN-1997 14:53:49.00

SUBJECT: event memo

TO: Elena Kagan (CN=Elena Kagan/OU=OPD/O=EOP @ EOP [OPD])

READ:UNKNOWN

TEXT:

===== ATTACHMENT 1 =====

ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

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June 8, 1997

PRESENTATION OF THE CLONING REPORT

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

I. PURPOSE

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

II. BACKGROUND

In February, following reports of the first successful cloning of an adult sheep, you asked NBAC to review the profound ethical issues raised by the possible cloning of human beings.

At this event, Dr. Harold Shapiro, the Chair of the Commission and President of Princeton University, will formally present you with its report.

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

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

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

moratorium you called for in March while legislation is pending.

III. PARTICIPANTS

Briefing Participants:

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

Event Participants:

The Vice President
Dr. Harold Shapiro, NBAC Chair

Also Seated on Stage:

Secretary Shalala
Harold Varmus

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

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

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

VI. REMARKS

Remarks Provided by Jordan Tamagni in Speechwriting.

Meet and Greet with National Bioethics Advisory Commission

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

Members of the National Bioethics Advisory Commission

Patricia Backlar, of Oregon, Senior Scholar at the Center for Ethics in Health Care, Oregon Health Sciences University.

Arturo Brito, M.D., of Florida, Assistant Professor of Clinical Pediatrics at the University of Miami School of Medicine.

Alexander M. Capron, L.L.B., of California, co-director of the Pacific Center for Health Policy and Ethics at the University of Southern California.

Eric J. Cassell, M.D., F.A.C.P., of New York, Physician to In-Patients at The New York Hospital-Cornell Medical Center.

R. Alta Charo, J.D., of Wisconsin, Assistant Professor in the University of Wisconsin Medical and Law Schools.

James F. Childress, Ph.D., of Virginia, Edwin B. Kyle Professor of Religious Studies and Professor of Medical Education at the University of Virginia, and co-director of the Virginia Health Policy Research Center.

David R. Cox, M.D., Ph.D., of California, Professor of Genetics and Pediatrics at the Stanford University School of Medicine.

Rhetaugh Graves Dumas, Ph.D., of Michigan, Vice Provost for Health Affairs, The University of Michigan.

Ezekiel J. Emanuel, M.D., Ph.D., of Massachusetts, Assistant Professor of Medicine, Social Medicine and Clinical Epidemiology at the Dana-Farber Cancer Institute, Harvard Medical School. **He is Rahm Emanuel's brother.*

Laurie M. Flynn of Virginia, Executive Director of the National Alliance for the Mentally Ill.

Carol W. Greider, Ph.D., of New York, Senior Staff Scientist, Cold Spring Harbor Lab.

Steven H. Holtzman of Massachusetts, Chief Business Officer, Millenium Pharmaceuticals, Inc.

Bette O. Kramer of Virginia, President of the Richmond Bioethics Consortium.

Bernard Lo, M.D., of California, Professor of Medicine and Director of the Program in Medical Ethics at the University of California, San Francisco.

Lawrence H. Miike, J.D., M.D., of Hawaii, Director of the Dept. of Health, State of Hawaii.

Thomas H. Murray, Ph.D., of Ohio, Professor of Biomedical Ethics and Director of the Center for Biomedical Ethics at the Case Western Reserve University School of Medicine.

Diane Scott-Jones, Ph.D., of Pennsylvania, Associate Professor in the Department of Psychology, Temple University.

June 8, 1997

Automated Records Management System
Hex-Dump Conversion

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 the National Bioethics Advisory Commission (NBAC) cloning report and the cloning legislation you will announce Monday. It also discusses three decisions 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; (3) and whether to use NBAC's precise definition of cloning in the legislation.

NBAC's Findings and Recommendations

In its final report NBAC states that 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 (which do not involve the creation of entire human beings), and the cloning of animals, are scientifically important and not ethically problematic. 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;
- calling on all scientists and clinicians to adhere to the voluntary moratorium; and
- working with other countries to enforce common aspects of cloning restrictions.

Proposed Legislation

The legislation you will announce tomorrow::

- 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 property used in violating the Act;
- 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 your draft bill -- would not ban the creation of cloned embryos for research purposes. NBAC simply did not evaluate the ethics of this activity. NBAC declined to speak to the issue because a 1994 NIH panel has already evaluated embryo research ethics, and because using somatic cell nuclear transfer to create embryos for research does not pose distinct ethical questions. 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. 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.

You have already acted to restrict embryo research. In 1994 you banned the use of NIH funds to create embryos for research purposes (the NIH panel had recommended permitting the funding of certain limited research on embryos in the first 14 days after fertilization), and Congress has similarly prohibited the use of HHS funds. But privately-funded embryo research is not restricted.

The right-to-life community has already criticized NBAC for not recommending a ban on creating cloned embryos. Still, we recommend against your prohibiting this activity in the legislation you announce Monday. There is no moral rationale for treating embryos created through cloning differently from embryos developed through other means (e.g. in vitro fertilization). Prohibiting the creation of embryos for research using private funds could halt important research on infertility and possibly other medical conditions and would be strongly opposed by the scientific and fertility communities. In short, it is a controversial step that merits further consideration. Therefore, we suggest you limit the scope of the legislation to the issue the Commission addressed. If asked about your position on embryo research, you could 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 states strongly that any legislative prohibition on cloning include a sunset clause to ensure that Congress review the issue after a specified period of time. Commissioners who oppose cloning because of safety concerns alone insist on a time-limited ban because time may mitigate such concerns. But those who think cloning is inherently morally wrong also support a time-limited ban because (1) there has been so little time to fully consider the moral issues and it is possible their position may evolve; (2) the 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; 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.

Some will argue that a time-limited prohibition is inconsistent with the view that, notwithstanding safety concerns, cloning is inherently wrong because of its psychological social, or religious implications. Given your previously expressed views on this issue, if you propose a sunset provision you may face that criticism.

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 affect change. Jack Gibbons and Harold Varmus oppose this modification to your draft legislation. The Vice President prefers this modified approach.

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

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This memo summarizes the National Bioethics Advisory Commission (NBAC) cloning report and the cloning legislation you will announce Monday. It also discusses three decisions 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; (3) and whether to use NBAC's precise definition of cloning in the legislation.

NBAC's Findings and Recommendations

In its final report NBAC states that 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 (which do not involve the creation of entire human beings), and the cloning of animals, are scientifically important and not ethically problematic. 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;
- calling on all scientists and clinicians to adhere to the voluntary moratorium; and
- working with other countries to enforce common aspects of cloning restrictions.

Proposed Legislation

The legislation you will announce tomorrow::

- 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 property used in violating the Act;
- 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 your draft bill -- would not ban the creation of cloned embryos for research purposes. NBAC simply did not evaluate the ethics of this activity. NBAC declined to speak to the issue because a 1994 NIH panel has already evaluated embryo research ethics, and because using somatic cell nuclear transfer to create embryos for research does not pose distinct ethical questions. 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. 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.

You have already acted to restrict embryo research. In 1994 you banned the use of NIH funds to create embryos for research purposes (the NIH panel had recommended permitting the funding of certain limited research on embryos in the first 14 days after fertilization), and Congress has similarly prohibited the use of HHS funds. But privately-funded embryo research is not restricted.

The right-to-life community has already criticized NBAC for not recommending a ban on creating cloned embryos. Still, we recommend against your prohibiting this activity in the legislation you announce Monday. There is no moral rationale for treating embryos created through cloning differently from embryos developed through other means (e.g. in vitro fertilization). Prohibiting the creation of embryos for research using private funds could halt important research on infertility and possibly other medical conditions and would be strongly opposed by the scientific and fertility communities. In short, it is a controversial step that merits further consideration. Therefore, we suggest you limit the scope of the legislation to the issue the Commission addressed. If asked about your position on embryo research, you could 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 states strongly that any legislative prohibition on cloning include a sunset clause to ensure that Congress review the issue after a specified period of time. Commissioners who oppose cloning primarily because of safety concerns insisted on a time-limited ban because time may mitigate such concerns.

You may be criticized for proposing a sunset provision, however, since this approach appears to conflict with the position that cloning is inherently morally wrong. But some who share this view support a time-limited ban because (1) there has been so little time to fully consider the moral issues and it is possible their position may evolve; (2) the 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; 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 affect 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.

A BILL

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

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

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

SECTION 2. FINDINGS.

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

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

(1) NBAC has found that:

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

for regeneration and repair of human tissues.

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

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

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

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

(5) NBAC further recommended that Federal legislation

be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning.

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

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

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

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

animals.

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

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

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

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

SECTION 4. DEFINITIONS.

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

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

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

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

SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act

shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:

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

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

SECTION 7. PENALTIES.—

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

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

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

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

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

SECTION 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT.—No

later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

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

A BILL

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

(7) NBAC specified that within several years 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.

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

SECTION 8. EFFECTIVE DATE.—This Act shall take effect on the date of enactment.

SECTION 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT.—No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic

cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

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RECORD TYPE: PRESIDENTIAL (NOTES MAIL)

CREATOR: Elizabeth Drye (CN=Elizabeth Drye/OU=OPD/O=EOP [OPD])

CREATION DATE/TIME: 8-JUN-1997 12:04:07.00

SUBJECT: Draft briefing memo w/Elena, Eliz, OSTP edits.

TO: Elena Kagan (CN=Elena Kagan/OU=OPD/O=EOP @ EOP [OPD])
READ:UNKNOWN

TO: Christa Robinson (CN=Christa Robinson/OU=OPD/O=EOP @ EOP [OPD])
READ:UNKNOWN

TO: Rachel E. Levinson (CN=Rachel E. Levinson/OU=OSTP/O=EOP @ EOP [OSTP])
READ:UNKNOWN

TEXT:

===== ATTACHMENT 1 =====
ATT CREATION TIME/DATE: 0 00:00:00.00

TEXT:

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June 8, 1997

PRESENTATION OF THE CLONING REPORT

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

I. PURPOSE

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

II. BACKGROUND

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

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

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

- Propose legislation prohibiting [**for 5 years**] the use of somatic cell nuclear transfer to create a human being. The legislation also directs NBAC to report back in 4 ½ years on whether to continue the ban.
- Keep in effect the moratorium you put in place in March so that while legislation is pending no federal funds will be used to clone human beings,
- Urge privately-funded scientists and clinicians to adhere to the voluntary moratorium you called for in March while legislation is pending.

III. PARTICIPANTS

Briefing Participants:

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

Event Participants:

The Vice President
Dr. Harold Shapiro, NBAC Chair

Also Seated on Stage:

Secretary Shalala
Harold Varmus

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

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

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

VI. REMARKS

Remarks Provided by Jordan Tamagni in Speechwriting.

Meet and Greet with National Bioethics Advisory Commission

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

Members of the National Bioethics Advisory Commission

Patricia Backlar, of Oregon, Senior Scholar at the Center for Ethics in Health Care, Oregon Health Sciences University.

Arturo Brito, M.D., of Florida, Assistant Professor of Clinical Pediatrics at the University of Miami School of Medicine.

Alexander M. Capron, L.L.B., of California, co-director of the Pacific Center for Health Policy and Ethics at the University of Southern California.

Eric J. Cassell, M.D., F.A.C.P., of New York, Physician to In-Patients at The New York Hospital-Cornell Medical Center.

R. Alta Charo, J.D., of Wisconsin, Assistant Professor in the University of Wisconsin Medical and Law Schools.

James F. Childress, Ph.D., of Virginia, Edwin B. Kyle Professor of Religious Studies and Professor of Medical Education at the University of Virginia, and co-director of the Virginia Health Policy Research Center.

David R. Cox, M.D., Ph.D., of California, Professor of Genetics and Pediatrics at the Stanford University School of Medicine.

Rhetaugh Graves Dumas, Ph.D., of Michigan, Vice Provost for Health Affairs, The University of Michigan.

Ezekiel J. Emanuel, M.D., Ph.D., of Massachusetts, Assistant Professor of Medicine, Social Medicine and Clinical Epidemiology at the Dana-Farber Cancer Institute, Harvard Medical School. **He is Rahm Emanuel's brother.*

Laurie M. Flynn of Virginia, Executive Director of the National Alliance for the Mentally Ill.

Carol W. Greider, Ph.D., of New York, Senior Staff Scientist, Cold Spring Harbor Lab.

Steven H. Holtzman of Massachusetts, Chief Business Officer, Millenium Pharmaceuticals, Inc.

Bette O. Kramer of Virginia, President of the Richmond Bioethics Consortium.

Bernard Lo, M.D., of California, Professor of Medicine and Director of the Program in Medical Ethics at the University of California, San Francisco.

Lawrence H. Miike, J.D., M.D., of Hawaii, Director of the Dept. of Health, State of Hawaii.

Thomas H. Murray, Ph.D., of Ohio, Professor of Biomedical Ethics and Director of the Center for Biomedical Ethics at the Case Western Reserve University School of Medicine.

Diane Scott-Jones, Ph.D., of Pennsylvania, Associate Professor in the Department of Psychology,

Temple University.

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

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

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

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

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

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

I believe strongly that this conclusion reflects a national consensus . . . and I believe personally that it is right. Today, I am sending legislation to Congress that prohibits anyone -- in either the private or the public sector -- from using these techniques to create a child [for the next five years]. Until the day I sign that legislation into law, the moratorium I declared in March will remain in effect. And once again, I call on the private sector to refrain voluntarily from using this technology to attempt to clone a human being. It is untested, it is unsafe, and it is wrong.

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

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

[To make sure that all of our voices are heard as we explore the possibility of human cloning, the legislation specifically requires the National Bioethics Advisory Commission to continue to study the issue and report back to Congress within four-and-a-half years. At that time, we will decide whether the ban will continue.]

It is my own opinion that banning human cloning is the right thing to do. Creating a child through cloning calls into question our most fundamental beliefs about what it means to be human. It has the potential to undermine the sacred family bonds that are at the very core of our ideals. And it has the potential to encourage prejudices and preferences that threaten our unity as a nation.

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

Thank you and God bless you.

Draft 6/8/97 6:30pm

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THE ROSE GARDEN
JUNE 9, 1997**

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

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

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

Thank you and God bless you.

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 address 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; 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 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

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 could 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 morally wrong, 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 morally 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.

TO THE CONGRESS OF THE UNITED STATES:

Automated Records Management System
Hex-Dump Conversion

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

Following the February report that a sheep had been successfully cloned using a new technique, I requested my National Bioethics Advisory Commission to examine the ethical and legal implications of applying the same cloning technology to human beings. The Commission concluded that at this time "it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning" and recommended that Federal legislation be enacted to prohibit such activities. I agree with the Commission's conclusion and am transmitting this legislative proposal to implement its recommendation.

Various forms of cloning technology have been used for decades resulting in important biomedical and agricultural advances. Genes, cells, tissues, and even whole plants and animals have been cloned to develop new therapies for treating such disorders as cancer, diabetes, and cystic fibrosis. Cloning technology also holds promise for producing replacement skin, cartilage, or bone tissue for burn or accident victims, and nerve tissue to treat spinal cord injury. Therefore, nothing in the "Cloning Prohibition Act of 1997" restricts activities in other areas of biomedical and agricultural research that involve: (1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or (2) the use of somatic cell nuclear transfer techniques to create animals.

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

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

WILLIAM J. CLINTON

THE WHITE HOUSE
June 9, 1997

"CLONING PROHIBITION ACT OF 1997"

FACT SHEET

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

The National Bioethics Advisory Commission (NBAC) Report

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

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

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

Cloning Prohibition Act of 1997

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

Further Actions By The President

As recommended by the NBAC, President Clinton today also:

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

- **Urged privately funded scientists and clinicians to adhere to the voluntary moratorium he called for in March.** The President asked these professionals to work through their societies and associations to ensure that all adhere to the current voluntary ban while his proposed legislation is pending.
- **Pledged to work with other countries to enforce the prohibition.** Several other countries, including Great Britain, Denmark, Germany, Australia, and Spain, have banned human cloning.

Draft 6/8/97 2:00pm

**PRESIDENT WILLIAM J. CLINTON
REMARKS FOR CLONING EVENT
THE ROSE GARDEN
JUNE 9, 1997**

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

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

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

Just three months ago, scientists unlocked a profound mystery of human life . . . and unleashed the troubling possibility that this discovery could be used to create a child from human genetic material. I said then and I believe just as strongly now that any discovery that touches upon human creation is not simply a matter of scientific inquiry; it is a matter of morality and spirituality.

The possibility of creating a child through these new techniques mandates that we proceed with caution, and with conscience. That is why I acted immediately to ban the use of any federal funds for the cloning of human beings, and I urged the private sector to do the right thing and observe this ban voluntarily. And that is why I asked the National Bioethics Advisory Commission to prepare this report.

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

We are taking immediate action to prevent that possibility. Today, I am sending legislation to Congress that prohibits anyone -- in either the private or the public sector -- from

using these techniques to create a child for the next five years. Until the day I sign that legislation into law, the moratorium I declared in March will remain in effect. Once again, I call on the private sector to refrain from using these techniques to attempt to clone a human being. There is still too much that we do not know -- and too much that we do not agree on -- to take the risk of creating innocent children in this untested way.

I want to make clear that there is nothing inherently immoral or wrong with these new techniques. In fact, they hold out the promise of revolutionary new medical treatments and life-saving cures; of better crops and stronger livestock. Cloning human tissues and cells is already helping to improve the lives of millions of people, and this legislation will not prohibit it. Finally, this bill will not ban the cloning of animals.

What this legislation will do is give us time to continue the national dialogue we began three months ago. It will give the scientific community time to investigate the viability and the safety of these new techniques. It will give us time to reaffirm our most cherished beliefs about the miracle of human life, and the God-given individuality that each person possesses. Or, it will give us time to broaden those beliefs to include a new mystery, if to do so harms none and benefits all.

To make sure that all of our voices are heard as we explore the possibility of human cloning, the legislation specifically requires the National Bioethics Advisory Commission to continue to study the issue and report back to Congress after four and a half years. At that time, we will decide whether the ban will continue, or whether we will enter a new chapter of human life.

We are still a long way from understanding all of the implications of this remarkable breakthrough. But it is our obligation and our honor to confront the issues it raises -- as a people. I am confident that the step we are taking today will continue that process. Once again, I thank the National Bioethics Advisory Commission for the work you have done and will continue to do in the coming years.

Thank you and God bless you.

Qs and As on NBAC's Report on Cloning

- Q. What did the Commission recommend?**
- A. The Commission recommends legislation to prohibit anyone in either the public or private sector from attempting to create a child using the technology that made possible the creation of "Dolly" -- so-called "somatic cell nuclear transfer" technology. The Commission also supports a continuation of the current moratorium on federal funding of creating a child by cloning while the legislation is pending. NBAC is also asking the private sector to comply with the voluntary moratorium President Clinton called for in March, pending the legislative prohibition. Finally, NBAC also called for continuing public dialogue on these issues to further understand the ethical and social implications of this technology.**
- Q. What exactly does the President's legislation ban?**
- A. The President's legislation prohibits the use of somatic cell nuclear transfer to create a human being (specifically, "with the intent of introducing the product into a woman's womb or in any other way creating a human being").**
- Q. How will the prohibition be enforced?**
- A. The legislation gives the Attorney General authority to seek injunctive relief, impose civil fines up to \$250,000 or twice the profit from a violation of the Act (whichever is greater), and seize any and all property used in violating the Act (including entire laboratories).**
- Q. Why doesn't it make cloning a criminal act and impose jail time?**
- A. We think the penalties in the bill provide an effective deterrent. In particular, they make it clear no one will profit from this activity. It's appropriate to be cautious about criminalizing any activity, and at this point we don't have any indication that we need the threat of criminal sanctions to deter this activity.**
- Q. But what if Congress wants to impose criminal sanctions?**
- A. We have seriously considered this option and would be willing to look at it again.**

Q. Why is there need for a “sunset” provision?

NBAC recommends -- and the President supports -- a sunset provision, combined with review by an advisory body prior to the sunset date. There are several reasons to take this approach. First, a sunset provision provides a strong incentive for Congress and the Administration to renew the national debate on cloning within several years, ensuring continued attention to the ethical questions; second, there has been little time to fully consider the moral issues, and it is possible that convictions may evolve; and third, there is a high probability that we 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.

follow-up

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

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

Q. Why ban the cloning of humans?

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

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

A. There are legitimate and beneficial applications of cloning cells, DNA, tissues, and animals: including the development of medicines, and therapies for diseases such as cancer, cystic fibrosis, and diabetes. Cloning also

furtheres our knowledge about developmental biology that may one day lead to such advances as regeneration of tissue in severe burns and spinal cord injuries.

- Q. Why is any additional legislation necessary? Why not extend the President's moratorium?**
- A. The President's moratorium covers only federally funded activities. In March, President Clinton called for a voluntary ban on privately funded activities. Legislation is necessary, however, to ensure that the privately funded research and clinical centers comply with the proposed prohibition on cloning of human beings using the somatic cell nuclear transfer technique.**
- Q. With the proposed legislation, are we interfering with people's reproductive freedom?*
- A. No. We don't think people should have the "freedom" to do this activity. It's unsafe and ethically objectionable.
- Q. How will the recommendations and legislation affect research?*
- A. NBAC found that a ban on human cloning will not impede any important research at this time. Basic research in such areas as animal husbandry and drug development will continue. Similarly, basic research using somatic cell nuclear transfer technology to study, for instance, the potential for regenerating tissues and organs will continue. However, under current federal restrictions, human embryo research using federal funds will remain prohibited.
- Q. Why would you (or the Commission) support a total ban on cloning people, but not on creating embryos using cloning technology for research?**
- A. The issue of embryo research is an important but separate question. NBAC found that the technology that created Dolly doesn't raise new questions related to embryo research. By contrast, the use of somatic cell nuclear transfer technology to create a child raises a host of new and different ethical issues relating to safety, individuality, and family integrity. The President's legislation is directed at these concerns. Further, the President has prohibited the use of federal research funds to create an embryo for research purposes -- whether created through cloning or other means.**
- Q. If human embryo research is bad, why not ban it in the private sector as well?**

- A. Whether to ban privately-funded embryo research is a question that needs careful deliberation, as such research may offer medical benefit, particularly with respect to treating infertility. We simply need further discussion about regulation of this activity in the private sector before pursuing legislation.**
- Q. Does the Federal Government have any jurisdiction over privately funded research with human embryos?**
- A. If the research is part of an effort to develop a drug, biologic, or medical device, the research is subject to regulation by the Food and Drug Administration. Otherwise, it is unregulated.**
- Q. What happens to human embryos created for research? If they are not implanted, isn't that tantamount to abortion, or even murder?**
- A. Creation of human embryos for research is a prohibited use of Federal funds. The extent of such research under private sponsorship is unknown; therefore, we have no reliable information on the fate of human embryos used in this way.**
- Q. *How will this affect childless couples who see cloning as their only chance to have genetically related offspring?***
- A. Prohibiting this technology will have little practical effect on such couples. Currently neither the science base nor safety considerations make it possible to produce a child by somatic cell nuclear transfer.**
- Q. Is the United States acting unilaterally on this issue? Are we treating this issue any differently than other countries?**
- A. Some European countries have already established legal prohibitions on the cloning of humans. To the extent that there are common aspects to our respective policies, we will certainly cooperate with these nations regarding enforcement.**