

THE WHITE HOUSE
WASHINGTON

June 8, 1997

MEMORANDUM FOR THE PRESIDENT

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

Elena Kagan
Deputy Assistant to the President for Domestic Policy

SUBJECT: Cloning Policy Decisions

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

NBAC's Findings and Recommendations

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

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

Proposed Legislation

The legislation you will announce tomorrow, as currently written:

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

Key Legislative Issues

1. Embryo Research

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

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

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

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

2. Sunset Provision

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

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

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

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

THE WHITE HOUSE
WASHINGTON

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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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.

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 to create a child;" and (3) propose a time-limited moratorium instead of a ban. USDA and HHS support this position.

Approve ____ Disapprove ____

Attachment

France's Proposed Language for G-8 Communique

We have taken note with great concern of recent scientific experiments which could open the way to reproductive human cloning. We agree that the prohibition of any form of reproductive human cloning needs both strict domestic legislation and close international cooperation to adapt current international law. We are encouraged by the reflections underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal ban on reproductive human cloning.

Our Proposed Substitute Language

We have taken note that further development of the technology that enabled the recent cloning of a sheep offers the promise of enormous medical and agricultural benefits. We have also taken note with great concern that this scientific advance could open the way to using this technology (by which we mean somatic cell nuclear transfer technology) to create a child. We agree on the need for appropriate domestic legislation and close international cooperation to prohibit the use of somatic cell nuclear transfer to create a child while countries explore ethical and scientific implications in greater depth. We are encouraged by the reflections already underway within national ethics committees as well as in various regional and international fora. We are determined to give a strong impetus to their work with a view to arriving as soon as possible at a universal moratorium on the use of somatic cell nuclear transfer to create a child.

rec'd 6/5/97 a.m.

cc: AID's, Gwin, Smith,
Foster, Phelps

THE PRESIDENT HAS SEEN

6-4-97

THE WHITE HOUSE

WASHINGTON

June 3, 1997

Copied to:

Kagan

Gibbons

Emmanuel

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

February 24, 1997

Dr. Harold Shapiro
Chair
National Bioethics
Advisory Commission
Suite 3C01
6100 Executive Boulevard
Bethesda, Maryland 20892-7508

Dear Dr. Shapiro:

As you know, it was reported today that researchers have developed techniques to clone sheep. This represents a remarkable scientific discovery, but one that raises important questions. While this technological advance could offer potential benefits in such areas as medical research and agriculture, it also raises serious ethical questions, particularly with respect to the possible use of this technology to clone human embryos.

Therefore, I request that the National Bioethics Advisory Commission undertake a thorough review of the legal and ethical issues associated with the use of this technology, and report back to me within ninety days with recommendations on possible federal actions to prevent its abuse.

Sincerely,

Bill Clinton

February 25, 1997

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

Dear Mr. President:

I am writing in my role as Chairman of the National Bioethics Advisory Commission in response to your letter of February 24. The Commission is pleased to undertake the task you have outlined. We will certainly do our best to report back to you within ninety days, as you have requested.

Sincerely,

Harold T. Shapiro

bc: Dr. John H. Gibbons
Dr. William F. Raub
Ms. Henrietta Hyatt-Knorr

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

March 12, 1997

The Honorable Louis Stokes
Subcommittee on Veterans' Affairs, HUD,
and Independent Agencies
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

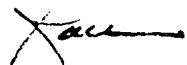
Dear Representative ~~Stokes~~ Stokes:

Thank you for your interest, expressed during my testimony on March 5, 1997, in the National Bioethics Advisory Commission (NBAC) and in the actions President Clinton took regarding prohibition of federal funding for cloning human beings. For your information, NBAC will be meeting on March 13 and 14 at the Watergate Hotel. The meeting agenda is enclosed. I hope the information enclosed will provide useful background about these two topics.

I am also enclosing the answers to your questions on cloning from the hearing. The answers to additional questions from the hearing are in preparation and will be forwarded to your office at a later date.

Please feel free to contact me with any further questions. The Commission staff can be reached at (301) 402-4242; the acting Executive Director is Dr. Bill Raub.

Sincerely,


John H. Gibbons
Director

Enclosures.

March 7, 1997

FINAL DRAFT

NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC)

March 13, 1997

Watergate Hotel, Continental Chesapeake Extender Room
2650 Virginia Avenue, NW, Washington, DC
(202) 298-4466 (for messages)

AGENDA*/Day One

- 8:00 AM **Welcome and Introduction**
Dr. Harold Shapiro, Chair
- 8:15 AM **Report of the Human Subjects Subcommittee**
Dr. James Childress, Subcommittee Chair
- 9:15 AM **Report of the Genetics Subcommittee**
Dr. Thomas Murray, Subcommittee Chair
- 10:15 AM **Coffee Break**
- 10:45 AM **Discussion: Approach to the President's Request**
- 11:15 AM **Lunch**
- 12:15 PM **Science and Technology in Cloning**
Dr. Shirley Tilghman, Princeton University
- 1:15 PM **Discussion**
- 1:45 PM **Coffee Break**
- 2:15 PM **Religion-Based Perspectives on Cloning of Humans I**
Protestantism:
Dr. Gilbert Meilaender (Valparaiso University)
Dr. Nancy Duff (Princeton Theological Seminary)
Discussion
Roman Catholicism:
Dr. Lisa Cahill (Department of Theology, Boston College)
Rev. Dr. Albert Moraczewski (National Conference of Catholic Bishops)
Discussion
- 3:45 PM **Discussion**
- 4:15 PM **Statements by the Public**
- 5:00 PM **Adjournment for the Day**

* Please note: This agenda might be slightly revised before or at the meeting at the discretion of the Chair.

FINAL DRAFT

NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC)

March 14, 1997

Watergate Hotel, Continental Chesapeake Extender Room
2650 Virginia Avenue, NW, Washington, DC
(202) 298-4466 (for messages)

AGENDA*/Day Two

- 8:00 AM **Welcome and Summary of Previous Day**
Dr. Harold Shapiro, Chair
- 8:15 AM **Religion-Based Perspectives on Cloning of Humans II**
Judaism:
Dr. Elliot Dorff (University of Judaism, Los Angeles)
Dr. Moshe Tendler (Yeshiva University)
Discussion
Islam:
Dr. Aziz Sachedina (University of Virginia)
Discussion
- 9:45 AM **Coffee Break**
- 10:00 AM **Views on Cloning**
Possible Benefits:
Dr. John Robertson (University of Texas Law School)
Dr. Ruth Macklin (Albert Einstein College of Medicine)
Discussion
Possible Risks:
Dr. Leon Kass (University of Chicago)
Dr. Jim Nelson (University of Tennessee)
Discussion
- 11:30 AM **Lunch**
- 12:30 PM **Discussion**
- 2:00 PM **Future Meetings**
- 2:15 PM **Coffee Break**
- 2:30 PM **Statements by the Public**
- 4:30 PM **Adjournment**

* Please note: This agenda might be slightly revised before or at the meeting at the discretion of the Chair.

NATIONAL BIOETHICS ADVISORY COMMISSION FACT SHEET

On October 3, 1995, the President signed Executive Order 12975, establishing the National Bioethics Advisory Commission. The Commission came about as the result of a proposal developed by the Office of Science and Technology Policy (OSTP), in consultation with members of the National Science and Technology Council and interested members of Congress, to create a standing body of experts to consider bioethical issues arising from research on human biology and behavior, including clinical research, and the applications of such research. The goal was to establish a panel of non-government experts in the relevant scientific disciplines, law, philosophy and theology, as well as community representatives, to provide advice and recommendations to the Federal government. Broader public participation in the discussion of such a group's role and composition was sought via a *Federal Register* notice and communication with advocacy groups and professional societies. The Commission reports to the President's National Science and Technology Council and operates under the provisions of the Federal Advisory Committee Act.

OSTP began developing this proposal at the request of the Departments of Energy and Health and Human Services, in October 1993. These agencies were contemplating the establishment of a joint advisory panel to examine issues related to the confidentiality of genetic information resulting from the Human Genome Project. It became clear that there were a number of other bioethical issues that would benefit from consideration by an expert, standing advisory body. Thus, the interagency working group was expanded to include representatives of DOD, NASA, VA, USDA, NSF and Justice. The products of these discussions were the draft charter and preamble that were published in the *Federal Register* (August 12, 1994). The charter was signed by Dr. John H. Gibbons, Assistant to the President for Science and Technology, on July 28, 1996. The key points of the charter are:

- The immediate charge to the Commission is to consider issues in the protection of the rights and welfare of human research subjects and management and use of genetic information.
- The general charge to the Commission is to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research. The Commission has the authority to establish its own priorities and agenda, in accordance with four criteria described in the charter, and subject to the approval of the National Science and Technology Council.
- The Commission is composed of experts in the fields of philosophy and theology, social and behavioral science, law, medicine and biological research, in addition to representatives of the general public. Its members are appointed by the President.

The President appointed 18 members to the Commission, which is chaired by Dr. Harold Shapiro, President of Princeton University. The inaugural meeting was held on October 4, 1996. A roster of the members is attached.

ROSTER OF NBAC MEMBERS

Chair

Harold T. Shapiro, Ph.D.

President

Princeton University

One Nassau Hall

Princeton, NJ 08544-0015

(July 19, 1996 - July 18, 2000)

R. Alta Charo, J.D.

Professor of Law

University of Wisconsin

6108 Law Bldg., 975 Bascom Mall

Madison, WI 53706

(July 19, 1996 - July 18, 2000)

Patricia Backlar

Senior Scholar

Center for Ethics in Health Care

Oregon Health Sciences University

Portland, OR 97207

(July 19, 1996 - July 18, 1998)

James Childress, Ph.D.

Department of Religious Studies

University of Virginia

Cocke Hall, Rm. 101

Charlottesville, VA 22903

(July 19, 1996 - July 18, 1999)

Arturo Brito, M.D.

Assistant Professor of Clinical Pediatrics

University of Miami School of Medicine

1601 NW 12th Avenue

Miami, FL 33136

(July 19, 1996 - July 18, 1999)

David R. Cox, M.D., Ph.D.

Professor of Genetics and Pediatrics

Stanford University School of Medicine

Department of Genetics, M-336

Stanford, CA 94305

(July 19, 1996 - July 18, 1999)

Alexander M. Capron, LL.B.

Co-Director

Pacific Center for Health Policy and Ethics

Univ of Southern California Law Center

699 Exposition

Los Angeles, CA 90089-0071

(July 19, 1996 - July 18, 2000)

Rhetaugh Graves Dumas, Ph.D., R.N.

Vice Provost for Health Affairs

The University of Michigan

3088 Fleming Administration Building

Ann Arbor, MI 48109-1340

(September 16, 1996 - September 15, 1999)

Eric J. Cassell, M.D.

Professor of Public Health

Cornell Medical College

1550 York Avenue

New York, NY 10028

(July 19, 1996 - July 18, 1998)

Ezekiel J. Emanuel, M.D., Ph.D.

Associate Professor of Medicine

and Social Medicine

Dana-Farber Cancer Institute

44 Binney Street

Boston, MA 02115

(July 19, 1996 - July 18, 1998)

Laurie M. Flynn
Executive Director
National Alliance for the
Mentally Ill
200 N. Glebe Road, Suite 1015
Arlington, VA 22203
(July 19, 1996 - July 18, 2000)

Carol Widney Greider, Ph.D.
Senior Staff Scientist
Cold Spring Harbor Laboratory
1 Bungtown Road
Cold Spring Harbor, NY 11724
(October 29, 1996 - October 28, 1998)

Steven H. Holtzman
Chief Business Officer
Millenium Pharmaceuticals Inc.
640 Memorial Drive
Cambridge, MA 02139
(July 19, 1996 - July 18, 1999)

Bette O. Kramer
President
Richmond Bioethics Consortium
1803 Hanover Avenue
Richmond, VA 23220
(September 16, 1996 - September 15, 1998)

Bernard Lo, M.D.
Director
Program in Medical Ethics
University of California, San Francisco
521 Parnassus Avenue, Rm. C126
San Francisco, CA 94143-0903
(July 19, 1996 - July 18, 2000)

Lawrence H. Miike, M.D., J.D.
Director
State Department of Health
1250 Punchbowl Street
Honolulu, HI 96813
(July 19, 1996 - July 18, 1998)

Thomas H. Murray, Ph.D.
Director, Center for Biomedical Ethics
School of Medicine
Case Western Reserve University
10900 Euclid Avenue
Cleveland, OH 44106-4976
(July 19, 1996 - July 18, 1999)

Diane Scott-Jones, Ph.D.
Professor
Department of Psychology
Temple University
564 Weiss Hall
1701 North 13th Street
Philadelphia, Pa 19122-6085
(July 19, 1996 - July 18, 2000)

[FR Doc. 94-19568 Filed 8-11-94; 8:45 am]
BILLING CODE 4710-20-M

OFFICE OF SCIENCE AND TECHNOLOGY

National Bioethics Advisory Commission Proposed Charter

AGENCY: Office of Science and
Technology Policy (OSTP).

ACTION: Request for Comments.

SUMMARY: This notice describes a proposal to establish a National Bioethics Advisory Commission within the Executive Branch. The Commission would be charged to consider issues of bioethics arising from research on human biology and behavior, and the applications of that research.

DATES: Comments must be received on or before October 11, 1994.

ADDRESSES: Submit written comments by mail to: Bioethics Docket, Office of Science and Technology Policy, Room 436, OEOB, Washington, D.C. 20500, or by FAX to: 202-456-6027.

FOR FURTHER INFORMATION CONTACT: By mail: Rachel E. Levinson, Assistant Director for Life Sciences, Office of Science and Technology Policy, Room 436, OEOB, Washington, D.C. 20500. Office telephone number: 202-456-6137.

SUPPLEMENTARY INFORMATION: OSTP proposes that a standing advisory body be established within the Executive Branch to consider issues of bioethics arising from research on human biology and behavior, and the applications of that research. This action would fulfill a need recognized by all branches of the Federal government. For example, a report by the House of Representatives Committee on Government Operations recommended establishment of an advisory committee to examine the ethical, legal and social implications of the Human Genome Project. The proposed advisory body would expand the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; the Department of Health, Education and Welfare's Ethics Advisory Board, and the President's Commission for the Study of Ethics Problems in Medicine and Biomedical and Behavioral Research.

OSTP seeks comments on a draft charter for the proposed National Bioethics Advisory Commission. The Commission would be part of the Executive Branch, and would be charged to consider issues of bioethics arising from research on human biology and behavior, and the applications of that research. The Commission would be required to have a balanced membership. Naturally, selection of Commission members is going to be a delicate process that should take into account the social and cultural mores of the times in order to establish a body that is sensitive to the potential impacts of its deliberations and recommendations. The draft charter proposes that members be appointed by the President. Suggestions for potential members or membership posts are sought through this Notice.

deliberations and recommendations of the NBAC for the Executive Branch agencies most heavily invested in biological and behavioral research.

The Commission would be asked to identify and develop broad overarching principles to govern the ethical conduct of biological and behavioral research, and the applications of that research. The proposed NBAC would not have responsibility for the review and approval of individual projects.

The draft charter seeks to strike a balance between defining the NBAC's agenda so as to fulfill governmental needs, and allowing the Commission sufficient flexibility to advise the government on issues this group of experts and stakeholders believe should be addressed.

The charter specifies two prospective areas of inquiry, issues in the management and use of genetic information and protection of the rights and welfare of research subjects. Discrete issues that fall under these two broad topics include: issues of genetic privacy, screening for genetic disorders, intellectual property rights, access to research data or materials developed with public funding, current views on informed consent, adequacy and implementation of Federal human subject research guidelines, and the concept of "minimal risk."

In addition, several other potential issues for consideration by the Commission have been raised in discussions to date including: adequacy and implementation of Federal human subject research guidelines, recommendations on requirements to maintain research data, and the ethical aspects of access to costly health care technology. The question is, how best might the scope of the Commission's charge be defined so as to meet public needs for deliberation of pressing issues in bioethics, without being so broad as to limit its effectiveness? An alternative option for addressing the last issue, for example, might be referral to a body more directly involved with decisions related to the provisions of health care and relevant cost/benefit analysis.

The Commission would be established in accordance with the Federal Advisory Committee Act (FACA). As such, its meetings would be open to the public and announced in advance to facilitate public participation. In addition, reports produced by the NBAC would be made available to public either in totum or in summary. The purpose of this statement is to solicit comments on the draft charter of the NBAC, and to solicit suggestions for potential members or membership posts.

As a FACA committee, the NBAC will be required to have a balanced membership. Naturally, selection of Commission members is going to be a delicate process that should take into account the social and cultural mores of the times in order to establish a body that is sensitive to the potential impacts of its deliberations and recommendations. The draft charter proposes that members be appointed by the President. Suggestions for potential members or membership posts are sought through this Notice.

Draft Charter

Proposed National Bioethics Advisory Commission

Purpose

The National Bioethics Advisory Commission will provide advice and make recommendations to the National Science and Technology Council, other appropriate entities and the public, on bioethical issues arising from research on human biology and behavior, and the applications of that research.

Authority

42 U.S.C. 6617(a)(2). This Commission is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation of advisory committees, and implementing regulations (41 CFR 101-6.10).

Functions

The National Bioethics Advisory Commission shall advise, consult with, and make recommendations to the National Science and Technology Council and other appropriate entities, and also make their advice and recommendations available to the public. The Commission's purview includes the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior, and applications of that research. The Commission shall identify broad, overarching principles to govern the ethical conduct of research, citing individual projects only as illustrations for such principles. The Commission shall not be responsible for the review and approval of individual projects.

As a first priority, the Commission will direct its attention to consideration

of the management and use of genetic information and

B. Protection of the rights and welfare of research subjects.

In receiving and responding to requests for advice and recommendations from the National Science and Technology Council, the Commission shall consider four criteria in establishing priority for its activities:

- A. The public health or public policy urgency of the bioethical issue.
- B. The relation of the bioethical issue to the goals for Federal investment in science and technology.
- C. The absence of another body able to fruitfully deliberate on the bioethical issue.
- D. The extent of interest in the issue across the government. (The Commission ordinarily will not deliberate on a bioethical issue of interest to just one department or agency.)

The Commission also shall have the authority to identify bioethical issues, on its own behalf, for deliberation. The Commission will accept suggestions of issues for consideration from Federal agencies, Congress and the public. The Commission's decision to deliberate on a specific topic shall be made in consultation with the National Science and Technology Council. In all such instances, the four stated criteria for establishing priority shall pertain.

Structure

The National Bioethics Advisory Commission shall consist of not more than 15 members, including the Chairperson. Appointments shall be made by the President, who shall select from knowledgeable non-Government experts and community representatives with special qualifications and competence to deal effectively with bioethical issues of concern to the participating departments and agencies. At least one member shall be selected from each of the following categories of primary expertise: (i) bioethics/theology; (ii) social/behavioral science; (iii) law; (iv) medicine/allied health professions; and (v) biological research. At least three members shall be selected from the general public, bringing to the Commission expertise other than that listed. The membership shall be approximately evenly balanced between scientists and non-scientists.

Members shall be appointed for overlapping four-year terms. Initially, members will be appointed for two-, three- or four-year terms. Terms of more than two years are contingent upon renewal of the National Bioethics Advisory Commission by approval of a joint resolution of the House of Representatives. All members shall be appointed by the

President. The term of office for the Chairperson shall be two years, renewable by appropriate action of the President.

If a vacancy occurs on the Commission, the President shall make an appointment to fulfill the term. Any member appointed to fill a vacancy occurring prior to expiration of the term for which his or her predecessor was appointed shall serve for the remainder of such term. Members may serve after the expiration of their terms until their successors have taken office.

The Commission may conduct inquiries, hold hearings and establish subcommittees, as necessary.

The Commission is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on the Commission, the Commission is also authorized to contract for the services of non-governmental consultants who may conduct analyses, prepare reports and background papers or prepare other materials for consideration by the Commission, as appropriate.

In order to avoid duplication of effort, the Commission may, in lieu of, or as part of any of its authorized activities, incorporate the results of the deliberations of another entity as long as the Commission sets forth its reasons for doing so.

The Assistant to the President for Science and Technology shall be notified upon establishment of each subcommittee, and shall be provided information on the name, membership (including chair), function, estimated duration of the subcommittee, and estimated frequency of meetings.

Management and support services shall be provided by the Office for Protection from Research Risks, Department of Health and Human Services. Additional resources including, but not limited to personnel, office support and printing will be provided by other NSTC member agencies.

Meetings

Meetings of the Commission shall be held up to 10 times a year at the call of the Chairperson with the advance approval of a Federal Government official who shall also approve the agenda. Meetings of the subcommittee(s) shall be convened as necessary. A Federal Government official shall be present at all meetings.

Meetings shall be open to the public, except as otherwise determined by the Commission. The Commission shall also hold public hearings on issues of concern to the public.

Meetings shall be conducted, and records of proceedings kept, as required by applicable laws and Federal regulations.

Compensation

Members may be compensated at a rate not to exceed the maximum pay authorized by 5 U.S.C. 3109, plus per diem and travel expenses as in accordance with standard government travel regulations.

Annual Cost Estimate

The estimated annual cost for operating the National Bioethics Advisory Commission, including compensation and travel expenses for members and contracting and publication services costs, but excluding that for staff support, \$1,500,000. The estimated annual person years of staff support is six, at an estimated annual cost of \$500,000.

Reports

Reports by the National Bioethics Advisory Commission on specific issues shall be submitted to the National Science and Technology Council, the appropriate committees of Congress, and other appropriate entities. The Commission may specifically identify the Federal department, agency or other entity to which particular recommendations are directed and request a response from the Federal department, agency or other entity within 180 days of publication of such recommendations.

Executive summaries of each report of the Commission shall be promulgated in the Federal Register. Such summaries shall specifically list the department, agency, or other entity to which any recommendations are directed and the date by which such responses are expected.

An annual report shall be submitted to the National Science and Technology Council and the appropriate committees of Congress. It shall contain, at a minimum, (i) the Commission's function; (ii) a list of members and their business addresses; (iii) the dates and places of meetings; (iv) a summary of the Commission's activities during the year; (v) a summary of the Commission's recommendations made during the year; and (vi) a summary of responses made by departments, agencies, or other entities to the Commission's recommendations during the year.

Public Access

The Commission shall make available to the public, in electronic and printed form, all reports, recommendations, and other materials developed by the Commission.

terminate two years from the date this charter is approved.

Barbara Ann Ferguson,

Administrative Officer, Office of Science and Technology Policy.

[FR Doc. 94-19688 Filed 8-11-94]

BILLING CODE 3170-01 OSTP-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Criteria and Application Process for the Secretarial Award for Excellence in Transportation Technology Research and Development

AGENCY: Department of Transportation, Office of the Secretary.

ACTION: Notice of Request for Nominations.

SUMMARY: The Department of Transportation (DOT) announces procedures for nominating individuals and organizations for the Secretarial Award for Excellence in Transportation Technology Research and Development. Awards are made annually by the Secretary of Transportation to recognize research and development contributions advancing the ability of the U.S. transportation industry to compete globally.

DATES: Nominations must be postmarked no later than October 30, 1994.

ADDRESSES: An original and three copies of the nomination should be sent to: Noah Rifkin, Director of Technology Deployment, Office of the Secretary, U.S. Department of Transportation, 400 7th Street, SW, Washington, DC 20590, Room 10200.

FOR FURTHER INFORMATION CONTACT: John E. Hohl, Technology Sharing Officer, Research and Special Programs Administration, U.S. DOT 400 7th Street, SW, Washington D.C. 20590 Telephone: (202) 366-4978.

SUPPLEMENTARY INFORMATION:

Background

This notice solicits nominations for the Secretarial Award for Excellence in Transportation Technology Research and Development and provides relevant information on the nomination and selection process. The award is honorary recognition in the form of a certificate from the Secretary of Transportation. Awards will be presented annually.

Purpose

The U.S. Department of Transportation (DOT) is committed to promoting the advancement of transportation technology research and development.

technologically advanced transportation system that promotes economic growth, enhances international economic competitiveness, and contributes to a secure and healthy environment. In fulfilling this mission, the Department intends to accelerate technological advances that promote the development and export of transportation technology and manufactured products. To further these goals, the Secretary of Transportation has established the Secretarial Award for Excellence in Transportation Technology Research and Development to recognize significant contributions to expanding the technology knowledge base and the ability of the transportation industry to compete internationally.

Organization Defined

- For purposes of this award, organizations include but are not limited to:
 - Domestic or U.S. Corporations, including nonprofit corporations;
 - Partnerships;
 - Professional associations;
 - Institutions of higher education;
 - Federal, State, or local government; and
 - Professional teams assembled for the specific projects.

Evaluation Criteria

Nominations will be evaluated based on the following criteria:

- Quality and innovative nature of the technology developed;
- How the technology has enhanced industry competitiveness, both domestically and internationally.
- Significance of individual or organization nominated to the success of the development effort:
 - Entrepreneurial nature of research effort (nature of collaboration);
 - Potential for positive economic benefits to the U.S. or specific region; and
 - Applicability to more than one mode of transportation.

The qualifying work may be a singular accomplishment or a series of accomplishments that have had a substantial effect over time. Generally, technologies applicable to more than one transportation mode will be more favorably considered.

Examples of achievements that may be recognized include but are not limited to:

- **Safety Improvements**—Technology that reduces the likelihood of vehicle accidents or the likelihood of serious injury when a vehicle accident does occur, or that improves the overall safety of the transportation system.

include research and development of instrumentation equipment, human factors, or biomechanics.

- **Energy Savings**—Technology that saves energy in the production, operation, or disposition of vehicles through research in materials development, alternative fuels, engine and propulsion modifications, aerodynamic modeling and drag reduction, and combustion research.

• **Environmental Quality**—Technology applicable to transportation that reduces emissions; hazardous, solid or toxic waste; noise. This could include research and development of products, processes, or measurement instrumentation.

• **International Industrial Competitiveness**—Technology that allows the U.S. transportation industry to achieve sustainable world-class capabilities to compete in the global marketplace through the sale of transportation vehicles and equipment in overseas markets or the provision of freight and passenger transportation services to support international trade and travel.

• **Job Creation**—Transportation technology that creates jobs and makes a positive contribution to the U.S. economy.

Evaluation Process

The DOT Research and Technology Coordinating Council, chaired by the Director of Technology will appoint an Evaluation Committee to evaluate nominations under the prescribed criteria and to recommend awardees.

Recommendations of the Evaluation Committee will be reviewed by a Selection Committee made up of members of the Research and Technology Steering Committee. Final selections will be made by the Secretary of Transportation.

Nominating Procedures

Any person may nominate individuals or organizations from industry, academia, or government. Nomination should be in the form of a letter and must demonstrate that the nominee has provided significant contributions, through technology research and development, to advancing the ability of the U.S. transportation industry to compete globally in an area of transportation systems development, vehicle or facility design, construction, operation, or maintenance. Nominations must include the following:

- Name and address of the individual or organization being nominated;
- A description of the technology and its contribution to the transportation industry.

Presidential Documents

Title 3—

Executive Order 12975 of October 3, 1995

The President

Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Review of Policies and Procedures.* (a) Each executive branch department and agency that conducts, supports, or regulates research involving human subjects shall promptly review the protections of the rights and welfare of human research subjects that are afforded by the department's or agency's existing policies and procedures. In conducting this review, departments and agencies shall take account of the recommendations contained in the report of the Advisory Committee on Human Radiation Experiments.

(b) Within 120 days of the date of this order, each department and agency that conducts, supports, or regulates research involving human subjects shall report the results of the review required by paragraph (a) of this section to the National Bioethics Advisory Commission, created pursuant to this order. The report shall include an identification of measures that the department or agency plans or proposes to implement to enhance human subject protections. As set forth in section 5 of this order, the National Bioethics Advisory Commission shall pursue, as its first priority, protection of the rights and welfare of human research subjects.

(c) For purposes of this order, the terms "research" and "human subject" shall have the meaning set forth in the 1991 Federal Policy for the Protection of Human Subjects.

Sec. 2. *Research Ethics.* Each executive branch department and agency that conducts, supports, or regulates research involving human subjects shall, to the extent practicable and appropriate, develop professional and public educational programs to enhance activities related to human subjects protection, provide forums for addressing ongoing and emerging issues in human subjects research, and familiarize professionals engaged in nonfederally-funded research with the ethical considerations associated with conducting research involving human subjects. Where appropriate, such professional and educational programs should be organized and conducted with the participation of medical schools, universities, scientific societies, voluntary health organizations, or other interested parties.

Sec. 3. *Establishment of National Bioethics Advisory Commission.* (a) There is hereby established a National Bioethics Advisory Commission ("NBAC"). NBAC shall be composed of not more than 15 members to be appointed by the President. NBAC shall be subject to the Federal Advisory Committee Act, as amended (5 U.S.C. App.).

(b) The President shall designate a Chairperson from among the members of NBAC.

Sec. 4. *Functions.* (a) NBAC shall provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters:

(i) the appropriateness of departmental, agency, or other governmental programs, policies, regulations, internal guidelines, and regulations as they relate to research involving human subjects or human subjects

- (2) applications, including the clinical applications, of that research.
- (b) NBAC shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles.
- (c) NBAC shall not be responsible for the review and approval of specific projects.
- (d) In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council.

Sec. 5. Priorities. (a) As a first priority, NBAC shall direct its attention to consideration of: protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information, including but not limited to, human gene patenting.

(b) NBAC shall consider four criteria in establishing the other priorities for its activities:

- (1) the public health or public policy urgency of the bioethical issue;
- (2) the relation of the bioethical issue to the goals for Federal investment in science and technology;
- (3) the absence of another entity able to deliberate appropriately on the bioethical issue; and
- (4) the extent of interest in the issue within the Federal Government.

Sec. 6. Administration. (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide NBAC with such information as it may require for purposes of carrying out its functions.

(b) NBAC may conduct inquiries, hold hearings, and establish subcommittees, as necessary. The Assistant to the President for Science and Technology and the Secretary of Health and Human Services shall be notified upon establishment of each subcommittee, and shall be provided information on the name, membership (including chair), function, estimated duration, and estimated frequency of meetings of the subcommittee.

(c) NBAC is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on NBAC, the Secretary of Health and Human Services may contract for the services of nongovernmental consultants who may conduct analyses, prepare reports and background papers, or prepare other materials for consideration by NBAC, as appropriate.

(d) Members of NBAC shall be compensated in accordance with Federal law. Members of NBAC may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

(e) To the extent permitted by law, and subject to the availability of appropriations, the Department of Health and Human Services shall provide NBAC with such funds as may be necessary for the performance of its functions. The Secretary of Health and Human Services shall provide management and support services to NBAC.

Sec. 7. General Provisions. (a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to NBAC, except that of reporting annually to the Congress, shall be performed by the Secretary of Health and Human Services in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) NBAC shall be under the jurisdiction of the Administrator of General Services.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit, trust, or responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

William J. Clinton

THE WHITE HOUSE,
October 3, 1995.

[FR Doc. 95-24921

Filed 10-3-95; 2:11 pm]

Billing code 3195-01-P

**President Clinton Announces Steps to
Prevent Cloning of Human Beings While Nation Examines Ethical Issues
March 4, 1997**

Announcement

President Clinton today issued a directive to ensure that no federal funds will be used to clone human beings. The current restrictions on the use of federal funds do not ensure this result. They do not explicitly cover human embryos created by cloning for implantation and do not cover all federal agencies. The directive President Clinton is signing today will make it crystal clear that no federal funds will be used to clone human beings.

- o **President Clinton called on privately-funded scientists to implement a voluntary moratorium on all efforts to undertake human cloning, until the National Bioethics Advisory Commission -- and the entire nation -- have considered its profound ethical implications.** Since privately-funded scientists and clinicians are not covered by the President's directive, a voluntary moratorium would ensure that ethical issues are fully debated before there are any efforts to clone human beings.

Background

- o **The February 27 issue of *Nature* contains an account of the first successful cloning of an adult sheep.** The new technology could lead to major beneficial advances in science, agriculture, and medicine. For example, it may 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. But the new technology also raises profound ethical issues, particularly with respect to its possible use to clone human beings.
- o **On February 24 President Clinton asked the National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues involved and to report back within 90 days on possible federal actions.**
- o **The President does not believe federal funds should be used for human cloning, and current restrictions on federal funds do not fully assure that result.** In December, 1994 the President directed the National Institutes of Health not to fund the creation of human embryos for research purposes. Congress extended this prohibition in 1996 and 1997 appropriations bills, barring the Department of Health and Human Services from supporting certain human embryo research. These restrictions do not explicitly cover human embryos created by cloning for implantation and do not cover all federal agencies.
- o **Privately-funded scientists and clinicians are not prohibited from cloning human beings.** Although most scientists believe that the possibility of cloning human beings in the near future is remote, a voluntary moratorium would assure that the nation fully considers ethical issues before any attempts are made to clone human beings.

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

March 4, 1997

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

THE WHITE HOUSE
Office of the Press Secretary

For Immediate Release

March 4, 1997

REMARKS BY THE PRESIDENT
ON CLONING

The Oval Office

9:25 A.M. EST

THE PRESIDENT: Good morning. I'm glad to be joined this morning by the Vice President, Secretary Shalala, Dr. Harold Varmus, the head of NIH; Dr. Harold Shapiro, the President of Princeton and the Chairman of our Bioethics Advisory Commission; and Dr. Jack Gibbons, the President's Advisor on Science and Technology, all of whom know a lot about and care a lot about this issue we are discussing today.

The recent breakthrough in animal cloning is one that could yield enormous benefits, enabling us to reproduce the most productive strains of crop and livestock, holding out the promise of revolutionary new medical treatments and cures, helping to unlock the greatest secrets of the genetic code. But like the splitting of the atom, this is a discovery that carries burdens as well as benefits.

Science often moves faster than our ability to understand its implications. That is why we have a responsibility to move with caution and care to harness the powerful forces of science and technology so that we can reap the benefit while minimizing the potential danger.

This new discovery raises the troubling prospect that it might someday be possible to clone human beings from our own genetic material. There is much about cloning that we still do not know. But this much we do know: any discovery that touches upon human creation is not simply a matter of scientific inquiry, it is a matter of morality and spirituality as well.

My own view is that human cloning would have to raise deep concerns, given our most cherished concepts of faith and humanity. Each human life is unique, born of a miracle that reaches beyond laboratory science. I believe we must respect this profound gift and resist the temptation to replicate ourselves.

At the very least, however, we should all agree that we need a better understanding of the scope and implications of this most recent breakthrough. Last week, I asked our National Bioethics Advisory Commission, headed by President Harold Shapiro of Princeton, to conduct a thorough review of the legal and the ethical issues raised by this new cloning discovery, and to recommend possible actions to prevent its abuse, reporting back to me by the end of May.

In the meantime, I am taking further steps to prevent human cloning. The federal government currently restricts the use of federal funds for research involving human embryos. After

reviewing these restrictions, our administration believes that there are loopholes that could allow the cloning of human beings if the technology were developed. Therefore, today I am issuing a directive that bans the use of any federal funds for any cloning of human beings.

Effective immediately, no federal agency may support, fund, or undertake such activity. Of course, a great deal of research and activity in this area is supported by private funds. That is why I am urging the entire scientific and medical community, every foundation, every university, every industry that supports work in this area to heed the federal government's example. I'm asking for a voluntary moratorium on the cloning of human beings until our Bioethics Advisory Commission and our entire nation have had a real chance to understand and debate the profound ethical implications of the latest advances.

As we gain a fuller understanding of this technology, we must proceed not just with caution, but also with a conscience, by insisting that not a single taxpayer dollar supports human cloning. And by urging a moratorium on all private research in this area, we can ensure that as we move forward on this issue, we weigh the concerns of faith and family and philosophy and values, not merely of science alone. Thank you very much.

THE WHITE HOUSE

WASHINGTON

February 24, 1997

Dr. Harold Shapiro
Chair
National Bioethics
Advisory Commission
Suite 3C01
6100 Executive Boulevard
Bethesda, Maryland 20892-7508

Dear Dr. Shapiro:

As you know, it was reported today that researchers have developed techniques to clone sheep. This represents a remarkable scientific discovery, but one that raises important questions. While this technological advance could offer potential benefits in such areas as medical research and agriculture, it also raises serious ethical questions, particularly with respect to the possible use of this technology to clone human embryos.

Therefore, I request that the National Bioethics Advisory Commission undertake a thorough review of the legal and ethical issues associated with the use of this technology, and report back to me within ninety days with recommendations on possible federal actions to prevent its abuse.

Sincerely,

Bill Clinton

February 25, 1997

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

Dear Mr. President:

I am writing in my role as Chairman of the National Bioethics Advisory Commission in response to your letter of February 24. The Commission is pleased to undertake the task you have outlined. We will certainly do our best to report back to you within ninety days, as you have requested.

Sincerely,

Harold T. Shapiro

cc: Dr. John H. Gibbons
Dr. William F. Raub
Ms. Henrietta Hyatt-Knorr

Questions and answers from Representative Stokes concerning cloning.

Are you aware of any other areas where an administration has made public determinations not to pursue research?

There are numerous other examples in which a determination was made not pursue specific research projects because they posed ethical or safety dilemmas that could not be resolved. The President's action is similar to past actions taken independently by the scientific community on a voluntary basis. Following the discovery of techniques to cut and splice DNA in the 1970's, the scientific community called for a moratorium until the safety of the procedures could be determined and guidelines developed for proper use. Under those guidelines research that poses unreasonable environmental or public health risks may not be permitted. In another example, for the past several years, scientists have not pursued germ-line gene therapy because we do not have consensus on the ethical aspects of this research. Finally, In December 1994, President Clinton directed the National Institutes of Health not to fund research in which human embryos would be created solely for research purposes.

I would like to clarify exactly what is covered in the President's March 4 prohibition on the use of Federal funds for cloning human beings. This ban refers to any attempts to use cells from an existing person to create another person that would be a genetic replica, as reported last month in sheep. The prohibition does not apply to in vitro fertilization, by which I mean fertilizing an egg with sperm for the treatment of infertility. The prohibition also does not apply more broadly to research that may involve cloning genes, cells, or DNA from humans, animals or lower organisms. The President also called on the private sector to follow the government's lead in abstaining from the cloning of human beings.

Has any other country with a significant research posture adopted a similar policy?

So far, we know that the Japanese Science and Technology Council is looking into it and there has been some reaction in the U.K. On March 7, the Norwegian Parliament passed a law banning cloning of humans and other "highly developed organisms." The law, which would have blocked the cloning of Dolly herself, may be the farthest reaching cloning ban now on the books. The measure has alarmed some Norwegian scientists, who say its hasty preparation and passage reflects the country's deep suspicion of biotechnology. Also, four states have new bills pending, most would codify the President's prohibition.

How likely do you believe it is that privately funded research entities will voluntarily follow the President's urging?

We have received a statement of support for the President's call for a voluntary moratorium from the biotechnology industry. We have not yet heard from any group representing private clinics who assist infertile couples wishing to have children.

THE WHITE HOUSE
WASHINGTON

Elizabeth —

this might be easier to
read than the fax.

— Sarah

THE PRESIDENT HAS SEEN

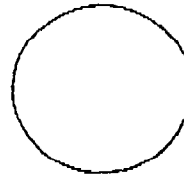
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ROBERT SCHULLER

the

March 4, 1997

Dear Mr. President:

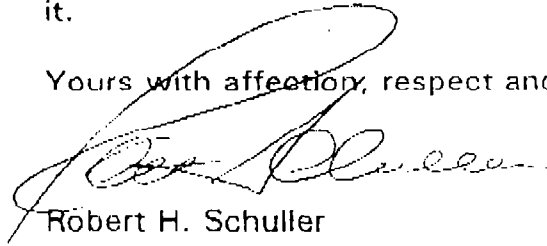
I was listening to the morning news and heard your "call" for a moratorium request on "Cloning."

Thank you ... that is strong, protective leadership!

Just this past Sunday I said to my congregation, "The human being is not by nature humane."

I am enclosing a copy of an Op. Ed. piece I have just completed for the *Los Angeles Times* and wanted you to have a first look at it.

Yours with affection, respect and esteem,



Robert H. Schuller

President Bill Clinton
The White House
1600 Pennsylvania Avenue NW
East Wing, Room 214
Washington, DC 20500-2000

RHS/bh

Enclosure

THE CRYSTAL CATHEDRAL
12141 LEWIS STREET, GARDEN GROVE, CALIFORNIA 92640

"YOU CAN'T CLONE THE HUMAN SOUL"

According to modern sages, genetics are the road map of human existence because they are said to explain not only what we are, but who we can be. Recently, when a team of Scottish scientists cloned a female sheep, shockwaves of awe and fear were sent throughout the world's scientific, religious and legal communities. Many wonder what the implications are if humans can be similarly duplicated.

The cloning of "Dolly," as the sheep is called, was important for two reasons. This was the first time a clone had been made from an adult creature. Thus its characteristics at maturity could be observed and selected. For many this is as close to a guaranteed product as anything. If two identical beings can be created, what are the implications for the human soul? If the body is made up of the same genetic material, what happens to the mind and soul?

If we agree, as seems to be the current fashion, that humans and other creatures in God's creation are merely the sum of their parts, then genetic engineering poses some real threats. A duplicate Adolf Hitler or a mass murderer would probably also commit genocide or mass murder.

But the fact is that human beings are more than the sum of their biological parts. The whole of each individual consists of the physical and spiritual nature.

Teilhard de Chardin says: We are not human beings on a spiritual journey, rather we are spiritual beings on a human journey. And the spirit cannot be cloned. Even if the biological material is the same, differences in spiritual makeup could also create differences in physical appearance.

Take for example two individuals who appear to be identical; one abstains from drugs, promiscuous sex, and other vices. He worships and has faith in God. The other disregards the Commandments of God, and pursues a reckless life of sin and self destruction. Can you picture the difference? Although similar, the two would develop drastically different personalities. Certainly once you got to know them, they would seem worlds apart.

From the time we are infants, and we begin to grow and make choices (or have choices made for us), our physical states undergo change. Thus, even with the same genetic material a cloned child would end up very different in "appearance" than the adult he or she was cloned from. We all become a collection of recorded experiences, which are not carried in human genes. And identical human spirits cannot be cloned. Bones, muscles, hair and blood may be cloned. But memory systems cloned? Never!

The soul has a profound influence on the appearance of an individual. Some would phrase this argument in terms of nature and nurture. If two identical twins were brought up by different parents, in different cultures and socio-economic circumstances, chances are they would see and make different choices in their lives.

This is very important. It is not our physical make-ups which most prominently mark our uniquenesses. It is our power to privately make personal choices. The evolving human personality can emerge into a person marked as either "kind" or "mean." One fact is irrefutable — you cannot inseminate and predetermine the "soul."

Choice. We have the choice to bring good or evil into existence for ourselves. The extent to which we choose either accounts for the only truly significant disparity in human nature. And the choices we make are based on the extent to which we try to civilize our souls and refine our character. This is an individual quest, and something that no scientist anywhere can ever recreate.

As scientists explore the unfathomable depths both within and outside the human body, they are often fascinated to find traces of the divine master plan. They call them, DNA, "The Theory of Relativity," "The Big Bang Theory," and other names. But these names are only metaphors, or useful lamp posts leading to the real nature of things. As such, they should not be mistaken for the deeper truths that lay beneath the surface.

As a person of faith, I would be interested to see how the cloned sheep develops under different environmental circumstances than its cloning parent. I'd avoid any milk or meat produced by a clone for now. But the question remains, should we lose sleep over men with God complexes trying to tinker with nature? As I ponder

this question, I take solace in the fact that science cannot transcend the human soul, because the human soul transcends science.

As the debate continues over whether or not humans are next to be cloned, the faithful should take heart. No matter how clever we become, we cannot have the power to control God's creation. Every person is endowed with the power to observe and select. And no two persons will be identical in all of their responses, reactions, choices and decisions. So we may be able to clone bodies — but the cloning of "persons" will be impossible. If science could possibly clone the personality, spirit, mind, soul and memory system, the end product would not be a "person" defined by the freedom to choose. Instead of a "person" we would have a "product," not a human soul.

11-00 Wed mty.

MSG: Bill Raab ←

MSG: Lana Skirball
- May Beers

✓ Rachael Cerasim

211

✓ Bill Marshall

✓ Tony Dorenfeld

✓ Christina

Javier Moreglin

Susan Brophy

Tracy Thomson

Rich Tarplin

Eric Olsen

Press - Damon Thomas / Victor

- Rich Tarplin

Cloning TO DO

6/3/97

Language to:

- Bill Marshall
- HHS Claudia / Codley
- OSTD
- VP

Not going
it out before
Saturday

POSS - Call Victor - - Danon Thompson
- Q's and A's - -

Substance Questions

Findings - Dick Reenberg / Henry
OGC

Legislation Event

Working Group

- Bill Marshall - Bill Rains
- Toby - Lana Skirboll
- Rachael - Mary Beth
- W4 leg Affairs / HHS leg Affairs
- USDA Eric Olsen
- Andrea

- Rains -

- Q's and A's - - Thursday at COB -

- Outreach to Congress -

- Janet Muefua -
- Susan Brophy -
- Tracy Thornton -

- [11:00 - 12:00 DPC 211] -

Ned McCaughy

224-4042

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- o **President Clinton called on privately-funded scientists to implement a voluntary moratorium on all efforts to undertake human cloning, until the National Bioethics Advisory Commission -- and the entire nation -- have considered its profound ethical implications.** Since privately-funded scientists and clinicians are not covered by the President's directive, a voluntary moratorium would ensure that ethical issues are fully debated before there are any efforts to clone human beings.

Background

- o **The February 27 issue of *Nature* contains an account of the first successful cloning of an adult sheep.** The new technology could lead to major beneficial advances in science, agriculture, and medicine. For example, it may 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. But the new technology also raises profound ethical issues, particularly with respect to its possible use to clone human beings.
- o **On February 24 President Clinton asked the National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues involved and to report back within 90 days on possible federal actions.**
- o **The President does not believe federal funds should be used for human cloning, and current restrictions on federal funds do not fully assure that result.** In December, 1994 the President directed the National Institutes of Health not to fund the creation of human embryos for research purposes. Congress extended this prohibition in 1996 and 1997 appropriations bills, barring the Department of Health and Human Services from supporting certain human embryo research. These restrictions do not explicitly cover human embryos created by cloning for implantation and do not cover all federal agencies.
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Question:

What impact does the directive have on the private sector?

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The directive only federally-supported research. Therefore, I am asking the broader scientific and medical communities to also refrain from cloning human beings at this time, until NBAC has had time for its deliberations.

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What are the next steps?

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I have asked the National Bioethics Advisory Commission (NBAC) to report back to me in 90 days with recommendations for possible federal action. They will review the ethical and legal implications in open, public meetings. I look forward to receiving and reviewing NBAC's recommendations.

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Human Cloning
Possible Q's & A's

Question:

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

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

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

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Is this action really necessary? Are scientists really ready to clone human beings?

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While the majority of scientific experts believe that successfully cloning human beings is very unlikely in the near future -- we can not rule it out. It is important that we stop now and consider the ethical implications.

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NOTE TO: Bill Marshall, WH Counsel
Toby Donenfeld, OVP
Mary Beth Donahue, HHS
Claudia Cooley, HHS

FROM: Elizabeth Drye, DPC
Rachael Levinson, OSTP

SUBJECT: Initial draft of Cloning Legislation

As you know, the President is scheduled to announce this legislation on Monday or Tuesday next week, and we are hosting a meeting in 211 OEOB Wednesday, 11:00 am, to discuss the legislation and the roll out. PLEASE BE READY TO PROVIDE YOUR INFORMAL COMMENTS ON THIS DRAFT OF THE LEGISLATION AT THAT TIME.

In particular, we'd like your input on:

- (1) Enforcement/Penalties. Should we simply state that the AG shall take appropriate injunctive and other equitable relief, or should we specify limits (e.g. up to \$10,000 or 3 years imprisonment or both, consistent with Senator Glenn's human subjects bill and FDA's law); and
- (2) Committee review prior to sunset of legislation; and
- (3) Length of moratorium; and
- (4) Findings section -- these are all NBAC's findings -- should we state that up front explicitly?

Finally, as you will see, we need your technical edits to put this in standard bill form.

Thanks.

DRAFT CLONING LEGISLATION

SEC 1. FINDINGS.

[The National Bioethics Advisory Commission has found] --

(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) 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.

(c) 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.

(d) The National Bioethics Advisory Commission 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 the somatic cell nuclear transfer technique.

(e) The Commission's consensus is based on the total lack of information on the safety and effectiveness of this method in humans and that an attempt to create a child using this technique would violate important ethical obligations.

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

(g) The National Bioethics Advisory Commission 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 voluntarily comply with the intent of the Federal moratorium.

(h) The National Bioethics Advisory Commission 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 technology.

(i) The National Bioethics Advisory Commission recommended that such legislation include a sunset clause to ensure that the issue be reviewed [Congress will review the issue] after a specified time in order to decide whether or not the prohibition needs to be continued.

(j) The Commission concluded that any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to inadvertently and unnecessarily 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.

(k) The Commission also found that research on the cloning of 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.

SEC. 2. PURPOSES -- The purposes of this Act are --

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

(c) To provide for further review of the ethical and scientific issues associated with the use of this technique in humans.

SEC 3. DEFINITIONS

(a) "Cloning" means the production of a precise genetic copy of molecule (including DNA), cell, tissue, plant, animal, or human [science chapter, p2., ln 3]

(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.

SEC 4. MORATORIUM -- It shall be unlawful for any person to create or attempt to create a child using somatic cell nuclear transfer.

SEC 5. PROTECTED BIOMEDICAL RESEARCH -- Nothing in this statute shall restrict other areas of biomedical research, including important and promising work that involves:

- (1) the cloning of molecules, DNA sequences, cell lines, and tissues; or
- (2) the use of somatic cell nuclear transfer techniques to create animals.

SEC 6. PENALTIES. -- Any person who violates Section 4 shall be fined not more than \$10,000 (?) or imprisoned not more than three years (?), or both(?). The provisions in Section 4 shall be enforced by the Attorney General. Nothing in this statute shall give any individual or person a private right of action against any person or the United States [is this needed?].

SEC 7. SUNSET PROVISION -- This Act shall take effect on the date of enactment and remain in effect for four years from that date.

SEC 8. REPORT -- No later than one year before the expiration date of this Act, the Secretary of Health and Human Services shall direct and advisory body [composed of at least 7 members including persons from medicine, biotechnology, genetics, law bioethics and religion, as well as from the general public], to reevaluate (1) the state of the science of somatic cell nuclear transfer, (2) the ethical and scientific issues associated with the potential use of this technology in humans, and (3) the advisability of continuing the moratorium established by this Act. The Secretary of Health and Human Services shall direct the advisory body to report their findings to the President and the Congress no later than 6 months prior to the date this Act expires.