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[Folder 2]: Human Cloning - National Bioethics Advisory Commission / BIO [Biotechnology Industry Organization]/ PhRMA [Pharmaceutical Research & Manufacturers of America]

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S	115	2	9	3

National Bioethics Advisory Commission

6100 Executive Boulevard • Suite 5B01
Rockville, MD 20892-7508
Telephone: (301) 402-4242
Facsimile: (301) 480-6900

February 6, 1998

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

Dear Mr. President:

Last February, in the wake of the startling announcement that researchers in Scotland had apparently succeeded in creating a genetic copy of an adult sheep through somatic cell nuclear transfer, you asked the National Bioethics Advisory Commission to review the legal and ethical issues that would arise from the use of this technology to clone human beings.

The Commission immediately began a series of meetings and consultations. We heard not only from physicians and scientists but from religious leaders, ethicists, lawyers, and members of the public in an effort to understand the full range of views on this controversial and multifaceted subject. Of course, given the need for a prompt report, we recognized that while we might resolve some of the issues, many would remain for which we could supply a road map but not ourselves reach final conclusions.

In *Cloning Human Beings,* the report that we presented to you at the White House on June 9, 1997, we concluded that the use of this new technique to create a child would entail unacceptable risks and ought not to be attempted now by anyone. Beyond the issues of safety, we found that concerns relating to the potential harms to children and effects on the moral, religious, and cultural values of society merit further reflection and deliberation. We therefore recommended that no attempt be made at this time to create a child using somatic cell nuclear transfer.

You immediately transmitted to Congress a bill embodying our recommendations. Despite hearings in both houses, Congress did not adopt legislation on human cloning in 1997. As you recognized last week in the State of the Union address, recent developments make clear that such legislation is needed. Some legislators have called for enacting a permanent ban not just on the creation of children by cloning but on studies with embryonic cells, even though such research could offer an important means of finding a cure for cancer and other lethal diseases.

We continue to believe that sweeping legislation would be a mistake, and we urge you to work with Congress to ensure that any legislation follows the basic points of the bill you sent to Congress last June, namely to:

- stop anyone in the private as well as the public sector from using somatic cell

nuclear transfer techniques to create a child at this time,

- clearly distinguish the area of concern (the attempt to create a human child using these techniques) from the cloning of human DNA, genes, or cells in the laboratory, and

- place a time limit on the ban. The major reasons for a moratorium—concerns about safety and unresolved social, legal and ethical issues—all need to be reexamined as scientific research and public discussion move forward.

We would be pleased to provide whatever help we can to achieve the adoption of public policies on human cloning that attain an appropriate balance among competing goals and values.

Sincerely,

Harold T. Shapiro

Harold T. Shapiro
Chair

BIO
BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

News Release

1625 K Street, N.W. · Suite 1100 · Washington, D.C. 20006 · (202) 857-0244 · FAX: (202) 857-0237

FOR IMMEDIATE RELEASE

CONTACT:
Dan Eramian
Libby Mikesell
202-857-0244

BIO Calls For FDA To Assert Its Authority On Cloning

(WASHINGTON, D.C., January 13, 1998)...Carl B. Feldbaum, president of the Biotechnology Industry Organization (BIO) sent the attached letter to Health and Human Services Secretary Donna Shalala asking her to assert the Food and Drug Administration's (FDA) authority and jurisdiction over any possible attempts to clone a human being:

"It is clear that society is not ready for the cloning of a human being. We need to listen carefully, and analyze thoughtfully the ethical, moral and safety issues that have been raised.

"Recognition and assertion of the FDA's regulatory power over human cloning will protect biomedical advances and at the same time will give everybody some breathing room to debate this issue. Bioethics issues will occur with further advances in science. We need to be certain, before we move ahead, that advances will clearly benefit human kind and not set us back into some new age of uncertainty about our values and the quality of human life."

The Biotechnology Industry Organization (BIO) represents over 745 biotechnology companies, academic institutions, and state biotechnology centers in 46 states and more than 25 nations. BIO members are involved in the research and development of health care, agricultural and environmental biotechnology products.

###

Bio

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

January 13, 1998

The Honorable Donna E. Shalala, Ph.D.
Secretary,
Department of Health and Human Services
615F Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Dear Secretary Shalala:

The recent announcement from Dr. Richard Seed regarding his proposal to establish a clinic for the cloning of human beings has caused significant controversy. BIO supports President Clinton's and the National Bioethics Advisory Commission's (NBAC) moratorium on the cloning of a human being. Cloning a human being poses major ethical and moral questions, as well as deeply troubling medical safety issues. The experience with "Dolly," in which there were 276 unsuccessful attempts before an apparently healthy sheep was born, points to the experimental nature of this technology in animals. It is plainly inappropriate to attempt to apply this technology to human beings. While these questions remain unresolved, government and public opposition to the cloning of a human being remains strong. Society needs to be heard and respected on this issue.

Several members of Congress have recently expressed interest in legislation that would ban the cloning of human beings. They may not be aware that the Food and Drug Administration (FDA) has broad authority to regulate biological products. Last February, FDA published a regulatory framework for the regulation of cellular and tissue-based products. The level of FDA oversight is dictated by the degree of human manipulation of cells or tissues. Those products which are subject to a low level of oversight are those which are defined as 'minimal manipulation' when the processing does not alter the biological characteristics of the cells or tissue.

But in those cases where there is more than 'minimal manipulation,' FDA has stated its intent to subject such products to formal regulatory review including the investigational new drug (IND) regulations and license review regulations.

BIO believes that the Dr. Seed's proposal to clone humans using nuclear transfer technology is much more than minimal manipulation as the original function of the egg cell is unmistakably altered by the removal of the parental haploid DNA and insertion of DNA from a somatic cell from another person. Thus, any such research along these lines should be subject to the IND regulations that require patient informed consent, review by an institutional review board (IRB) where the research is being conducted, and FDA review under 21 CFR Part 312.

In addition to raising profound ethical issues, nuclear transfer technology has not been reliably proven to work in animal models and raises serious safety issues. We believe that for the foreseeable future, FDA should issue a clinical hold on any IND submission to proceed with such experiments.

A public statement by senior officials within HHS as to the regulatory status of nuclear transfer technology would be welcomed and useful as the public debate continues.

Sincerely,

Carl B. Feldbaum /ag

Carl B. Feldbaum
President

CBF:ag

cc: Michael Friedman, MD, Food and Drug Administration

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

January 13, 1998

MEMORANDUM FOR DISTRIBUTION

FROM: JOHN H. GIBBONS

SUBJECT: Briefing on Cloning-Related Activities

The Biotechnology Industry Organization (BIO) is concerned that legislation intended to prohibit attempts to clone human beings may curtail a broader sphere of activities that are commonly used in biomedical and agricultural research. BIO is holding a number of meetings on the Hill, preparing op-ed pieces and working with patient advocacy groups to enlist support for carefully circumscribed legislation, such as the measure the President sent to the Hill last June. BIO issued a press release supporting the President's moratorium and the recommendations of the President's National Bioethics Advisory Commission.

BIO has offered to present a briefing to interested EOP staff on their ongoing efforts related to cloning. In light of the recent report that a private individual is eager to attempt to use cloning technology to produce a child, there is renewed interest in a legislative deterrent to such efforts. It would be useful to gain BIO's perspective, as well as that of the Pharmaceutical Research and Manufacturers of America and the American Society for Reproductive Medicine, on possible legislative initiatives and reactions from the biotechnology and health care communities.

OSTP has scheduled this briefing for tomorrow, Jan. 14, at 1 p.m., in Room 472, OEOB. Please contact Rachel Levinson (x66137) and indicate if you or your designee would be interested in attending.

Distribution:
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SUBMITTED 6/9/97

A BILL

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

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

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

SECTION 2. FINDINGS.

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

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

(1) NBAC has found that:

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

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

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

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

(4) NBAC recommended a continuation of the current moratorium on the use of Federal funds to support any attempt to create a child by somatic cell nuclear

transfer, and an immediate request to all firms, clinicians, investigators, and professional societies to comply voluntarily with the intent of the Federal moratorium.

(5) NBAC further recommended that Federal legislation be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning.

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

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

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

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

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

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

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

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

SECTION 4. DEFINITIONS.

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

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

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

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

SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:

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

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

SECTION 7. PENALTIES.—

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

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

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

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

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

SECTION 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT.—No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on (1) the state of the science of somatic cell nuclear transfer; (2) the ethical and social issues associated with the potential use of this technology in humans; and (3) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

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

Cloning Prohibition and Research Protection Act

SECTION 1. PROHIBITION. It shall be unlawful for any person to create a human child using somatic cell nuclear transfer technology.

SECTION 2. DEFINITIONS. For the purposes of this section, the following definitions apply:

(a) "somatic cell nuclear transfer technology" means transferring the nucleus of a somatic cell of an existing or previously existing human child or adult into an oocyte from which the nucleus has been removed;
(b) "the creation of a human child" means implanting the product of somatic cell nuclear transfer technology for gestation and subsequent birth;
(c) "somatic cell" means a differentiated. diploid cell;
(d) "oocyte" means the mature female germ cell, the egg;
(e) "nucleus" means cell structure that houses the chromosomes, and thus the genes; and
(f) "gestation" means the period during which an embryo develops into a fetus that is ready to be born.

SECTION 3. PREEMPTION OF STATE LAWS. This law shall preempt any state law that imposes on individuals or institutions using federal funds a prohibition or limitation with respect to research regarding somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, and tissues, to the use of somatic cell nuclear transfer techniques to develop animals, or to related research.

SECTION 4. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including but not limited to important and promising work that involves:

(a) the use of somatic cell nuclear transfer or other cloning technologies, to clone molecules, DNA, cells, and tissues; or
(b) the use of somatic cell nuclear transfer techniques to develop animals.

SECTION 5. EFFECTIVE DATE. This Act shall apply to somatic cell nuclear transfer performed after the date of its enactment.

SECTION 6. REAUTHORIZATION. The prohibition in this legislation shall expire five years from the effective date.

SECTION 7. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on

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

SECTION 8. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.

Total Pages: 6

LRM ID: RJP99

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Thursday, June 5, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: 202)395-6148

SUBJECT: White House Draft Bill on Somatic Cell Nuclear Transfer Moratorium

DEADLINE: 4:30 P.M. Thursday, June 5, 1997

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: The attached legislation will be announced by the President in a White House event on Monday, June 9th. The deadline is firm. PLEASE KEEP CLOSE HOLD.

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LRM ID: RJP99**SUBJECT:** White House Draft Bill on Somatic Cell Nuclear Transfer Moratorium

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RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:
(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: Robert J. Pellicci Phone: 395-4871 Fax: 395-6148
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ (Date)
_____ (Name)
_____ (Agency)
_____ (Telephone)

The following is the reponse of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this reponse sheet

DRAFT CLONING LEGISLATION

Title -- TBD

SEC 1. 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. NBAC has found that:

(1) 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.

(2) 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.

(c) 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 the somatic cell nuclear transfer technique. 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.

(d) 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.

(e) 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 voluntarily comply with the intent of the Federal moratorium.

(f) 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.

(g) NBAC also recommended that the U.S. cooperate with other countries to enforce mutually-supported restrictions on this activity.

(h) 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 to recommend whether the prohibition should be continued.

(i) 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.

(j) 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

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

SEC 3. DEFINITIONS

(a) "Cloning" means the production of a precise genetic copy of 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.

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 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.

SEC 6. PENALTIES. -- The Attorney General shall enforce Section 4 and seek appropriate injunctive relief, fines, and imprisonment. Any person that intentionally violates this Acts shall be imprisoned not more than 5 years. [Justice -- please advise on language; we understand this would permit monetary fines up to $250,000 or 2X any profit from the violation, please confirm].

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

SEC 8. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT -- No later than six months before the expiration date 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 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 Commission is authorized to continue for 5 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.

SEC 9. Nothing in this Act shall give any individual or person a private right of action against any person or the United States [DoJ -- is this needed?]

BACKGROUND ON CLONING LEGISLATION

The National Bioethics Advisory Commission (NBAC) is about to complete a review the President requested of the ethical and legal issues associated with cloning human beings. 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 -- 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 by somatic cell nuclear transfer is ethically acceptable and promises important benefits. Hence, the Commission cautions that any restrictions on cloning should not in any way 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.

The attached legislation implements NBAC's recommendation. The President will announce it in a White House ceremony Monday, June 9th.

Alan F. Holmer
PRESIDENT

PhRMA

May 28, 1997

The Honorable Daniel K. Tarullo
Assistant to the President
for International Economic Policy
The White House
Washington, D.C. 20500

Dear Dan:

I write to you in your role as the sherpa preparing the President for the Denver Summit. The President has announced his intention to seek, at the Summit, international cooperation to develop an AIDS vaccine within 10 years. President Chirac reportedly will seek international support at the Summit to ban the cloning of entire human beings. Since Denver is shaping up to be a pharmaceutical as well as economic Summit, I offer the expertise of the pioneer pharmaceutical and biotechnology industries to ensure that the President is accurately and comprehensively prepared on these and any related issues. We would be pleased to provide whatever information would prove helpful to you, other White House officials, your staff, or interested agencies.

In particular, we urge your attention to the expected proposal of President Chirac regarding the cloning of entire human beings. PhRMA member companies are complying with the President's call for a voluntary moratorium on privately-funded research aimed at cloning entire human beings. Anyone concerned about the health and welfare of the American people (or, indeed, the people of any nation) is anxious to distinguish clearly between (1) the cloning of *entire* human beings, and (2) the cloning of animals or human genes, cells and tissues and research for the purpose of developing medicines to help families by preventing, curing and treating diseases. We are concerned about:

- any proposal of a *legislative* ban on the cloning of entire human beings, because of the risks that even a narrowly targeted, carefully drafted proposal could be enlarged in the unpredictable legislative process or subsequently misinterpreted in litigation; and

- any use of the shorthand term "human cloning" (or its equivalent in other languages), which could be misinterpreted to include the beneficial activities of cloning human genes, cells or tissues – an engine of biomedical research essential to promote the public health.

Pharmaceutical Research and Manufacturers of America
1100 Fifteenth Street, NW, Washington, DC 20005 • Tel: 202-835-3420 • FAX: 202-835-3429

Therefore, if the Summit participants discuss any proposal by President Chirac related to the cloning of entire human beings, we urge that:

- the term uniformly used, orally and in any written communication, be strictly limited to "cloning of *entire* human beings";
- the President never use the shorthand term "human cloning";
- the President proactively seek to clarify the distinction between the cloning of *entire* human beings, and the cloning of human genes, cells and tissues; and
- any oral discussions or written communication explicitly affirm the value and importance of the cloning of human genes, cells and tissues, the cloning of animals, and biomedical (including genetic) research involving such cloning activities, all for the purpose of discovering and developing new medicines with which to help and heal patients.

Finally, we recognize the President's recent identification of privacy protections as one of four "ethical guideposts" regarding the beneficial use of science. We strongly support the need to maintain the confidentiality of patient-identifiable medical (including genetic) information, and the need for a patient's informed consent to any research involving that patient-identifiable data. However, certain pending legislative proposals (e.g., S.422, the Genetic Confidentiality and Nondiscrimination Act) aimed at promoting these objectives would unduly impede biomedical research, to the unintended detriment of individual patients. If, at the Summit, the President advocates enhanced privacy protections, we urge him also to stress explicitly the value and importance of biomedical research and the aim to promote privacy protections without unduly impeding such research.

PhRMA and our member companies remain ready to provide any assistance needed to facilitate a productive Summit.

Sincerely,

Alan F. Holmer

Attachments:

Tab 1 - PhRMA Position on Cloning of *Entire* Human Beings
Tab 2 - An AIDS Vaccine: Pioneering Science
Tab 3 - Protection of Patient-identifiable Biomedical Information and Promotion of Biomedical Innovation
Tab 4 - The Promise of Genomics for Human Healthcare
Tab 5 - PhRMA Genomics Primer
Tab 6 - Glossary on Genomics
Tab 7 - Legal Protection for Biotechnological Inventions in Europe
Tab 8 - TRIPS 1999 Review

cc: Secretary Donna Shalala
Dr. Jack Gibbons
Dr. Harold T. Shapiro

bcc: William Marshall

Draft Letter Regarding Legislation to Ban Cloning of Human Beings

We are writing to express our concern about legislation pending in the Congress to ban the cloning of entire human beings.

Let us be clear. We oppose the cloning of a human being. We see no ethical or medical justification for the cloning of a human being and agree with the conclusions of the National Bioethics Advisory Commission (NBAC) that it is unacceptable at this time for anyone in the public or private sector, whether in a research or clinical setting, to create a human child using somatic cell nuclear transfer technology. We recognize that this application of the technology raises fundamental ethical and social issues. This technology is not currently safe to use in humans.

The American Society for Reproductive Medicine, the Biotechnology Industry Organization, and the Federation of American Societies of Experimental Biology have all pledged that their members will not seek to clone a human being. These three associations include essentially every researcher or practitioner in the United States who has the scientific capability to clone a human being.

We agree with NBAC in its report on cloning that: "It is notoriously difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science." Poorly crafted legislation to ban the cloning of human beings may put at risk biomedical research which is vital to finding the cures to the diseases and ailments which our organizations champion. Cancer, diabetes, (list specific disease of signatories here) and many others will benefit from the advances achieved by biomedical researchers.

We urge the Congress to proceed with extreme caution and adhere to the ethical standard for physicians, "first do no harm." We believe that there are two distinct issues here, cloning of a human being and the healing which comes from biomedical research. Congress must be sure that any legislation which it considers does no harm to biomedical research which can heal those with deadly and debilitating diseases.

Please keep patients' concerns in mind as you proceed in analyzing this very complicated issue.

Sincerely,

PATIENT ADVOCACY GROUPS
PROFESSIONAL MEDICAL SOCIETIES

Total Pages: 9

LRM ID: RJP40

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Monday, March 10, 1997

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148

SUBJECT: **HHS Oversight Testimony on Cloning: Challenges for Public Policy**

DEADLINE: **NOON Tuesday, March 11, 1997**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: Hearing is before the Senate Labor and Human Resources Committee on Wednesday, March 12th. NIH Director Varmus is the witness.

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LRM ID: RJP40**SUBJECT:** HHS Oversight Testimony on Cloning: Challenges for Public Policy

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RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:

(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or

(2) sending us a memo or letter

Please include the LRM number shown above, and the subject shown below.

TO: **Robert J. Pellicci Phone: 395-4871 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

_____ **(Name)**

_____ **(Agency)**

_____ **(Telephone)**

The following is the reponse of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** _____ **pages, attached to this reponse sheet**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Harold Varmus, M.D., Director
Before ~~House Appropriations~~ Senate Labor and Human Resources
Subcommittee on ~~Labor, Health and Human Services, and Education and Related Agencies~~ Public Health and Safety
~~February 26, 1997~~ March 12, 1997

THIS STATEMENT WAS MADE IN RESPONSE TO MR. PORTER'S INQUIRY ON THE RECENT SCIENTIFIC RESEARCH ON SHEEP CLONING REPORTED IN *NATURE*, FEBRUARY 28, 1997.

Let me begin by telling you something about these experiments, perhaps describing them slightly more precisely to give you some idea of the intellectual context in which they arise. These experiments have strong antecedents in research that date back quite a long time, to work by Gurdon and his colleagues in England (1975) who showed that it was possible to take the nucleus of a frog skin cell that had been grown in culture and to transfer that into the egg of a frog that had been relieved of its own nucleus. The resulting cell grew to an embryonic stage and subsequently to the tadpole stage. These tadpoles never grew into full adults. Nevertheless, this was the first indication that one could take a cell that had a defined function--in this case a skin cell--and ultimately generate all the components of a tadpole.

The report you refer to is not the first that has been published from the Roslin Institute in Edinburgh. About a year ago, the same group of investigators, headed by Ian Wilmut, published a paper in *Nature* in which they had done the following kind of experiment with sheep. They followed the clue from frogs, starting with an egg and cells from a very young sheep embryo, that is an embryo at the 8 to 16 cell stage. In these experiments, the nucleus from the early embryo was introduced into an egg cell that had no nucleus of its own.

At this very early 8 to 16 cell stage, the embryo cells are still believed to have all the potential for making all of the tissues of the organism. So this earlier work wasn't as electrifying as the current experiment. But, it turned out that by fusing that embryonic cell in culture to the enucleated egg and implanting the reconstituted embryo, with its nucleus from a cultured cell, into a surrogate mother, sheep were born.

The investigators in Edinburgh then took the next step--using other sources of genetic

material, namely whole cells at other stages of development, and fusing them to the enucleated egg. Those additional sources of cells included older embryos, embryos that had been allowed to proceed to a much more complicated multi-cell stage; cells from a fetus representing a partly-developed sheep; and, most dramatically, cells that had been taken from the udder (the mammary gland) of a six year old female sheep.

They did this in each case by manipulating the cells--embryonic, fetal, or adult--in an interesting way. What was done was to take the cells after they had been grown in culture and to return them to a resting state by reducing the nutrients supplied to the cells. Normally when cells are grown in a petri dish, they are fed with serum obtained from animal sources. By reducing the level of serum, it is possible to make the cells quiescent, so they aren't undergoing growth. That appears to be quite important in the success of these experiments.

In any event, with all three new sources of genetic material--that is, older embryos, fetal cells or in one case mammary cells--a reconstituted egg, now carrying the nucleus from each of those three cell types, was returned to a prepared uterus and the investigators waited for a sheep to develop. In all three cases, they did. Only one out of 277 reconstituted eggs in the case of the cells derived from the adult female sheep developed into a sheep, so therefore, it was inefficient. Nevertheless, it was successful.

Now, as you know, public attention has been focused initially on the most sensational aspects of this. And that's only natural because it is quite clear that this experiment opens the possibility of being able to do the same experiment with virtually any other mammal. Naturally, given our imaginations and novelistic inclinations, the idea of generating human clones of mature individuals has been much discussed.

In my view, that makes interesting movies, but poor science and poor ethics.

Let me speak a little bit to the scientific importance of the experiments that were described, and then come back to some of the ethical issues. The first level of significance of the experiments is very much in the tradition of agricultural husbandry. In both plant and animal husbandry, there is a strong tradition of trying to recapitulate strains that are particularly effective for food production.

So whether it's the self-fertilization of corn, or the generation of in-bred strains of animals, or the twinning of cattle, there is tremendous interest in trying to enlarge a productive

population. In that sense, there are practical applications of the new experiments with sheep.

The second application has to do with the use of animals in medical research. There are a number of possible experimental routes that are opened by the experiments we've read about. In one case, the interest is in the production of medically useful products; proteins that are produced in animals (for example, in milk) could be made in large amounts in a more convenient way than is currently possible through recombinant DNA technology. It might also be possible to make organs for transplantation that have been made more like human organs because they are programmed to make antigens (proteins) on their surface that match human antigens. This would lead to fewer problems with rejection in transplantation procedures.

Equally important is the possibility of using animal models other than the mouse or the rat for certain disease states. I'm sure you're aware that in recent years scientists have made increasing use of our ability to manipulate the genetic constitution of mice. We can add genes to the mouse, we can change the genes that exist, and we can make use of our increasing knowledge of disease genes of humans to attempt to generate models for disease that can be used for developing novel therapies that will be applicable to man.

In not all cases, however, have those disease models reproduced faithfully and instructively the kinds of pathology that are seen in human beings. One good example is in the case of cystic fibrosis, where we have identified the human gene and know the mutations that exist in the gene. We can make the same mutations in the mouse, but the disease that results is different. Using an animal like the sheep might open the way to make better disease models that could be instruments for developing and testing more useful therapies for some of these disorders. The third area of importance is one that has been neglected for the most part in discussions to date, but to my mind is the most important. These experiments have opened the door to a much deeper understanding of how genes are turned off and turned on. I remind you that we as human beings have roughly 80,000 genes and that all of those genes are useful in some of our many different kinds of cells. We have perhaps 200 different types of cells in our bodies. Each expresses a different subset of those 80,000 genes.

During the course of our development into an organism that has a liver and skin and brain and many other organs, our bodies are programmed to turn genes on and off. It has generally been considered difficult, if not impossible, to redirect a cell of one type to behave like a cell of

another type.

In the sheep experiments we have been discussing, a cell that has the properties of a mammary epithelial cell has been reprogrammed to become a fully potent cell able to make every component of a sheep. That's a remarkable achievement. We know very little about what that process entails, save for the fact that it seems to be fostered by moving a growing cell into a quiescent state, as I mentioned before, by reducing the serum that is contained in the medium used for growth of the cell.

There are many applications that might come from greater knowledge of how genes are turned off and on. Let me begin with the simplest. We already use such a strategy for the treatment of sickle cell disease. In sickle disease, one of the globin genes is impaired. We know that we can overcome that impairment by expressing another form of globin gene that is normally expressed only in the fetus. Hydroxyurea, a drug currently in use for sickle cell disease, turns on the fetal globin gene in the adult and reduces severe attacks of sickle cell disease by about 50 percent. We still have an imperfect notion of how to turn that fetal globin gene back on, so anything further to help control that process would be very useful.

Let me give you some other examples. We know that when people undergo chemotherapy for cancer their bone marrows are frequently severely affected, and it has been increasingly common to treat such individuals with bone marrow transplants. Those transplants are difficult and sometimes fail because of rejection of the donated marrow due to protein incompatibility between the donor and the recipient. So one long-term goal has been to use marrow that is compatible with the recipient in such transplantation experiments. Sometimes that is done by using the marrow from the individual who is undergoing treatment. But that is obviously less than ideal, because those cells may include cancer cells.

The prospect of being able to take the nucleus from a skin cell and put it into another cell, such as an enucleated egg, and produce bone marrow cells in culture and return those to cancer patients is made real by the experiments with the sheep. This is far off, but nevertheless possible. One could also imagine helping people who have been incapacitated by massive burns and need skin transplantations. One can imagine taking the nucleus from a bone marrow cell, for example, putting it into another enucleated cell as a recipient, and making skin cells that could then be used for transplantation to the burned individual, without concern for rejection.

One could imagine similar kinds of experiments in neurodegenerative diseases, remodeling cells to behave as mature nerve cells with the properties--including the antigenic properties and the protein properties--of the recipient. So there are some remarkable possibilities that definitely require exploration and will be stimulated by the sheep experiments.

Let me say a few words about some of the ethical issues. We have been aware of the possibility of doing such experiments for some time. In 1994, I convened a panel headed by Dr. Steve Muller of the Johns Hopkins University to look at the ethical issues that surround many forms of human embryo research, including this type. The panel brought back recommendations about which kinds of experiment involving the human embryo would be suitable for Federal funding, unsuitable for Federal funding, or requiring further review.

The committee designated experiments in human beings of the sort described recently with sheep, that is creating another human being from a single cell, as not suitable for Federal support, for reasons that I think perhaps are worth reading. The panel said "the notion of cloning an existing human being or of making carbon copies of an existing embryo, appears repugnant to members of the public. Many members of the panel share this view, and see no justification for Federal funding of research involving nuclei transplantation for this purpose."

I agree with that point of view. Frankly, as an experimental strategy, it doesn't offer much. If one wants to look at the effects of environment on human development, using genetically identical subjects, that experiment has already been done--a much better experiment carried out in nature. Identical twins who are sometimes reared together and sometimes reared apart occur commonly in human populations.

Secondly, our sense of ourselves as human beings is very closely linked to our diversity. The notion of carrying out cloning human populations, to my mind, is not consistent with the traditional ideas of human individuality and diversity. This does not mean that cloning strategies should not be used in other animals for purposes of agriculture or for purposes of medical research. But in the case of human beings, the NIH panel rejected it. These experiments would also be forbidden by an amendment that is attached to our current appropriations law.

DR. VARMUS TESTIFIED ON MARCH 5, 1997 BEFORE THE HOUSE SCIENCE SUBCOMMITTEE ON TECHNOLOGY. THE FOLLOWING STATEMENT MADE BY DR. VARMUS ON MARCH 6, REFLECTS REMARKS HE MADE DURING THE HEARING.

As I have said on many occasions, I fully support the President's ban on federal support for human cloning, his appeal for a voluntary moratorium by the private sector, and the review he has requested by the National Bioethics Advisory Commission (NBAC). In my comments at yesterday's House hearing, I said that I hoped imminent legislation on cloning would be held off while the President's NBAC hears public testimony and deliberates about the matter.

At yesterday's hearing, I explicated the broad range of possible applications for cloning--in animals and humans. Among them was application of cloning techniques in such cases as untreatable infertility. This possible application is one that would likely be brought to the NBAC for consideration at its public hearings. I feel strongly that public discussions on all aspects of human cloning are important and that the NBAC is the right forum for that.

QUESTIONS AND ANSWERS REGARDING NBAC FOLLOWING DR. VARMUS' STATEMENT AT THE FEBRUARY 26 HOUSE APPROPRIATIONS HEARING:

MRS. LOWEY: ...And I want to say, I applaud the President's decision this week to appoint a high level panel to examine this issue. And I look forward to reading their report...

DR. VARMUS: I'd like to make one comment, Mrs. Lowey, because your point reminds me of something that I was hoping to say at some point; which is that I'm concerned about the rush to legislation in this arena. We have a new finding. It needs to be absorbed and discussed.

I, too, applaud the President's referral of this matter to his National Bioethics Advisory Commission, which as you know, was established about a year ago to consider questions of just this kind. And that is very well suited, in the light of the personnel who have been appointed to that commission, to discuss those issues and to make some recommendations.

I am worried, as my comments reflected, of the possibility that in rejecting one aspect of these experiments that all of us find repugnant, that is, the idea of cloning adult human beings, that we end up with legislation, be it State or Federal, that restricts the experimental possibilities that will be beneficial to all.

MS. PELOSI: ...I'm very pleased, too, that the President has this Bioethics Commision. I'm not completely familiar with it. If you want to say more about it....

DR. VARMUS: ...So there are many issues to which they might be assigned. The President was very wise in referring this issue to them and giving them three months to begin deliberations and to make some proposals about things that might be done. As I said earlier, I am a little concerned that in the frenzy of the excitement about the novelistic possibilities here that something more limiting of the research possibilities generated by these new findings would be done precipitously. Nothing is going to happen immediately in the scientific arena. It's worth exploring some of the deeper aspects of these experiments with respect to gene regulation before we throw the baby out with the bath water...

Policy Statement on Cloning

PhRMA member companies will comply with the voluntary moratorium on cloning of human beings proposed by President Clinton on March 4, 1997. PhRMA companies are not cloning entire human beings. The advent of cloning whole animals from adult cells raises basic, important questions for all of us. We welcome the President's request for advice about the ethical and legal implications of recent scientific advances from the National Bioethics Advisory Commission. Our society should consider these issues seriously and seek a common understanding.

PhRMA member companies are dedicated to the discovery and development of new medicines that help and heal human beings. To promote drug discovery and thereby help more patients, PhRMA member companies need to conduct genetic research. In their ceaseless search for new cures, pharmaceutical and biotechnology researchers use human genes, proteins, cells, tissues or organs under the highest ethical standards which are the cornerstone of our industry.

The hundreds of millions of patients PhRMA members serve in the United States and around the world are not harmed by the moratorium with which our members choose to comply while society considers the serious ethical and legal implications of any cloning of an entire human being. However, their hopes for better treatments and even cures would be devastated if PhRMA members were to delay genetic research. To try to fulfill as many of these hopes as possible, PhRMA members will continue to conduct genetic research under the highest ethical standards.

[Approved by PhRMA Genomics KIT, March 23, 1997]