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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. The President has extended the Commission until October 1999.



BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

News Release

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FOR IMMEDIATE RELEASE

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BIO Responds to Cloning Report

(WASHINGTON, D.C., January 7, 1998)...Carl B. Feldbaum, president of the Biotechnology Industry Organization (BIO), today issued the following statement in response to news reports that a Chicago scientist plans to begin work aimed at the cloning of a human being:

"BIO continues to support 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. As the NBAC documented at great length, 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 seek to apply this technique 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 the issue.

At the same time, since the announcement of "Dolly" the sheep last February, the public has come to learn of the benefits of cloning cells, genes and tissues, techniques which have been ongoing for 20 years. While these techniques do not lead to the cloning of a human being, they do have promise, for example, to enable us to regenerate spinal cord tissue for accident victims and skin for burn victims. It is essential that any restrictive legislation which may be adopted by Congress or state legislatures on the cloning of a human being, recognize the biomedical benefits of these existing cloning procedures and protect and encourage them."

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.

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**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

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.

Q Mr. President, what is the extent of your order today? How much funds -- do you know how much funds were being spent toward this human cloning, if any?

THE PRESIDENT: We attempted previously to have a ban on this, going back to '94, I believe. The nature of the new discovery raised the prospect that the technology was not covered specifically by the nature of the ban. So as far as I know, nothing is going on in government-funded research. I just want to make sure that we keep it that way, because our research dollars are spread all across the country in different institutions.

With regard to the private sector, let me say that our staff here in the White House has been in touch with a number of people in the biotech industry, and they seem to be glad that we called and anxious to

participate in a moratorium until we think through the implications of this.

I mean, I imagine a lot of you, not as journalists but in your own private homes have sat around talking about this discovery in the last few days; I know we have in our home. And I just think that we need the best minds that we can bring to bear and the distinguished people on the Bioethnics Advisory Committee to think through this, tell us about what we may be missing about if there's anything positive that could come from this, and also think through the other implications.

How can we get the benefits of our deep desire to find any possible cure for any malady that's out there without raising the kind of ethical implications that, in effect, we're in the business where people are trying to play God, or to replicate themselves.

END

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

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

June 9, 1997

REMARKS BY THE PRESIDENT
AT ANNOUNCEMENT OF CLONING LEGISLATION

The Rose Garden

11:56 P.M. EDT

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

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

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

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

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

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

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

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

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

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

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

We are still a long way from understanding all the implications of the present discoveries, but it is our moral obligation to confront these issues as they arise and to act now to prevent abuse. Today, I hope other countries will see what we are doing and do the same. And I pledge to work with them to enforce similar bans around the world that reflect these values.

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

END

12:02 P.M. EDT

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.

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