HUMAN CLONING CONTROVERSY

BACKGROUND MATERIALS

February, 1998

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HUMAN CLONING CONTROVERSY
BACKGROUND MATERIALS

1. "Cloning Human Beings", Report and Recommendations of the National Bioethics Advisory Commission, June 1997.

2. Legislation.

   - H.R. 922, Congressman Ehlers' "Human Cloning Research Prohibition Act" as reported from the House Science Committee.
   - H.R. 923, Congressman Ehlers' "Human Cloning Prohibition Act", March 5, 1997.
   - S. 368, Senator Bond's bill to prohibit the use of Federal funds for human cloning research, February 27, 1997.
   - S. 1599, Senator Bond's "Human Cloning Prohibition Act of 1998" and statement of Senator Frist, Congressional Record, February 2, 1998.
   - H.R. 1602, Senator Feinstein and Senator Kennedy's "Prohibition on Cloning of Human Beings Act of 1998" and accompanying press release, February 2, 1998.

3. Letter from select patient groups and professional societies urging "extreme caution" in legislating on human cloning, February 4, 1998.

4. Biotechnology Industry Organization (BIO).

   - BIO testimony on legislative proposals regarding cloning of human beings before the Subcommittee on Technology, July 22, 1997.
   - Discussion of current ban on federal funding of both embryo and cloning research.

5. Analysis of conflicting and unclear definitions of critical terms drawn from pending legislation and the National Bioethics Advisory Commission Report.

6. Press on cloning controversy.

   - "Cloning Plan Spawns Ethics Debate", Science Magazine, January 16, 1998.
   - "Small Spark Reignites Debate on Human Cloning", The New York Times, January 19, 1998.
   - "Cloning Without Human Clones", The Wall Street Journal, January 20, 1998.
   - "Strange Egg", The Washington Post, January 25, 1998.

- "Why the Rush to Ban Cloning?", The New York Times, January 28, 1998.

7. FDA Authority on Cloning.

- Legal memorandum, "FDA's Existing Statutory and Regulatory Authority Give the Agency the Broad Authority to Regulate the Cellular Materials Involved in Human Cloning", January 29, 1998.
- Press reports regarding FDA's broad authority under current law to regulate human cloning.
- Biotechnology Industry Organization (BIO) letter to Secretary Shalala regarding FDA's broad authority under current law to regulate human cloning, January 13, 1998.

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Divider Title: _____

CLONING HUMAN BEINGS

Report and Recommendations of the
National Bioethics Advisory Commission

Rockville, Maryland
June 1997

EXECUTIVE SUMMARY

The idea that humans might someday be cloned—created from a single somatic cell without sexual reproduction—moved further away from science fiction and closer to a genuine scientific possibility on February 23, 1997. On that date, *The Observer* broke the news that Ian Wilmut, a Scottish scientist, and his colleagues at the Roslin Institute were about to announce the successful cloning of a sheep by a new technique which had never before been fully successful in mammals. The technique involved transplanting the genetic material of an adult sheep, apparently obtained from a differentiated somatic cell, into an egg from which the nucleus had been removed. The resulting birth of the sheep, named Dolly, on July 5, 1996, was different from prior attempts to create identical offspring since Dolly contained the genetic material of only one parent, and was, therefore, a "delayed" genetic twin of a single adult sheep.

This cloning technique is an extension of research that had been ongoing for over 40 years using nuclei derived from non-human embryonic and fetal cells. The demonstration that nuclei from cells derived from an adult animal could be "reprogrammed," or that the full genetic complement of such a cell could be reactivated well into the chronological life of the cell, is what sets the results of this experiment apart from prior work. In this report we refer to the technique, first described by Wilmut, of nuclear transplantation using nuclei derived from somatic cells other than those of an embryo or fetus as "somatic cell nuclear transfer."

Within days of the published report of Dolly, President Clinton instituted a ban on federal funding related to attempts to clone human beings in this manner. In addition, the President asked the recently appointed National Bioethics Advisory Commission (NBAC) to address within ninety days the ethical and legal issues that surround the subject of cloning human beings. This provided a welcome opportunity for initiating a thoughtful analysis of the many dimensions of the issue, including a careful consideration of the potential risks and benefits. It also presented an occasion to review the current legal status of cloning and the potential constitutional challenges that might be raised if new legislation were enacted to restrict the creation of a child through somatic cell nuclear transfer cloning.

The Commission began its discussions fully recognizing that any effort in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term. Ethical concerns surrounding issues of embryo research have recently received extensive analysis and deliberation in our country. Indeed, federal funding for human embryo research is severely restricted, although there are few restrictions on human embryo research carried out in the private sector. Thus, under current law, the use of somatic cell nuclear transfer to create an embryo solely for research purposes is already restricted in cases involving federal funds. There are, however, no current federal regulations on the use of private funds for this purpose.

The unique prospect, vividly raised by Dolly, is the creation of a new individual genetically identical to an existing (or previously existing) person—a "delayed" genetic twin.

This prospect has been the source of the overwhelming public concern about such cloning. While the creation of embryos for research purposes alone always raises serious ethical questions, the use of somatic cell nuclear transfer to create embryos raises no new issues in this respect. The unique and distinctive ethical issues raised by the use of somatic cell nuclear transfer to create children relate to, for example, serious safety concerns, individuality, family integrity, and treating children as objects. Consequently, the Commission focused its attention on the use of such techniques for the purpose of creating an embryo which would then be implanted in a woman's uterus and brought to term. It also expanded its analysis of this particular issue to encompass activities in both the public and private sector.

In its deliberations, NBAC reviewed the scientific developments which preceded the Roslin announcement, as well as those likely to follow in its path. It also considered the many moral concerns raised by the possibility that this technique could be used to clone human beings. Much of the initial reaction to this possibility was negative. Careful assessment of that response revealed fears about harms to the children who may be created in this manner, particularly psychological harms associated with a possibly diminished sense of individuality and personal autonomy. Others expressed concern about a degradation in the quality of parenting and family life.

In addition to concerns about specific harms to children, people have frequently expressed fears that the widespread practice of somatic cell nuclear transfer cloning would undermine important social values by opening the door to a form of eugenics or by tempting some to manipulate others as if they were objects instead of persons. Arrayed against these concerns are other important social values, such as protecting the widest possible sphere of personal choice, particularly in matters pertaining to procreation and child rearing, maintaining privacy and the freedom of scientific inquiry, and encouraging the possible development of new biomedical breakthroughs.

To arrive at its recommendations concerning the use of somatic cell nuclear transfer techniques to create children, NBAC also examined long-standing religious traditions that guide many citizens' responses to new technologies and found that religious positions on human cloning are pluralistic in their premises, modes of argument, and conclusions. Some religious thinkers argue that the use of somatic cell nuclear transfer cloning to create a child would be intrinsically immoral and thus could never be morally justified. Other religious thinkers contend that human cloning to create a child could be morally justified under some circumstances, but hold that it should be strictly regulated in order to prevent abuses.

The public policies recommended with respect to the creation of a child using somatic cell nuclear transfer reflect the Commission's best judgments about both the ethics of attempting such an experiment and our view of traditions regarding limitations on individual actions in the name of the common good. At present, the use of this technique to create a child would be a premature experiment that would expose the fetus and the developing child to unacceptable risks. This in itself might be sufficient to justify a prohibition on cloning human beings at this time,

even if such efforts were to be characterized as the exercise of a fundamental right to attempt to procreate.

Beyond the issue of the safety of the procedure, however, NBAC found that concerns relating to the potential psychological harms to children and effects on the moral, religious, and cultural values of society merited further reflection and deliberation. Whether upon such further deliberation our nation will conclude that the use of cloning techniques to create children should be allowed or permanently banned is, for the moment, an open question. Time is an ally in this regard, allowing for the accrual of further data from animal experimentation, enabling an assessment of the prospective safety and efficacy of the procedure in humans, as well as granting a period of fuller national debate on ethical and social concerns. The Commission therefore concluded that there should be imposed a period of time in which no attempt is made to create a child using somatic cell nuclear transfer.[1]

Within this overall framework the Commission came to the following conclusions and recommendations:

I. The Commission concludes 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. We have reached a consensus on this point because current scientific information indicates that this technique is not safe to use in humans at this time. Indeed, we believe it would violate important ethical obligations were clinicians or researchers to attempt to create a child using these particular technologies, which are likely to involve unacceptable risks to the fetus and/or potential child. Moreover, in addition to safety concerns, many other serious ethical concerns have been identified, which require much more widespread and careful public deliberation before this technology may be used.

The Commission, therefore, recommends the following for immediate action:

- A continuation of the current moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer.

- An immediate request to all firms, clinicians, investigators, and professional societies in the private and non-federally funded sectors to comply voluntarily with the intent of the federal moratorium. Professional and scientific societies should make clear that any attempt to create a child by somatic cell nuclear transfer and implantation into a woman's body would at this time be an irresponsible, unethical, and unprofessional act.

II. The Commission further recommends that:

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[1] The Commission also observes that the use of any other technique to create a child genetically identical to an existing (or previously existing) individual would raise many, if not all, of the same non-safety-related ethical concerns raised by the creation of a child by somatic cell nuclear transfer.

- Federal legislation should be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning. It is critical, however, that such legislation include a sunset clause to ensure that Congress will review the issue after a specified time period (three to five years) in order to decide whether the prohibition continues to be needed. If state legislation is enacted, it should also contain such a sunset provision. Any such legislation or associated regulation also ought to require that at some point prior to the expiration of the sunset period, an appropriate oversight body will evaluate and report on the current status of somatic cell nuclear transfer technology and on the ethical and social issues that its potential use to create human beings would raise in light of public understandings at that time.

III. The Commission also concludes that:

- Any regulatory or legislative actions undertaken to effect the foregoing prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere with other important areas of scientific research. In particular, no new regulations are required regarding the cloning of human DNA sequences and cell lines, since neither activity raises the scientific and ethical issues that arise from the attempt to create children through somatic cell nuclear transfer, and these fields of research have already provided important scientific and biomedical advances. Likewise, research on cloning animals by somatic cell nuclear transfer does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees.

- If a legislative ban is not enacted, or if a legislative ban is ever lifted, clinical use of somatic cell nuclear transfer techniques to create a child should be preceded by research trials that are governed by the twin protections of independent review and informed consent, consistent with existing norms of human subjects protection.

- The United States Government should cooperate with other nations and international organizations to enforce any common aspects of their respective policies on the cloning of human beings.

IV. The Commission also concludes that different ethical and religious perspectives and traditions are divided on many of the important moral issues that surround any attempt to create a child using somatic cell nuclear transfer techniques. Therefore, we recommend that:

- The federal government, and all interested and concerned parties, encourage widespread and continuing deliberation on these issues in order to further our understanding of the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding this technology should the time come when present concerns about safety have been addressed.

V. Finally, because scientific knowledge is essential for all citizens to participate in a full and informed fashion in the governance of our complex society, the Commission recommends that:

- Federal departments and agencies concerned with science should cooperate in seeking out and supporting opportunities to provide information and education to the public in the area of genetics, and on other developments in the biomedical sciences, especially where these affect important cultural practices, values, and beliefs.

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Divider Title: _____

Ehlers Bill (H.R. 922) as Reported From House Science Committee

SECTION 1. SHORT TITLE.

This Act may be cited as the "Human Cloning Research Prohibition Act".

SEC. 2. PROHIBITION AGAINST EXPENDITURE OF FEDERAL FUNDS FOR RESEARCH ON CLONING HUMANS.

(a) Prohibition.– None of the funds made available in any Federal law may be obligated or expended to conduct or support any project of research that includes the use of human somatic cell nuclear transfer technology to produce an embryo.

(b) Definitions.– For purposes of this section–

(1) the term "human somatic cell nuclear transfer" means transferring the nucleus of human somatic cell into an oocyte from which the nucleus has been removed or rendered inert; and

(2) the term "somatic cell" means a cell of an embryo, fetus, child, or adult which is not and will not become a sperm or egg cell.

SEC. 3. REVIEW. The Director of the National Science Foundation shall enter into an agreement with the National Research Council for a review of the implementation of this Act. Not later than 5 years after the date of the enactment of this Act, the Director shall transmit to the Congress a report containing the results of that review, including the conclusions of the National Research Council on–

(1) the impact that the implementation of this Act has had on research; and

(2) recommendations for any appropriate changes to this Act.

SEC. 4. PROTECTED SCIENTIFIC RESEARCH. Nothing in this Act shall restrict other areas of scientific research not specifically prohibited by this Act, including important and promising work that involves–

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

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

HR 923 (EHLERS)
105th CONGRESS
1ST SESSION

To prohibit the cloning of humans.

IN THE HOUSE OF REPRESENTATIVES
March 5, 1997

Mr. EHLERS introduced the following bill; which was referred to the Committee on Commerce

A BILL

To prohibit the cloning of humans.

[Italic->] Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, [<-Italic]

SECTION 1. SHORT TITLE.

This Act may be cited as the 'Human Cloning Prohibition Act'.

SEC. 2. PROHIBITION AGAINST CLONING OF HUMANS.

(a) IN GENERAL- It shall be unlawful for any person to use a human somatic cell for the process of producing a human clone.

(b) CIVIL MONEY PENALTY- Any person who violates subsection (a) is liable to the United States for a civil money penalty in an amount not exceeding $5,000.

S 368 (BOND)
105th CONGRESS
1ST SESSION

To prohibit the use of Federal funds for human cloning research.

IN THE SENATE OF THE UNITED STATES
February 27, 1997

Mr. BOND (for himself and Mr. ASHCROFT) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To prohibit the use of Federal funds for human cloning research.

[Italic->] Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, [<-Italic]

SECTION 1. PROHIBITION ON CLONING RESEARCH.

(a) IN GENERAL- No Federal funds may be used for research with respect to the cloning of a human individual.

(b) DEFINITION- For purposes of this section, the term 'cloning' means the replication of a human individual by the taking of a cell with genetic material and the cultivation of the cell through the egg, embryo, fetal, and newborn stages into a new human individual.

Attachment #1

105TH CONGRESS
1ST SESSION

S. _____

S. 1599

IN THE SENATE OF THE UNITED STATES

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

A BILL

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

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 "Human Cloning Prohibition Act of 1998".

SEC. 2. FINDING.

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

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

SEC. 3. PROHIBITION ON CLONING.

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

"CHAPTER 16—CLONING

"§ 301 Prohibition on cloning

"(a) IN GENERAL.—It shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, to use human somatic cell nuclear transfer technology.

"(b) IMPORTATION.—It shall be unlawful for any person or entity, public or private, to import an embryo produced through human somatic cell nuclear transfer technology.

"(c) PENALTIES.—

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

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

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

"(d) DEFINITION.—The term 'human somatic cell nuclear transfer technology' means taking the nuclear material of a human somatic cell and incorporating it into an oocyte from which the nucleus has been removed or rendered inert and producing an embryo (including a preimplantation embryo).".

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

"16. Cloning § 301". .....

SEC. 4. COMMISSION TO PROMOTE A NATIONAL DIALOGUE ON BIOETHICS.

(a) ESTABLISHMENT.—There is established within the Institute of Medicine a commission to be known as the National Commission to Promote a National Dialogue on Bioethics (referred to in this section as the "Commission").

(b) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—The Commission shall be composed of 25 members, of whom—

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

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

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

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

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

(2) REQUIREMENTS.—Each individual described in subparagraph (A) through (D) of paragraph (1) shall ensure that members appointed to the Commission are representative of the fields of law, theology, philosophy or ethics, medicine, science, and society.

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

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

(5) MEETINGS.—The Commission shall meet at the call of its Chairperson or a majority of its members.

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

(7) VACANCIES.—A vacancy on the Commission shall be filled in the same manner in which the original appointment was made not later than 30 days after the Commission is given notice of the vacancy and shall not affect the power of the remaining members to execute the duties of the Commission.

(8) COMPENSATION.—Members of the Commission shall receive no additional pay, allowances, or benefits by reason of their service on the Commission.

(9) EXPENSES.—Each member of the Commission shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

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

ticipation and discourse concerning important bioethical issues including cloning, and provide for a report to Congress concerning the findings, conclusions, and recommendations of the Commission concerning Federal policy and possible Congressional action.

(d) STAFF AND SUPPORT SERVICES.—

(1) STAFF.—With the approval of the Commission, the chairperson of the Commission may appoint such personnel as the chairperson considers appropriate.

(2) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the Commission shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

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

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

mission. The facilities shall serve as the headquarters of the Commission and shall include all necessary equipment and incidentals required for the proper functioning of the Commission.

(e) POWERS OF COMMISSION.—

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

(2) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the Commission, the head of any Federal agency is authorized to detail, without reimbursement, any of the personnel of such agency to the Commission to assist the Commission in carrying out its duties. Any such detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

(3) TECHNICAL ASSISTANCE.—Upon the request of the Commission, the head of a Federal agency shall provide such technical assistance to the Commission as the Commission determines to be necessary to carry out its duties.

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

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

(5) OBTAINING INFORMATION.—The Commission may secure directly from any Federal agency information necessary to enable it to carry out its duties, if the information may be disclosed under section 552 of title 5, United States Code. Upon request of the Chairperson of the Commission, the head of such agency shall furnish such information to the Commission.

(6) ADMINISTRATIVE SUPPORT SERVICES.—Upon the request of the Commission, the Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

(7) PRINTING.—For purposes of costs relating to printing and binding, including the cost of personnel detailed from the Government Printing Office, the Commission shall be deemed to be a committee of the Congress.

(f) SUBCOMMITTEES.—

(1) IN GENERAL.—The Commission shall establish 6 subcommittees, including—

(A) a subcommittee on legal issues;

(B) a subcommittee on theological issues;

(C) a subcommittee on philosophical and ethical issues;

(D) a subcommittee on medical issues;

(E) a subcommittee on scientific issues; and

(F) a subcommittee on social issues.

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

(A) 1 expert to be appointed by the members of the Committee who were appointed under subparagraphs (A) and (C) of subsection (b)(1);

(B) 1 expert to be appointed by the members of the Committee who were appointed under subparagraphs (B) and (D) of subsection (b)(1);

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

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

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

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

(g) REPORT.—Not later than December 31, 1999, and annually thereafter, the Commission shall prepare and submit to the appropriate committees of Congress a report which shall contain a detailed statement of the recommendations, findings, and conclusions of the Commission.

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

SEC. 5. UNRESTRICTED SCIENTIFIC RESEARCH.

Nothing in this Act (or an amendment made by this Act) shall be construed to restrict areas of scientific research that are not specifically prohibited by this Act (or amendments).

SEC. 6. SENSE OF CONGRESS.

It is the sense of Congress that the Federal Government should advocate for and join an international effort to prohibit the use of human somatic cell nuclear transfer technology to produce a human embryo.

Statement of Senator Bill Frist
Congressional Record
February 2, 1998

In recent years, I have often voiced concern that medical technology is moving at an unprecedented pace, leaving the rest of society ill-prepared to cope with the increasingly complex moral and ethical dilemmas that follow in the wake of new inventions. We must never attempt to divorce scientific progress from ethical considerations. We must instead fashion timely answers to the timeless question "Is there a line that should not be crossed even for scientific or other gain, and if so, where is it?" (Washington Post editorial, Oct. 2, 1994)

The recent furor over Dolly the cloned sheep, and Dr. Seed's subsequent announcement that he intended to clone a human being through the same technique, has highlighted the necessity of an independent, balanced forum to address the ethical implications of new technological capabilities. Two temptations threaten both science and ethics in the current milieu. There is pressure on legislators (often unfamiliar with scientific issues) to rush to draft laws that could hamper important research efforts. There is a parallel tendency on the part of academic scientists to resist any input from law or ethics into their research. Thus, science and ethics are lost in the political morass, while the public often remains uninvolved and frightened. The example of the cloning debate provides ample evidence of this tendency.

There are no fewer than six legislative proposals to address cloning on the horizon, ranging from sweeping prohibitions to largely symbolic bans. The National Bioethics Advisory Commission (a commission appointed entirely by President Clinton) did a good job of trying to assimilate the information on cloning under their ninety day deadline last year, but they were unable to substantively address the ethical issues surrounding human cloning. The Commission cited inadequate time to tackle difficult ethical issues in the context of our pluralistic society, and primarily focused on scientific concerns as well as the less abstract issue of safety. They then appealed to each American citizen to step to the plate and exercise moral leadership in forming a national policy on human cloning.

In an effort to follow up on the Commission's recommendations, the Senate Labor Committee's Subcommittee on Public Health and Safety, which I chair, held a hearing June 17, 1997, entitled "Ethics and Theology: A Continuation of the National Discussion on Human Cloning." We heard testimony on all sides of the issue, from the Christian, Islamic, and Jewish traditions, and from philosophers well-schooled in biomedical ethics. We launched a broader public debate with questions about the nature of human individuality, family, and social structure.

However, time has shown that both a Presidential Commission, and the United States Congress are inadequate and inappropriate forums for bioethical issues of intricacy and importance. I am therefore proposing to establish a new independent National Bioethics Commission, representative of the public at large, with combined participation of experts in law,

science, theology, medicine, social science, and philosophy/ethics with interested members of the public.

It is my hope that this Commission will forge a new path for our country in the field of bioethics. That they will enable us to have an informed, thoughtful, scientific debate in the public square without fear or politics driving our decisions. The Majority and Minority Leaders of Congress would appoint members of the panel, but no current Member of Congress or Administration political appointee would be allowed to participate during their term of office. We simply must depoliticize these discussions while simultaneously broadening input from the general public. Each and every citizen should have the opportunity to contribute to these great debates.

I anticipate that some may question the role of theology in a public policy debate. Certainly the President's advisory commission found that their considerations were incomplete without examining the religious mores of our culture. Our founding fathers also recognized that public policy could not be formulated in a theological vacuum. While they forbade the establishment of a state religion, they simultaneously affirmed the rights of God-fearing people to make their voices heard in the public arena. Today, and throughout history, religion has been a primary source of the beliefs governing these decisions for men and women of all races and creeds.

So it is vital that our public debate and reflection on scientific developments keep pace, and even anticipate and prepare for new scientific knowledge. The moral and ethical dilemmas inherent in the cloning of human beings may well be our greatest test to date. We do not simply seek knowledge, but the wisdom to apply that knowledge. As with each of the mind boggling scientific advances of the last century, we know that there is the potential for both good and evil in this technology. Our task as legislators is to define the role of the federal government in harnessing this technology for good. Our task as citizens is to exercise responsible stewardship of the precious gift of life. May this Commission enable us to fulfill our trust.

O:\BAI\BAI98.172 S.L.C.

105TH CONGRESS
2D SESSION

S. 1602

IN THE SENATE OF THE UNITED STATES

Mrs. FEINSTEIN (for herself and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Public Health Service Act to prohibit any attempt to clone a human being using somatic cell nuclear transfer and to prohibit the use of Federal funds for such purposes, 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 "Prohibition on Cloning of Human Beings Act of 1998".

SEC. 2. FINDINGS.

Congress finds that—

(1) it has been reported that an adult sheep has been cloned using a technique called somatic cell nuclear transfer;

(2) the National Bioethics Advisory Commission (referred to in this Act as the "NBAC") has reviewed the scientific and ethical implications of the potential use of such technology to clone human beings;

(3) the NBAC has determined that—

(A) somatic cell nuclear transfer technology may have many applications for biotechnology, livestock productions, and new medical approaches including the production of pharmaceutical proteins and prospects for repair, regeneration, or transplant of human tissues or organs; and

(B) the possibility of using somatic cell nuclear transfer for the purposes of creating a child entails significant scientific uncertainty and medical risk, which could result in harm to a child;

(4) 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;

(5) the consensus of the NBAC is based on current scientific information indicating that this technique is not safe to use in humans at this time;

(6) in addition to issues of safety, the NBAC 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;

(7) the 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;

(8) the 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;

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

(10) the NBAC specified that such Federal 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;

(11) the NBAC 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;

(12) the NBAC 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; and

(13)(A) biomedical research facilities, including those conducting cloning, and reproductive services facilities engage in and affect interstate commerce;

(B) the products of biomedical research, including cloning, and the services provided by reproductive services facilities move in interstate commerce;

(C) patients travel regularly across State lines in order to access reproductive services facilities; and

(D) biomedical research facilities, including those conducting cloning, and reproductive services facilities engage scientists, doctors, and other staff in an interstate market, and contract for research and purchase medical and other supplies in an interstate market.

SEC. 3. PURPOSES.

It is the purpose of this Act to—

(1) prohibit any attempt, in this country or elsewhere, to clone a human being, that is, to use the product of somatic cell nuclear transfer to create a human being genetically identical to an existing or deceased human being;

(2) prohibit the use of Federal funds for any of the activities described in paragraph (1); and

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

SEC. 4. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by adding at the end the following:

"SEC. 498C. PROHIBITION ON CLONING.

"(a) DEFINITIONS.—In this section:

"(1) CLONING.—The term 'cloning' means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, organ, plant, animal, or human.

"(2) NUCLEUS.—The term 'nucleus' means the cell structure that houses the chromosomes, and thus the genes.

"(3) OOCYTE.—The term 'oocyte' means the female germ cell, the egg.

"(4) SOMATIC CELL.—The term 'somatic cell' means a mature, diploid cell.

"(5) SOMATIC CELL NUCLEAR TRANSFER.—The term 'somatic cell nuclear transfer' means transferring the nucleus of a somatic cell of an existing or deceased human child or adult into an oocyte from which the nucleus or all chromosomes have been or will be removed or rendered inert.

"(b) PROHIBITIONS.—It shall be unlawful for any person or other legal entity, public or private—

"(1) to implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus;

"(2) to ship the product of somatic cell nuclear transfer in interstate or foreign commerce for the purpose of implanting the product of somatic cell nuclear transfer into a woman's uterus, in the United States or elsewhere; or

"(3) to use funds made available under this Act, or any other Act, for an activity prohibited under paragraph (1) or (2).

"(c) PROTECTED RESEARCH AND PRACTICES.—Nothing in this section shall be construed to restrict areas of biomedical and agricultural research or practices not expressly prohibited in this section, including research or practices that involve the use of—

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

"(2) mitochondrial, cytoplasmic or gene therapy; or

"(3) somatic cell nuclear transfer techniques to create nonhuman animals.

"(d) NATIONAL BIOETHICS ADVISORY COMMISSION REPORT.—

"(1) IN GENERAL.—Not later than 4½ years, and subsequently, 9½ years, after the date of enactment of this section, the National Bioethics Advisory Commission shall prepare and submit to the President and Congress a report concerning—

"(A) the state of the science of cloning and relevant developments in cell biology;

"(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 under this section.

"(2) OTHER REPORTS.—The National Bioethics Advisory Commission may produce reports in addition to the reports required under paragraph (1) if the Commission determines that such reports are useful to clarify any of the topics described in paragraph (1), address changes in the state of science or society, or modify or clarify the recommendations of the Commission.

"(3) CONTINUATION OF COMMISSION.—The National Bioethics Advisory Commission is authorized to continue for the 10-year period described in subsection (i) to prepare reports under this section and for other purposes as established in Executive

Order 12975 and subsequent amendments to such Order. This paragraph shall be construed to supersede the termination and chartering provisions of section 14 of the Federal Advisory Committee Act (5 U.S.C. App 2).

"(e) PENALTIES.—

"(1) IN GENERAL.—Any person who intentionally violates the provisions of subsection (b) shall be fined the greater of $1,000,000 or 3 times the gross pecuniary gain or loss resulting from the violation.

"(2) CIVIL ACTIONS.—If a person is violating or about to violate the provisions of subsection (b), the Attorney General may commence a civil action in an appropriate Federal district court to enjoin such violation.

"(3) FORFEITURE.—Any property, real or personal, derived from or used to commit a violation or attempted violation of the provisions of subsection (b), or any property traceable to such property, shall be subject to forfeiture to the United States in accordance with the procedures set forth in chapter 46 of title 18, United States Code.

"(4) AUTHORITY.—The Attorney General shall have exclusive, nondelegable enforcement authority under this section.

"(5) ADVISORY OPINIONS.—The Attorney General shall, upon request, render binding advisory opinions regarding the scope, applicability, interpretation, and enforcement of this section with regard to specific research projects or practices.

"(f) COOPERATION WITH FOREIGN COUNTRIES.—It is the sense of Congress that the President should cooperate with foreign countries to enforce mutually supported restrictions on the activities prohibited under subsection (b).

"(g) RIGHT OF ACTION.—Nothing in this section shall be construed to give any individual or person a private right of action.

"(h) PREEMPTION OF STATE LAW.—The provisions of this section shall preempt any State or local law that prohibits or restricts research regarding, or practices constituting, somatic cell nuclear transfer, mitochondrial or cytoplasmic therapy, or the cloning of molecules, DNA, cells, tissues, organs, plants, animals, or humans.

"(i) EFFECTIVE DATE.—This section shall be effective for the 10-year period beginning on the date of enactment of this section. The prohibitions contained in this

section shall terminate at the expiration of such 10-year period.".

News from . . .

Senator Dianne Feinstein

of California

FOR IMMEDIATE RELEASE:
Monday, February 2, 1998

Contact: Susan Kennedy
Or Jim Hock
202/224-9629
www.senate.gov/~feinstein

Senators Feinstein and Kennedy Introduce Legislation to Ban Human Cloning

Washington, DC -- Senators Dianne Feinstein (D-CA) and Edward Kennedy (D-MA), ranking member on the Senate Labor and Human Resources Committee, introduced legislation today to place a 10-year federal moratorium on the cloning of human beings.

The Prohibition on Cloning of Human Beings Act of 1998 prohibits for 10 years any person from attempting to clone a human being using somatic cell nuclear transfer technology, the only technique on the horizon with the potential to allow human cloning.. The law, which would extend to both privately- or publicly-funded research, is carefully drafted so as not to prevent or interfere with other biomedical research vital to cancer treatment, fertility, and other disease research.

The legislation also authorizes the continuation of the National Bioethics Advisory Commission and requires the Commission to report to the President and Congress in 4 ½ and 9 ½ years on the science and ethical issues associated with cloning technology, and to recommend whether the federal moratorium should be continued.

"The cloning of a human being today remains scientifically dangerous, morally unacceptable, and ethically flawed," Senator Feinstein said. "It may never be acceptable from a moral standpoint, but we do not know enough today to permit the cloning of a human being, or to make a permanent determination about the dangers or potential use of this technology."

Following the news that a Scottish scientist successfully cloned a sheep last year using somatic cell nuclear transfer technology, President Clinton instituted a ban on federal funding related to attempts to clone human beings. The President also asked the National Bioethics Advisory Commission to issue a report on the ethical and legal issues surrounding the possible use of this technology to clone human beings.

-- more --

The Commission issued its report in June, concluding that, "at this time, it is morally unacceptable for anyone in the public or private sector...to attempt to create a child using somatic cell nuclear transfer cloning." The Commission cited unacceptable safety risks to the fetus or potential child, and unknown risks to the mother. The Commission further recommended that federal legislation be enacted "to prohibit anyone from attempting, whether in a research or clinical setting, to create a child though somatic cell nuclear cloning." "It is critical however," the Commission' report said, "that such legislation include a sunset clause to ensure that Congress will review the issue after a specified period of time..." and that any legislation should be carefully written so as not to interfere with other important areas of scientific research."

"This legislation is carefully drafted to prohibit attempts to clone a human being, while not impeding other vital research involving the cloning of cells, tissues, DNA and animals," Senator Feinstein said. "Senator Kennedy and I drafted this legislation after many discussions with the National Bioethics Advisory Commission, the American Society for Reproductive Medicine, the Department of Health and Human Services, NIH, FDA, and others, to ensure that it was drafted with great care and specificity."

"The life-saving possibilities for cloning technology are enormous," Senator Feinstein said. "Scientists at NIH indicate that cloning technology could revolutionize treatment for diabetes, cancer and severe burns, as well as lead to major breakthroughs in treating neurodegenerative diseases such as multiple sclerosis, Lou Gehrig's disease, Alzheimer's, Parkinson's, and repairing spinal cord injuries."

"Most importantly, these scientists indicate that all of these possibilities can be accomplished without using this technology to create a human being."

Senators Feinstein and Kennedy were joined at the news conference by two physicians, Dr. Douglas Melton of Harvard University who specializes in molecular and cellular biology and Dr. Marion Damewood, Associate Professor of Gynecology & Obstetrics at John Hopkins Hospital and a member of the Board of the American Society for Reproductive Medicine.

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3

Divider Title: _____

February 4, 1998

REGARDING: LEGISLATION TO BAN CLONING OF HUMAN BEINGS

Dear Member:

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 stated 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, such as the use of cloning techniques on human cells, genes and tissues, which is vital to finding the cures to the diseases and ailments which our organizations champion. Cancer, diabetes, allergies, asthma, HIV/AIDS, eye diseases, spinal cord injuries, Guillain-Barré syndrome, Gaucher disease, stroke, cystic fibrosis, kidney cancer, Alzheimer's disease, tuberous sclerosis, tourette syndrome, alcoholism, autoimmune diseases, osteoporosis, Parkinson's disease, infertility, heart disease, diseases of aging, ataxia telangiectasia and many other types of research 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,

AIDS Action Council
Allergy and Asthma Network/Mothers of Asthmatics, Inc.
Alliance for Aging Research
Alzheimer Aid Society
American Academy of Optometry
American Academy of Pediatrics
American Association for Cancer Education

(more)

American Association for Cancer Research
American Autoimmune Related Diseases Association
American College of Cardiology
American College of Medical Genetics
American Diabetes Association
American Heart Association
American Paralysis Association
American Pediatric Society
American Society for Reproductive Medicine
American Uveitis Society
Americans for Medical Progress
Association of Medical School Pediatric Department Chairmen
Association of Pediatric Oncology Nurses
Asthma & Allergy Foundation of America
A-T Children's Project
Cancer Research Foundation of America
Cancer Care, Inc.
Cancervive
Candlelighter's Childhood Cancer Foundation
Cystic Fibrosis Foundation
Federation of American Societies for Experimental Biology (FASEB)
Foundation for Biomedical Research
Guillain-Barré Syndrome Foundation International
International Patient Advocacy Association
Joint Council of Allergy, Asthma and Immunology
Juvenile Diabetes Foundation International
Kent Waldrep National Paralysis Foundation
Log Cabin AIDS Policy Institute
National Alliance for Eye and Vision Research
National Alliance of Breast Cancer Organizations (NABCO)
National Association for Biomedical Research
National Campaign to End Neurological Disorders
National Coalition for Cancer Research
National Foundation for Cancer Research
National Gaucher Foundation
National Kidney Cancer Association
National Osteoporosis Foundation
National Patient Advocate Foundation
National Stroke Association
National Tuberous Sclerosis Association
Oncology Nurses Association
Outpatient Ophthalmic Surgery Society, Inc.
Parkinson's Action Network
Radiation Research Society

(more)

Research!America
Research Society on Alcoholism
RESOLVE
Roswell Park Cancer Institute
Society for Pediatric Research
Society of Cardiovascular & Interventional Radiology
The Paget Foundation for Paget's Disease of Bone and Related Disorders
Tourette Syndrome Association, Inc.

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4

Divider Title: _____

Bio

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

TESTIMONY OF ALISON TAUNTON-RIGBY, Ph.D. PRESIDENT AND CEO, AQUILA BIOPHARMACEUTICALS WORCESTER, MASSACHUSETTS

ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

BEFORE THE SUBCOMMITTEE ON TECHNOLOGY COMMITTEE ON SCIENCE U.S. HOUSE OF REPRESENTATIVES

LEGISLATIVE PROPOSALS REGARDING CLONING OF HUMAN BEINGS

JULY 22, 1997

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http://www.bio.org

TESTIMONY OF
ALISON TAUNTON-RIGBY, Ph.D.
PRESIDENT AND CEO, AQUILA BIOPHARMACEUTICALS
WORCESTER, MASSACHUSETTS
ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION
BEFORE THE
SUBCOMMITTEE ON TECHNOLOGY
COMMITTEE ON SCIENCE
U.S. HOUSE OF REPRESENTATIVES
LEGISLATIVE PROPOSALS
REGARDING CLONING OF HUMAN BEINGS
JULY 22, 1997

EXECUTIVE SUMMARY

"Cloning" refers simply to the production of identical copies from a single entity, such as cells or genes. It is an essential process in modern biomedical research. Research is helping us learn how to "re-program" genes and switch them on and off so they can develop into different types of cells or create different proteins. Cloning of cells and genes has proved to be a cornerstone of biotechnology's ability to develop new drugs and diagnostics for many intractable diseases, including heart disease, cancer, diabetes and many infectious diseases. These same techniques hold the promise of many more treatments to come.

BIO agrees 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 may raise ethical and social issues regarding a diminished sense of individuality and personal autonomy. We believe that this technology is not currently safe to use in humans.

BIO reiterates here our recommendation to NBAC that legislation on the subject of the cloning of human beings not be enacted. In lieu of legislation, we continue to recommend that the current moratorium on the cloning of human beings be continued indefinitely.

If the Congress determines that it is necessary to enact legislation, we urge the Congress to proceed with extreme caution to ensure that the legislation does not inadvertently inhibit vital biomedical research.

The National Bioethics Advisory Commission cautioned in its report 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." We emphatically agree with this assessment.

The testimony includes an outline of our analysis of the legislation proposed by the Clinton Administration – by far the best bill that has been proposed – and the basis for our recommendation that, at a minimum, this bill be substantially revised. We raise twelve issues with the draft bill. The most serious issue is that this and the other pending bills do not use scientifically accurate terms, even of such key terms as "cloning" and "somatic cell

nuclear transfer." They also focus on the "intent" of a researcher, an approach which involves an unpredictable review of the psychology of scientists.

We are not able here to provided our recommendation regarding an appropriate alternative to the Administration, Ehlers, and Bond bills. We have been working to draft an alternative for more than three months and have found it an exceedingly difficult challenge. NBAC did not even attempt to draft a bill. The White House drafted a bill in less than a week's time and as our analysis indicates it is fundamentally flawed. We have convened a group of experts, scientists and lawyers, to focus on the task and have been through dozens of drafts. We only found out late last week that a mark-up was scheduled for this week.

We will not provide any proposals to the Subcommittee until we are confident that our proposal is precise, uses terminology with which scientists will understand and agree, and will not inadvertently cover technology beyond that which gave rise to this debate. To do so would be irresponsible and unethical.

The drafting challenge is to define the critical term, "somatic cell nuclear transfer." That may not sound difficult, but we have the following definitions already on the table: two NBAC definitions; one Administration definition; one Ehlers definition, and one Bond definition. Our tentative conclusion is that none of these definitions is accurate and we are developing our own definition. Obviously if we cannot define the key term -- the term which drives the whole statute -- then it is not appropriate to go forward at this time.

If legislation must be enacted, we can make some general recommendations.

We believe that it should focus only on research funded by the Federal government. We urge the Subcommittee to take great care to ensure that this legislation does not become a vehicle for legislation on other issues going beyond the cloning of human beings.

Any such legislation should include a sunset provision, as NBAC recommends and the Administration has done in its proposed bill, a preemption provision, a findings section, a section defining protected research, and a prohibition on private rights of action.

In our view, there are important bioethics issues associated with the enactment of any bill which would inhibit vital biomedical research. This research has the potential to reduce human suffering, one of the highest callings from the point of view of bioethics.

Finally, we wish to express our appreciation for the care with which NBAC and the Administration have considered the issue and the obvious concern which they both have shown to ensure that no action is taken and no bill is enacted which will undermine vital biomedical research into cures and therapies for deadly and disabling diseases and research into infertility. We commend the Administration for its efforts to convert the NBAC recommendations into statutory language. This effort helps to focus the debate and highlights the complexity of the task.

Appendix A: Curriculum Vitae for Dr. Alison Taunton-Rigby and Disclosures Regarding Aquila Biopharmaceuticals and BIO
Appendix B: Summary of BIO Recommendations to National Bioethics Advisory Commission, April 23, 1997
Appendix C: BIO Analysis of Clinton Administration Draft Bill
Appendix D: Bill Proposed by Clinton Administration
Appendix E: HR 922 (Ehlers), 105th Congress, 1st Session
Appendix F: HR 923 (Ehlers), 105th Congress, 1st Session
Appendix G: S 368 (Bond), 105th Congress, 1st Session

TESTIMONY OF
ALISON TAUNTON-RIGBY, Ph.D.
PRESIDENT AND CEO, AQUILA BIOPHARMACEUTICALS
WORCESTER, MASSACHUSETTS
ON BEHALF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION
BEFORE THE
SUBCOMMITTEE ON TECHNOLOGY
COMMITTEE ON SCIENCE
U.S. HOUSE OF REPRESENTATIVES

Madam Chairwoman and members of the Subcommittee. My name is Dr. Alison Taunton-Rigby and I am President and Chief Executive Officer of Aquila Biopharmaceuticals, a biotechnology company based in Worcester, Massachusetts.

I am pleased to testify today on legislative proposals regarding the cloning of entire human beings. I testify on behalf of the Biotechnology Industry Organization (BIO), which represents 730 biotechnology companies and others engaged in biotechnology research on medicines and diagnostics, agriculture, pollution control, and industrial applications. I serve on BIO's Board of Directors and as Chairman of the Emerging Company Section (ECS), which represents the development stage research companies who are the majority of BIO's membership.

Medical Benefits of Cloning Technology

"Cloning" refers simply to the production of identical copies from a single entity, such as cells or genes. It is an essential process in modern biomedical research. Research is helping us learn how to "re-program" genes and switch them on and off so they can develop into different types of cells or create different proteins. Cloning of cells and genes has proved to be a cornerstone of biotechnology's ability to develop new drugs and diagnostics

for many intractable diseases, including heart disease, cancer, diabetes and many infectious diseases. These same techniques hold the promise of many more treatments to come.

Bottom-Line

As all entrepreneurs must do, let me begin with the bottom-line. BIO agrees 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 may raise ethical and social issues regarding a diminished sense of individuality and personal autonomy. We believe that this technology is not currently safe to use in humans.

BIO reiterates here our recommendation to NBAC that legislation on the subject of the cloning of human beings not be enacted. In lieu of legislation we continue to recommend that the current moratorium on the cloning of human beings be continued indefinitely.

If the Congress determines that it is necessary to enact legislation, we urge the Congress to proceed with extreme caution to ensure that the legislation does not inadvertently inhibit vital biomedical research.

The National Bioethics Advisory Commission cautioned in its report 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." We emphatically agree with this assessment.

In my testimony today, I will outline our analysis of the legislation proposed by the Clinton Administration -- by far the best bill that has been proposed -- and the basis for our recommendation that, at a minimum, it be substantially revised. We raise twelve issues with the draft bill. The most serious issue is that this and the other pending bills do not use scientifically accurate terms, even of such key terms as "somatic cell nuclear transfer." The issues we raise about the Administration's bill greatly undermines our confidence that legislation can be enacted which will not unintentionally inhibit vital biomedical research.

I also outline our analysis of the bills introduced by Congressman Ehlers and Senator Bond. They were introduced long before and do not benefit from the substance of the NBAC debate and report. The bills do not use terms which are correct from a scientific point of view. The Ehlers bills contain no definitions at all, meaning that there is sure to be a broad interpretation of its scope and a chilling effect on research far beyond that which the NBAC report addressed.

We are not able here to provided our recommendation regarding an appropriate alternative to the Administration, Ehlers, and Bond bills. It is exceedingly difficult to draft terms which are precise and not overbroad. NBAC did not even attempt to draft a bill. The White House drafted a bill in less than a week's time and as our analysis indicates it is fundamentally flawed. We only found out late last week that a mark-up was scheduled for this week and have not been able to develop recommendations in this short period of time. We will not provide any proposals to the Subcommittee until we are confident that our proposals are precise, use terminology with which scientists will understand and agree, and

will not inadvertently cover technology beyond that which gave rise to this debate. To provide language in which we have no confidence would be irresponsible and unethical.

The drafting challenge is to define the critical term, "somatic cell nuclear transfer." That may not sound difficult, but we have the following definitions already on the table: two NBAC definitions; one Administration definition; one Ehlers definition, and one Bond definition. Our tentative conclusion is that none of these definitions is accurate and we are developing our own definition. Obviously if we cannot define the key term -- the term which drives the whole statute -- then it is not appropriate to go forward at this time.

If the Congress determines that a statute must be enacted, it must be a statute which speaks to scientists -- the key audience -- in terms they understand. Because this a new area of science, there is not a consensus among scientists on some of the key concepts and terms. This is why the drafting is so difficult. Obviously, if the statue is imprecise, and does not use appropriate terms of art, it will be particularly likely to chill a broad range of research, will not communicate effectively to scientists, and may well be subject to ridicule.

As stated, we prefer that legislation not be enacted. If legislation must be enacted, we can make here some general recommendations.

We believe that it should focus only on research funded by the Federal government. Of the two bills introduced by Congressman Ehlers, only the one focusing on Federally funded research, H.R. 922, was referred to the House Science Committee. The other bill focuses on all research; it was not referred to this committee.

We urge the Subcommittee to take great care to ensure that this legislation does not become a vehicle for legislation on other issues going beyond the cloning of human beings.

Specifically, we agree with the NBAC conclusions that any legislative or regulatory actions taken with respect to somatic cell nuclear transfer be "carefully written so as not to interfere with other important areas of research." NBAC stated, and we agree, that "no new regulations are required regarding the cloning of human DNA sequences and cell lines, since neither activity raises the scientific and ethical issues that arise from the attempt to create children through somatic cell nuclear transfer, and these fields of research have already provided important scientific and biomedical advances." NBAC concluded, and again we agree, that "research on cloning animals by somatic cell nuclear transfer does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees."

We urge the Subcommittee to include a sunset provision in any legislation it proposes, as the Administration has done in its proposed bill. NBAC has stated, and we agree, that a sunset provision is "absolutely needed to ensure an opportunity to re-examine any judgment made today" because as "scientific information accumulates and public discussion continues, a new judgment may develop and we, as a society, need to retain the flexibility to adjust our course in this manner." The sunset provision ensures that there will be a review "when scientific and medical questions have been clarified, possible uses have been identified, and public discussion of the deeper moral concerns about this practice has matured."

We urge the Subcommittee to include a preemption provision in any legislation it proposed. Unfortunately the Administration bill does not do so. It is vital that we handle this complex issue on a national basis, not with 50 different state bills which vary widely in

scope and quality and could seriously harm local research efforts. Because we have seen "cloning" bills introduced in states which inadvertently address research wholly different from that which is subject to the NBAC report, federal legislation must preempt bills that would inhibit research with respect to somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, and tissues, to the use of somatic cell nuclear transfer techniques to create animals, or to related research.

We urge the Subcommittee to include a findings section similar to that proposed by the Clinton Administration and a section defining protected research. We urge you to include a prohibition on private rights of action with respect to these issues. The legislation would also need to include an effective date. We also urge that the legislation not deal with any intellectual property issues associated with biomedical research which could set a dangerous and unsettling precedent.

In our view, there are important bioethics issues associated with the enactment of any bill which would inhibit vital biomedical research. This research has the potential to reduce human suffering, one of the highest callings from the point of view of bioethics.

Finally, we wish to express our appreciation for the care with which NBAC and the Administration have considered the issue and the obvious concern which they both have shown to ensure that no action is taken and no bill is enacted which will undermine vital biomedical research into cures and therapies for deadly and disabling diseases and research into infertility. Although we prefer a moratorium to legislation on this subject, we commend the Administration for its efforts to convert the NBAC recommendations into statutory language. This effort helps to focus the debate and highlights the complexity of the task.