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Folder Title:
[Folder 2]: Human Cloning - Human Cloning Acts and Bills State Legislation on Human Cloning [1]

Stack:	Row:	Section:	Shelf:	Position:
S	115	2	9	3

PHOTOCOPY
PRESERVATION

Human Cloning Acts and Bills
State legislation on human cloning

Includes:

- Bond/Frist/Gregg Bill
- Human Cloning Prohibition Act (S. 1601)
- Cloning Prohibition Act of 1997
- Cloning Prohibition Act of 1998
- Cloning Prohibition and Research Protection Act
- Industry Bill

President Clinton's proposal (not yet introduced)

POSITIVES:

- Focuses only on the act of cloning a human being using somatic cell nuclear transfer, not on "research."
- Includes a five year "sunset" provision to determine the science and public sentiment on the issue in the future. (Just as public and political views have changed about artificial insemination, heart transplants and test tube babies.)
- Includes "findings" section which describes value of biomedical research.
- Includes clause that describes areas of critical protected biomedical research.

NEGATIVES:

- Definition of violation is over broad. One example is that as written it would limit treatments for mitochondrial disease.
- Violations turn on "intent" of individual to clone. The concept of "intent" comes from the criminal law and has no meaning in the context of a statute with civil penalties. Implementing an "intent" test includes a complex assessment of the psychological state of mind of a researcher, opens up the possibility of abuse by prosecutors and other enforcers, and provides no predictability to researchers.
- Does not preempt state laws.
- Draconian penalties (fine plus confiscation of entire research property).

Bond (S. 368)
(Referred to Senate Labor Committee)

POSITIVE:

- Good intentions.

NEGATIVES:

- Outlaws "research" on cloning a human being, does not focus only on the act of cloning a human being using somatic cell nuclear transfer.

- Scientific terms need further definition or refinement.

    - For example, there is no definition of "replication" — does not require individuals to be genetically identical in terms of nuclear DNA and the bill appears to cover all "cells" taken from any source.
    - It does not appear to require taking of cells from an existing or previously existing human being.

- Definition of violation is over broad. For example it would limit treatments for mitochondrial disease.

- Does not preempt state laws.

- Does not include "findings" section which describes value of biomedical research.

- Does not include clause describing areas of "protected biomedical research."

- Does not bar private right of action to enforce prohibition

Ehlers (HR 922)
(Substitute bill reported from House Science Committee: referred to House Commerce Committee).

POSITIVE:

- Includes clause describing areas of "protected biomedical research."

NEGATIVES:

- Focuses on 'research," not on the act of cloning a human being using somatic cell nuclear transfer technology.
- Focuses only on "creation of..an embryo," not on the act of cloning to produce a baby which, must include implementation and birth of clone.
- Does not include any "sunset" provision to mandate reconsideration.
- Does not preempt state laws (this could result in 51 separate cloning statutes — one federal and 50 state laws that confuse and inhibit valuable biomedical research.)
- Does not bar private right of action to enforce prohibition.

Elhers (HR 923)
(referred to House Commerce Committee)

POSITIVE:

- Focuses on the act of cloning a human being using somatic cell nuclear transfer, not on "research" about cloning.

NEGATIVES:

- No definition of scientific terms.
- Does not include any "sunset" provision to reconsider legislation.
- Does not preempt state laws.
- Does not include "findings" section which describes value of biomedical research.
- Does not include clause describing areas of "protected biomedical research."
- Does not bar private right of action to enforce prohibition.

California Cloning Law

POSITIVES:

- Focuses only on the act of cloning a human being using somatic cell nuclear transfer, not vaguely on "research."
- Includes a five years "sunset" provision.
- Includes a "findings" section which describes value of biomedical research.

NEGATIVES:

- Piecemeal approach to national issue.
- Definition of violation is over broad — for example it would limit treatments for mitochondrial disease.
- Violations turn on "purpose" of individual to clone. The concept of "purpose" comes from the criminal law ans has no meaning in the context of a statute with civil penalties. Implementing a "purpose" test once again involves a complex assessment of the psychological state of mind of a researcher, opens up the possibility of abuse by prosecutors and the enforcers.
- Does not include a description of "protected biomedical research."
- Does not bar private right of action to enforce prohibition.

CURRENT BAN ON FEDERAL FUNDING OF BOTH EMBRYO AND CLONING RESEARCH

The Fiscal Year 1996 and 1997 Labor, HHS Appropriations bills have included a broad ban on funding for **embryo** research. The text of this ban follows:

> (a) None of the funds made available in this Act may be used for -- (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero... (b) For purposes of this section, the term 'human embryo or embryos' include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning or any other means from one or more human gametes.

The Fiscal Year 1998 Labor, HHS Appropriations bill, H.R. 2264, as passed by the House and Senate, and signed into law, was **amended in both bodies to provide that this ban be extended to any embryo or embryos that is derived by "human diploid cells." Human diploid cells are precisely the type of cells used in the sheep cloning experiment which led to the human cloning debate.** The new language in both bills reads as follows:

> (a) None of the funds made available in this Act may be used for -- (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero... (b) For purposes of this section, the term 'human embryo or embryos' include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning or any other means from one or more human gametes **or human diploid cells.**[1]

Neither the National Bioethics Advisory Commission (NBAC) nor the President have reviewed or made any recommendations regarding enactment of any legislation regarding embryo and fetal tissue research.

> We do not revisit either the question of the cloning of humans by embryo-splitting or the issues surround embryo research. The latter issue has, of course, recently received

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[1] This reference to "human diploid cells" may be over broad and prevent use of any human cell line -- say cancer cells lines -- in research, not just use of these cells for somatic cell nuclear transfer cloning.

careful attention by the National Institutes of Health panel, the Administration, and the Congress. Letter of Harold Shapiro, NBAC Chairman (June 9, 1997).

The bill reported in July by the House Science Committee, H.R. 922, focuses only on Federal funding of embryo research. The substitute amendment adopted by the Committee in reporting the bill provides that "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." This would, in effect, make the current ban on embryo research permanent.

The House Commerce Committee and Senate Labor Committees have jurisdiction over bills, H.R. 922 (Ehlers) and S. 368 (Bond), respectively, which could ban all embryo research, irrespective of Federal funding.

industry proposal

MEMORANDUM

To: Elizabeth Drye
Rachel Levinson
Toby Donenseld
Bill Marshall
William Raub

Subject: Legislative Language

Date: May 28, 1997

We continue to urge NBAC and the White House to oppose enactment of a law on the subject of human cloning. Support for a law will unleash a rush to legislate here, at the G-7 Summit, and abroad which will be extremely difficult to control. We are giving you the attached language in the event that opposition to legislation is not acceptable to NBAC and the White House.

The attached legislative language is given to you as a very rough draft. We are in a continuous process of revising it and will get you copies of additional drafts as they become available. We are giving this draft to you early so you can begin your own drafting process.

Every word of this draft is subject to interpretation. We have a no confidence that we have covered all the issues of interpretation, scope, terms of art, etc. The draft uses many new terms for the U.S. Code which have never been defined.

The in vitro fertilization language should be reviewed by persons expert in that technology. The savings clause may not be all inclusive of critical technologies.

We insist that the authorship of this draft not be revealed to anyone for any purpose at any time. The authors continue to oppose the enactment of any law on these subjects and provide this draft only as a service which you have specifically requested of us in the event that opposition to a law is unacceptable. If this confidentiality were breached, we would no longer be able to assist you.

We will attempt to provide any assistance you request as this process goes forward and we all seek to ensure that vital biomedical research is not undermined by actions with respect to this issue. It is not an exaggeration to say that lives hang in the balance here.

Thanks very much for your support. We look forward to working with you in the coming months on this sensitive and critical issue. We have great confidence in you as a team and in the Administration's commitment to biomedical research.

LEGISLATIVE LANGUAGE TO ENFORCE A MORATORIUM ON THE USE OF NUCLEAR TRANSFER TECHNOLOGY TO REPLICATE AN ENTIRE HUMAN BEING

SEC. 1. FINDINGS AND PURPOSES.

(a) FINDINGS. -- Congress finds the following:

(1) It has been reported that a genetic replica of an adult sheep was developed at the Roslin Institute in Scotland through nuclear transfer technology using the nucleus from an adult sheep differentiated somatic cell;

(2) The use of nuclear transfer technology has raised ethical questions as to the potential application of this technology to the replication of an entire human being;

(3) Cloning technologies are used to duplicate cells and genes and are distinct from nuclear transfer technologies; such cloning technology is integral to the process used to develop breakthrough medicines, diagnostic products and vaccines to treat heart attacks, various cancers, kidney disease, diabetes, hepatitis, multiple sclerosis, cystic fibrosis and other deadly and disabling diseases; and such cloning technology raises no moral or ethical issues;

(4) More than 100 million people worldwide have already benefited from medicines and vaccines resulting from biotechnology research, some of which research involved the cloning of genes and cells;

(5) Scientists are conducting critical research involving cloning of human cells and genes, including cells which can be differentiated into tissues and organs. This technology could produce replacement skin, cartilage and bone tissue for burn and accident victims and may produce, for example, cells useful for cancer therapy and result in ways to regenerate retinal or spinal cord tissue;

(6) Biotechnology research is seeking to develop replacement internal organs in transgenic animals for human transplantation;

(7) The cloning of human cells and genes is not, and cannot be, used to replicate an entire human being and is essential to research that will provide profound new insights into

how genes control human development and contribute to human diseases;

(8) A general moratorium on the use of "cloning" technology not limited as provided in Section 3 of this Act would inadvertently limit vital biomedical research on cures and therapies for deadly and disabling diseases and is not in the public interest;

(9). The National Bioethics Advisory Commission has reviewed the ethical issues associated with "Dolly" at the request of the President and has recommended [that a narrowly drafted law be enacted to enforce a moratorium on certain uses of nuclear transfer technology]; and

(10) The United States government must ensure that any law or regulation regarding the use of nuclear transfer technology for the purposes specified in this Act be narrowly drafted so that it does not limit vital biomedical research.

(b) PURPOSES. -- The purposes of this Act are --

(1) to enforce a moratorium on the use of nuclear transfer technology as defined in this Act to replicate an entire human being;

(2) to establish uniform national rules for a moratorium on the use of nuclear transfer technology to replicate an entire human being; and

(3) to protect vital biomedical research to discover and develop new medicines, diagnostic products and vaccines for the benefit of patients.

SEC. 2 DEFINITIONS. -- For purposes of this Act --

(a) "Cloning" means the production of identical copies from a single entity, such as cells and genes;

(b) "Somatic cell" means cells in the body other than sperms and ovum, including muscle, bone, and nerve cells; and

(c) "Nuclear transfer technology" means the transfer of a cell nucleus from one cell into a fertilized egg from which the nucleus has been removed.

SEC. 3. MORATORIUM. -- No person may replicate a live entire human being using the transfer of a nucleus derived from a differentiated somatic cell of an existing or previously existing human being to an oocyte, followed by the implantation of said oocyte with it being carried to term and birth *(followed by the implantation of said oocyte and the subsequent*

egg, embryo, fetal, and newborn stages of development for such oocyte).

SEC. 4 PROTECTED BIOMEDICAL RESEARCH.

(a) Nothing in this statute shall restrict vital biomedical research which uses nuclear transfer technology and other cloning techniques, including use of this technology -

(1) on genes, polymorphisms, mutations, regulations, functions, as well as cells;

(2) for animal research, including the use of nuclear transfer technology and the development of transgenic animals;

(3) to research human genes and cells to identify, investigate, and develop new drugs and biologics, diagnostics and other technologies to benefit humankind;

(4) for research on embryos, in compliance with the guidelines of the National Institutes of Health Human Embryo Research Panel;

(5) for agriculture research to enhance production of quality fruits, vegetables, and other plants to benefit food production; and

(6) for environmental research on microbes;

(b) Nothing in this statute shall restrict other biomedical research and development of new medicines and diagnostic products for any purpose other than the purpose for which the moratorium has been established in this Act.

[SEC 5. PROTECTED IN VITRO FERTILIZATION. -- Nothing in this statute shall restrict in vitro fertilization technology, the administration of fertility enhancing drugs, or other medical procedures used to assist a woman in becoming or remaining pregnant, so long as that pregnancy is not specifically intended to result in the production of an entire human being/a human child who is genetically identical, with respect to the nucleus, to another human being, living or deceased.]

SEC. 5. CIVIL REMEDIES. -- Provisions in this section shall be enforced by the Attorney General taking appropriate injunctive and other equitable relief in an appropriate district court. Nothing in this statute shall give any individual or person a private right of action against any person or the United States.

SEC. 6. NATIONAL STANDARDS. -- This bill shall preempt any State law that relates to the use of nuclear transfer technology and/or the cloning of an entire human being.

SEC. 7. SUNSET CLAUSE AND STUDY. -- This Act shall take effect on the date of enactment and remain in effect for four years from that date. No later than one year prior to the expiration of this Act, the National Bioethics Advisory Commission shall present a study to the President and the Congress evaluating the scientific, medical, moral, and ethical issues raised by the moratorium in Section 3 of this Act and the adverse impact, if any, of this moratorium on the development of medicines and vaccines resulting from biotechnology research.

SEC. 8. INTERNATIONAL BIOMEDICAL RESEARCH PROTECTIONS. -- The Director of the National Institutes of Health, in collaboration with other appropriate federal officials, shall seek international agreements which protect vital biomedical research and which include moratoria on the replication of an entire human being using the transfer of a nucleus as defined in Section 3 of this Act.

MODEL LEGISLATIVE LANGUAGE REGARDING HUMAN CLONING

The following legislative language is technically accurate from a scientific point-of-view and focuses only on the cloning of a human being.

SECTION 1. TITLE. This act shall be called the "Human Cloning Prohibition Act of 1998."

SECTION 2. PROHIBITION. It shall be unlawful for any person to use federal funds to create a human child identical in terms of nuclear deoxyribonucleic acid (DNA) to an existing or previously existing individual using somatic cell nuclear transfer technology.

SECTION 3. DEFINITIONS. For the purposes of this section, the following definitions apply:

(a) "somatic cell nuclear transfer technology" means transferring the nucleus of a somatic cell of an existing or previously existing human child or adult into an oocyte from which the nucleus has been removed;

(b) "the creation of a human child" means implanting the product of somatic cell nuclear transfer technology for gestation and subsequent birth;

(c) "somatic cell" means a differentiated, diploid cell;

(d) "oocyte" means the mature female germ cell, the egg;

(e) "nucleus" means the cell structure that houses the chromosomes, and thus the genes; and

(f) "gestation" means the period during which an embryo develops into a fetus that is ready to be born.

SECTION 4. PREEMPTION OF STATE LAWS. This law shall preempt any state law which imposes on individuals or institutions using federal funds a prohibition or limitation with respect to research regarding somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, and tissues, to the use of somatic cell nuclear transfer techniques to develop animals, or to related research.

SECTION 5. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including but not limited to important and promising work that involves:

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

(b) the use of somatic cell nuclear transfer techniques to develop animals.

SECTION 6. EFFECTIVE DATE. This Act shall apply to somatic cell nuclear transfers performed after the date of its enactment.

SECTION 7. REAUTHORIZATION. The prohibition in this legislation shall expire five years from the effective date.

SECTION 8. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on

(a) the state of the science of somatic cell nuclear transfer;

(b) the ethical and social issues associated with the potential use of this technology in humans; and

(c) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 9. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.

Draft3 1-13-98
ASRM

CLONING PROHIBITION AND RESEARCH PROTECTION ACT

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

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

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

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

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

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

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

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

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

(a) the state of the science of somatic cell nuclear transfer;

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

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

SECTION 9. PENALTIES.

(a) Any person who intentionally violates Section 1 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

California Law Penalties

(a) If the violator is a corporation, firm, clinic, hospital, laboratory, or research facility, by a civil penalty of not more than one million dollars ($1,000,000) or the applicable amount under subdivision (c), whichever is greater.

(b) If the violator is an individual, by a civil penalty of not more than two hundred fifty thousand dollars ($250,000) or the applicable amount under subdivision (c), whichever is greater.

(c) If any violator derives pecuniary gain from a violation of this section, the violator may be assessed a civil penalty of not more than an amount equal to the amount of the gross gain multiplied by two.

CLONING

LEGISLATIVE OPTIONS

BACKGROUND

Cloning

Cloning means making a precise copy of a molecule (such as a gene), a cell, or an individual plant or animal. It is done routinely in laboratories and clinics around the world in order to understand how proteins work in an organism, to construct new drugs with fewer side effects, to engineer foods with better nutritional characteristics, or to produce animals as models for human disease. Forensic experts clone DNA to identify crime perpetrators, cartilage cells are cloned to repair damaged knees and a few of the more than 5,000 genetic defects are being treated by inserting properly functioning cloned genes into the patient's cells.

Dolly reviewed

Dolly was news because she is thought to be a replica of an adult sheep. We already have human replicas, or twins, which occur naturally and through assisted reproductive technology known as blastomere splitting. However, identical twins are born at the same time and have no identical forebears. Dolly was the product of somatic cell nuclear transfer (SCNT), a technique that may have applications ranging from reconstituting an AIDS patient's own immune system or producing skin cells for burn victims, bone marrow cells for cancer patients, insulin-producing cells to treat diabetes, leukemia and liver damage. Much of this research is prohibited at its earliest stages under the Federal ban on creating embryos for research purposes.

Embryo research

Federal funding for the creation of human embryos for research purposes is banned under a December 2, 1994 Presidential directive and other embryo research is also prohibited via restrictions on DHHS appropriations. (See Attachment A for further discussion.) Embryo research in support of improvements in assisted reproductive medicine is carried out in the private sector with virtually no Federal regulation.

We must assess the need to engage in the issue of embryo research in the context of a cloning bill and follow closely other legislative initiatives.

LEGISLATION

The issues of greatest concern [to scientists and industry] are what is prohibited and how the prohibited act(s) is(are) defined. (See Attachment B for discussion of options)

IMPACT OF FDA AUTHORITY ON CLONING OPTIONS

Recent reports notwithstanding, FDA is still in the process of developing a determination of its authority to regulate the use of somatic cell nuclear transfer (SCNT) for the purpose

of creating a child. Assuming for the moment that FDA **does** have this authority, how would that effect our strategy with respect to legislation?

The Food, Drug and Cosmetic Act gives FDA authority to regulate products and procedures on the basis of safety and efficacy—not ethics. Our bill would prohibit any attempt to create a child using SCNT and provide for further review of the ethical and scientific. FDA's likely authority takes care of the former, for some period of time, but does not address the need for public discourse. Therefore, there is still a need to pursue legislative options.

Prohibitions, Part 1

Prohibition	Administration	possible revision I
wording	Administration Bill (June 9, 1997) 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.	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 in order to create a child.
discussion	**"Or in any other way creating a human being"**—The meaning of this phrase is unclear. It can be interpreted to mean creating a human being in any way other than by using SCNT, or, as we intended, creating a human being through extra-uterine gestation, a technology that is unlikely to become available prior to significant development of SCNT.	**"intent"**—Questions for the legal scholars – is intent a term associated only with criminal statutes? Would its inclusion make this language more difficult to enforce? What does it add? Does it make sense in reference to a legal entity? Is "other legal entity" necessary?
discussion	**"human being"**--We have not and probably would prefer not to attempt to define: a human being, the means for creating a human being, nor the definitive act that results in the creation of a human being. Therefore, one option is to substitute "child" in place of "human being," as the National Bioethics Advisory Commission chose to do. While this leaves open the question of when a fetus becomes a child, there is greater agreement on this point, i.e., at birth, than on when life begins	
implication		
implication		
implication		

Prohibitions, part 2

possible revision II	ASRM	Council of Europe
It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer when the product of that transfer is introduced into a woman's womb [~~in order to create a child~~].	It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.	Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
	This is a very straightforward statement but is burdened by implications regarding abortion.	Does not mention any specific type of cloning technology, which may be desirable. Invites definitional issue of when a human being is created.
Violation begins at time of introduction of the product of SCNT into a woman's uterus	Violation occurs at the time of birth (unless one believes that a child is created before birth) and so allows anything up to that point including creating an embryo via SCNT and introducing it into a woman's uterus	The word "seeking" is vague leaving open possibility of inhibiting a range of research involving other forms of cloning.
Would allow creation of an embryo (only with private funding) using SCNT, as long as transfer to woman's uterus does not occur.	Would require abortion at some point before birth	Similar to ASRM prohibition above
Would maintain status quo for private sector IVF research	Would allow embryo research (using private funds), regardless of whether or not the embryo was transferred to a woman for gestation, thus permitting fertility and other biomedical research	Could be used to proscribe a broad range of research involving other forms of cloning.
Would be consistent with current public sector ban on embryo research, precluding opportunity to capitalize on SCNT for research into treatment for spinal cord and other nerve cell regeneration, AIDS, skin grafts, and replacement organs		May prohibit blastomere or embryo splitting; a reproductive technique currently in use in this country, depending on definition of human being

Definitions	Administration	ASRM	ASRM
wording	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.	"somatic cell means a mature, diploid cell."	"the creation of a human child" means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth."
discussion	"Somatic cell" – See alternative definition below. While ours differs from others, it is a reasonable, accurate lay language definition of a technical term. The goal of groups such as ASRM and BIO is to create a more narrow set of definitions in order to protect a rather broad class of research. Ours is not so encumbered, leaving out any oblique references to embryo research.	"Diploid" corresponds to our definition; mature is an addition intended to permit certain types of infertility or other biomedical research. For example, under this definition research might be carried out to improve the efficiency of in vitro fertilization and other treatments for infertility using cells taken from an embryo.	ASRM's intent is to prohibit the birth of a child created using SCNT technology but their definition is unclear with respect to the act of implantation.
		Research of more general interest might be done using cells not yet deemed to be mature, or so-called stem cells, cells which have not yet differentiated into their final form. Embryonic stem cells are cells from an early embryo that can go on to form any cell of the organism. Embryonal stem cells from mice have been grown in culture and can be stimulated to form precursors of blood, nerve and muscle cells. Human embryonal stem cells could be cultured similarly and engineered to prevent transplant rejection.	

OTHER	Administration	possible revision (suggested by Sen. Feinstein's staff)
wording	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:	SECTION 6. PROTECTED BIOMEDICAL RESEARCH AND MEDICAL PRACTICE.—Nothing in this Act shall restrict other areas of biomedical and agricultural research and medical practice, including important and promising work that involves:
discussion		Includes reference to medical practice.

shall be ineligible to receive any contract or subcontract made with funds made available in this Act, pursuant to the debarment, suspension, and ineligibility procedures described in sections 9.400 through 9.409 of title 48, code of Federal Regulations.

SEC. 507. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

[SEC. 508. None of the funds appropriated under this Act shall be expended for any abortion except when it is made known to the Federal entity or official to which funds are appropriated under this Act that such procedure is necessary to save the life of the mother or that the pregnancy is the result of an act of rape or incest.][1]

SEC. [509] *508.* Notwithstanding any other provision of law—

(1) no amount may be transferred from an appropriation account for the Departments of Labor, Health and Human Services, and Education except as authorized in this or any subsequent appropriation Act, or in the Act establishing the program or activity for which funds are contained in this Act;

(2) no department, agency, or other entity, other than the one responsible for administering the program or activity for which an appropriation is made in this Act, may exercise authority for the timing of the obligation and expenditure of such appropriation, or for the purpose for which it is obligated and expended, except to the extent and in the manner otherwise provided in sections 1512 and 1513 of title 31, United States Code; and

(3) no funds provided under this Act shall be available for the salary (or any part thereof) of an employee who is reassigned on a temporary detail basis to another position in the employing agency or department or in any other agency or department, unless the detail is independently approved by the head of the employing department [of] *or* agency.

[SEC. 510. None of the funds made available in this Act may be used for the expenses of an electronic benefit transfer (EBT) task force.]

SEC. [510] *509.* Not to exceed 1 percent of any discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act, as amended) which are appropriated for the current fiscal year for titles I, II, and III of this Act may be transferred between appropriations, but no such appropriation shall be increased by more than 3 percent by any such transfer: Provided, That such transfers may be made only between appropriations within each title: Provided further, That the Public Health and Social Services Emergency Fund appropriation under title II of this Act shall not be subject to the 3 percent limitation of this section.

SEC. [511] *510.* None of the funds made available in this Act may be used to enforce the requirements of section 428(b)(1)(U)(iii) of the Higher Education Act of 1965 with respect to any lender when it is made known to the Federal official having authority to obligate or expend such funds that the lender has a loan portfolio under part B of title IV of such Act that is equal to or less than $5,000,000.

[SEC. 512. (a) None of the funds made available in this Act may be used for—

(1) the creation of a human embryo or embryos for research purposes; or

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term "human embryo or embryos" include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.][2]

SEC. [513] *511.* (a) LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES.—None of the funds made available in this Act may be used for any activity when it is made known to the Federal official having authority to obligate or expend such funds that the activity promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812).

(b) EXCEPTIONS.—The limitation in subsection (a) shall not apply when it is made known to the Federal official having authority to obligate or expend such funds that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that Federally-sponsored clinical trials are being conducted to determine therapeutic advantage.

[SEC. 514. (a) DENIAL OF FUNDS FOR PREVENTING ROTC ACCESS TO CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps (in accordance with section 654 of title 10, United States Code, and other applicable Federal laws) at the covered educational entity; or

(2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

(b) DENIAL OF FUNDS FOR PREVENTING FEDERAL MILITARY RECRUITING ON CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or

(2) access by military recruiters for purposes of Federal military recruiting to the following information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity:

(A) student names, addresses, and telephone listings; and

(B) if known, student ages, levels of education, and majors.

(c) EXCEPTIONS.—The limitation established in subsection (a) or (b) shall not apply to a covered educational entity if the Secretary of Defense determines that—

(1) the covered educational entity has ceased the policy or practice described in such subsection;

(2) the institution of higher education involved has a longstanding policy of pacifism based on historical religious affiliation; or

(3) the institution of higher education involved is prohibited by the law of any State, or by the order of any State court, from allowing Senior Reserve Officer Training Corps activities or Federal military recruiting on campus, except that this paragraph shall apply only during the one-year period beginning on the effective date of this section.

(d) NOTICE OF DETERMINATIONS.—Whenever the Secretary of Defense makes a determination under subsection (a), (b), or (c), the Secretary—

(1) shall transmit a notice of the determination to the Secretary of Education and to the Congress; and

(2) shall publish in the Federal Register a notice of the determination and the effect of the determination on the eligibility of the covered educational entity for contracts and grants.

(e) SEMIANNUAL NOTICE IN FEDERAL REGISTER.—The Secretary of Defense shall publish in the Federal Register once every 6 months a list of each covered educational entity that is currentiy ineligible for contracts and grants by reason of a determination of the Secretary under subsection (a) or (b).

(f) COVERED EDUCATIONAL ENTITY.—For purposes of this section, the term "covered educational entity" means an institution of higher education, or a subelement of an institution of higher education.

(g) EFFECTIVE DATE.—This section shall take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act, by which date the Secretary of Defense shall have published final regulations in consultation with the Secretary of Education to carry out this section.]

[2] The Administration proposes to delete this provision and does not support addressing this issue in legislation.

Human Embryo Research

Continuing Resolution 9 (P.L. 104-91) prohibited Federal funding for the "creation of a human embryo or embryos for research purposes..." and "for research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." The C.R. applied to funding for the entire FY 96. Identical language was placed in FY 97 DHHS Appropriations language (P.L.104-208). The President's FY 97 and 98 budgets proposed deleting the the second provision and did not support addressing this issue in legislation. The first section codifies the President's directive of Dec. 2, 1994. The second section addresses research on all human embryos, regardless of source. The second part goes substantially further in prohibiting a much larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

The second provision applies to embryos the same standards that are currently in place for research involving human fetuses. Research involving human fetuses is governed under DHEW 45 CFR part 46.208(a), "No fetus in utero may be involved as a subject in any activity covered by this subpart unless: (2) The risk to the fetus imposed by the research is minimal, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means." Minimal risk is defined as, "The probability and magnitude of harm or discomfort expected in the research is no greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." **Therefore, research that would involve manipulation of the preimplantation embryo that might result in its death, injury, or harm, is precluded under the Congressional ban, regardless of the source of the embryo.** This includes six of nine applications for funds for research on human in vitro fertilization that might have received NIH funding, in compliance with the President's directive of Dec. 1994.

Taken in sum, both phrases prohibit virtually all human embryo research that might be conducted with Federal funds under other circumstances. Due to the large demand for in vitro fertilization to circumvent certain male and female causes of infertility, there is considerable work under way in this area in the private sector, funded by patients. There are no standards in place governing such procedures, other than FDA requirements for approval of the component drugs and devices.

A preimplantation human embryo exists from a few days after conception until about 3 weeks, at which time implantation occurs. The NIH Human Embryo Research Panel highlighted research involving up to 14-day old embryos because it is at this time that the "primitive streak" appears; a line of cells that will eventually form the nervous system. Prior to development of the primitive streak, the embryo is a disc-shaped collection of cells that have yet to develop specific functions. This multi-function potential makes them especially valuable in the development of a wide range of therapeutic agents for leukemia, sickle cell anemia, Parkinson's disease, diabetes, and spinal cord injury. This field is emerging as one with significant potential to understand human biology and address illness and disease affecting millions of Americans.

CHRISTOPHER S. BOND
MISSOURI
COMMITTEES
APPROPRIATIONS
SMALL BUSINESS
BUDGET
ENVIRONMENT AND
PUBLIC WORKS

Health

United States Senate

WASHINGTON, DC 20510-2503

January 9, 1998

Dear Colleague:

Please join me as a cosponsor of the "Human Cloning Prohibition Act". I intend to introduce the measure when the Senate reconvenes at the end of this month.

Reports this week that a Chicago-based scientist is prepared to move forward with human cloning experimentation forces an immediate debate on how far out on the moral cliff we are willing to let science proceed before we as a nation insist on some meaningful constraints. My legislation will send a strong message that this type of research is clearly unethical and unacceptable by placing an emergency ban on human cloning research.

Plant and animal cloning, and research taking place at the Human Genome Center offer great hope in addressing how to prevent, diagnose, and treat many devastating diseases. However, we must draw the line at human cloning. The belief that all human beings are unique and created by God is shared by billions of us around the world. Human cloning, or man's attempt to play God, would change the very meaning of life, of what it is to be human. Are we ready for that? Hardly.

The United States should show the moral courage and follow the example of several other countries by banning and criminalizing all human cloning research, whether public or private. Recent news accounts show that we no longer have the luxury of waiting for this morally reprehensible act to occur.

If you would like to join me, or if you have any questions, please call me or have your staff contact Joe Pierle of my staff at 4-5721.

Sincerely,

Kit Bond

Christopher S. Bond

(R) MO

DIANNE FEINSTEIN
CALIFORNIA

COMMITTEES ON FOREIGN RELATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

United States Senate
WASHINGTON, DC 20510-0504

Heath

January 15, 1998

Dear Colleague:

I am writing to invite you to join me in cosponsoring legislation to prohibit human cloning, whether funded publicly or privately.

According to recent press reports, Dr. G. Richard Seed, a Chicago-area physicist, announced that he intends to clone a human being and that eight people have already volunteered to be cloned.

I agree with the recommendation of the National Bioethics Advisory Commission, 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 concluded that this technique is not safe to use in humans and that it raises "serious ethical concerns . . . which require much more widespread and careful public deliberation before this technology may be used."

Commendably, President Clinton on March 4, 1997, directed federal agencies not to use federal funds for the cloning of human beings. This prohibition, however, does not extend to privately-funded research and on June 10, the President proposed the Cloning Prohibition Act to cover both the public and private sector.

The legislation I will introduce will make it unlawful, for ten years, for any person or other legal entity, public or private, to use cloning to create human beings. It will also require the National Bioethics Advisory Commission to report to the President and the Congress on the (1) state of the science of somatic cell nuclear transfer and (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 the bill.

I hope you will join me in cosponsoring this bill and working for its prompt enactment. If you have any questions, please feel free to call me or Glenda Booth or Richard Pfohl at 4-3841 on my staff.

Sincerely,

Dianne Feinstein

Dianne Feinstein
U. S. Senator

DF:gb

JUDD GREGG
NEW HAMPSHIRE

CHIEF DEPUTY WHIP

COMMITTEES:
BUDGET
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United States Senate

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99 PEASE BOULEVARD
PORTSMOUTH, NH 03801
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January 14, 1998

Dear Colleague:

When we return for the second session of the 105th Congress, there is an issue that will require our immediate action: the cloning of human beings. I firmly believe that there needs to be an outright prohibition on the possible development of this procedure. Current law prohibits federal funds going toward human embryo research, but we must clearly now extend the ban to private activities as well. That is why I will be introducing legislation upon our return to ban human embryo creation by the process of cloning.

It has been almost 12 months since the world learned that, after 276 unsuccessful attempts, Dr. Ian Wilmut of the Roslin Institute in Scotland had actually managed to clone a sheep that became known as "Dolly." Since that time, the debate has gone from the theoretical to the possible implications of this ability to clone living beings. However, the overwhelming consensus has been that while cloning may hold some important scientific promise for producing therapies where they may not exist -- such as growing skin from skin cells for burn victims -- as well as potential for important agricultural and botanical advances, there is little tolerance for those who entertain the notion of reproducing human "carbon copies."

My legislation is modeled on a law that was enacted last year in the State of California, that became effective January 1, 1998. Similar to the California law, my bill makes the cloning of a human being unlawful. My bill differs from the California law, however, in that it outlaws human embryo creation even for the purpose of research. My proposal does allow certain genetic research that does not involve cloning human embryos to continue. This legislation sets up a system of penalties for the violation of this law that will serve as a deterrent for such activities in either the public or the private sector.

I hope that you will join me as a cosponsor of this legislation, which I will circulate shortly. I do not believe that we here in the Senate have the luxury of time on this issue. I hope to see this legislation considered expediently upon our return. If you are interested in being a cosponsor, please contact Kimberly Spaulding or Alan Gilbert of my staff at 4-0136.

Sincerely,

Judd Gregg
U.S. Senator

Submitted 6/9/97

A BILL

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

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

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

SECTION 2. FINDINGS.

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

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

(1) NBAC has found that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 4. DEFINITIONS.

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

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

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

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

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

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

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

SECTION 7. PENALTIES.—

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

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

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

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

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

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

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

Bio

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

PLEDGE BY BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) TO SUPPORT MORATORIUM ON CLONING OF A HUMAN BEING

March 27, 1997

The Honorable William J. Clinton
President of the United States
The White House
Washington, D.C. 20500

Dear Mr. President:

The recent cloning of a sheep from the genetic material of an adult cell has riveted the world. Previously, researchers had reported using genetic material from animal embryos to create new organisms. But, as you observed, this latest development raises profound new issues. When two individuals are created from the same embryonic genetic material, identical twins result. We are quite familiar with identical twins in our everyday lives. However, "Dolly" raises new prospects for which we are not so adequately prepared. While our everyday lives may include identical twins of the same age, we have never experienced identical twins substantially different in age, indeed, perhaps alive during entirely different periods in history. In our everyday lives we may decide to procreate a child and wait in wonder and awe to see the unique individual he or she will turn out to be. We do not, on the other hand, have experience creating a child where part of that decision may include an evaluation of the life, health, character and accomplishments of an adult from whom we will take the genetic material that will become the child's entire genetic makeup.

These new prospects challenge some of the most fundamental concepts we hold about ourselves as social and spiritual beings. These concepts include what it means to be a parent, a brother or sister, a family. We believe that it was in response

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to this moral and spiritual challenge that you requested the nation's biomedical research community to agree to a voluntary moratorium on the cloning of human beings until the National Bioethics Advisory Commission can review the meaning of this scientific breakthrough. We share your desire for a reflective examination of the moral issues raised by Dolly. We support this moratorium on cloning human beings.

In the days since the announcement of Dolly, the potential benefits to be derived from cloning procedures in agricultural and laboratory animal species have been widely discussed. Cloning, the duplication of specific genes and individual types of cells -- is an essential tool in biotechnology. The techniques involved are integral to the process used to produce breakthrough medicines, diagnostics and vaccines to treat heart attacks, various cancers, kidney disease, diabetes, hepatitis, multiple sclerosis, cystic fibrosis and other diseases. More than 100 million people worldwide have already benefited from biotechnology medicines and vaccines.

There is also valuable research into cloning human cells, organs and other tissue. This could produce replacement skin, cartilage and bone tissue for burn and accident victims. This avenue of study may produce cells for cancer therapy and result in ways to regenerate retinal or spinal cord tissue. Research is also under way to develop replacement internal organs in transgenic animals for human transplantation.

Perhaps even more important, human cells used in a subset of the cloning procedures -- that is, procedures that by themselves could not create a new human being -- could provide profound new insights into how genes control human development. These fundamental insights, in the decades ahead, will provide the basis for even greater biomedical advances in the service of humanity.

Mr. President, we are pleased to report that the Board of Directors of the Biotechnology Industry Organization fully supports your call for a moratorium on research efforts undertaken for the purpose of cloning a human being while the National Bioethics Advisory Commission considers the implications of Dolly. But we firmly believe that research involving duplication of cellular material has such enormous potential benefits for society that it should proceed without hindrance. Accordingly, we ask you to oppose, as we do, any hastily drafted laws to ban the cloning of human beings that may, however well intentioned, inadvertently also ban this valuable research.

Sincerely,

Henri A. Termeer
Chairman

Carl B. Feldbaum
President

PLEDGE BY AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE (ASRM) TO SUPPORT MORATORIUM ON CLONING OF A HUMAN BEING

At its October 18, 1997 meeting, The Board of Directors of The American Society for Reproductive Medicine approved a voluntary moratorium on cloning human beings.

Resolved: The American Society for Reproductive Medicine declares a voluntary five-year moratorium on cloning human beings, where "cloning human beings" is defined as the duplication of an existing or previously existing human being by transferring the nucleus of a differentiated, somatic cell into an enucleated human oocyte, and implanting the resulting product for intrauterine gestation and subsequent birth.

In addition, the following statement was issued on June 5 (date of releaase of NBAC report)

FOR IMMEDIATE RELEASE: CONTACT: Heather E. Kowalski June 5, 1997
(202) 863-2439 Hkowalski@asrm.com

ASRM STATEMENT ON HUMAN CLONING THROUGH NUCLEAR TRANSPLANTATION

(Washington, DC) -- The American Society for Reproductive Medicine (ASRM) is issuing the following statement:

The American Society for Reproductive Medicine (ASRM) finds the practice of cloning an existing human being unacceptable. However, ASRM believes that the broader field of human embryo research is acceptable and important, and guidelines both promoting and limiting the research should be set on the national level. The current moratorium on federal funding of human embryo research should be overturned and oversight for such research should be given to the National Institutes of Health.

The American Society for Reproductive Medicine (ASRM)), founded in 1944, has more than 10,000 members who are devoted to advancing knowledge and expertise in reproductive medicine and biology, including obstetrician-gynecologists, urologists, endocrinologists, research scientists, medical technologists, and allied health professionals.

# # #

PLEDGE BY THE FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY (FASEB) TO SUPPORT MORATORIUM ON CLONING OF A HUMAN BEING

For more information, contact:
Howard Garrison, 301/571-0657

September 18, 1997

FASEB ENDORSES VOLUNTARY MORATORIUM ON CLONING HUMAN BEINGS

Bethesda, Md -- Federation of American Societies for Experimental Biology (FASEB) President Ralph G. Yount announced the adoption of a voluntary moratorium on cloning human beings. Members of FASEB's Public Affairs Executive Committee, representing the 14 member societies of the Federation, unanimously voted in favor of the following statement at a recent meeting:

> RESOLVED: The Federation of American Societies for Experimental Biology (FASEB) adopts a voluntary five year moratorium on cloning human beings, where "cloning human beings" is defined as the duplication of an existing or previously existing human being by transferring the nucleus of a differentiated, somatic cell into an enucleated human oocyte, and implanting the resulting product for intrauterine gestation and subsequent birth.

In accord with the recommendations by the National Bioethics Advisory Commission, this moratorium will be in effect for a period of five years, with subsequent reconsideration for possible extension.

Yount, a Professor of Biochemistry and Chemistry at Washington State University, noted that the Federation adopted this moratorium for several important reasons.

> "First and foremost," stated Yount, "we seek to reassure Americans that biologists have no intentions of cloning human beings. Indeed, we would regard cloning a human being as an unethical and reprehensible act. But, we have also recognized that there is a role for us -- as scientists -- to play in this debate. We need to ensure that imprecise or misused technical language is not included in legislation designed to prevent the cloning of human beings. If

enacted, such laws could hinder vital biomedical research that can lead to the repair of diseased and damaged human tissues and organs, and to possible cures for diabetes, cancer, Parkinson's Disease and other neurodegenerative diseases."