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Cloning [3]

Stack:	Row:	Section:	Shelf:	Position:
S	26	7	11	2

Senator Dianne Feinstein
Ranking Minority Member
Senate Judiciary Committee
Technology, Terrorism and Government
Information Subcommittee
Hart 807
Washington, D.C. 20510
Tel # (202) 224-4933 Fax # 228-0466

Facsimile Cover Sheet

TO: **Lucia Wyman**

January 30, 1998
2:00 pm

FAX NUMBER: **456-2604**

PHONE NUMBER:

FROM: **Richard Pfohl**
Counsel
(202) 224-6443

SUBJECT: **Latest Draft Human Cloning Bill**

TOTAL NUMBER OF PAGES SENT: **10**

If you do not receive all pages, please call: **(202) 224-6443**

COMMENTS:

As we discussed, following is the most recent draft. Please keep it confidential for now.

Thanks,
Richard

O:\BAI\BAI98.133 S.L.C.

DRAFT

105TH CONGRESS
2D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mrs. FEINSTEIN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To prohibit any attempt to clone 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 "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 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; and

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

SEC. 4. DEFINITIONS.

In this Act:

(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 has been removed or rendered inert.

SEC. 5. PROHIBITION.

It shall be unlawful for any person or other legal entity, public or private, to implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus.

SEC. 6. PROTECTED BIOMEDICAL RESEARCH

Nothing in this Act shall be construed to restrict areas of biomedical and agricultural research or practices not expressly prohibited in this Act, 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 or cytoplasmic therapy; or

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

SEC. 7. PENALTIES.

(a) IN GENERAL.—Any person who intentionally violates the provisions of section 5 shall be fined the greater of $250,000 or 2 times the gross pecuniary gain or loss resulting from the violation.

(b) CIVIL ACTIONS.—If a person is violating or about to violate the provisions of section 5, the Attorney General may commence a civil action in an appropriate Federal district court to enjoin such violation.

(c) FORFEITURE.—Any property, real or personal, derived from or used to commit a violation or attempted violation of the provisions of section 5, 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.

(d) AUTHORITY.—The Attorney General shall have exclusive, nondelegable enforcement authority under this Act.

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

SEC. 8. 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 section 5.

SEC. 9. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT.

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

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

(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 under this Act.

(b) OTHER REPORTS.—The National Bioethics Advisory Commission may produce reports in addition to the

reports required under subsection (a) if the Commission determines that such reports are useful to clarify any of the topics described in subsection (a), address changes in the state of science or society, or modify or clarify the recommendations of the Commission.

(c) CONTINUATION OF COMMISSION.—The National Bioethics Advisory Commission is authorized to continue for the 10-year period described in section 12 to prepare reports under this section and for other purposes as established in Executive Order 12975 and subsequent amendments to such Order.

SEC. 10. RIGHT OF ACTION.

Nothing in this Act shall be construed to give any individual or person a private right of action.

SEC. 11. PREEMPTION OF STATE LAW.

The provisions of this Act shall preempt any State law that prohibits or limits research or practices regarding somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, tissues, or organs, or the use of somatic cell nuclear transfer techniques to develop animals.

SEC. 12. EFFECTIVE DATE.

This Act shall be effective for the 10-year period beginning on the date of enactment of this Act. The prohibi-

tions contained in this Act shall terminate at the expiration of such 10-year period.

Rachel E. Levinson 02/03/98 03:53:58 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Bond bill

I have copies of the Bond bill available in Room 436. It is unclear in intent but appears to prohibit a much broader range of activities than our June draft. It has internal inconsistencies that would appear to make it difficult to determine if any research involving the use of human cells in somatic cell nuclear transfer might be carried out. The bulk of the language is devoted to establishing a Commission to promote a national dialogue on bioethics.

I hope to get a draft letter on Kennedy-Feinstein around shortly. That bill will dropped "shortly" but probably not today.

Message Sent To:

Toby Donenfeld/OVP @ OVP
Wendy A. Taylor/OMB/EOP
gips_d @ a1.eop.gov @ inet
Clifford J. Gabriel/OSTP/EOP
Jeffrey M. Smith/OSTP/EOP
Lucia A. Wyman/WHO/EOP
Thomas L. Freedman/OPD/EOP
Jerold R. Mande/OSTP/EOP
William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

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.

105TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

Mr. BOND (for himself, Mr. FRIST, and Mr. GREGG) introduced the following bill; which was read twice and referred to the Committee on _____

Lott, Hutchison, Kay Bailey, Shelby, Lugar, Nickles, Gramm (MN)

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 somatic cell nuclear transfer technology, it is right and proper to prohibit 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. 2. PROHIBITION ON CLONING.

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

"CHAPTER 16—CLONING

"Sec.
"301. Prohibition on 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 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 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 '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 8 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 subsistance 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 participation and discourse concerning important bioethical issues including cloning, and provide for a report to Con-

gress 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 Commission. 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 personnal 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 3 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

1 to prohibit the use of somatic cell nuclear transfer tech-
2 nology to produce a human embryo.

Ergothics Commission

Bond doesn't want to sunset crim

Meeting And Closing 2/3

*(1) Process call to Jennifer Van Horn - Trust
call Jane - Bill 14 not And 1 due to Fri

(2) Jane/SDr prep for call to Trust on science

(3) options on bill - sunset &/or exception

(4) amendments to Bill

(5) letter to Feinstein from HHS

(6) SDP reference one leg

(7) HHS delay

(8) House Commerce Feb. 12
Hearing Closing

Mack ask
? WR out or
delay for input from
research scientists.

Hatch

support Frist statements
but concerned that Vac
bill ~~doesn't~~ hasn't had
hearings!!

Frist - what he says his bill does -

(1) Permanent 24 ethical commissioners
3 yrs term

---

(1) whip ~~do~~ ~~for~~ to sustain
Feinstein
(2) ~~we~~ ~~table~~ ~~to~~ ~~tab~~
table bill to send
back thru approp process
(3) amendments

May get Hatch & Mack on
procedure

Rachel E. Levinson 02/04/98 01:23:21 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: draft cloning letter for discussion at 4 today

I commend you on your introduction of S. 1602 the "Prohibition on Cloning of Human Beings Act of 1998." If enacted, this bill would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research. The bill, which closely parallels the bill I submitted last June, also follows the findings and recommendations presented to me by my National Bioethics Advisory Commission. I said then and reaffirmed this belief in my January 10 radio address that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. I called on Congress to enact legislation making it illegal for anyone to clone a human being at this time. I am pleased to see your response to my challenge.

Trying to draft a bill that walks the fine line between defining the unacceptable act of producing a child that is the genetic replica of another person, while protecting biomedical and agricultural research is a formidable task. My bill offered one way to achieve those dual goals; your bill clearly reaches for the same result. In this case, imprecise wording carries the threat of impeding research that might one day offer hope to those suffering from spinal cord injury, Parkinson's disease, diabetes or AIDS. We must not make such a mistake in our haste to close the doors to those who would subvert this promising new technology by using it for unethical purposes.

I am also pleased that you have heeded my proposal to put a time limit on this prohibition. The sunset provision ensures a continuing examination of the risks and benefits of this technology, while we are free from worry that someone will use it prematurely.

Society shouldn't make decisions about the application of a specific technology without first understanding its full potential, both good and bad. Asking the National Bioethics Advisory Commission to return to this complex issue in four and one-half years will promote a deeper awareness of the power we hold to alleviate the burden of human illness and a broader debate on the ethical and moral limits we ought to impose on exercising that power. We are not ready to answer these enormously challenging questions today.

That is why we must act now to reassure the public that this government will not tolerate anyone using somatic cell nuclear transfer to create a child. I thank you for your efforts on

behalf of the American people and look forward to signing this bill.

Message Sent To:

Toby Donenfeld/OVP @ OVP
Wendy A. Taylor/OMB/EOP
gips_d @ a1.eop.gov @ inet
Clifford J. Gabriel/OSTP/EOP
Jeffrey M. Smith/OSTP/EOP
Lucia A. Wyman/WHO/EOP
Thomas L. Freedman/OPD/EOP
Jerold R. Mande/OSTP/EOP
William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

Rachel E. Levinson 02/03/98 04:35:24 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: BIO's analysis

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 02/03/98 04:34 PM ----------

cludlam @ mail.bio.org
02/03/98 02:31:57 PM

Record Type: Record

To: levinson

cc:
Subject: analysis

ANALYSIS OF BOND/FRIST/GREGG
HUMAN CLONING BILL

First Issue: The Bond/Frist/Gregg human cloning bill bans the act of "producing an embryo (including a preimplantation embryo)" through the use of a specified technology (somatic cell nuclear transfer). It would ban the production of this embryo even if the production of such an embryo is for purposes completely unrelated to the cloning of a human being.

The bill, therefore, would effectively ban some research to generate stem cells for the following types of treatments:

cardiac muscle cells to treat heart attack victims and degenerative heart disease;

skin cells to treat burn victims;

spinal cord neuron cells for treatment of spinal cord trauma and paralysis;

neural cells for treating those suffering from neurodegenerative diseases;

pancreas cells to treat diabetes;

blood cells to treat cancer anemia, and immunodeficiencies;

neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS);

cells for use in genetic therapy to treat 5,000 genetic diseases, including Cystic Fibrosis,

Tay-Sachs Disease, schizophrenia, depression, and other diseases;
blood vessel endothelial cells for treating atherosclerosis;
liver cells for liver diseases including hepatitis and cirrhosis;
cartilage cells for treatment of osteoarthritis;
bone cells for treatment of osteoporosis;
myoblast cells for the treatment of Muscular Dystrophy;
respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer;
adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration;
modified cells for treatment of various genetic diseases; and
other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions.
To be precise, the bill would ban the generation of stem cells for these purposes where the stem cells have nuclear DNA from a "human somatic cell" -- see critical discussion below and somatic cell nuclear transfer technology was used.

It would not ban stem cell research where the stem cell is generated without the use of somatic cell nuclear transfer or does not involve nuclear DNA from a "human somatic cell" -- again, see the critical discussion below.

If the legislation is limited to somatic cells with nuclear DNA identical to that of an existing or previously exisiting human being -- again, see critical discussion below -- the specific type of stem cells research which is banned is "customized" stem cell research. A researcher or doctor might want to create a human zygote with DNA identical to that of an existing or previously existing person through the use of somatic cell nuclear transfer -- the act prohibited in the Bond/Frist/Gregg bill -- in order to create a customized stem cell line to treat the individual from whom the DNA was extracted. By using the same DNA the stem cell would be more likely to be compatible and not rejected by the person when the stem cell is transferred (back) to the person for the treatment.

The statement released by Senators Bond/Frist/Gregg about the impact of their bill on biomedical research is technically accurate but highly misleading. The title of the document is "CURRENT RESEARCH UNTOUCHED BY THE BOND/FRIST/GREGG LEGISLATION" and it is followed by a list of such research, including "In Vitro Fertilization," "Stem Cell Research," "Gene Therapy," "Cloning of Cells, Tissues, Animals and Plants," "Cancer," "Diabetes," "Birth Defects," "Arthritis," "Organ Failure," "Genetic Disease," "Severe Skin Burns," "Multiple Sclerosis," "Muscular Dystrophy," "Spinal Cord Injuries," "Alzheimer's Disease," "Parkinson's Disease," and "Lou Gehrig's Disease." The title to this document includes a critical qualification -- an asterisk. The asterisk qualification states, "The Bond/Frist/Gregg bill would not prohibit any of this research, even embryo research, as long as it did not involve the use of a very specific technique (somatic cell nuclear transfer) to create a live cloned human embryo."

This qualification swallows the list. It acknowledges that the bill would, in fact, ban some types of stem cell research and other research, as explained above. Given the importance of the asterisk, the title to the document and the list of protected research are highly misleading.

The statement of Senators Bond/Frist/Gregg is a challenge to patient disease groups to seek to include in the legislation a specific guarantee that research on the diseases they list is not, in fact, stifled. Such an exemption might read as follows:

"NOTHING IN THIS ACT shall apply where the acts or research are for the purpose of producing or generating stem cells to treat or diagnose deadly or disabling diseases and other medical conditions including the following: cardiac muscle cells to treat heart attack victims and degenerative heart disease; skin cells to treat burn victims; spinal cord neuron cells for treatment of spinal cord trauma and paralysis; neural cells for treating those suffering from neurodegenerative diseases; pancreas cells to treat diabetes; blood cells to treat anemia, immunodeficiencies, and cancer; neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS); cells for use in genetic therapy to treat 5,000 genetic diseases, including Cystic Fibrosis, Tay-Sachs Disease, schizophrenia, depression, and other diseases; blood cells for use in treating patients with cancer, anemia, or immunodeficiency diseases; blood vessel endothelial cells for treating atherosclerosis; liver cells for liver diseases including hepatitis and cirrhosis; cartilage cells for treatment of osteoarthritis; bone cells for treatment of osteoporosis; myoblast cells for the treatment of Muscular Dystrophy; respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer; adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration; modified cells for treatment of various genetic diseases; and other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions; or for the purpose of conducting scientific research into the mechanisms of interaction between the genes and their intracellular and extracellular environments in order to control and redirect the specialization of somatic cells into novel treatments or diagnostic products for deadly or disabling diseases and other medical conditions."

If Senators Bond/Frist/Gregg are, in fact, determined to protect this research, they could not object to including this explicit guarantee in their bill.

The stem cell technology is exciting and potentially revolutionary. Scientists are developing an entirely new approach for treating human diseases that depend not on drugs like antibiotics but on living cells that can differentiate into blood, skin, heart, or brain cells and potentially treat cancers, spinal cord injuries, or heart disease. This research -- called stem cell research -- holds the potential to develop and improve cancer treatments by gaining a more complete understanding of cell division and growth and the process of metastasis. This could also lead to a variety of cancer treatment advances.

The kinds of cells that make up most of the human body are differentiated, meaning that they have already achieved some sort of specialized function such as blood, skin, heart or brain cells. The precursor cells that led to differentiated cells come from the embryo. They are called stem cells because functions stem from them like the growth of a plant. Stem cells have the capacity for self-renewal, meaning that they can produce more of themselves, and differentiation, meaning that they can specialize into a variety of cell types with different functions. In the last decade, scientists studying mice and other laboratory animals have discovered powerful new approaches involving cultured stem cells. Studies of such cells obtained from mouse stem cells show that they are capable of differentiating in vitro or in vivo into a wide variety of specialized cell types. Stem cells have been derived by culturing cells of non-human primates and promising efforts to obtain human stem cells have also recently been reported.

Stem cell research has been hailed as the "[m]ost tantalizing of all" research in this field. The reason for this is because adults do not have many stem cells. Most cells are fully differentiated into their proper functions. When differentiated cells are damaged, such as cardiac muscle when someone suffers a heart attack, the adult cells do not have the ability to regenerate. If stem cells could be derived from human sources and induced to

differentiate in vitro, they could potentially be used for transplantation and tissue repair.

Using the heart attack sufferer as an example, we might be able to replace damaged cardiac cells with healthy stem cells that could differentiate into cardiac muscle. Research with these stem cells could lead to the development of "universal donor cells" of invaluable benefit to patients. Stem cell therapy could make it possible to store tissue reserves that would give health care providers a wholly new and virtually endless supply of the cells listed above. The use of stem cells to create these therapies would lead to great medical advances. We have to be sure that nothing we do in this legislation concerning human cloning would obstruct in any way this vital research.

Second Issue: The bill bans the use of somatic cell nuclear to transfer a "human somatic cell" but it does not state that this is limited to somatic cell which contains nuclear DNA identical to that of an existing or previously existing person. This means that the bill is not limited to cloning (creating a person or embryo with nuclear DNA identical to that of someone else), but would also apply to the use of somatic cell nuclear transfer of nuclear DNA which is not identical. It would, in fact, prohibit the use of somatic cell nuclear transfer where the nuclear DNA is the product of normal, sexual reproduction -- that is the opposite of cloning. It would also prohibit the use of somatic cell nuclear transfer where the somatic cell had been modified in some way prior to the use of somatic cell nuclear transfer. In short, the bill prohibits a broad range of uses of somatic cell nuclear transfer having nothing whatever to do with cloning, such as use of this technology to treat mitochondrial disease.

Message Sent To:

Toby Donenfeld/OVP @ OVP
Wendy A. Taylor/OMB/EOP
gips_d @ a1.eop.gov @ inet
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From Kennedy staff

HUMAN CLONING BAN COMPARISON: S. 1602 (FEINSTEIN/KENNEDY) AND S. 1599 (BOND)

Scientific issues

Both bills deal with the use of the cloning technology called "somatic cell nuclear transfer". Somatic cell nuclear transfer means taking the nucleus (which contains the DNA or genes) from a somatic cell (a mature cell, not an egg or sperm cell) and putting that nucleus into an egg cell from which the original nucleus has been removed. **The product of somatic cell nuclear transfer is not a fertilized egg**. Rather, it is an unfertilized egg cell that contains DNA from another source, such as an adult human being. If this egg cell is implanted into a woman's womb, it will develop into a baby. But if that cell is instead grown under special laboratory conditions, it does not become a baby but instead becomes a specific tissue, such as muscle, nerve, or skin. This would allow us to make genetically-identical tissues and organs for treatment of a vast array of diseases. **It is important to understand that we can chose whether the product of somatic cell nuclear transfer becomes a human child or becomes a tissue for medical use. This technology does not create "wasted embryos".**

The Bond bill bans the **act of somatic cell nuclear transfer**. (The authors of the Bond bill define the product of somatic cell nuclear transfer as an embryo.) In contrast, the Feinstein-Kennedy bill bans the **implantation of the product of somatic cell nuclear transfer** into a woman's womb. This distinction means that **the Bond bill, but <u>not</u> the Feinstein-Kennedy bill, will ban:**

1. The production of genetically-identical tissues for treatment of disease and transplantation. This tissue will not be rejected by the patient since it is can be made from the patient's own DNA and will not require the recipient to take immunosuppressive drugs. This could lessen the strain on the organ donation system and eliminate the risk of transmission of viruses. It will also decrease the need for fetal tissues. Treatments which could use this tissue include:

- Blood cell therapies for diseases such as leukemia and sickle cell anemia
- Nerve cell therapies for neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease, Lou Gehrig's disease, and multiple sclerosis
- Nerve cell therapies for spinal cord injuries
- Islet cell transplants for diabetes
- Skin cell transplants for severe burns
- Liver cell transplants for liver damage
- Muscle cell therapies for muscular dystrophy and heart disease
- Cartilage cells for reconstruction of joints damaged by arthritis or injuries

2. Use of somatic cell nuclear transfer for non-cloning purposes which treat diseases carried in the cytoplasm (the non-nuclear material in a cell). Parents whose children would otherwise inherit cytoplasmic diseases can have healthy children using a

variation on somatic cell nuclear transfer. After standard in vitro fertilization from egg and sperm cells, the nucleus from the resulting cell is transferred into a fresh egg cell that does not carry the cytoplasmic disease. This is not cloning- it is curing a disease. This therapy would be banned by the Bond bill.

Length of ban

The Bond bill is a permanent ban.
The Feinstein-Kennedy bill is a ten year ban.

Bioethics commission

The Bond bill creates a new permanent committee, the National Commission to Promote a National Dialogue on Bioethics. This committee would operate within the Institute of Medicine and issue annual reports. The Feinstein-Kennedy bill utilizes an already existing entity, the National Bioethics Advisory Commission. NBAC will issues reports at four and one-half and nine and one-half years.

Penalties

Violations of the Bond bill include sentencing of up to ten years in prison and a fine of not more than two times the gross pecuniary gain.

Violations of the Feinstein-Kennedy bill include a fine of the greater of $1,000,000 or three times the gross pecuniary gain or loss; civil actions; and forfeiture of property.

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.".

NIH.

Review of Senate Bill: "Human Cloning Prohibition Act of 1998"

As of February 2, 1998, Senators Bond, Frist, Gregg, Lott, Hutchison, Lugar, Nickles are co-sponsors of the bill.

Summary: This bill does two things. It bans human somatic cell nuclear transfer technology for the purpose of creating an embryo and it creates a new Bioethics Commission which is accountable to Congress. More details and comments on each of these provisions follow.

Prohibition on cloning:

The language:

1. The bill makes it unlawful "for any person or entity, public or private, in or affecting interstate commerce, to use human somatic cell nuclear transfer technology." Somatic cell nuclear transfer technology is defined as: "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)."
2. Importation of an embryo made using this technology is also banned.

Comments:

- This is a straight forward banning of the technology of somatic cell nuclear transfer in humans for the purpose of making an embryo
- The term embryo is not defined, but the fact that they specify "including preimplantation embryo" suggests that embryo would include the single cell egg with a full complement of DNA.

Commission to Promote a National Dialogue on Bioethics

The language:

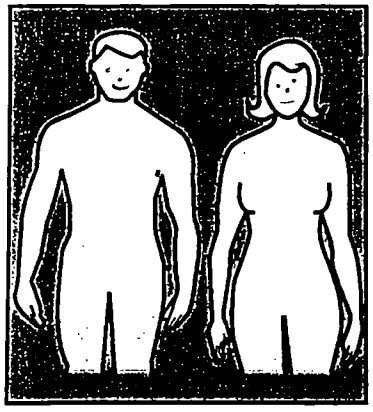
1. Establishes within the IOM a commission called "the National Commission to Promote a National Dialogue on Bioethics." This Commission:

- will have 25 members appointed by the Senate and House leadership, with equal representation from Democrats and Republicans. These members are to represent law, theology, philosophy *or* ethics, medicine, science and society
- will "provide an independent forum for broad public participation and discourse concerning important bioethical issues including cloning,
- report to Congress concerning the findings, conclusions, and recommendations of the Commission concerning Federal policy and "possible Congressional action."
- "may hold public hearings and undertake such other activities" as they determine necessary

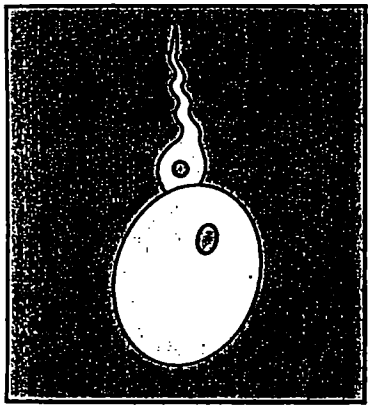
- secure directly from any Federal agency information necessary...as long as the information may be disclosed under section 552 of Title 5
- will establish 6 subcommittees: legal, theological, philosophical and ethical, medical, scientific and social issues.
- will report to Congress no later than 12/31/99 and annually thereafter a detailed statement of recommendations, findings, and conclusions

Comments:

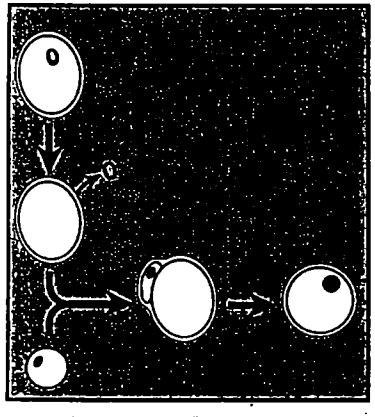
- this is a duplication of NBAC. The main difference is that the new Commission would be a Congressional body and not part of the Executive branch
- there is no comment regarding the relationship of the new Commission with NBAC.
- the new Commission could have a very influential advisory role. How much power would this Commission wield?
- there is little description of public discourse other than the fact that the Commission "may" hold public meetings. This needs clarification.



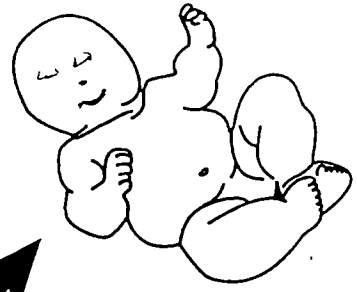
Man and Woman



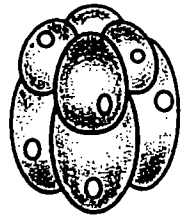
In Vitro Fertilization



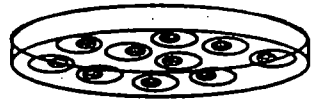
Somatic Cell Nuclear Transfer



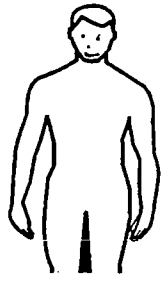
New Human Being



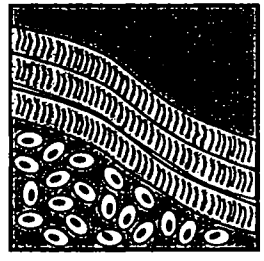
Early Embryonic Cells



Specialized Cells



Adult



Therapeutic Tissue

DRAFT

Draft letter to Senator Feinstein (04II98)

I am responding to your oral request for comments from a science perspective on your proposed legislation "Prohibition on Cloning of Human Beings Act of 1998".

Scope of the Prohibition: The scope of the proposed prohibition ("... to implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus.") is unambiguous as to the specific acts it would ban; and the phrasing avoids the ambiguity inherent in use of the word "intent". However, I note that, as the relevant science base grows, the practical effect of the ban may go beyond the cloning of human beings. In particular, as animal research yields progressively greater insight into the uses and limitations of somatic cell nuclear transfer, potential non-cloning uses of this technology may become possible – e.g., new modalities of assisted reproduction that employ somatic cell nuclear transfer to overcome mitochondrial or other cytoplasmic defects in human oocytes.

Several important arenas of research seem to fall outside the scope of the proposed prohibition. Privately funded scientists or clinicians would continue to be permitted to create and study in vitro those products of somatic cell nuclear transfer that involve a human oocyte. Moreover, scientists or clinicians, irrespective of their sources of funding, would continue to be permitted to create and study in vitro those products of somatic cell nuclear transfer that do not involve a human oocyte.

Definitions: The inclusion of the word "genetic" in the definition of "cloning" seems unnecessary. Absent the word "generic", the definition would be essentially identical to that used by the National Bioethics Advisory Commission (NBAC) in its report entitled Cloning Human Beings.

The definition of "nucleus" ends with the phrase "and thus the genes". To be precise, it could be expanded to say "except for those contained in mitochondria, which reside in the cytoplasm".

The term "somatic cell" covers developing diploid cells as well as mature diploid cells. The NBAC report (page 1) defines "somatic cell" as "any cell of the embryo, fetus, child, or adult which contains a full complement of two sets of chromosomes, in contrast with a germ cell, i.e., an egg or a sperm, which contains only one set of chromosomes".

Other Comments: In the section on "Protected Biomedical Research", inserting the adjective "non-human" before "animals" would eliminate an ambiguity. Also, in the "Penalties" section, the use of the phrase "attempted violation" seems redundant in light of the fact that the proposed prohibition covers not only implantation but also the attempt.

From

[redacted]

Science guy

DRAFT – NOT FOR RELEASE

February 4, 1998
(Senate)

S. 1601 - Human Cloning Prohibition Act
(Sen. Lott (R) MS)

On June 9, 1997, the President transmitted to Congress legislation making it illegal for anyone to clone a human being. The President believes that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. The Administration, however, opposes enactment of S. 1601 because it would have the ill-advised effect of permanently impeding significant scientific research in critical areas such as finding cures for diseases, enhancing treatments for infertility, and transplanting tissue and organs.

Instead, the Administration strongly supports enactment of the Feinstein/Kennedy amendment that will be offered as a substitue for S. 1601. The Feinstein/Kennedy amendment, which is based on the President's proposal, would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research.

Pay-As-You-Go Scoring

S.1601 could affect receipts; therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990. OMB's preliminary scoring estimate of this bill is zero.

* * * * * * * * * *

Rachel E. Levinson 02/04/98 05:20:54 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: amendments

Possible amendments include:

- Adding sunset (preferably 5 years as in Administration bill)
- Adding a list of exceptions like the following:

["( ) Subsection [( )] and [( )] shall not apply where the creation of the embryo is for the purpose of producing or generating stem cells to treat or diagnose deadly or disabling diseases and other medical conditions including the following: cardiac muscle cells to treat heart attack victims and degenerative heart disease; skin cells to treat burn victims; spinal cord neuron cells for treatment of spinal cord trauma and paralysis; neural cells for treating those suffering from neurodegenerative diseases; pancreas cells to treat diabetes; blood cells to treat anemia, immunodeficiencies, and cancer; neural cells to treat Parkinson's, Huntington's and amyotrophic lateral sclerosis (ALS); cells for use in genetic therapy to treat 5,000 genetic diseases, including cystic fibrosis, Tay-Sachs disease, schizophrenia, depression, and other diseases; blood cells for use in treating patients with cancer, anemia, or immunodeficiency diseases; blood vessel endothelial cells for treating atherosclerosis; liver cells for liver diseases including hepatitis and cirrhosis; cartilage cells for treatment of osteoarthritis; bone cells for treatment of osteoporosis; myoblast cells for the treatment of Muscular Dystrophy; respiratory epithelial cells for the treatment of cystic fibrosis and lung cancer; adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration; modified cells for treatment of various genetic diseases; and other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions; or for the purpose of conducting scientific research into the mechamisms of interaction between the genes and their intracelluar and extracellular enviroments in order to control and redirect the specializiation of somatic cells into novel treatments or diagnostic products for deadly or disabling diseases and other medical
conditions.]

- Penalties--delete criminal and insert the following:

(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.

- Delete reference to establishment of Commission

Message Sent To:

Toby Donenfeld/OVP @ OVP
Wendy A. Taylor/OMB/EOP
gips_d @ a1.eop.gov @ inet
Clifford J. Gabriel/OSTP/EOP
Jeffrey M. Smith/OSTP/EOP
Lucia A. Wyman/WHO/EOP
Thomas L. Freedman/OPD/EOP
Jerold R. Mande/OSTP/EOP
William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP
Robert J. Pellicci/OMB/EOP

OFFICE OF SCIENCE AND TECHNOLOGY POLICY
Science Division
Executive Office of the President
436 Old Executive Office Building
Washington, DC 20502

202-456-6130
202-456-6027 (FAX)

FAX TRANSMITTAL SHEET

DATE:

TO: Lucia

PHONE NUMBER:

FAX NUMBER:

FROM: Mandc GC018

NUMBER OF PAGES (INCLUDING COVER SHEET):

DRAFT -- NOT FOR RELEASE

DRAFT

February 5, 1998
(Senate)

S. 1601 - Human Cloning Prohibition Act
(Sen. Lott (R) MS)

On June 9, 1997, the President transmitted to Congress legislation making it illegal for anyone to clone a human being. The President believes that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. The Administration, however, has a number of serious concerns about S. 1601 and looks forward to working with the Congress to address these concerns. Specifically, the Administration supports amendments to S. 1601 that would:

-- Include a five year sunset on the prohibition on human somatic cell nuclear transfer technology. The sunset provision ensures a continuing examination of the risks and benefits of this technology, while being free from the worry that someone will use it prematurely.

-- Permit the ~~creation of an embryo for~~ use of SCNT in humans for the purpose of producing or generating ~~stem~~ cells to treat or diagnose deadly or disabling diseases and other medical conditions, including the treatment of cancer, diabetes, genetic diseases, and spinal cord injuries.

-- Repeal the bill's criminal penalties and instead make any property, real or personal, derived from or used to commit violations of the Act subject to forfeiture to the United States.

-- Repeal the bill's provisions establishing a new Commission to Promote a National Dialogue on Bioethics. The new Commission would unnecessarily duplicate the mission of the President's National Bioethics Advisory Commission.

The President's proposal, which in many ways is reflected in S. 1602 sponsored by Senators Feinstein and Kennedy, would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research.

Pay-As-You-Go Scoring

S.1601 could affect receipts; therefore, it is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990. OMB's preliminary scoring estimate of this bill is zero.

* * * * * * * * * *

Closing Fri 8/6

1. Jus Cloture Note

2. Bond bill SAP

3. letter on Feinstein bill - Daschle

4. letter for Kennedy from — Allyn
FDA Clinton auth could stop lead

5. likely comp:
(1) Commission FACA
mw ½R ½D let NBAC →
comp = no comp
Rachel emphatic re not giving up the Commission
(2) sunset 5 yrs
NBAC comm ed 3-5

6. NBAC sending letter to POTUS dup
POTUS bill

7. Harold Shapiro, Ch of NBAC calling Trust

Call Bruce Ziegler - Corp Gov

DRAFT

The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Labor and Human Resources
United States Senate
Washington, D.C. 20510-6300

Dear Senator Kennedy:

This is in response to your inquiry concerning the jurisdiction of the Food and Drug Administration (FDA) over human cloning activities. Apparently, some are suggesting that immediate Federal legislation is necessary to prevent the commencement of human cloning experiments that are intended to result in the creation of a human being through cloning techniques. FDA has jurisdiction over such experiments and is prepared to exercise that jurisdiction.

Human cloning is subject to FDA regulation under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. Under these statutes and implementing FDA regulations, clinical research on human cloning may proceed only when an investigational new drug application (IND) is in effect. Before such research may begin, the sponsor of the research is required to submit to the FDA an IND describing the proposed research plan, to obtain authorization from an independent institutional review board, and to obtain the informed consent of all participating individuals. FDA may prohibit a sponsor from conducting the study (often referred to as placing the study on "clinical hold") for a variety of reasons, including

DRAFT

if the agency finds that "(human subjects are or would be exposed to an unreasonable and significant risk of illness or injury," "the IND does not contain sufficient information required ... to assess the risks to subjects of the proposed studies," or "the clinical investigators ... are not qualified by reason of their scientific training and experience to conduct the investigation." At a minimum, the sponsor must wait at least 30 days after submitting its proposal to the FDA before beginning any study.

In the case of human cloning experiments, there are major unresolved safety questions. Until those questions are resolved, the agency could not permit any investigation of human cloning to proceed.

I hope this information is useful to you in your deliberations.

Sincerely,

Michael A. Friedman
Lead Deputy Commissioner
Food and Drug Administration

National Bioethics Advisory Commission

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

February 6, 1998

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

Dear Mr. President:

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

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

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

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

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

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

nuclear transfer techniques to create a child at this time,

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

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

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

Sincerely,

Harold T. Shapiro

Harold T. Shapiro
Chair

THE WHITE HOUSE

OFFICE OF LEGISLATIVE AFFAIRS
HOUSE LIAISON
--FAX COVER SHEET--

DATE: 2/10

TO: Nicole 224-8994
Daschle's Leadership Committee

FAX #: 224-5476

FROM:

- ___ JANET MURGUIA
- ___ AL MALDON
- ___ DAN TATE
- X LUCIA WYMAN
- ___ PETER JACOBY
- ___ STACEY RUBIN
- ___ ANDY BLOCKER
- ___ JEFF FORBES
- ___ ELISA MILLSAP
- ___ JESSICA GIBSON
- ___ PETER GREENBERGER

(202)456-6620 (TELEPHONE)
(202)456-2604 (FAX)

SUBJECT: Daschle's tele # is 456-6137

NUMBER OF PAGES: _____

Rachel E. Levinson 02/10/98 05:43:53 PM

Record Type: Record

To: Lucia A. Wyman/WHO/EOP

cc:
Subject: phone number

Howard Garrison, FASEB, 301-571-0657

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

February 9, 1998
(Senate)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

S. 1601 - Human Cloning Prohibition Act
(Sen. Lott (R) MS)

On June 9, 1997, the President transmitted to Congress legislation making it illegal for anyone to create a human being through cloning. The President believes that using somatic cell nuclear transfer cloning techniques to create a human being is untested, unsafe, and morally unacceptable. The Administration, however, believes S. 1601, as introduced, is too far-reaching because it would prohibit important biomedical research aimed at preventing and treating serious and life-threatening diseases. Therefore, the Administration would not support passage of the bill in its current form. The Administration looks forward to working with the Congress to address these concerns. Specifically, the Administration supports amendments to S. 1601 that would:

- Include a five-year sunset on the prohibition on human somatic cell nuclear transfer technology. The sunset provision would ensure a continuing examination of the risks and benefits of this, while being free from the concern that someone will use it prematurely.

- Permit somatic cell nuclear transfer using human cells for the purpose of developing stem cell (unspecialized cells capable of giving rise to specific cells and tissue) technology to prevent and treat serious and life-threatening diseases and other medical conditions, including the treatment of cancer, diabetes, genetic diseases, and spinal cord injuries and for basic research that could lead to such treatments.

- Strike the bill's criminal penalties and instead make any property, real or personal, derived from or used to commit violations of the Act subject to forfeiture to the United States.

- Strike the bill's provisions establishing a new Commission to Promote a National Dialogue on Bioethics. The new Commission would needlessly duplicate the mission of the President's National Bioethics Advisory Commission.

The President's proposal, which in many ways is reflected in S. 1602 sponsored by Senators Feinstein and Kennedy, would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research.

****

Rachel E. Levinson 02/10/98 05:28:28 PM

Record Type: Record

To: Lucia A. Wyman/WHO/EOP

cc:

Subject: Re: senate

I have letters from organizations or groups of individuals. I think they could call :

Chuck Ludlam at BIO 202-857-0244

Sean Tipton, ASRM 202-863-2494

Howard Garrison, FASEB 301-530-?? I'll get it

David Korn, AAMC 202-828-0509

FEB 1 1 1998

(Date)

Roll Call Vote

10:02 am

Legislative

NO. 10

SUBJECT: MOTION TO INVOKE CLOTURE ON MOTION TO PROCEED TO CONSIDER S. 1601

YEAS		NAYS
	Abraham	
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1	Allard	
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	Baucus	
	Bennett	
	Biden	
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	Byrd	
	Campbell	
	Chafee	
	Cleland	
	Coats	
	Cochran	
	Collins	
	Conrad	
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	Craig	
	D'Amato	
	Daschle	
	DeWine	
	Dodd	
	Domenici	
	Dorgan	
	Durbin	
	Enzi	
	Faircloth	
	Feingold	
	Feinstein	1
	Ford	2
	Frist	
	Glenn	
	Gorton	
	Graham, Florida	
	Gramm, Texas	
	Grams, Minnesota	
	Grassley	
	Gregg	
	Hagel	
	Harkin	
	Hatch	
	Helms	

	Grams, Minnesota	
	Grassley	
	Gregg	
	Hagel	
	Harkin	
	Hatch	
	Helms	
	Hollings	
	Hutchinson, Arkansas	
	Hutchison, Texas	
3	Inhofe	
	Inouye	3
	Jeffords	
	Johnson	
4	Kempthorne	
	Kennedy	
	Kerrey, Nebraska	
	Kerry, Massachusetts	
	Kohl	
	Kyl	
	Landrieu	
	Lautenberg	
	Leahy	
	Levin	+
	Lieberman	
	Lott	
	Lugar	
	Mack	4
	McCain	
	McConnell	
	Mikulski	
	Moseley-Braun	
	Moynihan	
	Murkowski	
	Murray	
	Nickles	
	Reed, Rhode Island	
	Reid, Nevada	+
	Robb	
	Roberts	
	Rockefeller	
	Roth	
	Santorum	
	Sarbanes	5
	Sessions	
	Shelby	
	Smith, New Hampshire	
	Smith, Oregon	
	Snowe	
	Specter	6
	Stevens	
	Thomas	
	Thompson	
	Thurmond	7
	Torricelli	
	Warner	+
	Wellstone	
	Wyden	5

GPO : 1997 42-148 (mac)

42 54

Somatic Cell Nuclear Transfer:
Reproductive vs Therapeutic Cloning

I Brief Introduction to Cloning
- somatic cell nuclear transfer --> better livestock --> cell therapy
- the goal of customized patient-specific cell therapies

II Applications
- somatic cell nuclear transfer creates "totipotent" cells
- fundamental investigation of early mammalian development
- applications in reproductive cloning vs. therapeutic cloning

Cell Type	Disease
• blood cells	leukemia, cancer, sickle cell anemia
• nerve cells	Parkinson's, Alzheimer's, spinal injury
• cardiac muscle	congestive heart failure, heart attacks
• insulin-producing cells	Diabetes
• vascular endothelium	atherosclerosis, coronary artery disease
• liver cells	liver failure, liver cancer
• osteoblasts (bone)	osteoporosis, fractures
• fibroblasts	wound healing, ulcers
• skin cells	burns

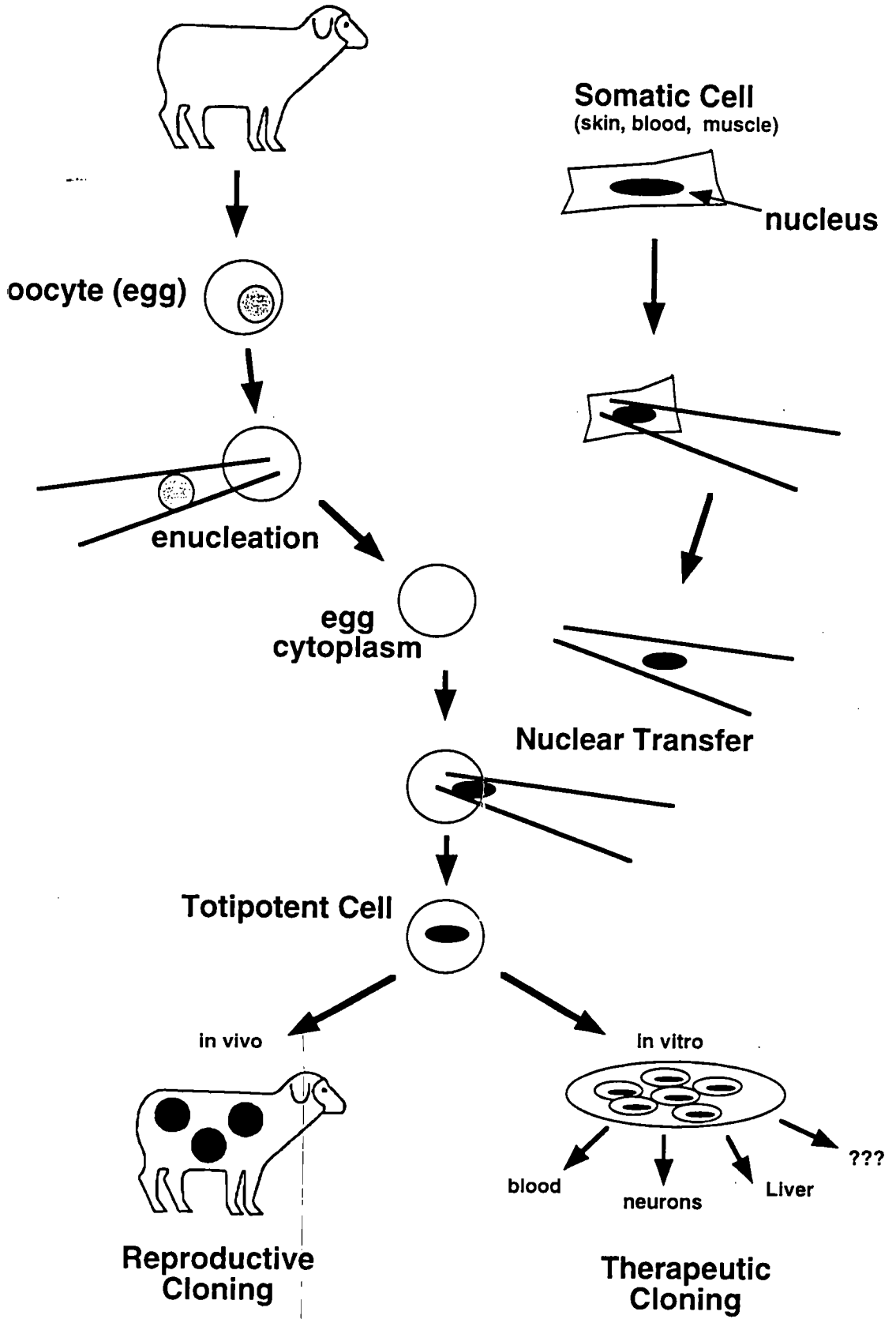
III Alternative Avenues of Research
- xenotransplantation; organs from other species (pig)
  concerns for immunologic rejection, animal viruses
- human fetal tissue transplantation
  concerns for procurement of tissue, immunologic rejection
- organ-specific adult stem cells
  concerns for isolation, expansion, longevity
- artificial organs/ tissue engineering
  concerns for bio-incompatibility

IV Advantages of Cloned Tissue -- Customized Cell Therapies
- totipotent, immortal cells
- excellent vehicles for gene therapy
- no risk of viral transmission

V Therapeutic Cloning -- Future Potential
- enormous academic interest
- emerging, active biotechnology industry
- exciting pre-clinical science, encouraging early clinical results
- significant practical advantages over alternative strategies

VI What is the nature of the cell created by somatic cell nuclear transfer?

George Q. Daley, M.D., Ph.D.
Democratic Policy Committee Presentation
February 12, 1998



Reproductive and Therapeutic Cloning by Somatic Cell Nuclear Transfer

Human Cloning Meeting
Wednesday, March 25, 1998
Room 476, OEOB
3:00 pm - 4:00 pm

List of Participants

Patient Advocacy Groups
Marguerite Donoghue, Capital Associates (Cancer Organizations)
Stephanie Marshall, National Health Council
Michael Langan, National Organizations of Rare Disorders
Eric Schutt, Juvenile Diabetes Foundation International
Larry Soler, Juvenile Diabetes Foundation International
Dan Perry, Alliance for Aging Research
Pamela Dougherty, American Cancer Society
Jo Merrill, March of Dimes Birth Defects Foundation
Rich Hamburg, American Heart Association

Scientific Organizations
David Korn, Senior Vice President, Association of American Medical Colleges
Ida Chow, Society of Developmental Biology
Roger Pederson, Board Member, Federation of American Societies for Experimental Biology
Francis Patrick White, The American Association of Immunologists
Janet Shoemaker, American Society for Microbiology
Dr. Paul Berg, Chair, Public Policy Committee, American Society for Cell Biology [Nobel Laureate in Chemistry]
Sean Tipton, American Society for Repreoductive Medicine
Kathy Bryant, American College of OBGYNs
Roberta Biegal, Society for the Advancement of Women's Health Research
Marion Priscilla Short, American Medical Association

Industry
Barry Caldwell, Vice President, Federal affairs, PhRMA
Walter Moore, Senior Director, Genentech, Inc.
Eleanor Kerr, Senior Director, Government Relations, Smith Kline Beecham
Victoria Blatter, Director, Government Relations, Merck & Co.
Carl B. Feldbaum, Biotechnology Industry Organization
Nancy Bradish, Biotechnology Industry Organization
Rita Norton, Amgen
Lisa Raines, Genzyme

→ Howard
Bliley
John Carrington
Ganske – OB/w Many
Armey will intro b/4 Easter recess.
H. Commerce may bill
CA bill as model??

Regulatory Approach
Thru: NIH & FDA

Industry ok w/ codifying FDA auth.
Dangers of leg –
criminal penalties
forfeiture
will dry up research

Patient grps –
also want regulatory approach

Sen. Mack
Specter
Hatch
Santorum –

Upton
Greenwood
Bilbray
Norwood