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Cloning [2]

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SCIENTIFIC ANALYSIS OF CLONING BILL PROPOSED BY SENATOR FEINSTEIN

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.

The phrase "attempt to create a human being" could be interpreted by certain factions as an attempt to create an embryo, although this distinction is cleared up in the prohibitions section.

SECTION 1. Short Title

This Act may be cited as the "Prohibition on Cloning of Human Beings Act of 1998".

This title is succinct and accurate, unlike the titles of other bills, such as the "Human Cloning Prohibition Act" which could imply prohibition of inadvertent twinning of some infertility treatments.

SEC. 2. Findings

This section accurately recounts the findings of the NBAC on cloning.

SEC. 3. Purposes.

It is the purpose of this Act to–

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

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

Once again, the phrase "attempt to create a human being" could be interpreted by certain factions as an attempt to create an embryo.

SEC. 4. Definitions.

In this Act:

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

Some scientists might argue that cloning is not a "precise" genetic copy, due to the invariable mistakes made in replicating DNA, and some would argue that a human is an animal, but this definition does not pose any negative implications for research.

(2) Nucleus– the cell structure that houses the chromosomes, and thus the genes.

Accurate for the purposes of this Act, but there are genes outside of the nucleus (mitochondrial genes.)

(3) Oocyte–the female germ cell, the egg.

Would this definition include immature oocytes? If it did not, this could possibly allow somatic cell nuclear transfer to create a human being to take place with an immature oocyte.

(4) Somatic cell–a mature, diploid cell.

Not entirely clear what "mature" means. If it means "differentiated" this would allow somatic cell nuclear transfer to create a human being using an undifferentiated embryo cell, which could allow for treatment of infertility due to mitochondrial diseases.

(5) Somatic cell nuclear transfer–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.

This language could allow (if one does not consider an embryo an existing human child) the use of this technology to treat infertility due to mitochondrial defects. Perhaps a small point of semantics, but does "transferring the nucleus of a somatic cell" include the fusion of a somatic cell with an oocyte? This is how Dolly was created. Perhaps could clarify by adding "or fusion of a somatic cell with an oocyte from which the nucleus…"

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.

This prohibition clearly states the scientific intent of the legislation, and avoids the question of when life begins or what "creating a human being" really means. It also clearly prohibits an act or an attempt at action, which is easy to assess, rather than an "intent" to act. This would protect researchers and others from being second-guessed about their intentions. This would allow the private sector to use somatic cell nuclear transfer technology to develop therapeutic cell lines for the treatment of many disorders via tissue transplantation. If the definition of somatic cell is interpreted as a differentiated diploid cell, and if "existing human child" is not interpreted to include an embryo, this would also allow the use of this technology to treat infertility due to mitochondrial diseases. One possible concern is that this would not prohibit attempts to implant such a product to an animal's uterus.

SEC. 6. Protected Biomedical Research.

Nothing in this Act shall be construed to restrict areas of biomedical and agricultural research or

practice not expressly prohibited in this Act, including research or practices that involve–

(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.

The inclusion of the phrase "or practices" protects activities such as animal husbandry or IVF that may not be considered research. Allowing the use of this technology "to clone molecules, DNA, cells, and tissues" would allow the private sector to pursue this technology to develop therapeutic tissues as mentioned above. Allowing the use of this technology to create animals will allow the continuation of a thriving research base in animal husbandry and transgenic animals for the production of therapeutic products and animal models. However, as mentioned previously, one could argue that a human being is an animal.

SEC. 7. Penalties.

(a) In General–Any person who intentionally violates the provision 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, U.S. 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.

This section uses phrases such as "attempted violation." The prohibition already includes the attempt to implant the product to a uterus. Would this then allow civil actions or forfeitures of "attempts at attempts" and would this lead to the difficult question of intentions on a researcher's part?

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.

Not later than 4 ½ years after the date of enactment of this Act, the National Bioethics Advisory Commission shall prepare and submit to the President a report concerning–

(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 in the Act.

The Commission is authorized to continue for the 10-year period described in section 12 to prepare such a report and for other purposed as established in Executive order 122975 and subsequent amendments to such Order.

Suggest adding provisions for additional review by NBAC after the initial report, particularly since the first report may still find insufficient scientific evidence of safety. Language could state "Not later than 4 ½ years after the date of enactment of this Act, and at intervals after that as necessary,..." Perhaps could broaden the nature of the report to include the state of the science of cell and tissue therapies to further investigate the potential for this technology. "Executive order 122975" may include a typo–NBAC's Website states the EO number as 12975.

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 which prohibits or limits research or practices regarding somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, or tissues, the use of somatic cell nuclear transfer techniques to develop animals, or related research.

This would prohibit poorly written State laws from prohibiting the cloning of DNA, cells or tissues (as a recent Florida bill would have done) or from prohibiting the private sector from investigating this technology for the development of therapeutic tissues or cells.

SEC. 12. Effective Date.

This Act shall be effective for the 10 year period beginning on the date of enactment of this Act. The prohibitions contained in this Act shall terminate at the expiration of such10-year period.

copied
Kagan
Gibbons
COS

Cloning

THE WHITE HOUSE
WASHINGTON
June 8, 1997

Bruce –
FYI. What we gave to the President this weekend.
Elena

THE PRESIDENT HAS SEEN
6/8/97

MEMORANDUM FOR THE PRESIDENT

FROM: TODD STERN TOS

SUBJECT: Proposed Cloning Legislation

At your cloning event tomorrow, you will receive the report of the National Bioethics Advisory Commission and announce legislation along the lines of NBAC's proposal. Elena Kagan and Jack Gibbons seek your views on two issues -- embryo research, which has already been run by you once, in the memo you received last week, and a sunset provision. *It would be desirable for you to reconfirm your views on the embryo issue before the event tomorrow, since you are likely to be asked about it. If you are comfortable deciding the sunset issue as well, you will be able to submit the legislation tomorrow. Alternatively, if you need more time, you can announce at the event tomorrow that you will be submitting legislation in the near future.* ***It would be very helpful for planning purposes if you could return this memo to our office today.***

Embryo research. In a nutshell, NBAC would ban the cloning of embryos for implanting in a woman's uterus (i.e., cloning humans), but take care not to inhibit cloning of human cells or tissues or the cloning of animals. NBAC's proposed legislation would *not* ban the cloning of embryos for research purposes, regarding that as ethically no different from the creation of research embryos through other techniques. You have banned the use of federal funds to create embryos for research, but have not supported a broader prohibition. The pro-life community will criticize any failure to ban the cloning of research embryos, but a ban on cloning for research would be strongly opposed by the scientific and fertility communities, since such a ban could halt research on infertility and possibly other conditions. **The attached Kagan/Gibbons memo recommends that you follow NBAC in *not* banning the cloning of embryos for research.**

Agree ✓ Disagree___ Discuss___

Sunset. Your proposed legislation currently includes a 5-year sunset provision and directs NBAC to report to the President in 4 ½ years on whether to continue the ban. This follows NBAC's strong recommendation. Some will criticize a sunset provision, however, saying that if you are banning cloning for ethical reasons (as opposed to, say, safety), then nothing will change in 5 years and there is no reason for a sunset. But even some who see cloning as ethically wrong think it would be a good idea to renew the national debate in a few years, see whether the legislative language needs adjustment, etc. And the biotech and pharmaceutical industries will very likely oppose cloning legislation *unless* there is a sunset. The Vice President favors NBAC review after 4 ½ years, but no built-in sunset; the biotech and pharmaceutical communities, as well as Gibbons and Varmus (NIH), oppose this approach.

5-year sunset ✓ No sunset/but review (VP idea)___ No sunset or review___ Discuss___

THE WHITE HOUSE

WASHINGTON

'97 JUN 8 PM12:47

June 8, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Jack Gibbons
Assistant to the President for Science and Technology

Elena Kagan
Deputy Assistant to the President for Domestic Policy

SUBJECT: Cloning Policy Decisions

This memo summarizes (1) the final version of the National Bioethics Advisory Commission (NBAC) cloning report completed yesterday, and (2) the cloning legislation we have prepared for you to submit to Congress on Monday. The memo addresses two issues about the legislation we would like you to focus on: (1) whether to prohibit the production of embryos (as well as human beings) through cloning; and (2) whether to sunset the prohibition on cloning after 5 years.

NBAC's Findings and Recommendations

In its final report NBAC states that at this time it is morally unacceptable for anyone to attempt to create a child using the technology that created Dolly the sheep (so-called somatic cell nuclear transfer technology). NBAC also concludes that the cloning of DNA, cells, and tissues, and the cloning of animals, are scientifically important and not ethically problematic. NBAC chose not to address at all the cloning of embryos for research purposes. NBAC calls for:

- Carefully-worded legislation that prohibits somatic cell nuclear transfer to create a child (without impeding important cloning research on DNA, cells, and animals), sunsets in 3-5 years, and provides for further review by an advisory body prior to the sunset date;
- Continuing your moratorium on the use of federal funds for cloning human beings while the proposed legislation is pending;
- Calling on all scientists and clinicians to adhere to the voluntary moratorium while the proposed legislation is pending; and
- Working with other countries to enforce common aspects of cloning restrictions.

Proposed Legislation

The legislation you will announce tomorrow, as currently written:

- Prohibits the use of somatic cell nuclear transfer with the intent of introducing the product into a woman's womb or in any other way creating a human being;
- Gives the Attorney General authority to seek injunctive relief, impose civil fines up to $250,000 or twice the profit from a violation of the Act (whichever is greater), and seize any and all property used in violating the Act (including entire laboratories);
- Sunsets the prohibition on cloning 5 years from the date of enactment; and
- Directs the National Bioethics Advisory Commission to report to you prior to the sunset date on the advisability of continuing the prohibition.

Key Legislative Issues

1. Embryo Research

NBAC's proposed legislation --and, as currently drafted, your bill --would not ban the creation of cloned embryos for research purposes. NBAC simply did not evaluate the ethics or scientific benefits of this activity; it focused exclusively on the use of cloning techniques to create an embryo that would then be implanted in a woman's uterus and brought to term. NBAC reasoned that other entities (including a 1994 NIH panel) already have discussed extensively the creation of embryos for research purposes and that the use of cloning technology in this context raises no distinct ethical issues. By contrast, the use of somatic cell nuclear transfer technology to create a child raises a host of new and different ethical issues relating to safety, individuality, and family integrity.

You took action in 1994 to restrict embryo research by banning the use of NIH funds to create embryos for research purposes. (The NIH panel had recommended permitting the funding of research on embryos in very limited circumstances.) You also signed a spending bill that included a prohibition on the use of HHS funds for embryo research. But your budget submissions for FY97 and FY98 stated in a footnote that the Administration did not support addressing this issue in legislation. Nor have you ever indicated support for extending the current restriction to privately funded embryo research.

The right-to-life community already has criticized NBAC for not recommending a ban on creating cloned embryos. But there are good reasons for not going so far. There is no moral rationale for treating embryos created through cloning differently from embryos developed through other means (e.g. in vitro fertilization) when embryos are used solely for research. Prohibiting the creation of embryos for research using private funds could halt important research on infertility and possibly other medical conditions and would provoke strong opposition from the scientific and fertility communities. In short, it is a controversial step that merits further consideration. We therefore recommend that you limit the scope of the legislation you submit to Congress on Monday to the issue the Commission addressed. If asked about your position on embryo research, you should note that it is an important but

separate question and reiterate your position that no federal funds should be used to create embryos for research purposes.

2. Sunset Provision

NBAC recommends strongly that any legislative prohibition on cloning include a sunset clause to ensure that Congress review the issue after a specified period of time.

Whether a sunset provision makes sense depends in part on why a cloning ban is appropriate. For those who believe cloning is unethical primarily because of safety concerns, a sunset is necessary because time may mitigate those concerns. But for those who believe that cloning is inherently immoral, a sunset provision may seem wrong because time cannot lessen the problem. If you propose a sunset provision, you will subject yourself to criticism on this score.

It is important to understand, however, that some who share your view that cloning is inherently wrong nonetheless favor a sunset provision. They reason that: (1) a sunset provision provides a strong incentive for Congress and the Administration to renew the national debate on cloning within several years, ensuring continued attention to the ethical questions; (2) there has been little time to fully consider the moral issues, and it is possible that convictions may evolve; and (3) there is a high probability that Congress will simply get the legislative language wrong the first time around, given our limited understanding of the science, the difficulty of defining terms, and the vagaries of the legislative process.

As an alternative to proposing a sunset provision, you could propose legislation that provides for review by NBAC in 4 ½ years but does not sunset the ban. This approach would shift the burden of proof to those who want to lift the ban, since Congress would have to act affirmatively to effect change. Jack Gibbons, Harold Varmus, and the scientific and biotechnology communities oppose this modification to your draft legislation. The Vice President prefers this modified approach.

Cloning

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

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

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

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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:

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Rachel E. Levinson/OSTP/EOP
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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.

* * * * * * * * * *

COMPARISON OF PROPOSED CLONING LEGISLATION

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Title	Cloning Prohibition Act of 1997	Prohibition on Cloning of Human Beings Act of 1998	Human Cloning Research Prohibition Act	Human Cloning Prohibition Act	Human Cloning Prohibition Act of 1998	Human Cloning Prohibition Act
Sponsor	William Clinton (Not yet sponsored)	Dianne Feinstein (D-CA)	Vernon Ehlers (R-MI)	Vernon Ehlers (R-MI)	Christopher (Kit) Bond (R-MO)	Ben Nighthorse Campbell (R-CO)
Findings	NBAC Report	NBAC Report	none	none	none	Congress finds that the Federal Govt has a moral obligation to the nation to prohibit the cloning of humans.
Purposes	To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and to provide for further review of the ethical and scientific issues associated with its use.	To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and to provide for further review of the ethical and scientific issues associated with its use.	To prohibit the obligation or expenditure of Federal funds to conduct or support any project of research that includes the use of a human somatic cell nuclear transfer technology to produce an embryo.	To prohibit the cloning of humans.	To prohibit any attempt to create an embryo using human somatic cell nuclear transfer, protect research	To prohibit the cloning of humans.
Definitions	Cloning[1]; Somatic cell[2]; Somatic cell nuclear transfer[3]	Cloning[4], Nucleus[5], Oocyte[6], Somatic cell[7], Somatic cell nuclear transfer[8]	Human somatic cell nuclear transfer[9], Somatic cell[10]	none	Embryo[11], Human somatic cell nuclear transfer[12], Oocyte[13], Somatic cell[14]	Clone & Cloning[15]

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Prohibitions	Unlawful for any public or private individual or entity to perform or use somatic cell nuclear transfer with the intent of introducing the product into a woman's womb or in any other way creating a human being.	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.	Prohibition against obligation or expenditure of Federal funds to conduct or support any project of research that includes the use of a human somatic cell nuclear transfer technology to produce an embryo.	Prohibition against the use of a human somatic cell for the process of producing a human clone.	Unlawful for any person or entity, public or private, to knowingly use human somatic cell nuclear transfer to produce an embryo or to knowingly purchase or sell an ovum, embryo, or fetus for that purpose, or obligate or expend Federal funds on research that includes that purpose.	Unlawful for any person to clone a human being or conduct research for the purpose of cloning a human being or otherwise creating a human embryo; no Federal funds may be obligated or expended to knowingly conduct or support any project of research for the above purposes.
Protected Research	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or the use of somatic cell nuclear transfer techniques to create animals.	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or the use of somatic cell nuclear transfer techniques to create animals.	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, other than human embryo cells, or tissues; or the use of somatic cell nuclear transfer techniques to create animals other than humans.	none	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, other than human embryo cells, or tissues; or the use of somatic cell nuclear transfer techniques to create animals other than humans.	none

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Preemption of State Laws	none	Preempt any state law which prohibits or limits research or practices regarding somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, or tissues, the use of somatic cell nuclear transfer techniques to develop animals, or related research.	none	none	none	none
Penalties Specified	Fines (the greater of $250,00 or 2X gross gain or loss), Civil Action by the AG, forfeiture of property derived from or used to commit act.	Fines (the greater of $250,00 or 2X gross gain or loss), Civil Action by the AG, forfeiture of property derived from or used to commit act.	none	Civil money penalty not to exceed $5,000.	Fines, up to 5 years in prison, forfeiture of property from or used to commit violation.	Civil money penalty not to exceed $5,000 for each violation; ineligibility for Federal funds for 5 years after violation.
Effective Date	Date of Enactment--Applies to acts performed within 5 years after that date.	Act is effective for the 10 year period after the its enactment and will terminate at the expiration of 10 years.	none mentioned	none mentioned	none mentioned	none mentioned

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Provisions for Review	Review by NBAC 4 ½ years after enactment, on the state of the science of somatic cell nuclear transfer, the ethical and social issues associated with the potential use of this technology in humans, and advisability of continuing the prohibition established in the Act.	Review by NBAC 4 ½ years after enactment, on the state of the science of somatic cell nuclear transfer, the ethical and social issues associated with the potential use of this technology in humans, and advisability of continuing the prohibition established in the Act.	Review by NRC in agreement with the Director of NSF, not later than 5 years after the date of enactment, on the impact that the implementation of the Act has had on research and recommendations for any appropriate changes to the Act.	none	Review by Directors of NSF and NIH in agreement with NRC, not later than 5 years after enactment, on the impact that the implementation of the Act has had on research and recommendations for any appropriate changes to the Act.	None
Status	Legislative package was transmitted to Congress on June 9, 1997.		The bill was introduced on March 5, 1997, and jointly referred to the House Committees on Commerce, and Science. Hearings on substitution held July 22, 1997. Marked-up and passed out of the House Science Committee July 29, 1997.	The bill was introduced on March 5, 1997, and jointly referred to the House Committees on Commerce, and Science.		The bill was introduced on January 27, 1998 and referred to the Senate Committee on Labor and Human Resources.

PREPARED BY OSP

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

2. Somatic cell--any cell of the body other than germ cells (eggs or sperm.)

3. Somatic cell nuclear transfer--the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

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

5.Nucleus–the cell structure that houses the chromosomes, and thus the genes.

6.Oocyte–the female germ cell, the egg.

7.Somatic cell–a mature, diploid cell.

8.Somatic cell nuclear transfer–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.

9. Human somatic cell nuclear transfer-- transferring the nucleus of a human somatic cell into an oocyte from which the nucleus has been removed or rendered inert.

10. Somatic cell--a cell of an embryo, fetus, child, or adult which is not and will not become a sperm or egg cell.

11. Embryo–The developing organism from the time of fertilization, or from the time of the single cell stage at the inception of growth and development of an organism, until significant differentiation has occurred.

12.Human somatic cell nuclear transfer–transferring the nucleus of a human somatic cell into an oocyte from which the nucleus has been removed or rendered inert.

13.Oocyte–the mature female germ cell, the egg.

14.Somatic cell–any cell of an embryo, fetus, child, or adult that is not a germ cell or is not destined to become a germ cell.

15.Clone & Cloning–the practice of creating or attempting to create a human being by transferring the nucleus from a human clel from whatever source into a human cell from which the nucleus has been removed for the purpose of, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being.

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 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
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William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

Rachel E. Levinson 02/04/98 09:55:34 AM

Record Type: Record

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

cc:
Subject: Telegram on Proposed Cloning Legislation

fyi
---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 02/04/98 09:54 AM ----------

hgarrison @ faseb.org
02/04/98 09:16:50 AM

Record Type: Record

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

cc: See the distribution list at the bottom of this message
Subject: Telegram on Proposed Cloning Legislation

During yesterday's Public Affairs Executive Committee (PAEC) conference call, the PAEC instructed us to send the following telegram to all members of the U.S. Senate:

"The Federation of American Societies for Experimental Biology (FASEB) urges the Senate to proceed extremely cautiously as it considers legislation regarding human cloning. While the Federation considers the cloning of a human being to be reprehensible, dangerous, and unethical, we are concerned that overly restrictive legislation could unintentionally preclude critical research of great benefit to the American people. We believe that S. 1599, currently pending consideration by the Senate, would be damaging to worthwhile research. By flatly banning all use of human somatic cell nuclear technology for any purpose, this legislation would close off key areas of research which do not involve the creation of humans. We urge that the Senate not approve this legislation in its current form as it does not balance appropriate ethical considerations with the health needs of the American people."

The message was sent yesterday evening for delivery today.

Howard H. Garrison, Ph.D.
Director, Office of Public Affairs
Federation of American Societies for Experimental Biology
9650 Rockville Pike
Bethesda, MD 20814

voice: (301) 571-0657
fax: (301) 571-0686

Message Sent To:

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rablab @ uci.edu
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brinkley @ bcm.tmc.edu
brd @ virginia.edu
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partrinc @ wpogate.slu.edu

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Message Sent To:

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Clifford J. Gabriel/OSTP/EOP
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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
Clifford J. Gabriel/OSTP/EOP
Jeffrey M. Smith/OSTP/EOP
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Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

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
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gips_d @ a1.eop.gov @ inet
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Suggested Potus remarks on cloning for AAAS

This week Congress turned its attention to a vexing and complicated problem -- what steps should government take to prevent attempts to make a cloned child. No issue better illustrates the conflicting expectations we have for scientists.

On the one hand, we are counting on you to unravel for us the mysteries of human life. On the other hand we need you to preserve our sense that as human beings God has touched us in some indecipherable way. It is a delicate balance to strike.

I have called on Congress to pass legislation that would prohibit for 5 years, cloning experiments designed to produce a human being. But I have insisted that the legislation must be drafted to allow scientists to explore other uses of somatic cell nuclear transfer -- theprocedure used to clone Dolly the sheep last year. In our effort to prevent human cloning, we must not miss the opportunity to revolutionize treatments for diabetes, many cancers, burns, sickle cell anemia, and heart disease.

Two days ago, in a significant victory for scientific reasoning, 54 Democratic and Republican Senators voted to delay legislation that would have banned all somatic cell nuclear transfer experiments. The fight is not over, and I need your help. I urge you to speak out publicly to provide a sound scientific foundation for this debate.

clong

The New York Times

February 12, 1998, Thursday, Late Edition - Final

SECTION: Section A; Page 20; Column 1; National Desk

LENGTH: 830 words

HEADLINE: Senate, 54-42, Rejects Republican Bill to Ban Human Cloning

BYLINE: By LIZETTE ALVAREZ

DATELINE: WASHINGTON, Feb. 11

BODY:

The Senate today soundly defeated a Republican measure to ban human cloning, as a dozen Republicans joined Democrats to urge prudence, expressing grave concerns about the bill's effect on scientific research.

The bill was rushed to the Senate floor last week by Senator Trent Lott of Mississippi, the majority leader, a month after a scientist, Dr. Richard Seed, said that he wanted to open a human cloning clinic. Dr. Seed's declaration stirred public outrage, led President Clinton to renew calls for a ban on human cloning and prompted members of Congress to denounce the idea as a harrowing jump into the realm of science fiction.

So today the Senate, by a 54 to 42 vote, refused even to bring the bill to the floor for debate, despite serious reservations about human cloning. A majority of the senators, including some Republicans who usually oppose abortion, said they were unwilling to enact sweeping restrictions on cloning experimentation because of its potential value to medicine.

Those Republicans faced the ire of the National Right to Life Committee, which opposes human cloning for research, arguing that a cloned embryo, even one used only for research, would be a human being.

"The sponsors of this legislation know that it cannot stand up to public scrutiny," said Senator Edward M. Kennedy, the Massachusetts Democrat, "and they should not be making this extraordinary attempt to rush it through the Senate. Congress should ban the production of human cloning. But we should not ban scientific research that has so much potential to bring help and hope to millions of citizens."

Mr. Kennedy led the opposition to the measure, along with Senator Dianne Feinstein, Democrat of California.

Mr. Clinton, saying the bill was too far-reaching, opposed the measure. Its opponents in the Senate demanded a full set of hearings on how to deal with human cloning in the laboratory. Any legislation on human cloning is now likely to wind its way through the committee process, perhaps this year and perhaps not.

The bill, sponsored by Senators Bill Frist of Tennessee and Christopher S. Bond of Missouri, both Republicans, called for a full ban on the cloning of

human embryos through somatic cell nuclear transfer -- the procedure used by Dr. Ian Wilmut to clone Dolly the sheep last year. Animals like sheep and cows have been cloned from fetal cells but so far no mammal -- with the apparent exception of Dolly -- has been cloned from an adult cell.

Senator Frist, who is a heart surgeon, said he understood the concerns of scientists but said that his bill would not interfere with medical research or limit general scientific cloning. It would limit only human cloning, he said, and the law could always be revisited.

"Science has been abused in the past," Mr. Frist warned his colleagues on the Senate floor. "We can look back at what Hitler did in the name of science."

Mr. Bond attributed the bill's defeat to lobbying by biotechnology and pharmaceutical companies. "The big drug companies and other special interests are not just saying, go slow," he said. "They want to reserve the right to make huge profits off of unethical procedures."

Members of the medical and scientific industries formed a powerful unified front against the Republican proposal. This week a group of 27 Nobel Prize winners wrote to the President and to Congress urging that any legislation avoid "language that impedes critical ongoing and potential new research."

Scientists maintain that the ban would hamper research that could potentially save lives. Instead of a law banning cloning, scientists say, the Food and Drug Administration should handle the decisions on a case-by-case basis. The F.D.A. says it has jurisdiction over cloning, based on safety and efficacy rules.

Scientists also contend that, despite the pronouncement of Mr. Seed -- a 69-year-old physicist who has no financing and no doctors for a cloning clinic -- they have no plans to rush headlong into human cloning.

To try to stave off the Republican bill, Senators Kennedy and Feinstein led a filibuster and wrote their own alternative bill that would permit cloning research, but ban the implantation of a cloned embryo into a womb.

Today, 12 Republican Senators sided with Mr. Kennedy and Mrs. Feinstein in the vote against the Republican bill, which ultimately pitted medical and scientific groups against opponents of abortion.

Senator Connie Mack, a conservative Republican leader from Florida who consistently sides with abortion opponents, told his colleagues on the Senate floor today that they had an obligation to move slowly to avoid unintended consequences. Mr. Mack lost his father, mother and brother to cancer, and he, his wife and daughter have all been diagnosed with the disease at some point in their lives.

"Let's hear from the scientific community so they can tell us whether this is the right thing to do or the wrong thing to do," Senator Mack said.

LANGUAGE: ENGLISH

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

STATEMENT OF ADMINISTRATION POLICY

TO: **LARRY STEIN**
JOHN PODESTA
SYLVIA MATHEWS
BRUCE REED
ELENA KAGAN
JERRY MANDE
RACHEL LEVINSON
LUCIA WYMAN
CHARLES BROWN
TOM FREEDMAN
PAUL WEINSTEIN
JASON GOLDBERG

CC: **JACK LEW**
CHARLES KIEFFER

FROM: **Alice Shuffield**

DATE: **February 9, 1998**

SUBJECT: **FOR YOUR CLEARANCE --**
SAP on S. 1601 -- Human Cloning Prohibition Act

Attached is our draft SAP on S. 1601, the Human Cloning Prohibition Act. On Thursday (2/5), the Senate debated the motion and filed cloture on the bill. The cloture vote will occur on Tuesday (2/10).

Position: **The Administration does not support passage of the bill in its current form.**

Timing: We aim to send to the Hill as soon as possible on Monday.

Background: HHS and White House staff have been working with Congress to amend the bill as described in our SAP. NIH Director Harold Varmus met with Senator Frist on Thursday afternoon to encourage amendment to the bill. The Agency reports that the Senator was receptive in the meeting. The Administration has been working to delay consideration of the bill in an effort to incorporate these amendments.

Please contact Alice Shuffield (5-4790) ***by noon today*** *with your clearance or your concerns.*

DRAFT -- NOT FOR RELEASE

February 9, 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 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 does 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 technology [for purposes other than cloning a human being], while being free from the concern that someone will use it prematurely. (awaiting clearance from the scientists.)

-- 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 treat or diagnose deadly or disabling 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.

* * * * * * * * * *

(Do Not Distribute Outside Executive Office of the President)

This Statement of Administration Policy was developed by the Legislative Reference Division (Pellicci) in consultation with OSTP (Levinson), DPC (Kagan/Mande), and HLTH (Turman/ Garufi). Executive Associate Director Gotbaum has approved the proposed position. The Department of Health and Human Services (per Assistant Secretary for Legislation Tarplin) concurs in the proposed position. The Departments of Agriculture (Wachs) and Veterans Affairs (Prudhomme), and NASA (Costanzo), and NSF (Ashley) have no objection to the proposed position. The Department of Justice did not respond to our request for views.

OMB/LA Clearance:

Background

Both S.1601 and the Feinstein/Kennedy substitute bill (S. 1602) were introduced on February 3rd. Neither bill was the subject of committee hearings or markups. On June 9, 1997, the President transmitted to Congress legislation that would prohibit any attempt - public or private - to create a human being using somatic cell nuclear transfer technology, the method that was used to create Dolly the sheep. A cloture vote will occur on Tuesday, February 10th, on the motion to proceed with Senate consideration of S. 1601.

Summary of Legislation

S. 1601 - the "Human Cloning Prohibition Act (Lott)

S. 1601 would permanently ban the use of human somatic cell nuclear transfer technology for the purpose of creating an embryo. According to HHS, although the term embryo is not defined, the fact that the bill states "including a preimplantation embryo" suggests that embryo would include the single cell egg with a full complement of DNA. S. 1601 would impose the same penalties as those for illegally using fetal tissue -- a maximum of 10 years in prison and a $250,000 fine.

S. 1601 would also establish within the Institute of Medicine a Commission to Promote a National Dialogue on Bioethics to serve as an "independent forum for broad public participation and discourse concerning important bioethical issues, including cloning . . . ." The new Commission would be required to report to Congress annually beginning no later than December 31, 1999. The Commission would have 25 members, representative of the fields of law, theology, philosophy or ethics, medicine, science, and society. Of the 25 members, six would be appointed by the Majority Leader of the Senate; six by the Minority Leader of the Senate; six by the Speaker of the House; and six by the Minority Leader of the House. The Senate Majority Leader and the Speaker of the House would select the Chairperson of the Commission. S. 1601 would authorize such sums as may be necessary for the establishment and operation of the Commission.

S. 1602 - the "Prohibition on Cloning of Human Beings Act of 1998" (Feinstein/Kennedy)

The major provisions of S. 1602 are based on the President's proposal. Like the Administration's legislation, S. 1602 would prohibit any attempt to create a human being using somatic cell nuclear transfer technology. Unlike S. 1601, the Feinstein/Kennedy bill would permit cloning research until the implementation stage. For example, the bill would allow the use of cloning technologies (including embryo research) to seek cures for cancer, diabetes, burns, spinal cord injuries, infertility, birth defects, and other human illnesses. The ban on human cloning would be effective for 10 years from the date of the bill's enactment. (The Administration's bill included a five-year ban.) S. 1602 would provide for fines, civil actions, and forfeiture of property for violations of the Act.

Consistent with the Administration's proposal, S. 1602 would also require the National Bioethics Advisory Commission to report to the President and Congress in four and a half years and nine and a half years, and recommend whether the ban should continue. It would also preempt any State law affecting somatic cell nuclear transfer, human cloning, and related activities.

Pay-As-You-Go Scoring

According to BASD (Balis) and HLTH (Garufi), S. 1601 could affect receipts because the bill provides for criminal fines and civil monetary penalties for violations of the Act. Therefore, S. 1601 is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990. OMB's preliminary scoring of S. 1601 is zero.

in particular, for more than technical reasons, most analysts admit.

Many investors simply believe that it makes more sense to stay in stocks than to be out of them, given a still-healthy U.S. economy and subdued interest rates and inflation.

"The individual investor has had it drummed into him over the last 10 years to focus on the long term," said Tony Dwyer, chief market strategist at Ladenburg Thalmann & Co.

Unlike in 1987-88, when small investors retreated from stocks in the wake of the October 1987 market crash, U.S. stock mutual funds have continued to attract money since last October's mini-crash.

Falling interest rates have helped. Long-term bond yields have edged up in recent weeks, but remain near the 20-year lows set in mid-January. Lower rates make stocks more attractive vs. fixed-income investments.

The trend in rates has been influenced by expectations that the U.S. economy will slow this year as Asia's economic turmoil reduces demand for American exports.

Christopher Low, senior economist for HSBC Markets Inc. in New York, said the U.S. economy is strong now, with consumer confidence close to a 30-year high.

But Low, echoing recent comments by Federal Reserve Board Chairman Alan Greenspan, said that the fallout from Asia's woes will start taking a toll later this year.

"There are some ugly shocks still to come" for the economy, Low said.

The National Association of Purchasing Managers' index of export orders is at an all-time low, a signal that export sales will drop off in the second half of the year, Low said.

Clinton, Senate Democrats Rally Around Tough Tobacco Bill (Washn) By Alissa J. Rubin (c) 1998, Los Angeles Times

WASHINGTON President Clinton and a wide swath of Senate Democrats are rallying around tough tobacco control legislation that would raise the price of a pack of cigarettes by $1.50 over the next three years and deny the tobacco industry the protection from future lawsuits that it seeks.

The legislation, authored by Sen. Kent Conrad, D-N.D., and slated for introduction Wednesday, signals the increasingly cold climate in Washington for the tobacco industry, which has sought smaller cigarette price increases and broad protection from future lawsuits.

If Conrad's bill wins the support of most Senate Democrats, as its sponsors predict, it will have more backing than any comprehensive bill introduced so far to implement the mammoth settlement reached last year by the tobacco companies and the states. It also is the only proposal to win a White House endorsement.

Ultimately, without Republican support, the measure is unlikely to become law in anything like its current form. Still, it has injected momentum into a process that had appeared all but stalled.

"Conrad's bill sends a pretty strong signal," said Sen. John B. Breaux, D-La., a conservative Democrat. "To object to it is swimming upstream."

Breaux said he was signing onto the bill, which would allow far greater federal regulation of tobacco products than the agreement reached last June by the states attorneys general and the industry.

Breaux's comments were echoed by many of the Democrats emerging from the party's weekly luncheon, where Conrad briefed his colleagues on the bill's provisions.

Conrad's decision to give little ground to the tobacco companies in terms of future legal protections met with little criticism from Republicans, suggesting they also are unlikely to support the limits on liability sought by the tobacco industry.

White House officials voiced strong support for Conrad's bill, but also made it clear they would continue to work with Congress on formulating proposals Clinton could endorse.

"We think that this is a real step forward on the road to passing a bill," said Bruce Reed, domestic policy director for the White House.

The Conrad proposal would:

Settle the current state and local lawsuits against the tobacco industry and preclude federal lawsuits against the industry. But unlike the agreement forged between the state attorneys general and the industry, it puts no limit on future class action lawsuits and no cap on the amount that the industry would have to pay out in a year.

Increase the per pack price of cigarettes by $1.50 (50 cents per year over the next three years). The state/industry agreement would increase the per pack price by 62 cents over the next five years.

Grant full FDA authority to regulate tobacco as a drug. The state/industry agreement would limit the FDA's control in this.

Reimburse tobacco farmers $10 billion over the next five years to compensate for losses due to reduced sales of tobacco because of reductions in smoking. The state/industry agreement does not address this issue.

Require a 67 percent reduction in youth smoking rates in 10 years. The state/industry agreement calls for a 60 percent drop.

The tobacco industry sharply criticized the major provisions of Conrad's bill. And they said their opposition would imperil a key of the state/industry accord provision to halt tobacco advertising and marketing aimed at young people.

Steve Duchesne, a spokesman for the industry, noted that such a prohibition could not be accomplished without the industry's cooperation.

"Many of the advertising and marketing restrictions would be unconstitutional, and therefore could not be implemented unless the industry agreed to them," he said.

Vote Will Seek to Break Deadlock on Human Cloning Ban (Washn) By Edwin Chen (c) 1998, Los Angeles Times

WASHINGTON A bipartisan campaign to ban human cloning has stalled in Congress, where right-to-life forces who fear the destruction of genetically engineered embryos are pitted against those who contend a ban would block cutting-edge biomedical research.

In an effort to break the deadlock, Senate Majority Leader Trent Lott, R-Miss., has scheduled a vote Wednesday that could pave the way for the Senate to take up two competing measures to restrict cloning research. Whatever the outcome, it is now clear that the drive to outlaw human cloning will not proceed quickly or smoothly.

President Clinton first proposed a ban last year, responding to public clamor surrounding dramatic advances in animal cloning. His plan drew widespread support, although Congress never acted on it.

But opposition has intensified as the the scientific and pharmaceutical communities have issued dire warnings that an across-the-board ban would block pioneering research on diseases ranging from cancer to Alzheimer's.

Anti-abortion advocates are clamoring for a broad ban because they believe that any human cloning research necessarily involves the creation and destruction of genetically engineered human embryos.

That such a once-popular proposal has become mired in controversy reflects the fundamental difficulty Congress faces in grappling with complex scientific issues that have a profound moral dimension namely, when does life begin?

"Anything related to embryos or abortions is a big problem for Congress," said George Annas, a Boston University bioethicist.

The controversy, acknowledged Dr. George Q. Daley, a Harvard physician and geneticist who opposes a broad ban, "speaks directly to the definition of an embryo."

The stalemate is somewhat surprising, because virtually no has spoken up in favor of human cloning. Clinton, Lott and House GOP Leader Dick Armey, R-Texas, have taken the lead in promoting a ban. And leading researchers have voluntarily pledged to shun such experiments.

Only G. Richard Seed, a maverick physicist in Chicago, has publicly advocated human cloning. Last month, he claimed to have assembled a team to begin such experiments, prompting a stampede in Washington to outlaw the practice even though most experts say human cloning is at least three to five years away in terms of technological know-how.

Cloning is a genetic engineering technique in which scientists create an identical duplicate, or clone, of a living object. Though still in its infancy, cloning has already yielded an array of biomedical and agricultural advances. But it has never been achieved in humans.

Cloning made international headlines a year ago when Scottish researchers announced they had cloned a sheep named Dolly.

In the normal reproductive process, an egg and a sperm fuse, combining the genes of a male and a female to produce an embryo. In cloning, only the genes of one parent are used, with scientists removing the DNA from an egg and replacing it with the DNA of the person to be cloned.

A bill offered by Sens. Christopher S. Bond, R-Mo., and Bill Frist, R-Tenn., a heart-lung transplant surgeon, would permanently that technique as applied to human cells, with violators subject to criminal penalties, including up to 10 years in prison.

Bond called for "an immediate debate on how far out on a moral cliff we are willing to let science pro before we as a nation

Cloning

THE PRESIDENT HAS SEEN
6-4-97

THE WHITE HOUSE

WASHINGTON

June 3, 1997

Copied to:
Kagan
Gibbons
Emanuel
Bowles

MEMORANDUM FOR THE PRESIDENT

FROM: TODD STERN
PHIL CAPLAN

SUBJECT: Cloning Policy Options -- Report of National Bioethics Advisory Committee

The attached Gibbons/Kagan memo (Bruce Reed is recused) urges you to follow the recommendation of the NBAC to submit legislation banning human cloning but permitting cloning of human tissue, including embryos. NBAC's cloning report is to be released Saturday, though the Washington Post reported on a leaked draft today. Jack/Elena also recommend that the U.S. support a modified version of a French proposal for a cloning paragraph in the G-8 communique.

NBAC Report/Legislation. NBAC concludes that it is morally unacceptable for anyone to try to create a child using the cloning technology that created Dolly. But NBAC finds that other forms of "human cloning" -- e.g., of DNA sequences, cell lines, tissues, embryos -- are appropriate and scientifically important, as is animal cloning. Therefore, NBAC calls for narrowly worded legislation barring anyone from trying to create a child through somatic cell nuclear transfer techniques. The legislation would sunset and, prior to the sunset, an oversight body would report on the state of the technology and social/ethical issues.

Likely Reaction. While there is a broad consensus emerging (including AMA and World Medical Association) that cloning humans is wrong, biotech and pharmaceutical industries will strongly oppose legislation as they fear it will impede research. The right-to-life community will oppose on the ground that the ban should extend further -- to the cloning of human embryos for research. *This issue, incidentally -- whether to allow the cloning of embryos for research -- is exactly what the Post honed in on this morning.* (Currently, the Administration bars the creation of embryos for federally funded research only, and has opposed legislation on the subject.)

Jack/Elena recommend that you announce your support for NBAC-type legislation and that you propose specific legislative language. (A possible event where you could accept the NBAC report and announce your position is under consideration for Monday, June 9.) *Rahm concurs.*

Approve ✓ Disapprove___ Discuss___

G-8 Communique. France proposes a paragraph embracing national and international bans on reproductive cloning. Jack/Elena recommend that we support this proposal, but with critical modifications along the lines of the NBAC proposal. If you approve, Dan Tarullo will seek to negotiate specific language, but cautions that agreement by all eight countries may be difficult.

Approve ✓ Disapprove___ Discuss___

THE WHITE HOUSE

WASHINGTON

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May 29, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: JACK GIBBONS
Assistant to the President for Science and Technology

ELENA KAGAN
Deputy Assistant to the President for Domestic Policy

SUBJECT: CLONING POLICY OPTIONS

Two upcoming events create the need to develop a position on legislation banning the cloning of human beings. First, the National Bioethics Advisory Commission (NBAC) is about to complete the review you requested of the ethical and legal issues associated with cloning human beings. On Saturday, June 7, at its final public meeting, NBAC is expected to vote in favor of a legislative ban. Second, France has proposed that the Denver Summit communique include a paragraph urging countries to pass domestic legislative bans and to work together toward a global ban.

We recommend: (1) that you support domestic legislation banning human cloning, and that you announce specific legislation at the top of your June 10th press conference; and (2) that the U.S. support the gist of France's proposed cloning paragraph while insisting on critical modifications.

NBAC's Findings and Recommendations

In its draft final report, NBAC unanimously concludes that "it is morally unacceptable for anyone . . . to attempt to create a child" using the technology that created Dolly the sheep: somatic cell nuclear transfer -- that is, the transfer of the nucleus from an adult somatic (non egg or sperm) cell into an enucleated egg. NBAC bases this conclusion on safety concerns, finding that the technology is "likely to involve substantial risk to the potential child." The report also states that "serious ethical concerns... require a great deal more widespread and careful thought and public deliberation before this technology should be used."

NBAC also concludes, however, that other forms of "human cloning" -- such as the cloning of DNA sequences, cell lines, and tissues (which do not involve the creation of entire human beings) -- are scientifically important and not ethically problematic. Moreover, NBAC finds that animal cloning is ethically acceptable and promises important benefits. The Commission thus cautions that restrictions on cloning not impede these activities.

The Commission notes that current restrictions effectively prohibit federally funded and regulated entities from attempting to clone a human being through somatic cell nuclear transfer. However, fertility clinics and other privately-funded clinical and research establishments face no prohibition on human cloning, and NBAC questions whether some of these organizations will adhere to a voluntary moratorium.

Accordingly, NBAC's draft final report calls for carefully-worded national legislation prohibiting anyone from "attempting to create a child through somatic cell nuclear transfer techniques." The Commission specifies that the legislation should include a sunset provision and that, prior to the sunset date, an oversight body should review and report on the status of somatic cell nuclear transfer technology and the ethical and social issues associated with its use in humans. NBAC also recommends that the U.S. cooperate with other countries to enforce mutually-supported cloning restrictions.

National Legislation

We recommend that you embrace NBAC's proposal to establish a narrowly crafted time-limited legislative moratorium. Legislation is the only way to establish a comprehensive, enforceable prohibition on cloning entire human beings in all publicly and privately funded research and clinical activities. If carefully written, the ban will not preclude important research.

Reaction to proposed legislation will be mixed. A national and international consensus is emerging that attempting to apply the technology used to clone Dolly to humans is morally wrong. The American Medical Association has conveyed this view to NBAC, and the World Medical Association has issued a similar statement. Given NBAC's recommendation, we expect many in the scientific and ethics communities to accept a legislative moratorium.

But some who agree that cloning a human being using somatic cell nuclear transfer is morally unacceptable will oppose a legislated moratorium. In particular, the biotechnology and pharmaceutical industries strongly oppose legislation. These two industries are deeply concerned that a legislative debate will produce broadly drawn language that impairs critical research. Some academic researchers may share this view. Fertility clinics also may oppose legislation, but to date have not signaled a position.

Finally, some in the right-to-life community will argue from the other side that NBAC's proposed approach does not go far enough. This community will push for a comprehensive ban on the creation of embryos, through any means, for research purposes (i.e., not for the purposes of creating a child). The Administration has applied this restriction to federally-funded research, but opposed legislation on the subject. This is an issue NBAC declined to review, and we do not recommend revisiting it in this context.

We recommend that you announce your support for legislation and propose specific legislative language on June 10, at your scheduled press conference, three days after NBAC's

recommendation will become public. We anticipate that the release of NBAC's report will prompt Congressional hearings and legislative proposals. By acting quickly you can maintain your leadership on the issue and carefully frame the legislative debate, making clear the value of biotechnology research and the danger of overly broad regulation, while calling for the prohibition of an unethical use of a specific technology.

Approve ___ Disapprove ___

Group of Eight Statement on Cloning

France has proposed a paragraph for inclusion in the G-8 communique embracing national and international bans on "reproductive human cloning." Germany will support the statement; Canada will support it with some modification.

The U.S. biotechnology and pharmaceutical industries strongly oppose including any paragraph on cloning in the communique. They fear that it will not be carefully drafted and may inadvertently extend to the cloning of DNA, cells, and tissues as well as entire human beings. Further, industry is concerned that a statement on cloning ultimately could provide cover for protectionist efforts to restrict U.S. biotechnology products and activities.

Nevertheless, we recommend that the Administration support the French proposal with critical modifications. Specifically, we suggest that the U.S. insist on changes to: (1) affirm the potential medical and agricultural benefits of cloning technology; (2) limit the prohibition to the use of somatic cell nuclear transfer technology; and (3) propose a time-limited moratorium instead of a ban. USDA and HHS support this position.

Approve ___ Disapprove ___

DRAFT MEMORANDUM FOR THE PRESIDENT

FROM:

SUBJECT: Cloning: Legislative Options

Interest in cloning legislation was renewed by reports that a Chicago physicist plans to attempt to use this technology to create a child. Your January 10 radio address challenged Congress to enact a ban on private sector activities like the one you have imposed on the use of public funds. Congressional staff inquiries indicate that your challenge will be accepted. Both critics and supporters of your draft bill agree that this issue raises complex drafting problems. You have the opportunity at this juncture to stay with existing language or, alternatively, propose new wording that clarifies your position. Given the strong possibility that Congressional measures may deviate from the principles outlined in your draft bill, it may be desirable to assert your leadership and encourage your allies by providing more specific language.

Your June 9, 1997 draft legislation (Tab A): 1) prohibits the production of a child using somatic cell nuclear transfer, 2) protects valuable research, especially embryo research conducted without the use of Federal funds, 3) provides no new incentives for abortion, and 4) establishes a sunset provision. We believe these principles should underpin any cloning legislation. The prohibition wording options presented below are designed to clarify our position.

Whichever option you choose, you will have to struggle with the dichotomy between allowing most embryo research in the private sector, while maintaining a ban on the use of Federal funds with which much valuable science might be conducted. You addressed this issue in developing the current draft bill and might refer to the June 8 decision memorandum for useful discussion (Tab B). It is probable that cloning legislation will viewed by some members of Congress as a vehicle for extending a more permanent, broad ban on embryo research.

The memorandum also presents the pros and cons associated with a clause pre-empting state legislation of human cloning, and a possible legislative strategy.

I. Prohibition Wording Options

A. Support current language without changes

Current language:

```
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.
```

Your bill has been praised by the biomedical industry and professional societies for its narrow focus on the act of creating a human being through somatic cell nuclear transfer--the technology used to create Dolly the sheep--and the absence of any mention of embryo research.

These groups also applaud your protection of noncontroversial biomedical research and the 5-year sunset provision. Current language maintains the status quo with respect to freedom to carry out embryo research in the private sector under existing (albeit limited) Federal oversight, and does not affect nor address the ban on Federal funding for a much broader class of embryo research.

The biotechnology industry and fertility research community have identified three problems with this language: (1) it appears to equate introduction into the womb with creating a human being, (2) the meaning of the word "intent" is ambiguous, and (3) the meaning of the phrase "or in any other way" is unclear. Option B describes a solution for these problems, while continuing to uphold the principles expressed in your draft bill .

B. Refine current language

Suggested modification:
It shall be unlawful for any person or other legal entity, public or private, to introduce the product of somatic cell nuclear transfer into a woman's womb in order to create a child.

This language is an improvement in that it makes it clear that violation would occur at the time of introduction into the womb of the product of cloning. However, the phrase "in order to create child" carries with it two problems: (1) defining a child and when life begins, and (2) "in order to" still implies intent. Option C avoids these pitfalls/difficulties.

C. Continue to support the principles in the existing bill, but clarify its scope

Suggested modification:
It shall be unlawful for any person or other legal entity, public or private, to introduce the product of somatic cell nuclear transfer into a woman's womb.

You have been sensitive to the need to be very careful in setting a boundary around permissible biomedical research; hence this bills narrow focus. The phrase "in order to create a child" maintains that view. However, it suggests two potentially troubling scenarios of which you should be aware. First, it could be interpreted that it encourages abortion because transfer of the product of cloning would be prohibited only if it was done to create a child, but not if it was done with the intention to abort. Second, someone caught in the act of attempting to create a child using this method could avoid liability simply by aborting the cloned embryo or fetus. Therefore, we would suggest that "in order to create a child" be deleted.

This clear language means that during the time this law is in effect, no one in the public or private sectors may perform somatic cell nuclear transfer and implant the resulting product in a woman's uterus. Today, this is legal in the private sector, although it may be possible to exert some regulatory oversight, as discussed in the background attachment. Some fertility research would be precluded under this option, although it is difficult to determine how much because efforts are generally made to sustain a pregnancy after implantation, not to perform experiments

with the intention of aborting. Your National Bioethics Advisory Commission recommended a temporary ban on the use of somatic cell nuclear transfer to create child only after hearing testimony that a 3-5 year prohibition would not impede medical research progress, as long as animal cloning experiments were permitted. We have been told that the fertility research community would not object to this approach.

The right-to-life community has criticized your bill based on their interpretation that it would allow the creation of embryos for research purposes using private funds as long as those embryos were aborted subsequently. Option C still permits the creation of embryos, but removes the incentive for abortion. While the scientific and medical communities supported your earlier version, it is likely that you will retain their support even with this change in view of the larger threats that Congress might impose on research. However, it does make retention of the **sunset clause** all the more crucial. Sen. Bond, Rep. Ehlers, and others will oppose a sunset clause.

D. Adopt a more general prohibition

Your bill is intended to prevent anyone from creating a child who is a genetically identical copy of an existing or previously existing person. Somatic cell nuclear transfer is one way of accomplishing this feat and you endorsed the recommendation of your National Bioethics Advisory Commission in limiting the scope of your bill to the use of such technology to create a child. However, other groups including the American Society for Reproductive Medicine and Council of Europe have proposed more general, non-technology specific bans. One example might be the following:

```
It shall be unlawful to create a child who is genetically
identical to an existing or previously existing child or adult.
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We oppose this approach because it raises many of the same problems addressed in Options A and B; namely, defining a child and when life begins. It would also bar reproductive technology currently in use in the U.S.

Recommendation:

We propose that you select Option C so as to: maintain a narrowly focused prohibition, thus protecting the widest possible range of biomedical research while not creating any new incentives for abortion.

Approve: _____ Disapprove: _____ Discuss: _____

II. Federal Pre-emption of State Regulation

The industry is strongly advocating that the Administration use this bill to pre-empt state laws restricting cloning research. The industry cites the California Bill as an example of the type of provision that would prohibit appropriate

biomedical research on cloning and they fear that the political climate would likely pressure states to adopt unduly restrictive measures.

There are also a number of reasons arguing against pre-emption at this time. For example, federalism concerns would normally militate against preemption unless it could be shown that such action is necessary (e.g. when there is a need for national standards). In this case, although the industry might be inconvenienced by the existence of differing laws, there is no clear reason why uniform standards are required. Indeed, in the area of biomedical research, there is a strong argument in favor of allowing the states to experiment with a wide range of options because no single correct approach to this issue is immediately obvious. Moreover, the industry's fears that the states would act in concert to preclude important biomedical research, beyond the use of cloning to create a child, seem unwarranted. It is not likely that every state would choose to ban all research because the states that elect to forego restrictive regulation would be likely, on that account, to attract new industry. Finally, using this particular bill to preclude all state regulation of biomedical research is inconsistent with our position that this bill is designed to address only the limited issue of cloning and is not an attempt to address broader research issues.

Recommendation:

We recommend against adding a pre-emption clause.

Approve: _____ Disapprove: _____ Discuss: _____

III. Legislative Strategy

Because the amendment process is difficult to control and extreme amendments may make ultimate support of transmitted Administration legislation undesirable, we recommend encouraging our allies in Congress to incorporate your improved language into their legislation. Senator Diane Feinstein is currently drafting legislation and might be receptive.

Cloning legislation already introduced:
HR 922 by Ehlers - prohibition of Federal funds to conduct or support research on the cloning of humans. Passed out of House Science Committee. Jurisdiction claimed by House Commerce. No hearing date set.
HR 923 by Ehlers - prohibition on cloning humans. House Judiciary Committee. No hearing date.
S 368 by Bond - prohibition of use of Federal funds for human cloning research. No action to date.

Tabs:

A. June 9, 1997 draft Administration bill
B. June 8, 1997 Decision memorandum
C. Discussion of Impact of FDA Regulatory Authority on Legislative Strategy

DRAFT

MEMORANDUM FOR THE PRESIDENT

FROM:

SUBJECT: Cloning Legislative Options

Interest in cloning legislation was renewed by reports that a Chicago physicist plans to attempt to use this technology to create a child. Your January 10 radio address challenged Congress to enact a ban on private sector activities like the one you have imposed on the public sector. This issue is likely to appear in both the House and Senate very soon after they return. Based on bills introduced in the fall, and the difficulties inherent in trying to craft a bill of appropriate scope, there is a strong possibility that Congressional measures may deviate from the principles outlined in your draft bill.

This memorandum summarizes the following options with respect to a legislative strategy on cloning: (A.) continue to support the principles and language in your June 9, 1997 draft bill; (B.) support the principles but refine the current language; (C.) change the scope of prohibited activities to respond to criticism; or (D.) adopt a prohibition with a more general focus.

The memorandum also presents the pros and cons associated with a clause pre-empting state legislation of human cloning.

I. Substantive Prohibition

A. Support existing language without changes

Your bill has been praised by industry and professional societies for its narrow focus on the act of creating a human being through somatic cell nuclear transfer (SCNT), the technology used to create Dolly the sheep, and the absence of mention of embryo research. These groups also applaud your protection of noncontroversial biomedical research and the 5-year sunset provision. Current language maintains the status quo with respect to freedom to carry out embryo research in the private sector under existing (albeit limited) Federal oversight. The Federal ban on creation of human embryos for research purposes is unaffected by any of the options in this memorandum.

B. Refine current language

Continue to hold to the principles expressed in your draft bill but make the following changes to clarify the prohibition:

Current language:

```
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.
```

Suggested modification:
It shall be unlawful for any person or other legal entity, public or private, to introduce the product of somatic cell nuclear transfer into a woman's womb in order to create a child.

Rationale

- There is greater agreement on the definition of a child than there is on a human being, thus avoiding some, but not all of the embryo research and abortion debate.
- The term "or in any other way" created unnecessary confusion.
- "Intent" was included as protection for a defendant, but industry and medical practitioners suggested deleting it.

C. Continue to support the principles in the existing bill but broaden its scope

We would like you to focus on pros and cons of including the phrase "in order to create a child" as it appears in Option B.

You have been sensitive to the need to be very cautious in setting a boundary around permissible biomedical research through this bill; hence its narrow focus. The phrase "in order to create a child" maintains that view with its implied intent. However, it suggests two potentially troubling scenarios of which you should be aware. First, it may be interpreted to encourage abortion because transfer of the product of cloning would be prohibited only if it was done so as to create a child, not if it was done with intent to abort. Second, someone caught in the act of attempting to create a child using this method could avoid liability simply by aborting the cloned embryo or fetus.

Therefore, we would suggest that the prohibition be modified to read as follows:
It shall be unlawful for any person or other legal entity, public or private, to introduce the product of somatic cell nuclear transfer into a woman's womb.

This clear language means that during the time this law is in effect, no one in the public or private sectors may perform somatic cell nuclear transfer and implant the resulting product in a woman's uterus. Today, this is legal in the private sector, although it may be possible to exert some regulatory oversight, as discussed in the background attachment. Some fertility research would be precluded under this option, although it is difficult to determine how much because efforts are generally made to sustain a pregnancy after implantation; not to perform experiments with the intention of aborting.

The right-to-life community criticized your bill for allowing the creation of embryos for research purposes using private funds, as long as those embryos were aborted subsequently. This modification still permits the creation of embryos but removes the incentive for abortion. While the scientific and medical communities supported your earlier version, it is likely that you will retain their support even with this change in view of the larger threats to research emanating from

Congress. However, it does make the sunset clause all the more crucial. We have been told that the fertility research community would not object to this approach.

D. Adopt a more general prohibition

Your bill is intended to prevent anyone from creating a child who is a genetically identical copy of an existing or previously existing person. Somatic cell nuclear transfer is one way of accomplishing this feat and you endorsed the recommendation of your National Bioethics Advisory Commission in limiting the scope of your bill to the use of this technology to create a child. Another option would be to construct a more general, non-technology specific ban such as the following:

It shall be unlawful to create a child who is genetically identical to an existing or previously existing child or adult.

Violation of this ban will depend on one's definition of the point at which life begins. Some people believe that an embryo is a child, hence, creating identical embryos would be in violation of the law. Under this definition, an existing reproductive technology known as blastomere or blastocyst splitting would be prohibited. This method is used to treat women with reduced fertility, particularly those who are older and wish to have more than one child but are unable or unwilling to undergo the drug treatments necessary to stimulate hyperovulation. It may also be used with donor eggs. What is done, in essence, is to fertilize one egg and after just a few cell divisions, split the early embryo. This mimics the occurrence in nature of identical twins. However, the mother has the option of implanting both embryos, or freezing one and implanting it at a later date, thus creating non-contemporaneous twins.

If one believes that life begins at birth, then it would be permissible to create a cloned embryo, implant that embryo in a woman's uterus, and abort it at any point prior to birth. This course has the same shortcomings as Option 2 in that it may be interpreted to encourage abortion.

Recommendation:

We propose that you select Option C. so as to: maintain as narrow a prohibition as possible, thus protecting a wide range of biomedical research, and preserve the status quo with respect to incentives for abortion.

Approve: _____ Disapprove: _____ Discuss: _____

II. Federal Pre-emption of State Regulation

The industry is strongly advocating that the Administration use this bill to pre-empt state laws restricting cloning research. The industry cites the California Bill as an example of the type

of provision that would prohibit appropriate biomedical research on cloning and they fear that the political climate would likely pressure states to adopt unduly restrictive measures.

There are also a number of reasons arguing against pre-emption at this time. For example, federalism concerns would normally militate against preemption unless it could be shown that such action is necessary (e.g. when there is a need for national standards). In this case, although the industry might be inconvenienced by the existence of differing laws, there is no clear reason why uniform standards are required. Indeed, in the area of biomedical research, there is a strong argument in favor of allowing the states to experiment with a wide range of options because no single correct approach to this issue is immediately obvious. Moreover, the industry's fears that the states would act in concert to preclude important biomedical research, beyond the use of cloning to create a child, seem unwarranted. It is not likely that every state would choose to ban all research because the states that elect to forego restrictive regulation would be likely, on that account, to attract new industry. Finally, using this particular bill to preclude all state regulation of biomedical research is inconsistent with our position that this bill is designed to address only the limited issue of cloning and is not an attempt to address broader research issues.

Recommendation:

We recommend against adding a pre-emption clause.

Approve: _____ Disapprove: _____ Discuss: _____

Attachments:

A. Discussion of Impact of FDA Regulatory Authority on Legislative Strategy

B. H.R. 922 - Bill Introduced By Rep. Vernon Ehlers to prohibit the expenditure of Federal funds to conduct or support research on the cloning of humans.

(1) Lock V's w/ first stuff
- should someone call him
- who

(2) No send out SAP

(3) Can't use fed'l funds

(4) 3-5 yr. limit - State of Science

Will moral views change.
- carve out vs. the limit

Carve out vs. Sunset vs. both

- 5 yr.
- opposes us.
- clear difference btwn use / source.
  - commission
  - penalties
  - research

  } Concerns } SAP
- SAP - means we like our bill
- HHS

Specter - Amendment →

Strategy
① First - call refer → Unless to First
② delay - Kennedy, Daschle, Feinstein - Slow down
③ Bill, Jerry, Rachel
④ Luck to First
⑤ HHS - to Daschle / Kennedy
⑥ Warm

Feb. 12 hrngs.
- sunset
- penalties
- exception

Warm → - to Muscle Left