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Folder Title:
Human Cloning: [Correspondence]

Stack:	Row:	Section:	Shelf:	Position:
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November 14, 1998

Dr. Harold Shapiro
Chair, National Bioethics Advisory Commission
Suite 3C01
6100 Executive Boulevard
Bethesda, Maryland 20892-7508

Dear Dr. Shapiro:

This past week's report of the creation of an embryonic stem cell that is part human and part cow raises the most serious ethical, medical, and legal concerns. I am deeply troubled by this news of experiments involving the mingling of human and non-human species. I am therefore requesting the National Bioethics Advisory Commission to consider the implications of such research at its meeting next week, and to report back to me immediately thereafter.

I recognize, however, that other kinds of stem cell research raise different ethical issues, while promising significant medical benefits. Four years ago, I issued a ban on the use of federal funds to create human embryos solely for research purposes; the ban was later broadened by Congress to prohibit any embryo research in the public sector. At that time, the benefits of human stem cell research were hypothetical, while the ethical concerns were immediate. Although the ethical issues have not diminished, it now appears that this research may have real potential for treating such devastating illnesses as cancer, heart disease, diabetes, and Parkinson's disease. With this in mind, I am also requesting the Commission to undertake a thorough review of the issues associated with such human stem cell research, balancing all ethical and medical considerations.

I look forward to receiving your reports on these important issues.

Sincerely,

weekly draft

Human Cloning -- Congressional Activity: The Senate and House debated human cloning legislation this week. As you may know, the Republican House and Senate leadership want to use cloning legislation to further restrict embryo research. On Wednesday, Senator Lott sent legislation to the floor sponsored by Senators Bond and Frist that would criminalize all human somatic cell nuclear transfer (the procedure used to clone Dolly the sheep), including experiments designed solely to produce cell lines to treat diabetes and cancer. Your legislation would permit such research. In part because Lott bypassed committee review of the bill, 12 Republican Senators joined all 42 voting Democratic Senators to block cloture. We sent a Statement of Administration Position objecting to the bill in its current form. On Thursday, the House Commerce Committee held a cloning hearing. Once again, a number of Republicans joined Democrats in criticizing the Bond/Frist approach. This week's events demonstrate limited support for a bill the impedes "embryo" research aimed at preventing or treating serious and life-threatening disease. We are optimistic the Republican leadership now will consider a more narrow bill. Next week we will consult science and biotechnology industry leaders and seek meetings with key members of Congress (Frist, Mack, Feinstein, and Kennedy) to move cloning legislation forward.

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

February 9, 1998
(Senate)

STATEMENT OF ADMINISTRATION POLICY

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

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

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

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

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

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

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

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

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

February 9, 1998
(Senate)

STATEMENT OF ADMINISTRATION POLICY

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

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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.

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(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.

LEGISLATIVE REFERENCE DIVISION DRAFT
February 6, 1998 - 10:30 a.m.

DRAFT – NOT FOR RELEASE

February 6, 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 ~~unsafe and~~ morally unacceptable. The Administration, however, believes S. 1601, as introduced, poses a significant threat to important biomedical research, ~~and therefore, has concerns regarding~~ 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, while being free from the concern that someone will use it prematurely.

- Permit somatic cell nuclear transfer using human cells for the purpose of developing stem cell (unspecialized cells capable of giving rise to specific cells and tissue) technology to 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.

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DRAFT – NOT FOR RELEASE

is overbroad because it

February 6, 1998
(Senate)

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other

the Administration does not support

- 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, while being free from the concern that someone will use it prematurely.

for purposes other than cloning a human being (?)

- 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.

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(need to confirm with scientists)

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****

DRAFT -- NOT FOR RELEASE

DRAFT

believes S. 1601 poses a significant threat to important biomedical research and ~~is opposed to~~ its passage in its current form,

February 5, 1998
(Senate)

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

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

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

SCNT using human cells

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

technology

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

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

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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.

* * * * * * * * * *

DRAFT -- NOT FOR RELEASE

DRAFT

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February 5, 1998
(Senate)

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(Sen. Lott (R) MS)

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March 25, 1998

MEMORANDUM FOR ELENA KAGAN

FROM: Jerry Mande

SUBJECT: Today's Cloning Meeting

The goal of today's cloning meeting is to shore up our base of support. Simply holding a meeting led by senior White House staff will move us toward our goal. The key messages for the meeting are: 1) we will vigorously oppose a bad bill; and 2) we will succeed in blocking a bad bill if everyone does their part.

I recommend starting the meeting by thanking the groups for all that they have already done, then stating our messages, and then going around the room to hear from the groups.

Background -- Barbara Woolley has put together an excellent group for today's meeting. She has assembled representatives from the key patient groups, scientific organizations, and industry. These are the groups that turned around the cloture vote in our favor, and these groups can indeed block a bad bill if they each do their part.

As you may recall, we decided to call this meeting in response to a meeting held by the Republican leadership to put pressure on the industry.

Congressional Update -- There is some activity in Congress, but as far as the minority staff in the House and Senate can tell cloning legislation is stalled. It may be wishful thinking, but a couple of key minority staff members I spoke to in the House felt the Republicans would be unable to get a cloning bill back track because the Republicans have managed to trap themselves between two important constituencies -- the religious right and the biotech and pharmaceutical industry. It currently seems impossible to write a bill that doesn't anger one of these groups.

There is one development. The drug and biotech industries were called in a again a couple of weeks ago by Congressman Armey. He said he wanted a bill by Easter and asked for their help in drafting it. I have heard second hand that the industry is likely to propose an approach we are already exploring -- codifying FDA regulation and establishing a RAC-like committee (RAC -- Recombinant DNA Advisory Committee that was established to oversee gene therapy). The religious right will not favor this approach.

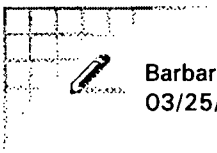
There is even less movement in the Senate. No hearings are currently planned even though that would seem to be an essential step given the cloture vote.

I am writing to ask you to work with me to enact into law this year restrictions that will prevent the cloning of a human being, without disrupting biomedical research. On June 9, 1997, I sent legislation to the Congress that would achieve these goals. My bill was carefully and narrowly crafted to prevent the cloning of a human being, but not interfere with important biomedical research that could lead to meaningful advances in treating illnesses such as cancer and diabetes. Reports this week of the cloning of more than 50 adult mice adds to the urgency of our task.

As you know, scientists, the public, and policymakers alike were stunned last year by reports that a scientist had cloned an adult sheep. Most experts had previously believed that it was not possible to reactivate all of the genes of an adult specialized cell. But as has happened so often, human ingenuity pierced old assumptions and provided a new understanding of what is possible. This technology holds great promise. Many scientists and doctors now believe cloning technology can be used to produce cell lines that could result in breakthrough treatments of many dreaded illnesses such as replacing a failing organ without the need for a donor or the risk of tissue rejection.

But the new technology also poses difficult moral questions. Scientific advancement should not occur in a moral vacuum. Technological developments divorced from values will not bring us one step closer to meeting the challenges of the next millennium. Virtually everyone agrees that the use of new cloning techniques to create a human being is untested, unsafe, and morally unacceptable.

I am concerned that efforts to address other moral issues, such as when does human life begin, in cloning legislation are endangering our chances of passing a bill this year. This week's reports on the advances in cloning technology make it important that we set aside politics and send a clear message that cloning a human being is not an acceptable endeavor. We have the opportunity to do that in the next two months. But we will only succeed if we stay focused on prohibiting the cloning of human beings, and not try to resolve other moral conundrums that at this time are best addressed by bodies such as that National Bioethics Advisory Committee.



Barbara D. Woolley
03/25/98 12:44:52 PM

Record Type: Record

To: Sara M. Latham/WHO/EOP

cc: Jerold R. Mande/OSTP/EOP
Subject: List of Human Cloning Participants

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

List of Participants

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

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

Industry
Barry Caldwell, Vice President, Federal affairs, PhRMA

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

THE WHITE HOUSE
Office of the Press Secretary
Saturday, January 10, 1998

Listen to Address with Real Audio player || Download in .au format (~3 Mb)

RADIO ADDRESS BY THE PRESIDENT TO THE NATION

Four Seasons Hotel
Houston, Texas

THE PRESIDENT: Good morning. Today I want to talk with you about the extraordinary promise of science and technology, and the extraordinary responsibilities that promise imposes on us.

As we approach the 21st century it is clearer than ever that science and technology are changing the way we live and work and raise our families. The remarkable breakthroughs in biomedical science are helping to unravel the mysteries of life, holding out new hope for lifesaving cures to some of our most dreaded diseases. In recent years, we've made real progress, lengthening the lives of people with HIV, finding the genes that can show heightened risk for breast cancer and diabetes. Now we're on the verge of discovering new treatments for spinal cord and even brain injuries.

For five years I have maintained our nation's solid commitment to scientific research and technological development, because I believe they're essential to our nation's economic growth and to building the right kind of bridge to the 21st century. The balanced budget I will submit in just a few weeks to Congress reflects that continued commitment. And, in my upcoming State of the Union address, I'll talk more about what we're doing to keep America on the cutting edge of the scientific and technological advancements that are driving our new global economy.

Still, it's good to remember that scientific advancement does not occur in a moral vacuum. Technological developments divorced from values will not bring us one step closer to meeting the challenges or reaping the benefits of the 21st century.

This week, like many Americans, I learned the profoundly troubling news that a member of the scientific community is actually laying plans to clone a human being. Personally, I believe that human cloning raises deep concerns, given our cherished concepts of faith and humanity. Beyond that, however, we know there is virtually unanimous consensus in the scientific and medical communities that attempting to use these cloning techniques to actually clone a human being is untested and unsafe and morally unacceptable.

We must continue to maintain our deep commitment to scientific research and technological development. But when it comes to a discovery like cloning, we must move with caution, care and deep concern about the impact of our actions. That is why I banned the use of federal funds for cloning human beings

while we study the risks and responsibilities of such a possibility. And that's why I sent legislation to Congress last June that would ban the cloning of human beings for at least five

years while preserving our ability to use the morally and medically acceptable applications of cloning technology.

Unfortunately, Congress has not yet acted on this legislation. Yet, it's now clearer than ever the legislation is exactly what is needed. The vast majority of scientists and physicians in the private sector have refrained from using these techniques improperly, and have risen up to condemn any plans to do so. But we know it's possible for some to ignore the consensus of their colleagues and proceed without regard for our common values. So today, again, I call on Congress to act now to make it illegal for anyone to clone a human being.

Our nation was founded by men and women who firmly believed in the power of science to transform their world for the better. Like them, we're bound together by common dreams and by the values that will drive our own vision for the future. And our commitment to carry those enduring ideals with us will renew their promise in a new century and a new millennium. We must never lose touch with that, no matter what the reason, or we'll lose touch with ourselves as a people.

Thanks for listening.

Draft 1/9/98 5:00pm

PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS ON CLONING
January 10, 1998

Good morning. This week, like many Americans, I learned the profoundly troubling news that a member of the scientific community is laying plans to clone a human being. Today, I want to talk about the reasons why we, as a nation, must condemn this plan as a violation of our deepest values.

Last year, news that scientists had successfully cloned a sheep astonished the world. We knew then that this remarkable breakthrough had the potential to yield enormous agricultural and medical benefits. But we also knew that with this great potential came the troubling possibility that these new techniques could be used to clone human being.

I said then and I believe just as strongly today that any discovery that touches upon human creation requires us to move with caution, care, and deep concern about the impact of our actions. That is why I banned the use of federal funds for cloning human beings while we study the risks and responsibilities of such a possibility. And that is why I asked the National Bioethics Advisory Commission to conduct a thorough review of the scientific, moral, and spiritual dimensions of cloning human being. The commission spent three months speaking to families, physicians, religious leaders, and researchers, all of whom agreed unanimously that attempting to clone a human being is unacceptably dangerous to the child and morally unacceptable to our society.

In response to this overwhelming consensus, I sent legislation to Congress last June that would ban the cloning of human beings for at least five years, while preserving our ability to study the morally and medically acceptable uses of cloning technology. Unfortunately, Congress has not yet acted on this legislation.

This week, we learned why we need it. While the vast majority of scientists and physicians in the private sector have refrained from using these techniques improperly -- and risen up to condemn any plan to do so -- we know now that there are those who ignore the consensus of their colleagues and proceed without regard for our common values. So today, I call again on Congress to act now to prevent the use of these techniques to clone a human being. It is untested, it is unsafe, and it is morally wrong.

Let me be very clear about this. I am firmly and fully committed to supporting scientific research and technological development, because I believe they are essential to our progress as we go forward into the 21st Century. The balanced budget I will submit in just a few weeks to Congress reflects that commitment. And in my upcoming State of the Union address, I will talk more about what we are doing to keep America on the cutting edge of the scientific and technological advances that are driving the global economy. But technology divorced from values

will not bring us one step closer to meeting the challenges or reaping the benefits of the 21st Century.

Ultimately, it is our values that drive our vision for the future -- and our commitment to carry those enduring ideals with us, and to renew their promise in a new century and a new millennium. We must never lose touch with that, no matter what the reason, or we will lose touch with ourselves as a people.

Thanks for listening.

Background

Mice cloning -- Today's Washington Post and New York Times ran lead stories based on a **Nature** paper reporting the first successful cloning of adult mice by scientists at the University of Hawaii. The same issue of **Nature** contains two papers confirming Dolly the sheep's status as the first clone of an adult mammal.

What's new here and what are the implications for cloning human beings?

Although it would seem that the cloning of larger mammals, such as sheep, would be more relevant than mice to the application of this technology to human reproduction, in fact, the opposite is true. Cloning Dolly took advantage of a relatively long period in sheep embryo development during which DNA from an adult donor cell could be reprogrammed by chemicals in the recipient egg. Human and mouse embryos, by contrast, depend on the DNA being ready for use at a much earlier time in their development, making it unclear whether or not the Scottish techniques used to produce Dolly would work in humans. Earlier attempts to clone mice failed repeatedly. These new mouse experiments demonstrate that this barrier has been overcome, making it conceivable that this technique can be used to produce human embryos.

Cloning for reproductive purposes is only one of many uses of this technology. The first application is more likely to be greater understanding of cell differentiation. This in turn can lead to reprogramming cells to become skin or nerve or blood cells.

Q: What is the Administration's current position on cloning?

A: The Administration still believes that it would be morally unacceptable for anyone in either the public or private sector to attempt to produce a human being using somatic cell nuclear transfer technology. Even with the greater success rate of the mouse experiments, there would still be too great a risk of harm to the child to justify its use. In addition, using this technology to produce children raises social and ethical concerns that require broad public discussion before anyone should even consider moving forward.

Q: Will the President support cloning legislation of the kind introduced by Congressional Republicans?

A: The President believes that using scientific techniques, like those used to create Dolly the sheep or the mice reported in Nature, to create a human being is untested, unsafe, and morally unacceptable. The President also believes that the leaders of Congress should put the public interest first and politics last and pass the legislation that he has sent up which would prevent the cloning of a human being. Congressional leaders should end their efforts to use cloning legislation as a back door effort to prohibit abortions.

The President believes that the Republican cloning bills are too far-reaching because they would prohibit important biomedical research aimed at preventing and treating serious

and life-threatening diseases.

Q: In the absence of legislation, will efforts to clone human beings now move forward unimpeded?

A: No. The Administration has acted to prevent the cloning of a human beings even while we continue to push for legislation. The Food and Drug Administration has determined that a human somatic cell clone is a product that is regulated by the agency under its law. In April, FDA issued guidance that makes clear that any effort to clone a human being without first receiving FDA approval would be a prohibited act subject to civil and criminal litigation.

Qs and As on Cloning
June 9, 1997

Q. **What did the Commission recommend?**

A. The Commission recommends legislation to prohibit anyone in either the public or private sector from attempting to create a child using the cloning technology that made possible the creation of "Dolly" --so-called "somatic cell nuclear transfer" technology. The Commission also supports a continuation of the current moratorium on federal funding of creating a child by cloning while the legislation is pending. NBAC is also asking the private sector to comply with the voluntary moratorium President Clinton called for in March, pending the legislative prohibition. Finally, NBAC also called for continuing public dialogue on these issues to further understand the ethical and social implications of this technology.

Q. **What exactly does the President's legislation ban?**

A. The President's legislation prohibits the use of somatic cell nuclear transfer to create a human being (specifically, "with the intent of introducing the product of that transfer into a woman's womb or in any other way creating a human being").

Q. **How will the prohibition be enforced?**

A. The legislation 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).

Q. **Why doesn't it make cloning a criminal act and impose jail time?**

A. We think the penalties in the bill provide an effective deterrent. In particular, they make it clear no one will profit from this activity. It is

appropriate to be cautious about criminalizing any activity, and at this point we don't have any indication that we need the threat of criminal sanctions to deter this activity.

Q. **But what if Congress wants to impose criminal sanctions?**

A. We have seriously considered this option and would be willing to look at it again.

Q. **Why is there need for a "sunset" provision?**

A. NBAC recommends --and the President supports --a sunset provision, combined with review by an advisory body prior to the sunset date. There are several reasons to take this approach. First, 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; second, there is a possibility that we will get the precise 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; and third, there has been little time to fully consider the moral issues, and it is possible that convictions may evolve.

Q. **But if you think cloning is morally wrong now, won't it be morally wrong for all time?**

A. Even if one thinks cloning is morally wrong, a sunset provision still makes sense. As I just noted, it will force a renewed national debate within several years and will keep the ethical issues squarely in view. A sunset provision will also make sure we revisit how we've defined the ban and ensure we have done it exactly right.

Q. **Why ban the cloning of humans?**

A. It is morally unacceptable for anyone in either the public or private sector to attempt this type of cloning. NBAC found it is simply unsafe; knowing that "Dolly" was the only successful case in 277 attempts,

there is no doubt that there would be substantial risk to the potential child. And the possibility of replicating ourselves raises other ethical and religious concerns about the implications of this technology for our society. These issues need further discussion before the technology is used.

Q. **Why not ban all cloning? What are the potential benefits of cloning research?**

A. There are legitimate and beneficial applications of cloning cells, DNA, tissues, and animals: including the development of medicines, and therapies for diseases such as cancer, cystic fibrosis, and diabetes. Cloning also furthers our knowledge about developmental biology that may one day lead to such advances as regeneration of tissue in severe burns and spinal cord injuries.

Q. **Why is any additional legislation necessary? Why not extend the President's moratorium?**

A. The President's moratorium covers only federally funded activities. In March, President Clinton called for a voluntary ban on privately funded activities. Legislation is necessary, however, to ensure that the privately funded research and clinical centers comply with the proposed prohibition on cloning of human beings using the somatic cell nuclear transfer technique.

Q. With the proposed legislation, are we interfering with people's reproductive freedom?

A. No. We don't think people should have the "freedom" to do this activity. It's unsafe and ethically objectionable.

Q. How will the recommendations and legislation affect research?

A. NBAC found that a ban on human cloning will not impede any important research at this time. research in such areas as animal husbandry and drug development will continue. Similarly, basic research using somatic cell nuclear transfer technology to study, for instance, the potential for regenerating tissues and organs will continue. However, under current federal restrictions, human

embryo research using federal funds will remain prohibited.

Q. **Why would you (or the Commission) support a total ban on cloning people, but not on creating embryos using cloning technology for research?**

A. The issue of embryo research is an important but separate question. NBAC found that the technology that created Dolly doesn't raise new questions related to embryo research. 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. The President's legislation is directed at these concerns. Further, the President has prohibited the use of federal research funds to create an embryo for research purposes --whether through cloning or any other means.

Q. **If human embryo research is bad, why not ban it in the private sector as well?**

A. Whether to ban privately-funded embryo research is a question that needs careful deliberation, as such research may offer medical benefit, particularly with respect to treating infertility. We simply need further discussion about regulation of this activity in the private sector before pursuing legislation.

Q. **Does the Federal Government have any jurisdiction over privately funded research with human embryos?**

A. If the research is part of an effort to develop a drug, biologic, or medical device, the research is subject to regulation by the Food and Drug Administration. Otherwise, it is unregulated.

Q. **What happens to human embryos created for research? If they are not implanted, isn't that tantamount to abortion, or even murder?**

A. Creation of human embryos for research is a prohibited use of federal funds. The extent of such research under private sponsorship is unknown; therefore, we

have no reliable information on the fate of human embryos used in this way.

Q. How will this affect childless couples who see cloning as their only chance to have genetically related offspring?

A. Prohibiting this technology will have little practical effect on such couples. Currently neither the science base nor safety considerations make it possible to produce a child by somatic cell nuclear transfer.

Q. Is the United States acting unilaterally on this issue? Are we treating this issue any differently than other countries?

A. Some European countries have already established legal prohibitions on the cloning of humans. To the extent that there are common aspects to our respective policies, we will certainly cooperate with these nations regarding enforcement.

November 12, 1998

Human Cells Revert to Embryo State, Scientists Assert

By NICHOLAS WADE

Venturing deep into uncharted realms of ethics and medicine, a small biotechnology company said Wednesday that its scientists had for the first time made human cells revert to the primordial, embryonic state from which all other cells develop, by fusing them with cow eggs and creating a hybrid cell.

The research comes from biologists who are well known in their field, but has yet to be confirmed or even published in a scientific journal. Their company, Advanced Cell Technology of Worcester, Mass., said the method could eventually be used to grow replacement body tissues of any kind from a patient's own cells, sidestepping the increasing scarcity of organs available for transplant and the problems of immune rejection.

The technique is likely to concern and perplex ethicists because it involves the creation of an embryonic cell that is part human and part cow, consisting of a human cell's nucleus inside a cow egg whose own nucleus has been removed. The company said the hybrid cell quickly became more human-like as the human nucleus took control and displaced cow proteins with human proteins. Creation of the embryonic cells is an important component of a strategy that in principle offers high medical benefits if it can overcome a doubtless high barrier to public acceptance.

The technique involves creating an embryo of uncertain moral status, and one that crosses the barrier between humans and other species. Even though the hybrid is in the form of cells, not a whole organism, the concept of half-human creatures arouses deeps anxiety, as is evident from the unfriendly powers ascribed to werewolves, centaurs, mermaids, Minotaurs and other characters of myth and folklore.

"Many people are going to be horrified by this scenario, others will say 'So what?' " said Thomas Murray, director of the center for biomedical ethics at Case Western Reserve University in Cleveland and a member of the National Bioethics Advisory Commission. "This is the sort of thing that makes me very

uncomfortable. I think we are likely to get a very powerful reaction to it, and I would like for all of us to have a breathing space here to articulate our moral concerns."

Another serious uncertainty is the preliminary nature of the company's work. No article has yet been submitted for peer review and publication in a scientific journal, an essential touchstone of credibility. Scientists asked about the company's work said they would require much more proof before believing that human embryonic stem-like cells had been created as claimed, and some were skeptical the technique would work at all.

The company said it had achieved the feat announced Wednesday with one cell three years ago. Michael West, Advanced Cell Technology's chief executive officer, said he was announcing the work done to date in order to test its public acceptability He said the company, which is privately held, was not planning to go public or raise money at this time but needed to decide whether to commit investment to development of the technique.

Some scientists praised West's decision to make his work public but others are critical, saying he has invited an emotional public debate on a slender basis of fact.

West is the founder of Geron, a biotechnology company that has had two spectacular successes this year in its research on aging. In January, the company developed a method for "immortalizing" human cells grown in the laboratory by making them leap the supposedly immutable barrier at which cells usually lapse into senescence. Last week, two university teams financed by Geron said they had isolated and cultivated human embryonic stem cells, the all-purpose cells from which the fetus develops. West lay the foundations for these developments by financing leading scientists in the two fields.

Advanced Cell Technology, which West joined in October, has focused on cloning and genetically improving cows, a technology developed by James Robl and colleagues at the University of Massachusetts in Amherst. West said he hoped to use the technology to further the founding concept of Geron: delving into the mystery of human aging and sidestepping some of its processes.

The company said work with human cells was performed in 1996 by Jose Cibelli, a colleague of Robl at the University of Massachusetts. Using 52 of his own cells, some of them white blood cells and others scraped from the inside of his cheek, Cibelli fused each one with a cow egg whose own nucleus and DNA had first been removed, the company said. Most failed to thrive but one embryo grew and divided five times, generating cells resembling embryonic stem cells. Cibelli and West say the method can be made more efficient with present technology.

Considering this work was sufficient to describe an invention, Robl and Cibelli filed a patent application and then set the research aside to focus on the more immediately practical field of cow cloning. Only two others besides himself and Robl knew what had been done, Cibelli said. The patent has not yet been issued but West said he was confident of receiving "important intellectual property" in the field. He said he is making the hybrid cell technique public now "because I want to be very open and level with everyone. We need to get the ethicists to talk about it so as to encourage a rational response to these new technologies."

Cibelli said he regarded any embryos obtained in this way as "not a separate

individual, just a de-differentiated cell from a patient." Differentiation is the process whereby the all-purpose cells of the very early embryo, known as human embryonic stem cells, become committed to their roles as the various specialized tissues of the body. The process is irreversible in nature but egg cells apparently have the ability to de-differentiate, or reset to default mode, the settings in a specialized cell's nucleus. This is presumably what happened in the experiment reported in July when mice were cloned by transferring the nucleus of an adult mouse cell into another mouse's egg cell.

Cibelli, who trained as a veterinary doctor in Argentina, said he believed that he and his colleagues "were the first to de-differentiate a human cell by nuclear transfer."

Asked if he was concerned about destroying, in principle, 52 potential twins of himself, he said, "I never thought about it, it's a good question. But if you use your own cells to treat a disease you may have, you are not taking cells from another person selfishly."

West and Cibelli said they had no intention of transferring the embryos to a uterus, a step they consider unethical and unsafe for it. The embryos would be created solely for the purpose of tissue culture. "Any technology can be abused but once the public understands how these cells can be used to treat any disease caused by loss or malfunction of cells, from Parkinson's to diabetes to heart disease, the concerns will be overshadowed," West said.

Whether or not West's prediction will be borne out depends on two major sets of factors, the scientific validity of the proposed method and the ethical and legal questions that related work has already raised.

From discussions with scientists, ethicists and lawyers in the past few days, several concerns have emerged.

Scientists are particularly critical of the lack of supporting evidence accompanying Advanced Cell Technology's announcement, saying in essence the claim could be true but there was no compelling reason yet to accept it. Even if the claim is valid, biologists note a serious uncertainty relating to an important part of the cells known as the mitochondria, components that produce the energy the cell needs and that are, in essence, the cell's batteries. If the bovine mitochondria should prove incompatible with their humanized environment the cells will not be viable.

Ethicists believe the mixing of species is likely to trouble the public severely, at least at first. Lawyers who specialize in issues of human reproduction note that the moral and legal status of the human embryo is undecided in American law, a fact pointed up by the isolation of the human embryonic stem cells announced last week. The new entity adds further complexity.

If Advanced Cell Technology can produce viable hybrid cells, those cells will offer a new route to grow tissue for transplant. This is the same goal held by the scientists who announced last week they had grown human embryonic stem cells in the laboratory. It is widely accepted in principle that embryonic stem cells can be directed to develop into any desired tissue, with enormous potential for medicine, even though this has yet to be achieved in practice.

West said the advantage of the Advanced Cell Technology method was that embryonic cells derived from the patient being treated would generate entirely compatible tissues. The two methods reported last week, by James Thomson of the University of Wisconsin and John Gearhart of Johns Hopkins University,

derive stem cells from human embryos or fetuses. Tissues made from these cells would be incompatible with the patient, a problem that has yet to be resolved.

In support of its claim, Advanced Cell Technology supplied a patent application and a photograph taken of its embryonic cells under a microscope. The patent application describes how the cells are made but provides no proof that they possess the properties to be expected of human embryonic stem cells. Robl said his laboratory was not set up to perform the required tests at the time the hybrid cells were made.

Shown the photograph of the hybrid cells, John Gearhart of Johns Hopkins University, author of one of the two methods reported last week, said that "they certainly could be embryonic stem cells" but that no scientific journal would publish the result without further proof. "It's not that I don't believe this biologically. I just think they could have given a little bit more assurance as to what was done here."

Roger Pedersen of the University of California at San Francisco, who also works on human embryonic stem cells, said he doubted the hybrid cells would last long enough to develop into useful tissue because of their cow-derived mitochondria.

Mitochondria, former bacteria enslaved by cells eons ago, have their own genes but operate in close cooperation with genes from the cell's nucleus.

Pedersen cited a recent experiment showing that within the human-ape-monkey family, each species' mitochondria is subtly different, the more so the longer the evolutionary distance between the species in question. The mitochondria of chimpanzees and gorillas work well enough in human cells but those of primate species that diverged more than 10 million years ago from the human line, do not work.

Because cows and humans last shared an ancestor so long ago, cow mitochondria are very unlikely to work well with a human nucleus, in Pedersen's view, and as most of the mitochondria in the hybrid cells are contributed by the cow egg, the cells would probably not remain viable for long. "It's hard to say this is a total sham, but I smell a sham here," he said.

Citing the same data, Gearhart said the mitochondria in the hybrid cell had clearly carried it through its first few divisions but might not sustain it in further development, unless the few human mitochondria that were also present somehow took over.

Pedersen said Advanced Cell Technology should be held to a high standard of proof "because of what the implications are for upsetting people unnecessarily -- if you cry fire in a crowded auditorium you may be liable if it's a false alarm."

The human embryonic stem cells announced last week have already pushed against the frontiers of ethical acceptance. Experts in biomedical ethics say the public is likely to be alarmed by the new technique, particularly because of the mingling of species. Murray of Case Western Reserve University said that the hybrid embryo "escapes our usual categories." When biologists first learned to transfer genes from one species to another, "The idea of human-animal hybrids was often raised as the kind of monstrosity that no morally perceptive person would ever create," he said.

"Even if it's only to create tissue, the minute you start mixing species you raise all kinds of red flags in people's minds," said Barnie Steinboch, a moral philosopher at the State University of New York in Albany. But she noted that pig valves are now seen as acceptable replacements in human hearts.

Rebecca Dresser, a law professor at Washington University in St. Louis, noted, as did several biologists, that distinctions between humans and other animals are less clear in nature than they are in people's minds. "Biologically a lot of this research is showing us similarities and the upshot in a hundred years may be that the lines between humans and non-humans will be viewed as a little bit grayer," she said.

A perplexing feature of the hybrid embryo is that it starts off mostly bovine and then becomes mostly yet not entirely human. But some legal experts have no doubt that it should be regarded from the start as a human embryo. "It doesn't matter that the mitochondria come from a cow, it also has human mitochondria and so has all the potentials of a human embryo," said Lori Andrews of the Chicago-Kent College of Law in Chicago.

"Once it's gone through that first division it has gone from being a somatic cell to a thing with potential life," she said, referring to the ordinary specialized cells of the human body. If transferred to a woman's uterus the embryos may or may not come to term, "but under state laws it doesn't matter whether the fetus is going to be born or not - it doesn't make them less human."

The human body consists of 100 billion cells. Should embryos created from them by the cow egg method be regarded as having special status when they can be made so easily and plentifully? Ms. Andrews said that human embryos are not so hard to make the usual way, and the fact that an embryo is easily made, by whatever means, is irrelevant to arguments about its status.

The moral status of the human embryo "is not clearly established in U.S. law," Dresser said. The embryo can be regarded as mere property, as a person, or as something in between but deserving of special respect. Congress, in banning the use of federal funds for research on human embryos, has favored the view that they are in the category of people. But in custody battles over fertilized embryos, courts have favored the special respect status. Dresser said the hybrid cells could be seen as somewhere between the property and special-respect status.

The hybrid cells were made by Cibelli in Robl's laboratory in the University of Massachusetts at Amherst. Michael Weinberg, executive secretary of the university's human subjects committee, said the experiment was given administrative approval, without review by the committee or any major discussion. Cibelli was using his own cells, not experimenting on other people, and self-experimentation does not require special consent. "If someone wants to inoculate themselves they can do that," Weinberg said.

March 17, 1998

Drug Makers Lobby Against Cloning

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

Filed at 4:06 p.m. EST

By The Associated Press

NEW YORK (AP) -- Drug makers, having blocked anti-cloning legislation in Congress, are now scrambling to do the same with bills that would make human cloning illegal in 24 states.

Two trade groups have launched a state-by-state campaign to combat 50 anti-cloning bills being taken up this year in legislatures from California to Connecticut.

The state bills, which emerged after Chicago physicist Richard Seed pledged in January to clone a human, ended drug makers' celebration over the decision by U.S. Senate leaders to put an anti-cloning bill on hold indefinitely.

Pharmaceutical companies say they agree with lawmakers who want to bar fringe scientists from creating human guinea pigs. But they argue the anti-cloning bills are so broadly worded they could also stop researchers from using routine techniques to develop new drugs.

Scientists now use cloning to test how identical cells react to different substances. Researchers hope one day to grow new skin for burn victims and overcome the need for liver and kidney donors by cloning whole organs. Cloning-related research has already led to heart attack, cystic fibrosis and stroke drugs.

A patchwork of state laws would be ``an absolute disaster for medical research,'' said Jeff Trewhitt, a spokesman for Pharmaceutical Research & Manufacturers of America, which is campaigning with state legislators.

``This is not the movie `Gattaca.' This is not `Star Wars,'" he said. ``This is well-accepted biomedical research.''

He'll have plenty of practice honing his message.

Since he started his three-month tour of state capitols last week, Trewhitt has visited Illinois, New York and New Jersey. Next week he'll join a living ``clone'' -- PhRMA genetics expert Gillian Woollett, who shares her genes with her identical twin, Brenda Armstrong -- in Pennsylvania. The sisters met with Washington policy makers in January to point out to that naturally occurring clones have long walked among us.

Another Washington, D.C.-based trade group, The Biotechnology Industry Organization, has been visiting state legislators since a Scottish scientist said he cloned a sheep named Dolly last February.

It's unlikely either group will hit all the states that have taken up anti-cloning bills this year: Alabama, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Kansas, Maryland, Michigan, Minnesota, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Virginia and Wisconsin.

``I've got my walking boots on,'' Trewhitt said.

The stakes are high. Drug makers are expected to spend an estimated $20.6 billion on research in the United States and Europe this year.

President Clinton has called for a federal ban, but drug researchers point out that the Food and Drug Administration already requires anyone performing human cloning research to file with the agency -- permission it's unlikely to give. If there has to be a law, industry groups prefer a federal ban forbidding only the cloning of a whole human being.

Some question the need for restrictions.

``I don't think anyone has really explained why cloning is bad,'' said Prof. Uwe Reinhardt, a Princeton University health economist. ``What is the advantage of playing a lottery where the baby you have may be severely deformed? ... What if you had only perfect babies? Why would such a world be bad?''

Opponents include anti-abortion activists who fear cloned fetuses would be used as lab animals.

``Don't be mistaken. They're going to abort ... until they find a workable form'' of clone, said Delaware state Sen. Donna Reed, a Republican who concedes her bill has little chance in a state controlled by Democrats. ``I don't want that done with humans.''

Drug makers were too late to block the nation's first state anti-cloning law. On Oct. 4 California Gov. Pete Wilson signed a bill making it a crime to clone a human being or buy fetal cells to do so. Fines range up to $1 million.

``The bill is not the worst one we've seen," said Carl Feldbaum, president of the biotech group. ``But it creates a precedent that is hard if not impossible to contend with."

Worse, he said, is a Florida bill that would forbid even the DNA fingerprinting prosecutors used in the O.J. Simpson trial.

In New Jersey -- home of half a dozen major drug companies -- opponents of the legislation acted in time. Charlotte Vandervalk, chairwoman of the committee that reviews cloning bills, shelved a measure that would have carried a maximum 20-year prison term for anyone guilty of cloning.

``There's a lot of medical research that can benefit humanity down the road" using cloning, she said. ``I don't think we can take the simplistic view and say we're going to ban it."

Senate GOP leaders could end the debate with a carefully worded federal ban, said Arthur Caplan, director of the Bioethics Institute at the University of Pennsylvania. But first lawmakers will have to agree on what they're arguing about, he said.

``So far the federal efforts seem to get bogged down in a battle between right-to-lifers and free inquiry types" he said.

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February 17, 1998

Report: Error Possible in Cloning

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | OLYMPICS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

Filed at 8:02 a.m. EST

By The Associated Press

LOUISVILLE, Ky. (AP) -- The Scottish scientist who cloned Dolly the sheep said he may have made a mistake and will try the task again with other kinds of animals, The Louisville Courier-Journal reported today.

``There is a remote possibility that the cell came from a fetus rather than from the adult,'' Ian Wilmut of the Roslin Institute said Monday at a genetics forum at the University of Louisville.

Scientists have been able to clone mammals from fetal cells for two decades. Wilmut said he had cloned Dolly using the nucleus from the cell of an adult sheep that had died three years earlier, the first time that a genetically identical mammal had been created from an adult cell.

But critics said a fetal cell accidentally could have been used since the sheep from which the cells to clone Dolly were taken was pregnant. Fetal cells can be present in the circulatory system of some animals during pregnancy, Wilmut said Monday.

``We and everybody else had completely overlooked it,'' he said.

Wilmut said he doesn't believe that he used a fetal cell to clone Dolly, ``but it has to be said that there is a remote possibility.''

For that reason, he said, tests are being performed to determine Dolly's genetic history. Wilmut also said he was confident that within a year, ``you will see reports from lots of labs that are making this work with other species and other cells.''

Wilmut has strongly opposed the cloning of humans.

Last month, two researchers suggested in a letter to the journal Science that Wilmut's claim about Dolly could be false.

Dr. Norton Zinder of Rockefeller University and Dr. Vittorio Sgaramella of the University of Calabria in Italy questioned Wilmut's claim because at least three labs have failed in attempts to duplicate the work.

They also questioned why the Scottish lab has not repeated the experiment. Scientific experiments usually must be repeated before they are verified and accepted by other scientists.

At the American Association for the Advancement of Science meeting in Philadelphia on Friday, Wilmut that he may be repeating the experiment to silence critics.

When asked why he hasn't duplicated the Dolly experiment, Wilmut said only, ``Perhaps we are." He also said is ``extraordinarily unlikely" that Dolly came from a fetal cell because such cells in the maternal blood are rare -- only one among several million adult cells.

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February 10, 1998

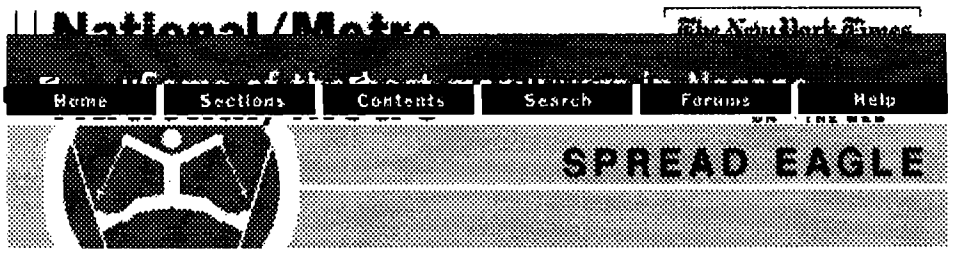
A Slapdash Proposal on Cloning

The shock caused by the physicist Richard Seed's grandiose intention to clone human beings may be about to cause more damage than anything Dr. Seed could do in the laboratory. Senate Republicans are now rushing to enact a bill that would outlaw cloning a human embryo and, in the process, ban a valuable technique that could potentially cure a wide range of diseases. No wonder a slew of scientific associations and high-tech industry groups are urging more carefully constructed legislation. The sensitive scientific and moral issues involved here require careful handling, not grandstanding by politicians more interested in pandering than in reaching a reasoned solution.

Congress may ultimately want to impose limits on cloning, a technique that has arrived sooner than expected with the announcement last year that Scottish scientists had cloned a lamb from the cell of an adult sheep. That achievement, if it proves practical in humans, would make it possible to take a cell from an adult and use it to produce a genetically identical twin many years younger than the parent. A national bioethics commission, the biotechnology and pharmaceutical industries and many scientific groups have all called for a moratorium on actually cloning a person until society has time to grapple with the ethical and moral issues.

But the bill sponsored by the Republican Senators Christopher Bond, William Frist and Judd Gregg does not simply prohibit the use of cloning to produce a human embryo for implantation in the womb. It would also prohibit use of the technique to produce genetically identical tissues in the laboratory to treat diseases or injuries where a person's existing cells are damaged or insufficient. Such ailments include leukemia, diabetes, Alzheimer's disease, spinal cord injury, heart attacks and severe burns, among others.

The Republicans contend that even these approaches require creating what amounts to an embryo in the laboratory and then experimenting on it to produce the desired tissues. But that is a complex matter of definitions and techniques that requires careful evaluation. The Republican bill and others on the subject have not even gone through committee hearings. When the matter comes up for a floor vote this week, the Senate should postpone action and demand more considered deliberation. It would be a shame if the rush to ban cloning of people ended up crippling biomedical research.



January 21, 1998

F.D.A. Stand on Cloning Raises Even More Questions

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- Join the Discussion: The Clones are Coming

By SHERYL GAY STOLBERG

WASHINGTON -- In announcing that it has the power to block scientists who try to clone people, the Food and Drug Administration may have thrown a kink into efforts to ban the practice, pitting the White House and Congress against leaders in science and industry who say legislation is now unnecessary.

In separate interviews Tuesday, officials of the Biotechnology Industry Organization and the Pharmaceutical Manufacturers Association of America said that while they oppose the cloning of humans, they believe the FDA, and not Congress, is the proper forum for controlling it.

"The FDA's assertion of jurisdiction would make legislation redundant," said Carl Feldbaum, president of the biotechnology trade group, which represents 750 companies. "I think it is the proper agency that has the scientific expertise to assess it."

A third organization, the American Society of Reproductive Medicine, which represents infertility doctors, Tuesday unveiled its own bill to ban the cloning of people. But a society spokeswoman said her group would be just as happy to let the FDA take care of cloning.

"If the FDA can handle it, that's great," said Heather Kowalski, the spokeswoman.

At the same time, questions emerged Tuesday about whether the FDA, which typically regulates drugs and therapies used to treat disease, can stretch its authority to cover baby-making by cloning. While agency officials insist they have jurisdiction, some experts in food and drug law -- as well as a congressman who proposes to ban the cloning of people -- said they were not so certain.

"It's hard to argue that a cloning procedure is a drug," said Rep. Vernon Ehlers, R-Mich., who has introduced one bill that would ban federal financing of experiments to clone people, and another that would ban similar experiments conducted with private money. "It is certainly open to question."

Ehlers said legislation remains the only way to effectively halt the cloning of people.

"A regulatory action can be reversed anytime the regulatory agency changes its philosophy," he said, and his sentiment was echoed by the White House. "We believe that it is important to enact legislation," said a White House spokesman, Barry Toiv, "and we're going to pursue it."

There were several attempts to legislate against the cloning of people last winter, after the announcement by Scottish scientists that they had cloned the udder cell of a six-year-old ewe to create a sheep named Dolly.

The bills, including one proposed by President Clinton, faltered in Congress. But the idea of controlling cloning has recently picked up steam, as public outrage has erupted over an Illinois physicist, Dr. Richard Seed, who says he plans to open a cloning clinic.

Last week, as members of Congress, as well as Clinton, announced they would renew their efforts to ban the cloning of people, Feldbaum's group sent a letter to Health and Human Services Secretary Donna Shalala suggesting that cloning falls under the FDA's broad authority to regulate the products known as biologics.

Biologics, which historically included blood products and vaccines, are today considered any product that is composed of a living organism, such as human cells or tissue.

Last February, the FDA issued a new set of guidelines governing cell and tissue products; under the guidelines, the agency may regulate any product in which the biological characteristics of the cells or tissue are substantially altered, through "more than minimal manipulation."

Feldbaum argues that cloning, which involves taking genetic material from one cell and inserting it into another, meets the "more than minimal manipulation standard."

The FDA's acting commissioner, Michael Friedman, has publicly agreed with Feldbaum, although the agency has yet to issue a formal policy statement on how it might govern cloning experiments. That may be by design, said Arthur

Levine, who worked as an FDA lawyer for 21 years and is now in private practice.

"It is not uncommon, in this kind of sensitive area involving medical ethics, for the FDA to take a position through various informal statements, pronouncements, drafts and meetings where they try to explore what the market will bear," Levine said. "These are informal ways that FDA tests the waters."

While Levine believes an argument can be made for the FDA to regulate cloning, another lawyer who is an expert in food and drug law, who spoke on the condition of anonymity, said he did not think the provisions cited by Feldbaum's group were applicable.

"Admittedly, you may be moving cells around," the lawyer said. "But it might not be considered a repair or enhancement or a therapeutic function. It is really to create a new human being."

With the FDA's recent announcements, agency officials now say that any scientist who wants to create a genetic replica of person will have to submit an "investigational new drug application," the same request that drug companies must submit when they want to test a new medicine.

The application requires researchers to prove that their experiments do not pose unreasonable dangers to the subjects. In the case of cloning, that would be difficult; it took Dr. Ian Wilmut, the Scottish scientist who cloned Dolly, 277 tries to create one sheep. There is consensus that any attempt to replicate the feat in humans would, at this point at least, be extremely dangerous.

"We regard this as a gene therapy or a cell therapy or both, and these therapies are subject to FDA requirements that cover clinical trials," said one agency official who spoke on the condition that he not be identified. "An investigator would have to come forward and say, 'Here's what I plan to do, and here's the information that shows it can be done safely in humans.'"

The official declined to speculate on what the agency would do if a researcher went ahead without agency permission, but he said the FDA has a variety of options, from sending a warning letter to asking a judge for a restraining order, to seeking criminal penalties.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

April 16, 1998

FDA's Jurisdiction Over Human Cloning Activities

This statement addresses FDA's jurisdiction over human cloning activities. FDA's jurisdiction over products used in cloning activities derives from the biological products provisions of the Public Health Service Act (PHS Act) and the drug provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act).[1]

I. Background

The term clone means a precise copy of a molecule, cell, or individual plant or animal. National Bioethics Advisory Commission, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission* (NBAC Report) app. 1 (June 1997). In the past year, the issue of cloning has received much media attention. In March of 1997, Scottish researchers announced that they had cloned an adult sheep. The researchers removed an egg from a female sheep and replaced the nucleus of the egg with the nucleus from a somatic cell[2] from another adult sheep. They used electrical pulses to introduce the new nucleus into the egg and to cause the cells to divide. The researchers then implanted the manipulated egg into the uterus of a female sheep, resulting in the birth of a cloned sheep. The technique that resulted in the cloned sheep is referred to as somatic cell nuclear transfer.

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[1]The medical device provisions of the FD&C Act also apply to some products used in human cloning activities but are not discussed in this statement.

[2]A somatic cell is a cell of an embryo, fetus, child, or adult not destined to become a sperm or egg cell. NBAC Report app.3.

Following the announcement of the cloned sheep, President Clinton directed that federal funds should not be used for cloning a human being. Because the prohibition on the use of federal funds for human cloning did not extend to non-federally funded research, President Clinton asked for a voluntary moratorium on human cloning by privately funded researchers. He also asked the National Bioethics Advisory Commission (NBAC) to address the legal and ethical issues raised by cloning and to submit a report to him. In its June 1997 report, the NBAC concluded that "at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or a clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning." NBAC Report at iii.

For purposes of this statement, the agency assumes that the technique used to clone a human being would be somatic cell nuclear transfer. The cloning process to create a human being would be similar to that used to create the cloned sheep discussed above in that the process would involve the transfer of a cell nucleus from a somatic cell of a human being into an egg from which the nucleus has been removed. The resulting cell (somatic cell clone) produced for the purpose of creating a cloned human being is a product subject to regulation by FDA.

II. Legal Authority

FDA has the authority to regulate numerous medical products, including biological products and drugs. As discussed more fully below, the cellular product and the components of the cellular product used in cloning fall within the definitions of biological products in the PHS Act and drug in the FD&C Act.[3] A product may be both a biological product and a drug. See Calise v. United States, 217 F.

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[3]Depending on the specific facts of any cloning process, there may be additional reasons why particular somatic cell clones would be biological and drug products.

Supp. 705, 709 (S.D.N.Y. 1962). The conclusion that FDA has jurisdiction over somatic cell clones under the PHS Act and the FD&C Act is consistent with the statutory purpose of public health protection. Courts have recognized that remedial statutes, such as the FD&C Act and the PHS Act, are to be liberally construed consistent with their public health purpose. See United States v. An Article of Drug ... Bacto-Unidisk, 394 U.S. 784 (1968); United States v. Loran, No. CV 96-4283 SVW (C.D. Ca. Oct. 17, 1997).

A. A Somatic Cell Clone is a Biological Product

FDA regulates biological products under section 351 of the PHS Act. 42 U.S.C. § 262. That section applies to "any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment or cure of diseases or injuries of man..." Id. Section 123(d) of the Food and Drug Administration Modernization Act of 1997 (FDA Modernization Act) amends the PHS Act by including within the definition of biological products "conditions" as well as diseases. 42 U.S.C. § 262(i) (effective February 19, 1998).

1. A Somatic Cell Clone is Applicable to a Disease or Condition of Human Beings

As set forth in the PHS Act, a biological product is subject to regulation if it is "applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i) (effective Feb. 19, 1998). A somatic cell clone used to create a cloned human being for an infertile individual is a product applicable to the treatment of infertility. Likewise, a somatic cell clone used to create a cloned human being to avoid transmission of a genetic disease from a prospective parent is a product applicable to the prevention of that genetic disease in the cloned human being. In addition, significant safety questions have been raised regarding whether the cloning process will produce a healthy human being who will develop normally.

For example, the cloned human being might have defects from the donor or during development, such as genetic, biochemical, or cellular defects.

2. A Somatic Cell Clone Is An Analogous Product Under the PHS Act

A somatic cell clone is not one of the specifically listed products in section 351 of the PHS Act. It is, however, an "analogous product" under the PHS Act and thus falls within the scope of this section.

The term "analogous" is defined as "resembling or similar in some respects, as in function or appearance, but not in origin or development." Dorland's Medical Dictionary 78(25th ed. 1974). A somatic cell clone has similarities in composition and function with blood and blood components. A somatic cell clone is analogous to white blood cells, a component of blood, in that both cells are similarly composed because they are somatic cells that contain a nucleus. A somatic cell clone is also like blood and blood components in that they contain cellular elements derived from a living human being and are applicable to diseases or conditions of human beings.

A somatic cell clone also is analogous to a toxin or antitoxin as those terms are described in FDA regulations.[4] The recent decision in United States v. Loran, No. CV 96-4283 SVW (C.D. Ca. Oct. 17, 1997) supports such a determination. In Loran, the court addressed whether a cell product consisting of neonatal rabbit and human fetal cells intended for the treatment of diabetes was an analogous product under the PHS Act. The court noted that the government reasonably construed the PHS Act and concluded that the cell product was a biological product. Given the common features between a somatic cell clone and the

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[4]A product is analogous to a toxin or antitoxin "if intended, irrespective of its source of origin, to be applicable to the prevention, treatment, or cure of disease or injuries of man through a specific immune process." 21 C.F.R. § 600.3(h)(5)(iii).

neonatal rabbit and human cells in Loran, that decision supports a determination that a somatic cell clone is an analogous product. Loran at 4-5, 11.

B. A Somatic Cell Clone is a Drug

Under the FD&C Act, the term "drug" is defined as "articles (other than food) intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(C). The term "drug" also includes components of a drug. 21 U.S.C. § 321(g)(1)(D). As described above, a somatic cell clone is a product intended to affect the structure or function (including the diseases or conditions) of the cloned human being. The continued growth and development of the cloned human being are the result of the maturation of the somatic cell clone. In addition, a somatic cell clone could be viewed as a product intended to affect the structure or function of the woman into whose uterus the somatic cell is to be implanted.

A product also is a "drug" if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B). A somatic cell clone used to create a cloned human being in order to avoid transmission of a genetic disease from a prospective parent with the disease would be an article intended to prevent the transmission of disease to the cloned human being and thus would fall within this definition. A somatic cell clone used with the intent to create a cloned human being for an infertile couple also could fall within this drug definition in that the product would be used to treat infertility.

A somatic cell clone also is a "new drug" under the FD&C Act in that it is a drug that is not generally recognized by experts as safe and effective to clone human beings. 21 U.S.C. § 321(p). Before new drugs may be marketed, FDA review and approval are required. 21 U.S.C. § 355(a).

III. Previous FDA Guidance on Cellular Products

FDA has issued a number of documents in the past several years addressing products that have similar characteristics to a somatic cell clone product. The agency's notices on somatic cell and gene therapy products and cellular and tissue-based products are consistent with a determination that a somatic cell clone would fall within FDA's jurisdiction.

A. Regulatory Approach to Somatic Cell and Gene Therapy Products

Although somatic cell products are not specifically listed in the statutory definition of biological product, FDA previously has stated that these products are biological products subject to regulation under the PHS Act and drugs within the meaning of the FD&C Act. In its October 1993 notice, FDA defined somatic cell therapy products as "autologous (i.e., self), allogeneic (i.e., intra-species), or xenogeneic (i.e., inter-species) cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics ex vivo to be administered to humans and applicable to the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries." 58 Fed. Reg. 53248, 53249 (Oct. 14, 1993). The agency advised persons interested in performing clinical investigations involving these products that FDA's regulations on investigational drugs and biological products apply, and that the products also are subject to the drug requirements of the FD&C Act.

B. FDA's Proposed Regulatory Approach for Cellular and Tissue-Based Products

In March of 1997, FDA announced its proposed regulatory approach for cellular and tissue-based products. See 62 Fed. Reg. 9721 (March 4, 1997). A finding that a somatic cell clone is a biological product and a drug is consistent with the position taken by FDA in its approach to cellular and tissue-based products. The

regulatory approach addresses a wide range of products such as skin, bone, and corneas, as well as somatic cell therapy products and gene therapy products. Because a somatic cell clone is a cellular-based product, the regulatory approach would apply.

Under this regulatory approach, FDA announced that it was planning to take a tiered approach to the regulation of cellular and tissue-based products, imposing requirements to the extent necessary to protect the public health. For some products, FDA would impose only requirements related to the prevention of communicable diseases.[5] For products raising additional public health concerns, such as products that undergo more than minimal manipulation or that have a systemic effect on the body, premarket review and approval would be needed.

In the regulatory approach, FDA addressed reproductive tissues and noted that such tissues have a long history of use in the medical community. FDA also recognized that such tissues raise a number of less substantial issues than those raised by other tissues that have a systemic effect on the body. As a result, FDA stated that such tissues would be subject to less regulation than other tissues that have a systemic effect on the body. Unlike the reproductive tissues discussed in the regulatory approach, tissues and cells for cloning of human beings raise additional significant health concerns not raised by processes in place for the reproductive tissues used in the past. Consistent with the tiered approach for cellular and tissue-based products, a somatic cell clone would be subject to FDA premarket review and approval because it is more than minimally manipulated.

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[5]For these products, FDA would only regulate the product under the communicable disease provisions of the PHS Act and not under the FDCA or the biological products provisions of the PHS Act. See 42 U.S.C. § 264.

IV. Prohibited and Permissible Acts

The FD&C Act prohibits the introduction into interstate commerce of unapproved new drugs and misbranded and adulterated drugs and the holding for sale of such misbranded and adulterated products after shipment in interstate commerce. 21 U.S.C. § 331 (a),(d),(k). The approval of a new drug application removes the prohibition on interstate shipment. The PHS Act also prohibits interstate shipment: "[n]o person shall sell, barter, or exchange, or offer for sale, barter or exchange" in interstate commerce any unapproved biological product. 42 U.S.C. § 262(a). Section 123(a) of the FDA Modernization Act amends the PHS Act by replacing the terms "sell, barter or exchange" with "introduce or deliver for introduction into interstate commerce." 42 U.S.C. § 262(a).

Under the authorities of both Acts, FDA promulgated regulations to allow clinical research on investigational drugs and biological products. Clinical research on these products can proceed only when an investigational new drug application (IND) is in effect. See 21 U.S.C. § 355(i) (authorizing FDA to promulgate regulations for research involving investigational new drugs), 42 U.S.C. § 262, 21 C.F.R. Part 312. Before such research may begin, the sponsor of the research is required to submit to FDA an IND describing the proposed research plan. The sponsor also is required to obtain authorization to proceed from an institutional review board (an independent group of experts and consumers which reviews the proposed study from a scientific and ethical perspective). 21 C.F.R. §§ 56.103, 312.23(a)(1)(iii) and (iv). In addition, the researcher is required to obtain the informed consent of the individuals who are considering whether to participate in a clinical study. See 21 U.S.C. § 505(i), 21 C.F.R. Parts 50 and 312. Thus, before an egg is removed from a woman or the cell containing the nucleus to be inserted into the egg is removed from the prospective genetic parent for the purpose of creating a cloned human being, an IND should be in place and informed consent obtained.

Once FDA receives a proposed study, it reviews the IND application to assess whether it is appropriate for the study to proceed.

Among the information reviewed by FDA is information related to the safety of the product, including pharmacology and toxicology information that the applicant believes shows that it is reasonably safe to conduct a clinical investigation. FDA may prohibit a sponsor from conducting the study (often referred to as placing the study on "clinical hold") for a variety of reasons, including if the agency finds that "[h]uman subjects are or would be exposed to an unreasonable and significant risk of illness or injury," "[t]he IND does not contain sufficient information required to assess the risks to subjects of the proposed studies," or "[t]he clinical investigators ... are not qualified by reason of their scientific training and experience to conduct the investigation..." For example, information raising concerns about the sterility of the product or data from animal studies showing serious adverse reactions in animals would cause FDA to question whether a study should proceed.

V. Regulatory Actions for Violations of the FD&C Act and PHS Act

Where violations of the Acts occur, such as shipment of an unapproved drug or biologic or misbranding or adulteration of a drug, the government has the authority to initiate regulatory actions, including administrative actions (e.g., clinical investigator disqualification proceedings) and civil and criminal litigation (e.g., seizures under the FD&C Act, injunctions, and criminal prosecution).

Office of the Commissioner
Office of Executive Secretariat
5600 Fishers Lane, HF-40
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Cloning

March 27, 1998

President William Jefferson Clinton
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President:

I am writing to request your cooperative effort in exercising leadership in the national debate on human cloning. The American people have made clear their overwhelming support for a ban on the cloning of humans, yet there has been no formal federal mechanism in place to allow their substantive participation in the ethical debate. Your last public statement, issued on February 9, 1998, during the Senate debate, indicated that your goals were in many ways reflected by S. 1602, the Feinstein-Kennedy bill. I am concerned that your show of support, however tempered, for this bill could result in the unintended consequences of human cloning.

The Feinstein-Kennedy bill has a serious scientific deficiency. The bill defines a somatic cell as a "mature, diploid cell." This is a critical technical definition that could be easily misunderstood, with enormous adverse consequences. In every person's bone marrow and blood there are a small number of somatic cells, called stem cells. These stem cells are not yet mature - they could become either blood or bone marrow. If such a cell, or its nucleus, is inserted into a female egg, whether animal or human, and activated, a human embryo would result.

By excluding these cells from the definition of a somatic cell, the Feinstein-Kennedy bill would allow them to be used in the creation of embryos, and then allow these embryos to be implanted in a uterus and grown into human clones. In addition, the Feinstein-Kennedy bill would simultaneously allow experimentation of this cloning technique on an unlimited number of live cloned human embryos generated from mature somatic cells. Thus, the bill could provide a framework for virtually unlimited human cloning.

Due to the complexity and emotional nature of this issue, Senators Feinstein and Kennedy may not be fully aware of this deficiency in their legislation. However, members of the scientific community who helped to draft this legislation have the necessary expertise to discern this serious flaw. In many ways, S. 1602 is a slightly more restrictive version of the much-touted private moratoriums endorsed by major scientific groups. This reflects the inescapable, and inherent conflict of interest that surrounds sole scientific involvement in regulation of science. Those driven by a quest for knowledge may view any regulation as an inappropriate and unwarranted intrusion into their rights of inquiry.

I find it disturbing that the debate on the ethics of creating cloned human embryos solely for research and destruction has been largely confined to a debate about what is and is not an embryo. Your leadership in immediately recognizing the grave moral implications surrounding the creation of cloned human embryos has been critical since the beginning of this debate, when you directed NBAC to examine this issue as a matter of priority, urging them to review "the serious ethical questions, particularly with respect to the possible use of this technology to clone human embryos."

From a scientific perspective, it is clear that we are indeed talking about human embryos. In fact, your own National Bioethics Advisory Commission "began its discussions fully recognizing that any effort in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term." (NBAC Report: Cloning Human Beings, Introduction, June, 1997) There should be no further confusion on this matter.

In order to address some of these concerns, the Subcommittee on Public Health and Safety, which I chair, will hold a hearing later this year. I am deeply concerned by a pattern of avoidance of a complete discussion of the ethics of human cloning. This is unfortunate, because we are entering a new era in our scientific understanding of the human genome. This cloning technology could be applied for the good of mankind, whether in the cloning of knee cartilage, or pharmaceutical advances through plant, animal and cellular cloning, or in the generation of human tissue for transplant. But cloning also holds the potential for chilling abuse. As you stated so eloquently, "It is up to us to determine whether it will be used as a force for good or evil...The answers to these questions require the application of ethical and moral principles that have guided our great democracy toward a more perfect union for more than 200 years now." (Commencement speech to Morgan State University, Baltimore, MD, May, 18, 1997)

Mr. President, as we pursue a legislative solution, I call upon you to put in place a formal, federal mechanism to address the urgent ethical issues surrounding the use of this technology. It is imperative that any review not be conducted solely by scientists and academics, but include the broad participation of the citizens of our country. As you yourself have said, "Science can serve the values and interests of all Americans, but only if all Americans are given a chance to participate in science. We cannot move forward without the voices and talents of everyone..." We stand ready to work with you on achieving this goal, and eagerly await your response.

Sincerely,

Bill Frist, M.D.
United States Senator

Rachel E. Levinson 07/23/98 11:00:56 AM

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To: Jerold R. Mande/OSTP/EOP

cc:
Subject: mice cloning

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 07/23/98 11:00 AM ----------

Jeffrey M. Smith
07/23/98 07:44:55 AM

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

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Subject: mice cloning

Additional talking points will be sent shortly (by 9:30 a.m.) to Mike McCurry and the press office

Mice cloning -- senior staff meeting talking points -- 7/23

What's new about this development?

This does have major implications for the ease with which humans might be cloned.

Last June, the President proposed legislation that would extend his ban on using federal funds to clone human beings to the private sector.

That legislation stalled, but there is now the Kennedy-Feinstein bill that is virtually identical to the President's measure. No movement on that legislation.

The key problem in Senator Kit Bond's and Congressman Ehlers' anti-cloning measures (Bond bill failed miserably under a cloture vote) is that they ban important cloning research on other important medical technologies.

In the days ahead, Republicans could well be expected to address this through an amendment to the HHS appropriations bill.

We (the Administration and a coalition of scientific and industrial organizations) are currently developing a two-pronged strategy:

1) HHS general counsel is now clarifying FDA's regulatory authority on the procedure to clone human beings (FDA only looks at safety and efficacy now). 2) The other part of our approach is to create an advisory structure that has input into a regulatory authority (like HHS) to examine the ethical questions posed by cloning human beings. NBAC is not a regulatory body.

Message Sent To:

Rachel E. Levinson/OSTP/EOP
Clifford J. Gabriel/OSTP/EOP
Arthur Bienenstock/OSTP/EOP
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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Monday, February 9, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148
SUBJECT: **HHS Report on S1601 Human Cloning Prohibition Act**

DEADLINE: **NOON Monday, February 9, 1998**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

* **COMMENTS:** Senator Kennedy has requested the attached letter for use during tomorrow's debate on S. 1601. **DEADLINE IS FIRM.** *

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LRM ID: RJP190 **SUBJECT:** HHS Report on S1601 Human Cloning Prohibition Act

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

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(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: Robert J. Pellicci Phone: 395-4871 Fax: 395-6148
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ (Date)

_____ _____ (Name)

_____ _____ (Agency)

_____ _____ (Telephone)

The following is the response of our agency to your request for views on the above-captioned subject:

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

_____ FAX RETURN of _____ pages, attached to this response sheet

DRAFT

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

Dear Senator Kennedy:

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

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

DRAFT

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

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

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

Sincerely,

Michael A. Friedman
Lead Deputy Commissioner
Food and Drug Administration

SUBMITTED 6/9/97

A BILL

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

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

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

SECTION 2. FINDINGS.

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

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

(1) NBAC has found that:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 4. DEFINITIONS.

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

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

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

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

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

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

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

SECTION 7. PENALTIES.—

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

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

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

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

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

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

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

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release December 2, 1994

Statement by the President

The Director of the National Institutes of Health has received a report regarding federal funding of research on human embryos. The subject raises profound ethical and moral questions as well as issues concerning the appropriate allocation of federal funds. I appreciate the work of the committees that have considered this complex issue and I understand that advances in in vitro fertilization research and other areas could derive from such work. However, I do not believe that federal funds should be used to support the creation of human embryos for research purposes, and I have directed that NIH not allocate any resources for such research. In order to ensure that advice on complex bioethical issues that affect our society can continue to be developed, we are planning to move forward with the establishment of a National Bioethics Advisory Commission over the next year.

-30-30-30-

National Bioethics Advisory Commission

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

February 6, 1998

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

Dear Mr. President:

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

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

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

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

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

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

nuclear transfer techniques to create a child at this time,

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

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

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

Sincerely,

Harold T. Shapiro

Harold T. Shapiro
Chair

LRM ID: RJP187 **SUBJECT:** Statement of Administration Policy on S1601 Human Cloning Prohibition Act

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RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

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(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or
(2) sending us a memo or letter
Please include the LRM number shown above, and the subject shown below.

TO: **Robert J. Pellicci Phone: 395-4871 Fax: 395-6148**
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

_____ **(Name)**

_____ **(Agency)**

_____ **(Telephone)**

The following is the response of our agency to your request for views on the above-captioned subject:

_____ **Concur**

_____ **No Objection**

_____ **No Comment**

_____ **See proposed edits on pages** _____

_____ **Other:** _____

_____ **FAX RETURN of** ____ **pages, attached to this response sheet**

202-456-0322

Bill Raub
690-5874
Diane

X62604

690-7694

105TH CONGRESS
1ST SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

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

A BILL

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

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

SECTION 1. SHORT TITLE.

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

SEC. 2. FINDING.

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

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

SEC. 3. PROHIBITION ON CLONING.

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

"CHAPTER 16—CLONING

"Sec.
"301. Prohibition on cloning.

"§ 301 Prohibition on cloning

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

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

"(c) PENALTIES.—

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

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

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

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

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

"16. Cloning §301". .....

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

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

(b) MEMBERSHIP.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) STAFF AND SUPPORT SERVICES.—

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

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

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

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

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

(e) POWERS OF COMMISSION.—

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

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

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

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

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

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

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

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

(f) SUBCOMMITTEES.—

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

(A) a subcommittee on legal issues;

(B) a subcommittee on theological issues;

(C) a subcommittee on philosophical and ethical issues;

(D) a subcommittee on medical issues;

(E) a subcommittee on scientific issues; and

(F) a subcommittee on social issues.

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

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

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

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

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

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

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

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

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

SEC. 5. UNRESTRICTED SCIENTIFIC RESEARCH.

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

SEC. 6. SENSE OF CONGRESS.

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

DRAFT -- NOT FOR RELEASE

DRAFT

believes S. 1601 poses a significant threat to important biomedical research

FDA + Gt DHHS review on juris doc.

February 5, 1998
(Senate)

① -
② -

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

poses a significant threat to broad research

its unacceptable on its current form

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

or other appropriate review mechanisms

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

triggered immediate review

not=prohibit use of SCNT in humans for the development of technology developing

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

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

severe civil penalties - private rights of action

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

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

Pay-As-You-Go Scoring

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

prohibit what the U.S. pop is concerned with implant & create child.

* * * * * * * * * * *

any prohibition on SCNT which would prevent basic research that could lead to

birth defects

Total Pages: ____

LRM ID: RJP187

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

URGENT

Thursday, February 5, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference

OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148

SUBJECT: **Statement of Administration Policy on S1601 Human Cloning Prohibition Act**

DEADLINE: **2:00 p.m. Thursday, February 5, 1998**

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. **Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.**

COMMENTS: Senate floor consideration of S. 1601 is scheduled to begin today. **DEADLINE IS FIRM.**

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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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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.

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.