Harold Varmus

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Bill Marshall - 6-6219 fax 301-983-8670

Rachael Levinson - 6-6137 page

Bill Raub 690-5874 ; 202 490-0322

Claudia Cooley 690-8084 205-2135 690-7928

Barbara Wodey

Ross Wiener - 6-7900

Demmetta 301-402-6060

514-2105 pn Joel Fishman

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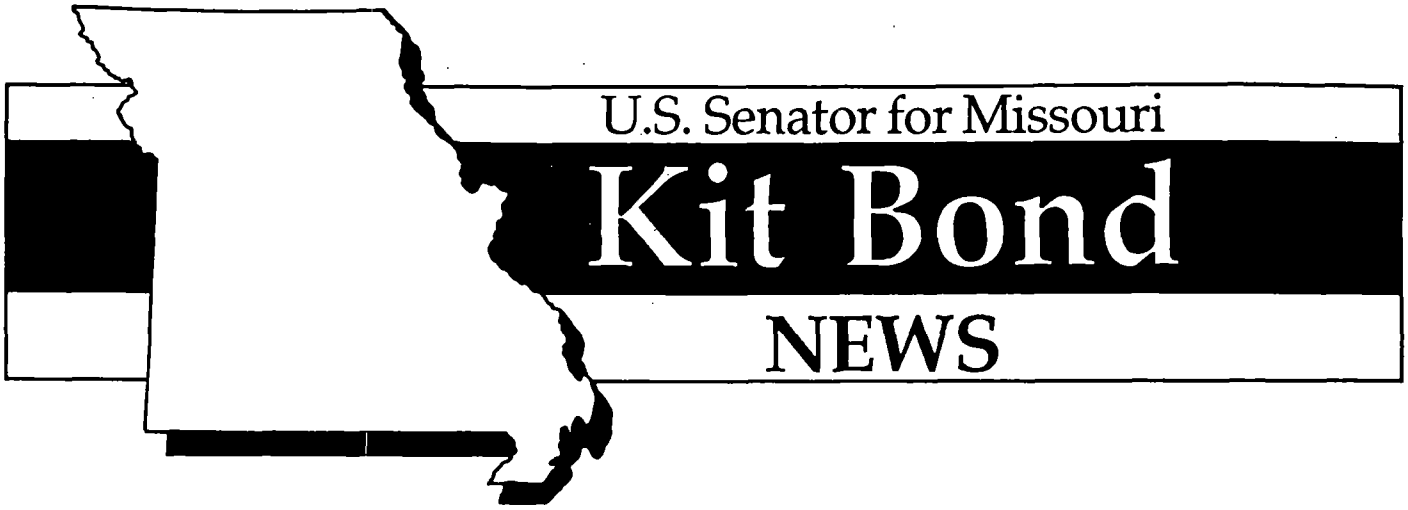
David Halberstam pn 514-4409 fax 514-0563

Bill Pellerin 6-4871

6-6047



FOR IMMEDIATE RELEASE
Saturday, June 7, 1997

CONTACT: LEANNE JEROME
202.224.4611

BOND SAYS CLONING COMMISSION PUNTED; HARD WORK NOW LEFT TO CONGRESS

(Washington) - Senator Christopher "Kit" Bond issued the following statement after the final meeting of the National Bioethics Advisory Commission on the human cloning issue today. Bond expressed concern about the commission's recommendation that cloning research be permitted to continue on human embryos, even though they would not permit implantation of cloned embryos.

"The Commission decided that 'at this time,' it is morally unacceptable for anyone to try to create a child through cloning. While I agree that it is unacceptable, I'm troubled by the phrase 'at this time.' They are leaving the door wide open to future cloning. By allowing cloning research on human embryos to continue in the private sector, they are basically saying 'go ahead, as far as you can, and when it gets dangerous, then we'll try to stop you.'"

"I had hoped that the federal ethics commission would not be afraid to make a strong moral statement that human cloning is wrong, period, and should be banned. But when it came to the tough questions, they punted, and now it will be up to Congress and state legislatures to resolve those issues."

###

In order to allow for continued public discussion - begins not end.

THE WHITE HOUSE
WASHINGTON

- Sheraton

Crystal City Marriott

Report to President
- Intro
- Recommendations
Lunch 1999 - Jeff Davis Hwy.
- Law policy chapter,
Recommended continued moratorium - on human cloning the
Effect a moratorium that would apply equally to public and private research. - Considering recommending legislation, but divided on whether

Concerns about legislation -
- nature of legislative debate
↳ very narrow provisions
↳ adapting legislation to changes as .

- consensus - concerns alone ~~[illegible]~~ for
ethical safety and ethical issues ⇒ cont. moratorium. - make it premature to do human cloning

↳ don't feel
- Science is going to be held up.

Open question -
who reviews later -
time limited - arbitrary
condition limited - arbitrating body

Issues
1st
form of the moratorium
- OSTP -

June 2, 1997
Handout: List for Cloning Report

National Bioethics Advisory Commission

Harold T. Shapiro, Ph.D. - Chair
President
Princeton University
Princeton, New Jersey

Patricia Backlar
Senior Scholar
Center for Ethics in Health Care
Oregon Health Sciences University
Portland, Oregon
Senior Research Associate
Department of Philosophy
Portland State University
Portland, Oregon

Arturo Brito, M.D.
Assistant Professor of Clinical Pediatrics
University of Miami School of Medicine
Miami, Florida

Alexander Morgan Capron, LL.B.
Henry W. Bruce Professor of Law
University Professor of Law and Medicine
Co-Director, Pacific Center for Health Policy and Ethics
University of Southern California
Los Angeles, California

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Clinical Professor of Public Health
Cornell University Medical College
New York, New York

R. Alta Charo, J.D.
Associate Professor of Law and Medical Ethics
Schools of Law and Medicine
University of Wisconsin
Madison, Wisconsin

James F. Childress, Ph.D.
Kyle Professor of Religious Studies
Professor of Medical Education
Department of Religious Studies
University of Virginia
Charlottesville, Virginia

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Stanford University School of Medicine
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Lucille Cole Professor of Nursing
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National Alliance for the Mentally Ill
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San Francisco, California

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Director
State Department of Health
Honolulu, Hawaii

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Professor and Director
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Diane Scott-Jones, Ph.D.
Professor
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Temple University
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FAX TRANSMISSION

OFFICE OF PUBLIC HEALTH & SCIENCE
DAMON THOMPSON
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200 INDEPENDENCE AVE. SW
WASHINGTON, D.C. 20201
PHONE: 202-205-1842 ← Communications Dept.
FAX: 202-690-4631 ← [illegible]

To: Elizabeth Drye

Date: June 6, 1997

Fax #: 94567431

Pages: 5, including this cover sheet.

From: Damon Thompson

Subject: cloning q's and a's

COMMENTS: Here are the modified q's and a's.

Lori McHugh.

690-7850 Shofield.

→ 690-5673

Elizabeth Drye
05/14/97 10:05:12 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc:
Subject: Re: NBAC report release

Can Shaprio say at Saturday's meeting -- "The White House let me know NBAC should take more time if needed since the President won't have an opportunity to accept the report before the week of June 9th"? Can I let Shapiro know POTUS will accept the report either from him or from full 18-member Commission, and that we will get back to him on that?

I'll call him w/OSTP once I hear from you.

FYI I made yesterday's call to Shapiro w/Jack's staffer, but will make sure Jack is informed.

- Can send single copy of report directly to the President

- FOIA gives us two weeks

Elizabeth Drye
05/14/97 10:05:12 AM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc:

Subject: Re: NBAC report release

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NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC)

Friday May 2, 1997
Sheraton Crystal City Hotel
1800 Jefferson Davis Highway
Arlington, VA 22202
Crystal Ballrooms 1 and 2
703-486-1111*

AGENDA**

7:30 AM	**Welcome and Introduction**
	Dr. Harold Shapiro, Chair
7:45 AM	**Scientific Issues**
	Dr. Greider
8:15 AM	**Ethics Issues**
	Dr. Bernard Lo
9:00 AM	**Coffee Break**
9:30 AM	**Legal and Policy Issues**
	R. Alta Charo, J.D.
10:15 AM	**Discussion**
	Commission Members
12:15 PM	**Lunch**
1:15 PM	**Statements by the Public**
1:30 PM	**The Draft Report: Discussion**
	Dr. Harold Shapiro, Dr. Kathi Hanna, and Members
3:15 PM	**Updates from the Subcommittees**
	Dr. James Childress and Dr. Thomas Murray
3:30 PM	**Adjournment**

PLEASE NOTE: *To leave messages, please call 703-486-1111 and ask for Ballrooms 1 and 2, National Bioethics Advisory Commission.
**Assigned times are approximate.

ROSTER OF NBAC MEMBERS

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(July 19, 1996 - July 18, 2000)

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(July 19, 1996 - July 18, 2000)

National Bioethics Advisory Commisson Members

Chair

Harold T. Shapiro, Ph.D.

Genetics Subcommittee

Chair

Thomas H. Murray, Ph.D.

Patricia Backlar
David R. Cox, M.D., Ph.D.
Ezekiel J. Emanuel, M.D., Ph.D.
Carol W. Greider, Ph.D.
Steven H. Holtzman
Bette O. Kramer
Bernard Lo, M.D.
Lawrence H. Miike, M.D., J.D.

Human Subjects Subcommittee

Chair

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Arturo Brito, M.D.
Alexandra M. Capron, LL.B.
Eric J. Cassell
R. Alta Charo, J.D.
Rhetaugh Graves Dumas, Ph.D., R.N.
Laurie M. Flynn
Diane Scott-Jones

Rachel E. Levinson 03/25/97 05:29:26 PM

Record Type: Record

To: Elizabeth Drye/OPD/EOP

cc: Clifford J. Gabriel/OSTP/EOP
Subject: NBAC meetings

April 12, Human Subjects Sub. and Ethics subgroup on cloning
April 13, full commission, Crystal City Marriott, 7:30 -3:30
April 23, Ethics subgroup in SF
May 2, Full Commission, Sheraton Crystal City

May 17, Full commission, Crystal City Marriott

June 7, Full commission, tentative, Crystal City Marriott

Tom Murray, Alta Chard — testified at first hearing 3/12.

Shapiro

1. Witnesses
2. Have experts prepare papers for committee by April
   - Survey of relevant legal landscape — fed and state — already underway — (Y/Z) Laurie Travis —
   - Survey of relevant legal landscape abroad — and position of NBAC-like commissions
   - review of moral and ethical concerns —
     - Georgetown Center bibliography on cloning —
     - Prof Bach, Brown University, agreed to survey the literature —
   - Survey of? (Tissue samples?) Courtney Campbell has agreed to do
   - review of current scientific potential benefits — including non-human cloning activities and (2) what would the research agenda look like? Janet Rogawski —
   - policy options / who

(?)

Kathy Hanna — working with working groups — will help analyze reports.

Won't be able to proceed in simple linear fashion

— 3-4 working groups, composed of commission members "lead writers" categories of work

Extend the life of the Commission

Groups proposed

(1) science issues.
leadership - Carol Ryder. —

(2) philosophical ethical concerns.
Pr. LO.

(3) law / regulation Alta Charo
policy options Alex Capron —

— If you have objections ... have to have better idea.
advise on persons or groups / for April meeting

Tom Murray re Hill testimony
House Subcommittee on Technology, Committee on Science. —
First hearing — Alta
Bond — bill to ban cloning —
Domenici — testified on generic privacy bill

Various — non-reproductive cells
— embryo manipulation
— babies

Alta represented the Commission
phrase "human cloning" in these bills - but
do/es is omitted a ambiguous.
Murray's from House hearing
what capital investment. — not much
rate limiting factor — cloning is very hard —
few scientists know how to do it.

(?) Count facts on
what cost-benefit of recent technologies have been

Consider claiming as scientific context.

Dr. Wilmet's report

Until recently - cloning meant reproducing gene in single cell - like bacteria

Why were scientists surprised that it worked
Why was the experiment so inefficient?

Normal reproduction

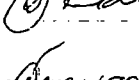
V. quickly - sperm and egg nuclei merge
- during this time, genes are silence
- have to be reactivated
- in mouse reactivation is very fast - after one division

- No sign of reactivation in steps or humans until 18 cell stage - 2-3 days

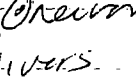
Selective gene silencing

red blood cells

Endocrine cells

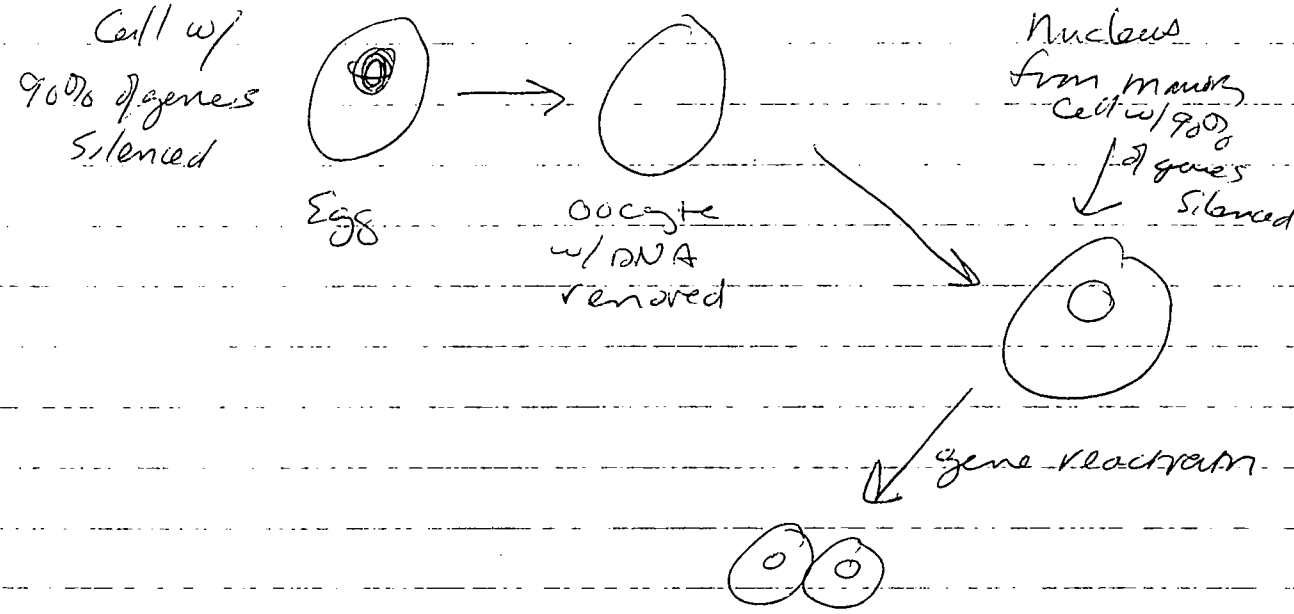


Neurons



livers

didn't think we could reactivate after selective silencing had occurred.



What was new? Mouse experiments had not been
- done w/ fertilized egg but had been done w/ fertilized eggs
- reactivation happens more slowly in sheep than mice
- source of cells - had been in quiescent state (hadn't divided in 3-4) days nuclei were in "silent state" possibly facilitates conversation SRW cytoplasm and nucleus necessary for development.

influences

277 eggs/cell fusions
247 survive 6 days in "oviduct culture"
29 had developed appropriated (10%) - implanted
1 live birth

why inefficient?

1) - physical disruption of egg itself while removing genetic material
2) - gene reactivation inefficient
3) - Negative consequences of mammary gene products on early development (products appropriate to mammary cell are toxic to cell ⇒ success of experiment is tissue specific.
4) - inefficient implantations

1 and 4 are inherent to all embryo manipulations

Scientific risks (that we don't know anything about)

- silent somatic mutation in the donor nucleus
  - We don't know the rate of somatic mutation
  - We know it occurs - cancer is consequence
  - may be benign in mammary cell
  - inherent risk of any experiment of this kind"

- inefficient re-activation of genes required late in development
  - could have incomplete reaction that does not effect early adopt but could effect later stages.

- DNA in mammary cells not reprogrammed to become fertilized eggs - Certain immune cells do that.

Current research – not in humans.

- adding extra DNA to an animals genome
  e.g. making a sheep that can produce a pharmalogically active protein in milk - 15 yrs old
- removing DNA from an animals genome – e.g. to make an animal model for human disease
  e.g. huntington's disease, neurological disorder.

Trasgenisis is inefficient

inject DNA into nucleus of fertilized eggs.

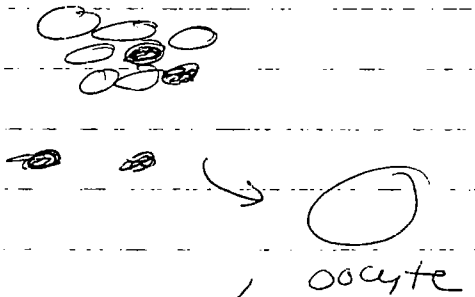
Transgenisis: 100 eggs → 20 mice born → 5 carry DNA → 0–100% express

Cloning as what would do: 100 eggs → ? transitional stage → born → 100% carry DNA → ? % express genes

for using cloning for transgenisis

mammary cell culture

↓ add gene of interest



100% of live progeny produce gene product in milk.

This is a form of gene therapy, but current gene therapy targets a small # of cells

This is NOT going on in humans. — because when you introduce new gene — don't know where it will end up.

[redacted] allows you to targeted gene addition

No credible work going on to create extra-uterine environments for development.

"half-baked" embryos may be produced ← blastocysts
embryonic stem cells

↓

blood stem cells. As tissue culture-line may get it to go in one direction or another.

Emmanuel

IVF success rate is 15-17%

That's only improving efficiency 4x from 3%

Card - (but Conf say that it's 3% after 1 live birth.

Shirley — probably will be a small contributor to basic science → how to stem cells choose pathway to, e.g., become a liver cell. Don't think it will contribute dramatically to this inquiry. Already been study reactivation.

May answer q – when we silence genes later on, is it permanent or impermanent.
In the end, predict a modest role in cell development

Mita – Mitochondrial DNA –
- 01% of our DNA is encoded outside nucleus in critical organelles that exist in cytoplasm.
Mitochondria There for energy metabolism. Critical. Don't survive without them.
Egg is chocked full of mitochondria –
– Don't know if mitochondria transfer
– clone may be a mosaic?
Answering unknowns is
Shirley – Long term research project in animals
we know how to design experiments.
– hardest question is somatic mutation

February 25, 1997

Question and Answer on Cloning

Should scientists in the United States be allowed to conduct the kind of research which led to the cloning of adult sheep in Scotland? Should regulations be instituted? What kind?

- There are no prohibitions in the United States on this kind of research in animals. The techniques used have valuable implications for pharmaceutical and agricultural applications. For example, such techniques might help produce larger quantities of drugs that are less expensive. Ailments that could be treated range from emphysema to hemophilia. Other applications could include protein therapies and organ transplants.

- In 1994, the National Institutes of Health convened a panel of experts to address the issues surrounding preimplantation human embryo research and to make recommendations regarding the development of guidelines for funding such research. The panel's recommendations also addressed areas of research which would not be acceptable for federal funding. Among these were two relevant areas which were identified as being unacceptable for funding:

  - Cloning of human preimplantation embryos by separating blastomeres or dividing blastocysts (induced twinning), followed by transfer to the uterus.

  - Studies designed to transplant nuclei into an enucleated egg, including nuclear cloning, in order to duplicate a genome or to increase the number of embryos with the same genotype with transfer [to the uterus].

- The NIH panel's recommendations were not put into effect. On December 2, 1994, President Clinton issued an Executive Order which stated that NIH was not to allocate any resources to support the "creation of human embryos for research purposes." During the 1995 appropriations cycle, Congress passed legislative language which prohibits the funding of research involving *in vitro* embryos.

- On February 24, 1997, President Clinton asked the National Bioethics Advisory Commission to examine the ethical and legal implications of cloning. The NBAC is to deliver its report to President Clinton in 90 days. Among the issues to be discussed is the role of privately funded research, which at the present time is unregulated.

DRAFT Q and A on Cloning
March 3, 1997

Q. Why do this Presidential Directive on human cloning when the President has already referred the matter to his National Bioethics Advisory Board?

A. This is an interim measure to assure that no human cloning is conducted or supported by the the federal government while the NBAC is assessing the complexities of this area over the next several months.

Q. Isn't there already a law banning human embryo research? Why do you need a Presidential Directive?

A. The law is in the appropriations language for HHS (FY 1996 and FY 1997). It bans use of HHS funds for creation of human embryos for research and research in which human embryos are discarded. First of all, the law right now only covers studies funded by HHS (not the whole federal government). Second, this is such new technology that we simply want to be very, very clear about what is being put on hold at this time. Third, the law bans creation of human embryos for research purposes and does not cover creation of human embryos for procreation.

Q. What impact does a Presidential Directive have on the private sector?

A. The Presidential Directive only covers federal work or federally supported work. But, as a part of his message today, the President is asking the scientific community to refrain from human cloning at this time, while the NBAC has its deliberations. But, let me be clear, the majority of scientific experts believe that any prospect of successfully applying this cloning method to human beings in the near future is extremely remote.

Q. Is animal research like the sheep experiment affected by this Presidential Directive or by the appropriations law on embryo research?

A. No. This Presidential Directive refers to cloning of humans. The legislative ban also covers only human research. There is no ban nor should there be any ban on animal cloning. There is very important scientific work that can be accomplished using animals. This work will have important benefits for agriculture, medicine, and veterinary medicine.
It could lead to improvements in organ transplantation and better treatments for burn patients and cancer patients. Also, by creating genetically identical animals, scientists testing drugs could use far fewer animals than they now need.

Q. And A. The Ban on Human Cloning

Q.The headline in today's Washington Post says that the Director of NIH is opposed to a ban on human cloning. Is that correct? Does this mean he disagrees with the President's stance?

A. Not at all. Dr. Varmus has said repeatedly (including at yesterday's Congressional hearing) that he supports the President's move to ban federal funding for human cloning. And the President's referral to the National Bioethics Advisory Commission. The headline of the Post is out of synchrony with the text and the facts. Dr. Varmus was commenting on the possibility of an imminent legislative ban.

Q. Didn't Varmus ask Congress at the hearings not to ban cloning?

A. Yes. He said he hoped that legislation on this matter is held off while the President's National Bioethics Advisory Commission hears public testimony and deliberates on the matter. (Their report due in 90 days from March 4.)

Q. Why did Varmus suggest that human cloning might be acceptable in some cases?

A. At the Congressional hearing, Varmus was laying out the broad range of possible applications for cloning--in animals and humans. Among them was application of cloning techniques in very rare circumstances, such as cases of untreatable infertility. He did not say he favored this application, only that consideration of it should be a part of public debate and the deliberations of the National Bioethics Advisory Board.

He has said repeatedly that he finds the notion of human cloning for experimental purposes personally offensive. He has said he agrees with the President's assertions that human cloning for any purposes poses huge ethical challenges.

Q. What does the President think about the use of cloning to treat infertility?

A. He's going to wait for the report from the National Bioethics Advisory Commission..

NOTE: Mr. Ehlers introduced two bills yesterday HR922 and HR923, one would permanently ban any federal funding for human cloning research and the other would ban human cloning altogether even with private funds.

NOTE: USED BUT NOT ISSUED.

3/6/97

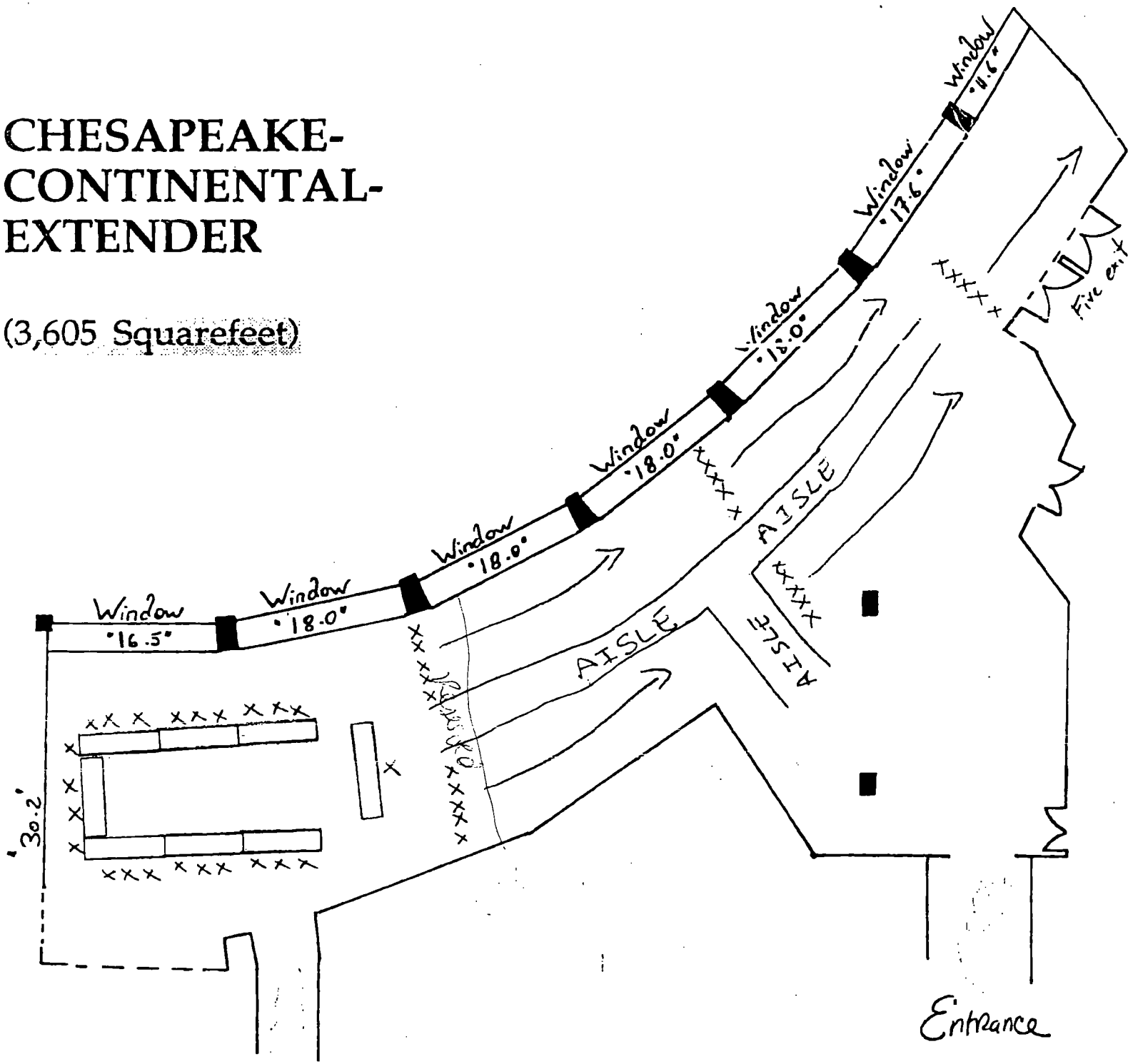
Q. Are studies on animal cloning now being conducted or supported by the government?

A. Yes. There are animal studies related to cloning being funded by the government. These are seen as important studies that are not affected by this Presidential Directive.

Anne Thomas, NIH
(301)-496-4461

CHESAPEAKE-CONTINENTAL-EXTENDER

(3,605 Squarefeet)



Elizabeth Drye
03/03/97 09:14:51 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP

cc: Elena Kagan/OPD/EOP, Cathy R. Mays/OPD/EOP
Subject: Cloning event 9:00 a.m. Tuesday

Reminder that you are scheduled to join the POTUS, VPOTUS, Shalala, Varmus, NBAC Chair Harold Shapiro, Gibbons etc. at 9:00 a.m for cloning I am leaving in Cathy's chair OSTP's briefing memo, the draft fact sheet, the draft directive, and another copy of the memo to POTUS. Drafts will be final once Varmus reviews in the early morning. OSTP is finishing up Q&A which I will get to you as well. Let me know if you need anything else. Thanks. Hope Florida was fun.

March 3, 1997

CLONING MEETING AND STATEMENT

DATE: March 4, 1997
LOCATION: Oval Office
TIME: 9:00 A.M.
FROM: Tim Newell

I. PURPOSE

You will meet with Administration officials in the area of research and ethics to 1) issue a statement on cloning to assure the public that federal funds will not be used to clone humans; and (2) call on the scientific community to voluntarily refrain from human cloning until the ethical issues can be considered.

II. BACKGROUND

The recent announcement that Scottish researchers have successfully cloned an adult sheep has received widespread attention, since, hypothetically, similar techniques could be used to clone humans. Because of the ethical concerns human cloning would present, on February 24 you asked your National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues involved and to report back within 90 days on possible federal actions (see attached letter to Dr. Shapiro, NBAC Chair).

Most scientists believe that human cloning faces major scientific barriers, and the majority of experts believe that any prospect of successfully applying this new cloning method to human beings in the near future is remote.

Human cloning research also faces federal funding barriers. On December 2, 1994, you issued a statement barring the use of federal funds to create human embryos for research purposes. Appropriations bills for FY96 and FY97 codified this policy and expanded it to cover HHS research in which human embryos are "destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." (The Administration has opposed addressing the issue through legislation and has supported repealing this provision)

There is some fear, however, that public concern over this issue could erode support for important genetic research programs, and/or result in overly-restrictive legislation. On February 26, testifying before the House Appropriations Subcom. on Labor, Health and Human Services, Dr. Varmus stated that while the idea of human cloning was "repugnant," he "would be concerned about a rush to legislate" a prohibition since legislation could also restrict related work that offers important medical, economic, and scientific benefits.

A consensus is emerging that researchers should not pursue the cloning of human beings at least until the nation has more thoroughly considered the ethical implications of the technology. The current restrictions do not assure this outcome for two reasons.

First, the current ban on using federal funds to create embryos for research does not explicitly prohibit all human cloning -- it only covers cloning of embryos that will be discarded (not implanted), and only covers HHS-funded research.

Second, the restrictions apply to federally-supported human embryo research only, not privately-funded activities. Privately funded facilities are free to engage in human cloning research under current law. There is a booming business in all forms of reproduction technology to assist infertile couples. Human cloning is not likely to be pursued in this context -- at least until it has a chance of competing successfully against existing technology -- but it cannot be definitively ruled out.

Congress has scheduled fact-finding hearings on human cloning March 5 (Technology Subcommittee, House Science Committee) and March 12 (Senate Subcommittee on Science, Technology and Space). NIH Director Harold Varmus has been asked to testify at both upcoming hearings.

Your statement at this time is intended to reassure the public; deter restrictive, ill-advised legislation; and strengthen the nation's resolve to consider ethical questions carefully before advancing human cloning by 1) clarifying that federal dollars cannot be used for human cloning and that you are signing a memorandum to that effect; 2) calling on the scientific community to refrain from human cloning at least until NBAC and the nation have carefully considered the issue.

III. PARTICIPANTS

Meeting Participants
The President
The Vice President
Secretary Shalala
Harold Varmus, Director of NIH
Harold Shapiro, President of Princeton University/Chair, Natl Bioethics Advisory Comm
Jack Gibbons
Bruce Reed
John Podesta
Tim Newell

Oval Office Event Participants
The Vice President
Secretary Shalala
Harold Varmus, Director of NIH
Harold Shapiro, President of Princeton University/Chair, Natl Bioethics Advisory Comm.
Jack Gibbons
Bruce Reed
John Podesta
Tim Newell
Elena Kagan
Elizabeth Drye
Cliff Gabriel
Rachel Levinson

IV. PRESS PLAN

Press Pool

V. SEQUENCE OF EVENTS

- At 9:00 AM, you will meet briefly in the Presidential Dining Room with the Vice President, Sec. Shalala, Dr. Varmus, Dr. Shapiro, Jack Gibbons, and Bruce Reed to discuss the Administration's response to the recent advances in cloning technology.

  -- Dr. Varmus will brief the Vice President and you on the biomedical implications of the new cloning technology.
  -- Dr. Shapiro will discuss how NBAC will respond to your request for a review of the ethical and legal implications related to cloning humans.

- At 9:10 AM, you will proceed into the Oval Office to the podium, accompanied by the Vice President, Sec. Shalala, Dr. Varmus, Dr. Shapiro, and Jack Gibbons.

- You will make a statement on cloning to the Press Pool.

- You will take questions from assembled press.

- You will depart the Oval Office.

VI. REMARKS

To be provided by Speechwriters

VII. ATTACHMENTS

24 Feb 97 letter to NBAC/Shapiro

March 4, 1997

Memorandum for Heads of Federal Agencies

Subject: Federal Funding of Human Cloning

Recent accounts of advances in cloning technology, including the first successful cloning of an adult sheep, raise important questions. They potentially represent enormous scientific breakthroughs that could offer benefits in such areas as medicine and agriculture. But the new technology also raises profound ethical issues, particularly with respect to its possible use to clone humans. That is why last week I asked our National Bioethics Advisory Commission to thoroughly review the legal and ethical issues associated with the use of this technology and report back to me in 90 days.

Federal funds should not be used for human cloning. The current restrictions on the use of federal funds for research involving human embryos do not fully assure this result. In December, 1994 I directed the National Institutes of Health not to fund the creation of human embryos for research purposes. Congress extended this prohibition in 1996 and 1997 appropriations bills, barring the Department of Health and Human Services from supporting certain human embryo research. These restrictions do not explicitly cover human embryos created for implantation and do not cover all federal agencies. I want to make it absolutely clear that no federal funds will be used for human cloning. Therefore, I hereby direct that no federal funds shall be allocated for cloning human beings.

President Clinton Announces Steps to
Prevent Cloning of Human Beings While Nation Examines Ethical Issues
March 4, 1997
---- DRAFT -----

Announcement

President Clinton today issued a directive to ensure that no federal funds will be used to clone human beings. The current restrictions on the use of federal funds do not assure this result. They do not explicitly cover human embryos created by cloning for implantation and do not cover all federal agencies. The directive President Clinton is signing today will make it crystal clear that no federal funds will be used to clone human beings.

- **President Clinton called on privately-funded scientists to implement a voluntary moratorium on all efforts to undertake human cloning, at least until the National Bioethics Advisory Commission -- and the entire nation -- have considered its profound ethical implications.** Since privately-funded scientist are not covered by the President's directive, a voluntary moratorium would ensure that ethical issues are fully debated before there are any efforts to clone human beings.

Background

- **The February 27 issue of *Nature* contains an account of the first successful cloning of an adult sheep.** The new technology could lead to major beneficial advances in science, agriculture, and medicine. For example, it may inform new methods for producing human proteins, creating model organism to study human diseases, and possibly reprogramming human cells for treatment of cancer, burns, and other disorders. But the new technology also raises profound ethical issues, particularly with respect to its possible use to clone human beings.

- **On February 24 President Clinton asked the National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues involved** and to report back within 90 days on possible federal actions.

- **The President does not believe federal funds should be used for human cloning, and current restrictions on federal funds do not fully assure that result**. In December, 1994 the President directed the National Institutes of Health not to fund the creation of human embryos for research purposes. Congress extended this prohibition in 1996 and 1997 appropriations bills, barring the Department of Health and Human Services from supporting certain human embryo research. These restrictions do not explicitly cover human embryos created by cloning for implantation and do not cover all federal agencies.

- **Privately-funded scientists and clinicians are not prohibited from cloning human beings.** Although most scientists believe that the possibility of cloning human beings in the near future is remote, a voluntary moratorium would assure that the nation fully considers ethical issues before any attempts are made to clone human beings.

THE WHITE HOUSE

WASHINGTON

March 3, 1997

MEMORANDUM FOR THE PRESIDENT

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

Bruce Reed
Assistant to the President for Domestic Policy

SUBJECT: Background and Suggested Presidential Statement on Cloning

As you know, the February 27 issue of *Nature*, a renowned scientific journal, contains an account of the first successful cloning of an adult sheep. Hypothetically, similar techniques could be used to clone humans. Because of the ethical concerns human cloning would present, on February 24 you asked your National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues involved and to report back within 90 days on possible federal actions.

We recommend that you: (1) issue a statement on cloning to assure the public that federal funds will not be used to clone humans; and (2) call on the scientific community to voluntarily refrain from human cloning while NBAC and the nation distinguish the facts from the hype and consider its ethical implications.

Background

Most scientists believe that human cloning faces major scientific barriers. For complicated scientific reasons, sheep may be more easily cloned than humans and other animals, and all attempts to clone other mammals such as mice starting with cells from mature animals have failed. The majority of experts believe that any prospect of successfully applying this new cloning method to human beings in the near future is extremely remote.

Human cloning research also faces funding barriers. On December 2, 1994, you issued a statement barring the use of federal funds to create human embryos for research purposes. Appropriations bills for FY96 and FY97 codified this policy and expanded it to cover HHS research in which human embryos are "destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." (The Administration has opposed addressing the issue through legislation and has supported repealing this provision). Senator Bond (R-MO) has begun to draft legislation making permanent the current ban on federal funding for human embryo research.

News reports have indicated that the Congressional ban prohibits using federal funds for human cloning, and no one in Congress has taken issue with this understanding. But the language is not as tight as it could be. It does not explicitly bar federally-supported scientists from creating human

embryos they intend to implant -- it only prohibits them from creating embryos they will discard. In addition, the Congressional ban only covers HHS-funded research.

Privately funded facilities are free to engage in human cloning research under current law. There is a booming business in all forms of reproduction technology to assist infertile couples. Human cloning is not likely to be pursued in this context -- at least until it has a chance of competing successfully against existing technology -- but it cannot be definitively ruled out.

Congress has scheduled fact-finding hearings on human cloning March 5 (Technology Subcommittee, House Science Committee) and March 12 (Senate Subcommittee on Science, Technology and Space). NIH Director Harold Varmus has been asked to testify at both upcoming hearings. On February 26, in testimony before the House Appropriations Subcommittee on Labor and Health and Human Services, Dr. Varmus stated that the idea of human cloning was "repugnant." He went on to say that he "would be concerned about a rush to legislate" a prohibition since legislation could also restrict related work that offers important medical, economic, and scientific benefits.

Rushed attempts to ban cloning could easily result in unintended harmful effects on important research. For example, Dr. Varmus has noted that sheep cloning might inform new methods for producing human proteins, creating model organisms to study human diseases, and possibly reprogramming human cells for treatment of cancer, burns, and other disorders. Therefore, any restraints on human cloning should be worded carefully to avoid unintended consequences on a broader sphere of biomedical and agricultural research.

A consensus is emerging, however, that researchers should not pursue human cloning at least until the nation has more thoroughly considered the ethical implications of the technology. The current restrictions do not assure this outcome for two reasons. First, as noted above, the current ban on using federal funds to create embryos for research does not explicitly prohibit all human cloning -- it only covers cloning of embryos that will be discarded (not implanted), and only covers HHS-funded research. Second, the restrictions apply to federally-supported human embryo research only, not privately-funded activities.

You could urge the non-federally funded scientific community to declare a self-imposed moratorium on human cloning. Some in science will question the need for this approach because they do not believe our ability to clone humans is imminent.. Some also believe that it would be inappropriate for you to take action before NBAC reports back to you with recommendations (your referral of the issue to NBAC received enthusiastic, bipartisan support at NIH's February 26 appropriations hearing). On the other hand, your calling for a moratorium might deter restrictive, ill-advised legislation, reassure the public, and strengthen the nation's resolve to consider ethical questions carefully before advancing human cloning. The scientific community favors a voluntary moratorium over a Congressional ban, and key scientists including Dr. Varmus would understand your calling for it.

Suggested Presidential Statement

We recommend that you issue a statement to:

- Affirm the scientific promise of the new cloning technique and its concurrent ethical challenges;
- Argue that ethical concerns must be confronted before people try to use the technology to clone humans;
- Restate that you have referred the issue to NBAC;
- Clarify that federal dollars cannot be used for human cloning and that you are signing a memorandum to that effect; and
- Call on the scientific community to refrain from human cloning at least until NBAC and the nation have carefully considered the issue.

- Tim Shroeder

Dick Riseberg - 301-443-2644
Rob Winer Har 202-245-8598

RRiseberg @ psc.dhhs.gov
05/19/97 08:50:04 AM

Record Type: Record

To:

cc: levinson
Subject: Post request for NBAC working drafts

Rachel,

Let me know whether you folks have any problems with this approach.

Dick

_____ Forward Header _____
Subject: Post request for NBAC working drafts
Author: Richard Riseberg at ~OGC_1
Date: 5/19/97 8:29 AM

As you know, the Washington Post has asked through its attorneys for "all drafts of the final report" of the National Bioethics Advisory Commission to be discussed "at the public meeting on" Saturday, May 17. Inasmuch as the request only came on the 16th nothing was provided and the request was put into normal FOI channels. As you also know, the Post argues that they are entitled to the drafts under FACA. Since the drafts are predecisional, there is certainly argument for withholding them. Also, they are not really the work of the Commission but rather just of individual members. On the other hand, in light of certain language in FACA, the Post's position is not frivolous.

At this point the NBAC chair would like to avoid a legal battle distracting NBAC from its mission. He is comfortable with releasing the drafts which have been discussed extensively in public session. I have reviewed the matter with the White House representative who sits with the Commission and she considers it highly unlikely that the WH would want to intervene to withhold. However, she is going to check and get back to me today if she is wrong.

In the meantime I have drafted a proposed letter which would provide for release because of the special issues before the Commission, while making it clear that the release is as a matter of discretion and not based on any legal obligation. Obviously before recommending such a step I would want to be sure you and Darlene are comfortable with such an approach. I am sending a copy of this note to Harriet in case she sees any issues from her perspective.

The proposed transmittal letter to the Post would read as follows:

"This is in reply to your letter of May 16, 1997, requesting all drafts of the final report of the National Bioethics Advisory Commission discussed at the meeting on May 17, 1997.

"In your letter you present legal arguments as to why you are entitled to these documents.

Without getting into the merit of these arguments, the special nature of the issues being considered by the Commission have led me to conclude that, as a matter of discretion, the materials you requested should be made available to you.

"We are in the process of making copies and will transmit them to you in the next day or two."

Tim/Darlene: Please let me know whether you have any problems with this approach.

Dick Riseberg

to Dock Ritzberg
attention: Jeno!!
Urgent

URGENT

The Washington Post
1150 15th STREET, N.W.
WASHINGTON, D.C. 20071
(202) 334-6000

KAREN M. KRAMER
STAFF ATTORNEY
(202) 334-7585
FAX (202) 334-6031

May 16, 1997

Harold T. Shapiro
Chairman, National Bioethics Advisory Commission
6100 Executive Blvd.
Suite 3C01
Rockville, MD 20892-7508

SENT BY FAX AND HAND DELIVERY

Re: FACA Request (Urgent)

Dear Mr. Shapiro:

This is a request pursuant to the Federal Advisory Committee Act ("FACA"), 5 U.S.C. App. II, for all drafts of the final report by the National Bioethics Advisory Commission prepared for and/or to be discussed at the public meeting on Saturday, May 17, 1997. I am writing on behalf of Rick Weiss, a writer for The Washington Post.

Under section 10(b) of the FACA, all "working papers and drafts," among other things, must be made available to the public.

This material may not be legally withheld on the grounds that it is covered by exemption 5 of the Freedom of Information Act (FOIA), which protects predecisional and deliberative interagency or intraagency memorandum from disclosure by agencies subject to the FOIA. Because the very purpose of the FACA is to ensure that deliberations by commissions be conducted publicly and openly, courts have held unequivocally that the FOIA exemption covering predecisional material is not available to commissions. See, e.g., Wolfe v. Weinberger, 403 F. Supp. 238 (D.D.C. 1975); Nader v. Dunlop, 370 F. Supp. 177 (D.D.C. 1973). In so holding, courts have recognized that permitting commissions to claim an exemption for predecisional material would swallow the FACA rule that debate and deliberations by commissions be conducted in full view of the public.

Moreover, it is the commission's legal duty to provide this material immediately and without delay. The FACA requires that access to material covered under section 10(b) be provided to requesting parties, at a minimum, "before or at the meeting at which the materials are used and discussed." The D.C. Circuit so held in Food Chemical News v. Dep't of Health and Human Services, 980 F.2d 1468, 1472 (D.C. Cir. 1993). Mr. Weiss requested the material from a Commission member yesterday by telephone. In order to comply with your obligation under the FACA, please provide the material immediately.

Very truly yours,

Karen Kramer

Karen M. Kramer

Rachel E. Levinson 05/19/97 10:43:35 AM

Record Type: Record

To: Clifford J. Gabriel/OSTP/EOP, Holly L. Gwin/OSTP/EOP, Elizabeth Drye/OPD/EOP

cc:
Subject: additional meeting coverage

a less informed take on saturday's meeting

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 05/19/97 10:42 AM ----------

racharo @ facstaff.wisc.edu
05/19/97 01:36:12 AM

Please respond to nbac-members@lists.Princeton.EDU

Record Type: Record

To: nbac-members @ lists.Princeton.EDU

cc:
Subject: additional meeting coverage

Document ID: C:\LEX40\DOWNLOAD\TODAY.TXT

Los Angeles Times

May 18, 1997, Sunday, Home Edition
SECTION: Part A; Page 1; National Desk

LENGTH: 797 words

HEADLINE: U.S. PANEL TO URGE HUMAN CLONING BAN

BYLINE: ROBERT A. ROSENBLATT, TIMES STAFF WRITER

DATELINE: WASHINGTON

BODY:

A special presidential commission, taking an unexpectedly tough stand, is preparing to call for a new federal law banning the creation of a human being by cloning.

The National Bioethics Advisory Commission, which met here Saturday, wants to extend to private corporate and medical laboratories the same kind of prohibition against cloning now imposed on researchers using federal dollars.

Members of the commission voiced strong sentiments against the creation of a human clone, a baby with just one biological and genetic parent.

The commission's final report will be delivered to President Clinton on May 27. He had imposed the moratorium on federal funding while awaiting the report.

Although the commission did not complete final language for the report, it was clear there is strong support for tough, restrictive federal legislation. Rather than rely on voluntary cooperation by researchers and fertility clinics, the commission would make it illegal for anyone to make a human clone.

"It's a safety concern" because babies created by cloning would have a high risk of "developmental defects and other physical abnormalities," said Dr. David Cox, professor of genetics and pediatrics at Stanford Medical School.

"There is an increased physical risk--that is why I feel it is an awful idea," Cox, a commission member, said in an interview. "I believe safety is an ethical issue."

"We're all agreed it shouldn't be done. We need to make it a firm prohibition," Dr. Eric J. Cassell, clinical professor of public health at Cornell Medical College, told his fellow panel members.

Commission members are strong supporters of continuing research in the cloning of animals, and of further work to develop medical treatments linked to gene therapy.

But they want to draw a clear line between these activities and the attempt to create a human baby that is a genetic carbon copy of just one parent.

To keep the line distinct, they are willing to take what for scientists is the rare step of calling for curtailment of the freedom of researchers.

Most federal commissions, faced with controversial issues such as this, have typically endorsed freedom for medical or scientific research while calling for procedural safeguards.

This time, however, the potential opportunities for abuse, and the intense publicity and concern over cloning, prompted a very different approach. Virtually all members of the commission, including scientists who have been quick to oppose any legislative restrictions on research in the past, are endorsing the proposed law.

Commission members include doctors, professors of ethics and religion, research scientists and a pharmaceutical company executive. Scottish researchers' cloning of a lamb named Dolly, which grew into a healthy adult, precipitated the current highly publicized debate.

Cloning is the production of an exact genetic duplicate of a living organism.

In the normal reproductive process, an egg and a sperm fuse, combining the genetic background of two parents, to produce an embryo. The embryo becomes a third adult, combining the genes contributed by each parent.

Cloning uses only the genes from one parent. Dolly was created with the genetic material from a cell from the udder of a ewe. Her only parent was her mother.

In human cloning, the child would not be a unique combination of genes with physical and mental aspects from two people, as is the case with every human being. Instead, the child would be an identical copy, genetically speaking, of the sole parent contributing the genes.

The commission's goal through a law is to "prohibit the first successful cloning of a human being," said Dr. Bernard Lo, professor of medicine and director of the medical ethics program at UC San Francisco.

A key target of the proposed law would be fertility clinics, where the egg from the mother and sperm from the father are combined to produce an embryo, which is then implanted in the mother.

Commission members fear fertility clinic doctors would produce embryos using the genes from just one parent. Perhaps a billionaire wanted to replicate himself in children, or a politician wanted a child identical to herself.

"For most of us, safety is a profoundly ethical issue. Safety is a moral issue," said the commission chairman, Princeton University President Harold Shapiro. "The chances of abnormal development in fetuses created this way is very high," he said.

Laws barring human cloning have been adopted in Britain, Denmark, Spain, Germany and Australia.

Commission members emphasize that the ban would apply only to cloning research aimed at making a human being.

"It is critical" to continue cloning research, which is the "foundation of modern biomedicine," Shapiro said.

LANGUAGE: English

LOAD-DATE: May 18, 1997

U.S. Newswire

May 16, 1997 16:30 Eastern Time
SECTION: NATIONAL DESK

LENGTH: 200 words

HEADLINE: Amendment to Executive Order on Bioethics Advisory Commission

CONTACT: White House Press Office, 202-456-2100

DATELINE: WASHINGTON, May 16

BODY:
The following was released today by the White House:

EXECUTIVE ORDER

- - - - - - -

FURTHER AMENDMENT TO EXECUTIVE ORDER 12975,
EXTENSION OF THE NATIONAL BIOETHICS ADVISORY COMMISSION By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to extend the term of the National Bioethics Advisory Commission, it is hereby ordered that section 7(b) of Executive Order 12975 further is amended to read, "NBAC shall terminate on October 3, 1999, unless extended by the President prior to that date."

WILLIAM J. CLINTON THE WHITE HOUSE,
May 16, 1997.
LANGUAGE: ENGLISH

LOAD-DATE: May 16, 1997

r. alta charo, j.d.
associate professor, law & medical ethics
university of wisconsin law school & medical school

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Bio

BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

July 9, 1997

Harold T. Shapiro, Ph.D.
President
Princeton University
One Nassau Hall
Princeton, NJ 08544

Dear Dr. Shapiro:

On April 23 BIO submitted recommendations to the Commission on the issue of the cloning of human beings recommending *inter alia* that the moratorium on the use of cloning technologies to create a human being be continued in lieu of any new federal law or regulation. NBAC has now recommended that a law be enacted and the White House has adopted this recommendation and submitted draft legislation to the Congress. Enclosed is a statement of BIO's current position on this issue and our analysis of the draft legislation.

BIO appreciates the care which NBAC and the White House have taken to differentiate the various types of cloning technologies and to emphasize the damage which would be done to vital biomedical research from a poorly drafted law. We also appreciate the recommendation that any law include a sunset provision.

We continue to believe that a continuation of the current moratorium is the preferable course to take, as stated in the enclosed statement of our position. The enclosed analysis explains why BIO cannot support this draft bill.

NBAC was prescient in its report when it stated that it is "notoriously difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science." We find that this concern applies to the draft bill.

We welcome the Commission's comments on our position and analysis. We believe it is important to continue our dialogue on this important issue and on the impact of any legislative proposal.

1625 K STREET, N.W., SUITE 1100
WASHINGTON, D.C. 20006-1604

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FAX 202-857-0237
http://www.bio.org

We will be communicating our position and expressing our concern about this draft bill to the Congress. We will also prepare analyses of the cloning bills which have been introduced in the Congress by Senator Bond and Congressman Ehlers. We will share these analyses with you when they are completed.

We hope to work with the Commission and Administration to ensure that any law which might be considered or enacted will not inadvertently ban vital research and that the debate on any such law will focus solely on issues raised by the Commission and in the draft.

We look forward to working with the Commission on a wide range of bioethics issues in the coming years.

Sincerely,

Charles E. Ludlam
Vice President for
Government Relations

Carl B. Feldbaum
President

CC: William Raub
Elizabeth Drye
Rachel Levinson
Don Gips
Toby Donenfeld
Bill Marshall

Enclosed: BIO Position and Analysis

BIO
BIOTECHNOLOGY INDUSTRY ORGANIZATION

July 9, 1997

BIO Position Regarding Legislation to Ban Human Cloning

With the news that the Roslin Institute and PPL Therapeutics, a BIO member company, had successfully used somatic cell nuclear transfer technology to create a sheep genetically identical to an adult sheep, BIO stated publicly that it opposes the potential use of this technology to create a human child. We stated that we finds no ethical or medical basis for use of this technology for this purpose.

BIO supported President Clinton's referral of this issue to the National Bioethics Advisory Commission (NBAC) for review and his call for a voluntary moratorium on research efforts undertaken for the purpose of using this technology to create a human child while NBAC studied the issue. We supported the establishment of NBAC and believe that it is the appropriate body to review these issues. We also encouraged the U.S. Congress and state legislatures not to enact legislation until NBAC issued its recommendations.

BIO appreciates the care with which NBAC and the Administration have considered the issue and the obvious concern they both have to ensure that no action is taken and no bill is enacted which will undermine vital biomedical research into cures and therapies for deadly and disabling diseases and research into infertility.

We commend the Administration for attempting to convert the NBAC recommendations into statutory language. This effort helps to focus the debate and highlights the complexity of the task.

BIO's Position and NBAC's Recommendations

On April 23, 1997, BIO submitted eight recommendations to NBAC. A copy of our recommendations are attached as Appendix A. We recommended that NBAC endorse a continuation of the current voluntary moratorium on the cloning

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of human beings beyond the period of NBAC review and that this moratorium be in lieu of any federal or state law or regulation regarding the use of somatic cell nuclear transfer technology. We pledged that our industry would abide by such a moratorium.

We agree with the NBAC conclusions in its report that it is unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to create a human child using somatic cell nuclear transfer technology. We recognize that this application of the technology raises ethical and social issues regarding a diminished sense of individuality and personal autonomy. We believe that this technology is not currently safe to use in humans.

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

NBAC takes solace in the inclusion of a sunset provision in any law enacted on this subject and the Administration's draft includes a sunset. NBAC has stated that a sunset provision is "absolutely needed to ensure an opportunity to re-examine any judgement made today" because as "scientific information accumulates and public discussion continues, a new judgment may develop and we, as a society, need to retain the flexibility to adjust our course in this manner." The sunset provision will require review "when scientific and medical questions have been clarified, possible uses have been identified, and public discussion of the deeper moral concerns about this practice has matured."

Our view is that a sunset provision is not adequate protection against the immediate damage which will be done to vital biomedical research by a poorly crafted statute. If there were an imminent probability that unethical and unsafe experimentation on human beings using somatic cell nuclear transfer technology would occur, then there might be a need for precipitous action. But, we do not believe that is the case and urge the Congress to show restraint in enacting a law which may have an adverse impact on vital biomedical research. (As our following analysis demonstrates, the proposed bill would have this impact.)

NBAC disagreed with our recommendation that legislation was not preferable and instead concluded that Federal legislation should be enacted with respect to somatic cell nuclear transfer in humans. NBAC stated that "[i]t is critical, however, that such legislation include a sunset clause to ensure that Congress will review the issue after a specified time

(three to five years) in order to decide whether the prohibition continues to be needed." NBAC has not submitted draft legislative language. The Administration has endorsed this recommendation and has submitted a draft of a bill to implement this recommendation.

NBAC is prescient in its report when it states that it is "notoriously difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science."

BIO's Analysis of Administration's Legislation

We have analyzed the proposed bill -- a copy of which is attached -- and we find the Administration's proposal troubling in many respects and have outlined here our specific concerns. We believe that NBAC may not have anticipated the practical difficulties involved with drafting a bill which would not unintentionally inhibit or prohibit vital biomedical research.

We have little confidence that we, the Administration, or the Congress can draft a bill which will not unintentionally inhibit or prohibit vital biomedical research. Indeed, we believe that any bill -- no matter how well crafted -- is likely to have unintended consequences in the terms of the bill, its interpretation or enforcement, or in the perception of researchers about its terms or possible interpretation or enforcement.

We believe it would be unethical to enact a bill which will inhibit vital biomedical research.

Issues Raised by Bill Proposed by Administration

A copy of the bill proposed by the Clinton Administration is attached to this analysis. This analysis raises issues about the bill's unintended consequences and other issues.

(a) "Cloning Prohibition Act"

The proposed short title for the draft bill -- "the Cloning Prohibition Act" -- is literally misleading. The draft bill would not, in fact, prohibit "cloning" and explicitly states that nothing in the bill should "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." Section 2 (b)(8). The draft also states 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." Section 2(b)(9). The draft defines the term "cloning" to include many technologies other than somatic cell nuclear transfer.

To give the draft bill this title might well increase the possibilities that the bill would be interpreted or enforced in ways which do, in fact, inhibit the use of cloning technologies to produce medicines and other beneficial products to treat deadly and disabling diseases. It would be preferable to have no title for any such law or a title which reflects its substance.

(b) Purposes Section

The purposes section, Section 3, does not include as one purpose the protection of vital biomedical research even though the bill as drafted includes -- in Section 6 -- such protections. Including this purpose in Section 3 would reduce the possibilities that the proposed bill would be interpreted and enforced in ways which would, in fact, inhibit the use of cloning technologies for beneficial purposes.

(c) "Introducing" and "Creating a Human Being"

The proposed bill refers to "introducing" the product of somatic cell nuclear transfer "into a woman's womb or in any other way creating a human being."

To begin with it is not clear whether this means that there are two possible violations or one. One violation might be "introducing" and the second might be "creating."

Another interpretation of this language is that "introducing" is equivalent to "creating a human being." It can be read that one way of "creating a human being" is to introduce the product of somatic cell nuclear transfer into a woman's womb. If this is a correct interpretation, this might be the first Federal statute which states or implies that a fertilized embryo in a woman's womb is already a "human being."

The ethical question of when a "human being" has been "created" is not an issue with respect to which our industry has expertise. These are not issues about technology; they are issues for society.

A further interpretation is that the draft bill contemplates that there are ways of "creating a human being" other than "introducing" an egg into a woman's womb. It might, for example, be interpreted to mean that a "human being" has already been created when an egg is fertilized outside the womb -- the standard practice with *in vitro* fertilization.

In addition, the word "introducing" is ambiguous. The term is not defined in the proposed bill and could refer to any number of different acts.

We are not aware of "any other way" of creating a human being other than birth. If the authors of the draft bill are aware of other ways, perhaps they should be specified. If there are no other ways, then this language is superfluous.

We only point out that this proposed bill has far reaching implications which go way

beyond the issue of somatic cell nuclear transfer technology and go to the fundamental ethical question of what constitutes a "human being."

(d) Acts vs. Intent

The proposed bill focuses on use of 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."

The use of the word "intent" here is quite confusing and troubling. Consider four possible scenarios:

> (1) If an individual has no intent to "introduce" or otherwise create a human being, then there is no violation even if the cell is, in fact, later introduced into a woman's womb by that individual. In this sense the proposed language does not violate the act of introducing or creating as long as there is no intent.
>
> (2) If an individual has no intent to "introduce" but a third party does, in fact, "introduce," then the first party is presumably not liable even if the introduction does, in fact, take place.
>
> (3) If an individual has the requisite intent, but does nothing to actually "introduce" the cell into a woman's womb, then the individual may be found liable. Read carefully, the draft bill does not require the actual "introduction" of the cell into a woman's womb, but only the "intent" to do so.
>
> (4) Finally, it is possible for an individual to "intend" to do something which is not only not done, but which is likely to be impossible to be done. If an individual announces that he "intends" to use nuclear transfer technology to create a human child, makes no attempts to do so, and then finds out that it is quite impossible to do so, he or she still might be liable.

None of these results makes sense.

The point is that the wording of the proposed bill does not focus solely on the final act of creating a human being. As a result, it is impossible to avoid the absurdity of prosecuting individuals even where no human being is created and not prosecuting individuals even though human beings have, in fact, been created.

If the gravamen of the violation is the act of using somatic cell nuclear transfer technology to create a human being, then intent should not be relevant. If no such act occurs, then there should be no violation no matter what the intent may be.

The only way to avoid these absurdities is to focus exclusively on the act of creating a

human being. Any focus on intent will very likely lead to unintended results.

(e) **Implementation of "Intent" Requirement**

We are concerned that a focus on "intent" would lead to unpredictable explorations of the psyche of researchers. What evidence would have to be produced to prove the "intent" of the individual? Would it be sufficient to demonstrate that the introduction or creation took place, or would additional evidence required to show that this was the specific "intent" of the researcher?

If "intent" is an element of the offense, would the individual be entitled to produce evidence to show that he or she has the equivalent of an insanity defense or is not able to recognize the consequences of the act?

It is particularly strange to focus on "intent" if the violation is that of a "legal entity" rather than a "person." There are many different legal entities -- universities, non-profit foundations, and companies. What evidence would be needed to prove that such an entity had the requisite "intent" to violate the prohibition? The concept of "intent" is not normally one which is relevant to the conduct of a "legal entity." If the requisite "intent" is that of the "legal entity," would that require that the "intent" be that of an officer of the entity who had legal authority to bind the entity, rather than that of an employee with no legal authority to bind the entity?

We believe that these are not quibbles over semantics given the fact that one of the penalties is confiscation of the entire legal entity by the government when a violation has been proven.

(f) **Research vs. Somatic Cell Nuclear Transfer**

As explained above, the draft bill focuses on the use of a specified technology with a specified intent. The gravamen of the violation is not, using the words of the draft bill, "creating a human being." Violations can occur even if a human being is not, in fact, created. This raises very serious issues about the potential chilling impact of the draft bill on biomedical research.

The fact that the bill is not confined to cases where a human being is created means that the draft bill is particularly likely to inhibit a broad spectrum of research, not just research which leads to certain end points. There are many intermediate points in the research process short of, say, infusing a drug into a human subject. Every one of the acts short of infusing the drug may be critical to the research and discovery process. This research can have totally different, non-controversial purposes, and involve no actual infusion of the drug. The reference to "intent" can give rise to fears that every act of research concerning somatic cell nuclear transfer is vulnerable to misinterpretation and that every researcher or institution involved with this technology is vulnerable to suit for research.

It may be that the authors of this proposed bill mean to prohibit unsuccessful as well as successful "attempts" to create a child. There are several other places in the draft bill which refer to the "attempt" to use this technology, rather than to the concept of "intent." (See Section 3, Purposes, where it refers to any "attempt" to create a human being.) The word "attempt" is quite different than the word "intent." "Attempts" involve specific acts, not mental states, and it would be easier to determine when a violation occurs. The determination would be less subjective.

Even if the proposed bill were to refer to "attempts" rather than "intent," it may still inhibit research. Every act of research might be characterized as an "attempt," just as it might be seen as evidence of "intent." Every act of research which might, after many additional steps, lead to creation of a human being could be questioned.

Again, the only way to avoid this unintended effect is to focus the proposed bill on the final and definitive act of creating a child using a specified technology, not on the intent or attempt to create a human being using the technology. Any statute which focuses on the technology, as distinct from the end use and application of the technology, inherently and necessarily inhibits research. The only way to avoid this result is to make the "creation of a human child" using this technology the violation.

(g) Definition of "somatic cell nuclear transfer"

The complexity of the issues raised by this draft bill are evident in the definitions of the key scientific terms it uses to specify the reach and impact of the prohibition and penalties. Some of the definitions are not correct from a scientific point of view. This creates ambiguity about the conduct which is subject to the prohibition and penalties and casts doubt on the wisdom of enacting this proposal. Ultimately this is a proposed bill which seeks to regulate scientists and, if it is not possible to draft it to include scientifically accurate terminology, it may well fail to deter conduct which is intended to be covered and deter conduct which is not controversial.

The draft bill would make it unlawful for a person or legal entity to "perform or use somatic cell nuclear transfer" for certain purposes. The draft bill's definition of a "somatic cell" excludes cells which are "germ cells (eggs or sperm)." Then the draft defines "somatic cell nuclear transfer" to mean the "transfer of a cell nucleus from a somatic cell to an egg from which the nucleus has been removed." The terms "germ cells, "eggs" and "sperm" are not defined in the draft bill.[1]

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[1] The glossary in the appendix to the NBAC report defines an "egg" as "the mature female germ cell; also called ovum, or oocyte." The glossary provides other interrelated definitions: a "germ cell" is defined as "a sperm or egg (all other body cells are known as somatic cells)"; "sperm" as "mature male reproductive cells, an egg as the mature female germ cell"; and a "gamete" as a "mature sperm or egg."

To add to the confusion the NBAC report glossary defines "somatic cells" as "any cell of an embryo, fetus, child or adult not destined to become a sperm or egg cell." And the first footnote in the NBAC report defines "somatic cell" as "any cell of the embryo, fetus, child, or adult which contains a full complement of two sets of chromosomes; in contrast with a germ cell, i.e. an egg or a sperm, which contains only one set of chromosomes."

At a minimum this means that the Administration's draft bill differs from the legislation which the NBAC report recommends be enacted.

It also means that we have three definitions of the critical term "somatic cell," one in the bill, and two in the NBAC report. This is hardly a reassuring situation. This is, after all, the term which defines the violation and with respect to which extreme penalties are prescribed. The fact that there is such wide disagreement about how to define this term casts doubt on the wisdom of enacting the draft bill.

In our view the most appropriate of the three definitions is the NBAC glossary definition -- with its reference to cells which are "not destined to become a sperm or egg cell." The other two definitions will cause confusion as they include a zygote as one type of somatic cell.[2]

In addition to these unsettling questions about the definition of a "somatic cell, " no mention is made in the draft bill of the cells which are destined to become gametes, which are not somatic cells (at least under two of the above definitions). These cells are not fully differentiated and therefore they are not gametes per se. Many researchers refer to the types of cells that will become eggs and sperms as "germ cells"; the terms "pre-meiotic germ cells," "primordial germ cells" or "progenitor germ cells" are also often used. These cells can be isolated from embryos which are only eight days old (in mice) and they are destined to become sperm or eggs when the diploid (double) cells split into haploid (single) cells. Thus, by these definitions diploid germ cells are present in adult animals.

We don't know if these pre-meiotic germ cells can be used for the purpose of nuclear transfer, but in mice it is possible to isolate these cells from fetuses, grow them *in vitro* (tissue culture) and maintain their totipotency, allowing them to contribute to all cell types in

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[2] The NBAC report includes the following interrelated definitions of "embryo," "fertilization," "oocyte," and "zygote": "embryo" is defined as "the developing organism from the time of fertilization until significant differentiation has occurred, when the organism becomes known as a fetus"; "fertilization" as "the process whereby male and female gametes unite [which] begins when a sperm contacts the outside of the egg cell and ends with the formation of a zygote"; "oocyte" as "the mature female germ cell, the egg"; and "zygote' as "the single-celled, fertilized egg." None of these definitions is included in the draft bill.

a new animal. The fact that the definitions of cell types mentioned in the draft bill are not scientifically precise and are defined differently by different scientists illustrates the extreme difficulty of drafting a bill on this subject.

The NBAC definition of an "egg" is not included in the draft bill although it appears to be correct from a scientific point of view. But there have been instances, in the murine and bovine systems, where two cell embryos, rather than eggs, have been enucleated and used as hosts for the donor nucleus. A "two cell embryo" is not an egg. An egg is an unfertilized, haploid gamete which when combined with a sperm forms a zygote. An embryo is created when the zygote divides for the first time. Although progenitor germ cells and two cell embryos were not mentioned in the Roslin Institute paper and are not covered in the draft bill, many different protocols and procedures could be adapted for use in this context. Again, we point out that the proposed bill is deficient from the point of view of science and that it is extremely difficult to draft a bill on this complex issue.

All of these definitional issues could be avoided if the legislation focuses on the final outcome of the research -- the use of somatic cell nuclear transfer to create a whole human being -- rather than on the complex scientific procedures which might be used to that or other ends.

(h) Penalties

The penalties proposed by the Administration for violation of the ban can only be described as draconian. This fact, combined with the vagueness of the description of the prohibited conduct, is likely to discourage research well beyond its explicit terms.

The penalties include a fine which is the greater of "$250,000 or two times the gross gain or loss from the offense" and confiscation of "any property, real or personal, derived from or used to commit a violation...or any property traceable to such property..."

If the violation occurs at a university, would the proposed bill permit confiscation of the entire university? If the violation were to occur at a company, would the proposed bill permit the confiscation of the entire company even if only one researcher were involved?

Researchers who are seeking grants from the National Science Foundation or other foundations would tend to avoid any research with any potential or possible connection, real or perceived, to this technology. No funding agency would dare to fund such research.

The draft bill refers also to penalties being imposed on "public" legal entities. By this we assume that the draft bill could refer to the National Institutes of Health or another public agency which performs biomedical research. We find it odd to contemplate the possibility of the Attorney General seeking to impose a fine on NIH or to confiscate its property.

It is obvious to us that the vagueness of the draft bill and the severity of the penalties could lead any prudent university or company or NIH institute to cease doing research even remotely connected to the type of technology covered by the statute.

Even if a company avoided this technology entirely, there is a danger that investors might misinterpret the company's research focus and be unwilling to put their capital at risk with that company. This is a clear case where the existence of even a narrowly crafted bill will have a chilling effect far beyond its specific terms.

In addition, the terms of the proposed penalties are vague. It appears that the proposed bill does not call for incarceration, but we are confused given the repeated use of the term "intent" in the proposed bill, a concept which is often associated with criminal law.

The penalty section provides for the payment of the greater of $250,000 or "two times the gross gain or loss from the offense." The concept of imposing a fine based on the "gross gain" of a firm, university, or institute presumably refers to its gross receipts or revenue and the concept of "gross...loss" presumably refers to its gross expenses. We know of no precedent for imposing a fine based on a multiple of the expenses incurred.

The concept of imposing fines based on gains and losses "from the offense" is also vague. Would it be a fine based on the receipts or expenses of the entire firm, university, or institute or a subset of that? The manner in which this provision might be implemented has potentially dire consequences.

The final ambiguity is how the proposed bill would be interpreted in the case of an individual researcher, acting without authorization. Would the firm, university, or Institute where the individual is employed or where he or she conducted the unauthorized research be fined or subject to confiscation? Would a failure to exercise reasonable supervision be evidence of "intent"?

(i) <u>Advisory Opinions</u>

Were a law to be enacted, we recommend that a mechanism be established to enable scientists to secure advisory opinions regarding the scope, interpretation and possible enforcement of the law with regard to specific research projects.

This would require the Justice Department to establish sufficient expertise and staff to respond to requests for advisory opinions. It could defer to the expertise of the National Institutes of Health, Institute of Medicine, National Science Foundation, and other bodies which have expertise on these issues or experts in the private sector.

To the extent that it would not compromise the confidentiality of research projects, the privacy interests of patients, or the intellectual property rights of the researchers, these advisory opinions should be published so that other researchers could benefit from the

information.

To be clear, we do not believe that such a mechanism would entirely eliminate the inevitable chilling impact of a law on this subject.

(j) Exclusive Remedy

The proposed bill provides that the Attorney General will have "exclusive enforcement authority under this Act." We suggest that this clause be interpreted to mean that the authority to seek enforcement cannot be delegated by the Attorney General to another official.

The draft bill also provides that it shall not be "construed to give any individual or person a private right of action." We are concerned that this language is not parallel to language elsewhere in the draft bill referring to a "person or other legal entity." This section should use this same language to clarify that the draft bill cannot be construed to confer a right of action on any "legal entity," not just any "person or individual."

(k) Preemption

The proposed bill fails to include a clause preempting state laws. We had thought that one of the reasons why NBAC and the Administration have proposed enactment of a Federal statute was concern about the potential for many conflicting state laws on these complex issues. Given how difficult it is proving to be to craft any statute on this issue, if enactment of a law is considered to be necessary, we believe enactment of one Federal law is essential, as opposed to enactment of many different state laws. The possibilities for differential interpretation and enforcement of state laws would have a particularly chilling impact on vital biomedical research.

To be effective the preemption clause must refer to all types of laws on the subject of cloning, including the cloning of cells and genes, not just somatic cell nuclear transfer, so that it covers appropriate laws even if they do not use any of the terms in the proposed Federal statute.

(l) Effective Date

We interpret the "effective date" section of the proposed bill to include both an effective date and a sunset provision. The proposed bill states that it "shall apply" to acts "performed within five years after the date of enactment." This implies that acts of this type performed thereafter would not be covered by the statue. It would be preferable and clearer if the effective date and sunset provisions were stated separately in distinct sections so there is no confusion.

If a statue is to be enacted, it should certainly include a sunset provision, as NBAC

has emphasized. This area of science is new and we need to reevaluate the impact of any law on the subject. Enactment of a permanent law without a sunset provision will increase the likelihood that the law will chill vital biomedical research. A sunset provision will at least focus the attention of the researchers and others on a process towards the end of the five year period when all of these issues can again be reviewed.

Comments on this position and analysis are welcome. Address them to Carl Feldbaum, Chuck Ludlam and Suzanne Tomlinson at the Biotechnology Industry Organization.

BILL PROPOSED BY CLINTON ADMINISTRATION

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.

May 18 Morgan State Commencement

NBAC MEETING SCHEDULE

TWO FULL COMMISSION MEETINGS

Have scheduled weekend meetings to deal with cloning.

MAY 2nd Friday in Washington

-- Will have legal analyis from states; international analysis; summary of ethical viewpoints; compile the results of survey from 54 scientific organizations done by end of April; already drafting a report

Because of FACA constraints, they can't make decisions behind closed doors -- Have to reach closure on recommendations in a public forum.
MAY 17th Saturday Crystal City Marriott

Shapiro is personally supervising the report.

-- recommend continuing a moratorium -- not clear that they will define scope of moratorium drawing the line at making babies or not making babies

- Don't understand the science and tech well enough now to assure the safety of the personc reated with the technology. Given that, too great a risk -- violates our own ethics guidelines to use this technology (can't ensure the safety of human subject); birth defects; longevity; social expectations. Not democratic -- religious groups think that blood transfusions are wrong, and we permit them. NBAC half scientists/half ethicists, lawyers, philosphers, business, theologians, patient representative.

- Centrality of human ethics.

-- need for further public discussion -- given the science

Not done with their report -- what would he say .... lay out some of the ethical questions...

Morgan State Speech

bioethics Commission status.

known – position. – publically

- working on conclusions

May 2nd mtg

May 17th action? press?

Status of draft

Public Hearings
Commissioned Reports > science and religion

- May 17th — close to resolution don't know if they'll be through —
  - don't know if they'll be done
  re. press attention
  - ballot by e-mail —

some of the conclusions will be in the public domain — what we've decided. — what's open. —

May 2nd Mtg. —

- Haven't decided when/how to make reports public —

One area already expressed themselves in public — expect to conclude that at least at the current time — inappropriate to do work on human clones. —
- Cellular
- molecular
- Whole ~~humans~~ animals —

Cloning of individual beings. —
— under discussion whether
— we take on the issue, —
resolved for now — spoke on
or when we spoke. —

7:30 – 3:30. —