Jerold R. Mande

07/29/97 08:46:45 AM

Record Type: Record

To: Elizabeth Drye/OPD/EOP

cc:
Subject: Cloning

Some Scientists Ask: How Do We Know Dolly Is a Clone?

By GINA KOLATA

In the five months since the clone named Dolly was announced, some scientists have begun to grumble. How do we know the whole thing wasn't a hoax? Why didn't the scientists who created Dolly go to greater lengths to prove that she really is what they say she is, a lamb produced by cloning the udder cells of an adult sheep? Why, some ask, is the rest of the world so willing to accept the world-shattering claim that an adult animal was cloned?

These are doubts voiced in conversation, not published arguments, and the critics are in the minority. Others, including Dr. Harold Varmus, the Nobel laureate and molecular biologist who is director of the National Institutes of Health, say they are satisfied by the evidence at hand and do not doubt that Dolly is a clone of an adult sheep.

But Dolly is, and remains, unique. Although a few scientists, including Dr. Neal First of the University of Wisconsin, are trying to repeat the Dolly experiment, the researchers who produced Dolly, Dr. Ian Wilmut of the Roslin Institute and Dr. Keith Campbell, now at PPL Therapeutics in Roslin, Scotland, have no immediate plans to clone another adult animal. They, like most other cloners, are driven by pragmatism. They want to use cloning for the genetic engineering of animals, adding genes to cells grown in the laboratory and then producing animals that are clones of those cells. For such purposes, it is sufficient to clone from fetal skin cells, which are easy to grow in the laboratory. In fact, Campbell and Wilmut announced last week that they had produced a cloned lamb in that way, an animal named Polly that has a human gene added to each of her cells.

Some other scientists are working on cloning adult animals, but no clones have been born yet. First has said informally that he had achieved some pregnancies in cattle but that none had gone to term.

So the murmurs continue. Among the most vocal is Dr. Norton Zinder, a professor of molecular genetics at Rockefeller University. The paper on the cloning that led to Dolly, published in the Feb. 27 issue of Nature, was "a bad paper," he thundered.

"I read this thing, and there's a simple experiment that could have been done," Zinder said. The scientists should have proved that Dolly was a clone by testing her mitochondria, tiny energy factories that lie in the cell cytoplasm, outside the nucleus, the genetic heart of a cell. Mitochondria have their own DNA, and mitochondrial DNA is passed from mothers to offspring because sperm do not contribute mitochondria to a fertilized egg.

After Dolly was created, Wilmut and Campbell reported that they had fused an udder cell from a 6-year-old sheep with a sheep egg whose nucleus they had removed. The adult udder cell's nucleus took over and directed the development of the egg, causing it to divide and grow into an embryo, then a fetus and a lamb. That leaves three possibilities for Dolly's mitochondria, Zinder said: Either Dolly has mitochondria only from the egg, or her mitochondria are identical to those of the udder cell or her mitochondria are a mixture, with some from the egg and some from the udder cell.

If an analysis of Dolly's mitochondria showed that they were identical to those of the egg or if it showed that they they were a mixture, that would prove that she had been produced through cloning, Zinder said. Cloning is the only way to produce a lamb with cells that have egg mitochondria in their cytoplasm and DNA in their nuclei that is identical to the DNA of the udder cell, he explained. The third possibility -- that all her mitochondria were like those of the udder cells -- would be inconclusive. She might be a clone, but she might not.

Without determining the origin of Dolly's mitochondria, Zinder said, the claims by Wilmut and Campbell are "just lousy science, incomplete science." He is not charging them with outright fraud, he said, but he would like to rule out error.

Another critic, Dr. Walter Gilbert, a Nobel laureate and molecular biologist at Harvard University, said he was not so interested in the mitochondria experiment because it would not prove that Dolly had been cloned from an adult rather than an embryo. For the last decade, scientists have cloned from early embryo cells, which are not yet specialized. What was unique about Dolly was that she was said to have been cloned from a highly specialized adult cell. He would like proof of that, indisputable evidence that there was not some lab mix-up that, for example, led Wilmut and Campbell to produce a clone of an embryo accidentally while thinking they were cloning an adult.

Gilbert criticizes Wilmut and Campbell for not keeping the live animal whose udder cells were used to clone Dolly. The udder cells had been frozen in a vial for three years before the researchers used them in their cloning experiment. Yes, the cells are still there, and Wilmut and Campbell showed that their DNA matched Dolly's DNA, which means her cells are genetically identical to those cells. But how can scientists be sure that the cells in the vial really are adult cells, Gilbert asked.

"The problem with such experiments is that you often mix things up," Gilbert said. He would like to see if transplanted tissues could go in each direction between the adult that provided those udder cells and Dolly; if the animals are genetically identical, transplants should not be rejected. That adult, unfortunately, is long dead, so Gilbert's experiment cannot be done. Only her udder cells remain.

Others, including Varmus, said they were satisfied by the DNA analysis that showed Dolly's DNA was identical to that of the udder cells.

Wilmut said there was another way to know that Dolly had been cloned from the udder cells: just look at her, he said. The udder cells were from a Finn Dorset sheep, dirty white with a pure white face; of all the hundreds of sheep living at the Roslin Institute, only Dolly was of that species.

"No other sheep at the Roslin Institute looks like Dolly," Wilmut said. Neither her surrogate mother, who is a Scottish blackface sheep, nor her egg donor, a poll Dorset, physically resembles her.

But could Wilmut and Campbell have mixed up the cells, using embryo cells from a Finn Dorset by accident? Not a chance, Campbell said. First, it is impossible to grow embryo cells in culture without having them change into something that looks like skin cells. Second, the cells were clearly udder cells because they had been collected from an adult for milk-production studies. And third, when

Campbell did the actual cloning, "there were no other cells from that type of sheep in the building," he said.

What about the mitochondria experiment? That, Campbell said, would prove only that he and Wilmut were not outright charlatans, that they did not take a lamb, wait until the animal matured, then remove some of the animal's udder cells and claim that they had a clone.

Wilmut and Campbell's many defenders include essentially every scientist who has tried to clone. These scientists say that the Dolly experiment is especially convincing because it built on years of previous work, including a paper, in 1996, by Wilmut and Campbell, showing that they could clone from fully differentiated fetal cells that had been grown in the lab.

Dr. Davor Solter, director of a molecular genetics lab at the Max Planck Institute in Freiburg, Germany, blew the whistle on a previous cloning claim that turned out to be unrepeatable. But he said he did not doubt the Dolly experiment.

Dr. Steen M. Willadsen, a cloning pioneer who lives in Windermere, Fla., said, "I can see that some people have a problem with the idea that there are these seemingly superficial people, like myself and possibly Ian, just a bunch of surgeons or manipulators who know nothing about molecular biology and who just go in and do some smart-aleck experiment and get lucky."

Dr. Alan Colman, the scientific director at PPL, said he would be happy to supply Dolly's cells and the udder cells from the sheep from which Dolly was cloned to scientists who wanted to test the mitochondria.

"No one's asked us directly" for the cells, Colman said. "But if people wanted to do that experiment, we'd be sympathetic."

TITLE V—GENERAL PROVISIONS[1]

SEC. 501. No part of the funds appropriated under this Act shall be used to provide a loan, guarantee of a loan, a grant, the salary of or any remuneration whatever to any individual applying for admission, attending, employed by, teaching at, or doing research at an institution of higher education who has engaged in conduct on or after August 1, 1969, which involves the use of (or the assistance to others in the use of) force or the threat of force or the seizure of property under the control of an institution of higher education, to require or prevent the availability of certain curricula, or to prevent the faculty, administrative officials, or students in such institution from engaging in their duties or pursuing their studies at such institution.

SEC. 502. The Secretaries of Labor, Health and Human Services, and Education are authorized to transfer unexpended balances of prior appropriations to accounts corresponding to current appropriations provided in this Act: Provided, That such transferred balances are used for the same purpose, and for the same periods of time, for which they were originally appropriated.

SEC. 503. No part of any appropriation contained in this Act shall remain available for obligation beyond the current fiscal year unless expressly so provided herein.

SEC. 504. (a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or film presentation designed to support or defeat legislation pending before the Congress, except in presentation to the Congress itself.

(b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress.

SEC. 505. The Secretaries of Labor and Education are each authorized to make available not to exceed $15,000 from funds available for salaries and expenses under titles I and III, respectively, for official reception and representation expenses; the Director of the Federal Mediation and Conciliation Service is authorized to make available for official reception and representation expenses not to exceed $2,500 from the funds available for "Salaries and expenses, Federal Mediation and Conciliation Service"; and the Chairman of the National Mediation Board is authorized to make available for official reception and representation expenses not to exceed $2,500 from funds available for "Salaries and expenses, National Mediation Board".

SEC. 506. Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles for the hypodermic injection of any illegal drug unless the Surgeon General of the United States determines that such programs are effective in preventing the spread of HIV and do not encourage the use of illegal drugs, except that such funds may be used for such purposes in furtherance of demonstrations or studies authorized in the ADAMHA Reorganization Act (Public Law 102-321).

SEC. 507. (a) PURCHASE OF AMERICAN-MADE EQUIPMENT AND PRODUCTS.—It is the sense of the Congress that, to the greatest extent practicable, all equipment and products purchased with funds made available in this Act should be American-made.

(b) NOTICE REQUIREMENT.—In providing financial assistance to, or entering into any contract with, any entity using funds made available in this Act, the head of each Federal agency, to the greatest extent practicable, shall provide to such entity a notice describing the statement made in subsection (a) by the Congress.

SEC. 508. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

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

[1] Although a full-year 1996 Labor/HHS/Education appropriations bill has not been enacted, certain provisions affecting HHS were enacted in law as a part of various continuing resolutions. Section 128 of P.L. 104-99 pertains to the use of Federal funds for embryo research. The Administration proposes to delete this provision and does not support addressing this issue in legislation.

The continuing resolution funding the Department of Health and Human Services through March 15, 1996, applies the terms and conditions of the FY 1995 appropriations bill to the Medicaid program, including a provision restricting funding for abortions. As with its FY 1996 Budget, the Administration proposes to delete this provision and will work with the Congress to address this issue.

Timothy L. Newell
03/04/97 03:29:51 PM

Record Type: Record

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

cc:

Subject: Status of outreach calls to biotechnology industry on Cloning

Here is the status of outreach calls to biotechnology industry execs on today's cloning announcement:

**Contacted directly, or briefed by their staff -- all supportive:
Henri Termeer, Chairman, Genzyme/Chairman, BIO
Art Levinson, CEO, Genentech
Ted Roth, Exec VP, Alliance Pharmaceutical
Ed Penhoet, Chairman, Chiron
Carl Feldbaum, President, BIO -- issued statement of support on behalf of BIO
Sandy Roberston -- Robertson, Stevens
John Doerr -- Kleiner, Perkins
Brook Byers -- Kleiner, Perkins

The following have been unavailable :
Gordon Binder, Chairman, Amgen
James Vincent, Chairman, Biogen
George Rathmann, Chairman, ICOS Corp.

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Message Sent To:

John Podesta/WHO/EOP
John B. Emerson/WHO/EOP
Cheryl M. Carter/WHO/EOP
Maria Echaveste/WHO/EOP
Christine K. Baer/WHO/EOP
Rahm I. Emanuel/WHO/EOP
Mary E. Glynn/WHO/EOP
Elena Kagan/OPD/EOP
Bruce N. Reed/OPD/EOP
Elizabeth Drye/OPD/EOP
Clifford J. Gabriel/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Toby Donenfeld/OVP @ OVP

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.

2/27

Gibbons on cloning —

- No attempt ~~right now to clone human~~ human cloning ~~research~~ right now

- Right now human cloning experiments — In Fed Funded research. It is prohibited.

Harold { — Presidents got a lot of good ~~points~~ at NIH appropriations ~~-right~~ hearing yesterday language —. Bipartisan affirmation -right level completed on using of reach,

— Harold is concerned that —
- ban on nothing is silly
- set the right tone
- slippery slope interpretation / president doesn't do what Congress did — dismiss it and congressional ban is silly.

— Misinterpreted in the Fine points.

DO nothing because nothing is happening

→ Reassure the public that there are

(1) appropriate protections is in the public sector. —

(2) restate NBAC

(3) We've given NBAC short term around time & ~~we want [illegible] time to look at their~~ ask that the private ~~[illegible]~~ Sector follow the policy we develop based on NBAC's recommendation.

important studies

Human cloning was repugnant — does not ~~time~~ impose

— Agree w/ Varmus that it's repugnant, —

— Act with similar restraint that they

6-5772 — showed ~~when~~ when we mastered ~~which~~ recombinant DNA technology
cutting and splicing

My NBAC is running quickly with 90-Days.
Positive nature of research.
10-2 organizational
Shapiro here from Princeton —

p. 694 F 947

Footnote #1

Dorothy Thelon Murder — confirmed I took leave

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

Announcement

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- **President Clinton called on privately-funded scientists to implement a voluntary moratorium on all efforts to undertake human cloning, until the National Bioethics Advisory Commission -- and the entire nation -- have considered its profound ethical implications.** Since privately-funded scientists and clinicians 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 organisms 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.

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- **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.

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President Clinton Announces Steps to
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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release March 4, 1997

March 4, 1997

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Prohibition on Federal Funding for Cloning of Human Beings

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 cloning of human beings. 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. The Congress extended this prohibition in FY 1996 and FY 1997 appropriations bills, barring the Department of Health and Human Services from supporting certain human embryo research. However, 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 of human beings.

WILLIAM J. CLINTON

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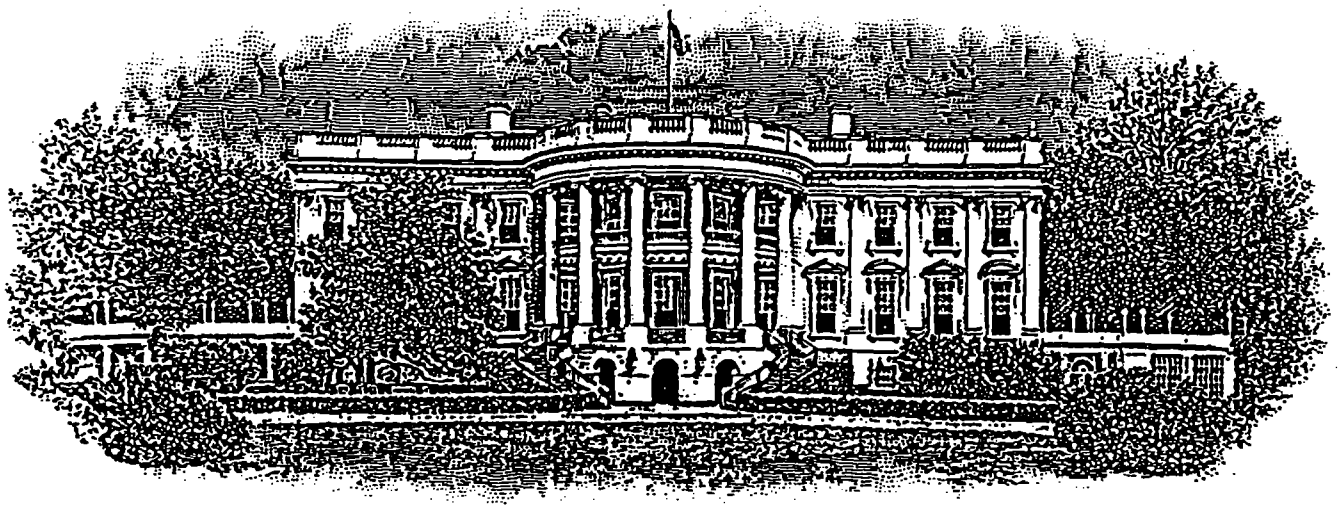

DOMESTIC POLICY

FACSIMILE TRANSMISSION COVER SHEET

TO: Victor Bonana

FAX NUMBER: 690-6247

TELEPHONE NUMBER: _____

FROM: Elizabeth Dye

TELEPHONE NUMBER: _____

PAGES (INCLUDING COVER): _____

COMMENTS: Final Fact Sheet Q & A —
& I'll send directive later

PRESIDENT WILLIAM J. CLINTON
REMARKS ON HUMAN CLONING
Tuesday, March 3, 1997

In recent days, the world witnessed the successful cloning of a sheep by Scottish researchers. It is a discovery that could yield enormous benefits -- enabling us to reproduce the most productive strains of crops and livestock; holding out the promise of groundbreaking medical treatments and cures; helping to unlock the greatest secrets of the genetic code.

But like the splitting of the atom, this is a discovery that carries burdens as well as benefits. Today, science often moves faster than our ability to understand its implications. That is why we have a responsibility to move slowly and cautiously -- to harness the powerful forces of science and technology, so that we can reap the benefits, while avoiding the potential dangers.

This new breakthrough raises the troubling prospect that it might someday be possible to clone human beings from our own genetic material. There is much about cloning that we still do not know. But this much we do know: any discovery that touches upon human creation is not simply a matter of scientific inquiry. It is a matter of morality, decency, and spirituality as well.

My own deeply-held view is that the prospect of human cloning would be wrong. ~~is morally repugnant.~~ It violates our most cherished concepts of faith and humanity. Each human life is unique -- born of a miracle that reaches beyond laboratory science. I believe that we must respect this profound gift, and resist the temptation to become our own creators.

At the very least, we need a better understanding of the scope and implications of this breakthrough. Last week, I asked our National Bioethics Advisory Commission, headed by Princeton University President Harold Shapiro, to conduct a thorough review of the legal and ethical issues raised by this new cloning technology, and to recommend possible actions to prevent its abuse, reporting back to me in 90 days.

In the meantime, I am taking steps to prevent (the more imminent) possibility of human cloning. After reviewing the current restrictions on the use of federal funds for research involving human embryos, we believe there are loopholes that could allow human cloning if the technology were developed. Today, I am issuing a directive that bans the use of <u>any</u> federal funds for human cloning. Effective immediately, no federal agency may support, fund, or undertake such activity.

Of course, a great deal of research and activity in this area is supported by private funds. That is why I am urging the entire scientific community -- and every foundation, university, and industry that supports work in this area -- to heed the federal government's example. I am asking for a voluntary moratorium on all efforts to undertake human cloning, until our Bioethics Advisory Commission and our entire nation have had a chance to understand and debate the profound ethical implications.

As we gain a fuller understanding of cloning, we must proceed not just with caution, but with <u>conscience</u> as well. By insisting that not a single taxpayers' dollar supports human cloning -- and by urging a moratorium on all private efforts to pursue human cloning -- we can ensure that as we move forward on this issue, we weigh the concerns of faith and family, and not just of laboratory science alone.

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2/24/97

OSTP

Sheep Cloning

Today's Washington Post reported the first successful cloning of a mammal, sheep, leading to speculation that this technology might be used to create genetically identical copies of humans.

Q. Is this likely?

A. Earlier technology had worked to clone only lower organisms (frogs) and had not been successful in getting mammalian cells to divide more than one or two times. The technology to be reported in this week's issue of **Nature** was used in sheep, a species much more closely related to humans. In theory, the same methods could be applied to create human embryos. The researchers, located in Scotland, state that they would not consider doing this work on humans. In the U.S., use of Federal funds for the creation of human embryos for research purposes is prohibited by: (1) President Clinton's December 1995 prohibition of the use of Federal funds for such purposes, and (2) Congress' FY 97 CR which goes even further in banning human embryo research that involves more than minimal risk to the embryo.

The NIH Ad hoc Panel on Human Embryo Research recommended that research involving the cloning of humans be considered unacceptable use of Federal funds.

Q. Is this research regulated by the Federal government?

A. No. The prohibitions described above apply only to Federally funded research. Research on human embryos funded from other sources is not regulated unless it is being done to support an application to the Food and Drug Administration for permission to market a drug or other health care product such as a device. In this case, human subject regulations apply that would force review and approval of the experimental product. FDA does not ordinarily regulate procedures. Research conducted in private clinics on *in vitro* fertilization, for example, is not regulated by the Federal government.

Q. What did the scientists in Scotland do?

A. Researchers took the genetic material out of unfertilized sheep eggs and replaced it with the complete set of genetic instructions (DNA) from another, adult sheep. After treating the empty egg and then subjecting the newly reconstituted egg with an electric pulse, the egg began to divide as a normal, fertilized egg would do. This embryo was implanted in a sheep uterus where it matured into a normal fetus and was delivered at term. The resulting sheep was an exact genetic replica of the sheep from which the DNA had been extracted.

Q. Is this procedure being examined for its ethical implications?

A. No Federal advisory body has been charged to consider the ethical dimensions of human cloning. The procedure is considered off limits due to ethical and funding considerations. Conceivably, the newly established National Bioethics Advisory Commission could consider the ethical aspects of human cloning, should it be deemed desirable.

NIH Human Embryo Research Panel Sept. 94 Rept.
- Panel held public hearings
Varmus received rpt ~~10/27/94~~ ~10/94
w/Diane Alexander
Varmus briefed Gelsten, others ~~10/27~~
Gelston understood science -
research into most immediately relevant to treatment of [illegible] Cancer
- a lot of research in private sector

Panel recommended federal guidelines
2 classes of research
~~Local review warranted~~
- national review (beyond IRB)
- unacceptable for Federal funds

Recombinant DNA — scientist did 18 mo. moratorium —

— Biotech industry is calling for a moratorium —
Cong Sensenbrenner
90 Day timeframe

Wednesday 2-3:30 House Technology
2 NBAC members — including BEO's mom —
Vs Biotech industry calls for ban on

cc: Fortenberry

Carl Feldbaum

Use to work for Specter

President / Biotech Industry Organization

- ~~Committee~~ Board mtg next Wednesday
- Floated idea / positive response from members
- Take on Wednesday
- Steve Holtzman - head of BIO's ethics panel and member of NBAC - will testify.

Dec 2, 1994

Cloning

Newer article comes out tomorrow

POTUS statement

POTUS — Ban on creating human embryos for research purpose —

"I do not believe that federal funds should be used to support the creation of human embryos for research purposes."

7/27/95 for FY96 — H. Report 2127 P.L. 104-91 Congressional Prohibition

but not all kinds of human embryo research — interviews from I.V. fertilization purposes.

will language → No funds may be used for ① the creation of human embryo or embryo for research purposes.

② Research in which embryos are destroyed — governed comes under Common rule.

Def. of human embryos or embryo

fertilization
cloning
or any other means
from human gametes.

precludes any research on in-vitro fertilization

get statement

President said in response to budget constraints that he doesn't think issue should be addressed —

Date: 02/27/97 Time: 08:48
NNIH director: Experiments in human cloning 'poor science

WASHINGTON (AP) Cloning human beings would be ''repugnant,'' but the technology does offer promise for growing tissue that could be used to treat serious diseases, the director of the National Institutes of Health says.

Testifying Wednesday before a House subcommittee, Dr. Harold Varmus said the recent cloning of an adult sheep in Scotland ''electrified'' the world because it raised the possibility that human being could be cloned. Most scientists would reject such research, Varmus said.

''Cloning of an existing human being is repugnant to the American public,'' he said. ''I agree with that point of view.''

The NIH director said people find experiments in human cloning offensive because ''our sense of wonder as human beings is linked to our diversity, and human cloning experiments are not consistent with our diversity.''

Furthermore, he said, cloning humans would answer no important scientific questions. ''It makes interesting movies but poor science,'' he said.

The technique that produced the cloned sheep in Scotland is ''fairly simple'' but fails to address any science objective, Varmus said. As a result, he said, it would be of little interest to most researchers.

Varmus said, however, that further research into cloning could teach science how to ''turn on genes'' so that tissue to treat disease could be made in the laboratory. Such research could make it possible to grow new skin for burn patients, culture bone marrow for treatment of cancer and manipulate genes to cure sickle cell anemia.

''These things are far off, but nonetheless, possible,'' Varmus told the subcommittee. ''These are some of the research possibilities ... that will be inspired by the sheep experiment.''

Current law prohibits spending federal money on human embryo experiments, but the prohibition expires Sept. 30. Sen. Christopher Bond, R-Mo., urged Congress on Tuesday to make that ban permanent.

''I want to send a clear signal,'' Bond said: ''This is something we cannot and should not tolerate. ... I'm going to do everything I can to ensure that human cloning stays in science fiction.''

Rep. Nita M. Lowey, D-N.Y., said a bill already has been introduced in her state's legislature to forbid research in human cloning.

''There is a great deal of justifiable anxiety,'' she said Wednesday. ''History shows that if a technology exists, it will be applied.'' She said people fear ''a world where freakish experiments know no bounds.''

Varmus said he opposes such quick, reflexive legislative action.

''I am concerned about such a rush to legislation,'' he said. ''We have a new finding that needs to be absorbed and assessed.

''I am concerned that in rejecting one aspect of this technology that all of us find repugnant ... that we end up with legislation that restricts important research possibilities.''
APNP-02-27-97 0857EST

SENT BY: C. Gabriel R Leeman 2-28-97 ; 20:22 ; SCI & TECH POLICY- 4155643731;# 2/ 3

DRAFT

Subject: Implications of Cloning Sheep

Background

The February 27 issue of **Nature**, a renowned scientific journal, contains an account of the first successful cloning (creating an identical genetic replica) of an adult sheep. This report raises the hypothetical possibility that similar techniques might be applied to cloning humans. Because of the ethical concerns this action would present, you tasked your National Bioethics Advisory Commission (NBAC) to review the associated legal and ethical issues and formulate recommendations on possible federal actions to prevent its abuse. The Commission's report is due back to you within ninety days.

From a scientific perspective, the majority of experts believe that due to substantial technical difficulties the likelihood of cloning humans successfully in the near future is remote. Our past cloning experience with frogs has resulted in only tadpoles that could not mature to frogs, and we have been unsuccessful in all attempts to clone other mammals such as mice, starting with cells from mature animals.

From a legal perspective, existing prohibitions on the use of federal funds for human embryo research preclude scientists in academia or government labs from attempting this line of investigation, **even if** they desire to do so. On December 2, 1994, you issued a statement barring the use of federal funds for research that entails the creation of human embryos for research purposes. Human cloning is presumed to be included under this rubric. Appropriations bills for FY 96 and 97 extend this prohibition significantly further. However, it is important to note that privately-funded facilities are free to engage in such research under current law. [As can be seen from ads in the popular press, there is a booming business in all forms of assisted reproduction technology. Would human cloning be a desirable avenue to pursue? Probably not until it has a chance of competing successfully against existing technology, but it can't be definitively ruled out.]

Staff have considered the option of your urging the non-federally funded scientific community to declare a self-imposed moratorium on human cloning. Those in science question the need for this approach given the technical uncertainties discussed above. Some also believe that it would be inappropriate to take action that would pre-empt NBAC's deliberations. On the other hand, a moratorium might deter restrictive, ill-advised legislation and reassure the public.

Congressional fact-finding hearings are scheduled for 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 appear at both 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 ~~on all animal cloning~~. Incidentally, Dr. Varmus reports that your referral of this issue to NBAC received enthusiastic, bipartisan support at this hearing.

in view of the possibility that the legislation might also restrict ~~[illegible]~~ related work that could offer important medical, economic, and scientific benefits.

[we have seen 1st page only]

Christopher Bond (R-MO) has begun to said that he intends to draft legislation making permanent the current ban on federal funding for human embryo research. Rushed attempts to ban cloning may result in unintended harmful effects on important research. For example, Dr. Varmus noted that the sheep cloning might provide a number of promising experimental routes such as new methods for producing human proteins, creating model organisms to study human diseases, and possibly reprogramming human cells for ~~new uses~~ treatment of cancer, burns, and other disorders.

Any further action by the WH regarding human cloning should be worded extremely carefully to avoid unintended negative influence on a broader sphere of biomedical and agricultural research.

Potential Talking Points

- The report that researchers have developed techniques to clone an adult sheep is exciting news--it opens up the possibility of important biomedical achievements such as more efficient means for producing pharmaceuticals, and to a more profound understanding of how cell genes are regulated.
- If this research is validated, it may also raise some important ethical questions, including its potential use for cloning humans.
- I think cloning an existing human is wrong, and I think I am not alone in holding that view.
- For this reason, I have asked my Bioethics Advisory Commission, chaired by Dr. Harold Shapiro, president of Princeton University, to review the ethical and legal questions and get back to me within 90 days with their recommendations. advice.
- Until we have had a chance to digest NBAC's recommendations, it would be wise to step back from trying this out on people. (?)

I would omit this ambiguous statement and just add to the previous bullet that any further action should be delayed until NBAC's advice is received. Could also include statement that he has been informed that any prospect of successfully applying methods to human beings in the near future is extremely remote.

Harold
I will be out of town until Sunday evening but can be reached, if necessary, through Vida Beaver. She will be at 610-868-5054 from noon Sat. to 2 PM Sun.

Harold Varmus

Lewis w/ NSC comments 3/2

Possible Talking Points on Human Cloning

Last week, scientists in Scotland reported that they had cloned an adult sheep. Cloning is not new. It is one of the tools of fundamental biomedical and agricultural research. It is used in the biotechnology and pharmaceutical industries every day to make valuable products. Cloning simply means making a genetically identical copy of a cell, a bacterium, a gene or a plant--even a frog, but the technique gets increasingly difficult with more complex organisms. What is so exciting about last week's announcement--if it is independently confirmed--is that it would be the first time an adult mammal had been cloned.

Like any scientific breakthrough, this work may solve old riddles while raising new ones. Investigators will try to learn how this method works and in the process will gain critical new insights into how genes are expressed and cells develop, attain special characteristics and age. For example, how do certain cells from a fertilized egg grow up into liver cells, or muscle, or bone, or nerves?

Another question--the one on everyone's mind, it appears--is can this new science be key in treating human diseases and infertility and could this technology be applied to humans? The answer is we don't know and aren't likely to find out for some time.

Even the very remote possibility that someone might try to clone a person raises serious ethical and emotional concerns. Such concerns must be confronted and resolved BEFORE people try to tranform the fundamental research into an acutal ability to clone.

That is why I asked the National Bioethics Advisory Commission to review the ethical and legal implications of human cloning IMMEDIATELY and report back to me in 90 days with recommendations for actions. This is a perfect example of why I established the Bioethics Commission--to have in place a body of knowledgeable, thoughtful individuals and to provide a public forum in which sensitive issues could be discussed in a deliberate manner.

Right now, we should all understand that human cloning is already prohibited for researchers using Federal funds. But this restriction does not apply to privately funded facilities. Therefore, I urge the private sector to follow the Federal example, pending the outcome of NBAC's review.

Let us learn from the precedent set 25 years ago when scientists first discovered how to cut and splice DNA. These researchers agreed to hold back on this work until guidelines assuring public health and safety were in place. I ask that you allow time to digest the Bioethics Commission's recommendations, and abide by guidelines ensuring ethical procedures.

We all recognize the huge societal benefits of biological research in preventing and treating disease and assuring an adequate food supply. I want to make certain that we

don't inadvertently close off important avenues of research. That is why I am NOT calling for a broad ban on all animal cloning research, only on human cloning.

The time is right to begin a thoughtful, balanced national dialogue about these important issues.

Vannus
Rachael - will want to see something in writing

— To Do → Transcript of vannus. —

— { Carolyn
Jonathan Prince — —

— Bruce Albert — President NAS —

who? — Vannus, Shapiro, Shalala, Gibbons — Transfer
— just met w/Rolle to —

— Chairman of BSO + Carl Feldman, —

Outreach — premature to talk about legislation —

Tim Newell
John
Gs Affairs
Hall
} do the list —

Kennedy
Glenn
Frost
Mikulla
Porter

— paper - directive
— list of people who will say the right thing.

662-9595

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release December 2, 1994

Statement by the President

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

-30-30-30-

APPENDIX

BUDGET OF THE UNITED STATES GOVERNMENT

Fiscal Year 1997

IB

Union Calendar No. 108

104TH CONGRESS
1ST SESSION

H. R. 2127

[Report No. 104–209]

Making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies, for the fiscal year ending September 30, 1996, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 27, 1995

Mr. PORTER, from the Committee on Appropriations, reported the following bill; which was committed to the Committee of the Whole House on the State of the Union and ordered to be printed

---

A BILL

Making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies, for the fiscal year ending September 30, 1996, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the following sums are appropriated, out of any money in the Treasury not otherwise appropriated, for the Departments of Labor, Health and Human Services, and

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

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

new language CR

P.L. 104-91

SEC. 511. None of the funds made available in this Act may be used for—

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

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

common rule

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

SEC. 512. None of the funds made available in this Act may be used to carry out any Federal program, or to provide financial assistance to any State, when it is made known to the Federal official having authority to obligate or expend such funds that—

(1) such Federal program or State subject any health care entity to discrimination on the basis that—

(A) the entity refuses to undergo training in the performance of induced abortions, to provide such training, to perform such abortions, or to provide referrals for such abortions;

(B) the entity refuses to make arrangements for any of the activities specified in subparagraph (A); or

(C) the entity attends (or attended) a postgraduate physician training program, or any other program of training in the health professions, that does not (or did not) require or pro-

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(B) the entity refuses to make arrangements for any of the activities specified in subparagraph (A); or

(C) the entity attends (or attended) a postgraduate physician training program, or any other program of training in the health professions, that does not (or did not) require or pro-

TELEFAX TRANSMITTAL SHEET

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mmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmmm

DATE: 24 February 1997

TO: Elizabeth Drye

TELEFAX NUMBER: 202-456-7028

COMMENTS: FYI

NUMBER OF PAGES, EXCLUDING COVER: 3

Sheep cloned by nuclear transfer from a cultured cell line

K.H.S. Campbell, J. McWhir, W.A. Ritchie and I. Wilmut *(1996)*
Nature Vol. 30 pp 64-66

Nuclear transfer has been used in mammals as both a valuable tool for embryonic studies and as a method for the multiplication of 'elite' embryos. Offspring have only been reported when early embryos, or embryo-derived cells primary culture were used as nuclear donors. Here we provide the first report, to our knowledge, of live mammalian offspring following nuclear transfer from an established cell line. Lambs were born after cells derived from sheep embryos, which had been cultured for 6 to 13 passages, were induced to quiescence by serum starvation before transfer of their nuclei into enucleated oocytes. Induction of quiescence in the donor cells may modify the donor chromatin structure to help nuclear reprogramming and allow development. This approach will provide the same powerfull opportunities for analysis and modification of gene function in livestock species that are available in the mouse through the use of embryonic stem cells.

Corrosponding author: Ian Wilmut, Roslin Institute, Roslin, Midlothian EH25 9PS UK

Briefing notes in relation to Nature paper on nuclear transfer

Can you describe simply what has been done in these experiments?

This is the first time that offspring have been produced by nuclear transfer from an established cell line.

What is involved in nuclear transfer?

You have two different cells in nuclear transfer: an unfertilised egg and a donor cell. The donor cells were obtained by culture of cells from sheep embryos over a period of several months. In this way it was possible to obtain many thousand genetically identical cells. The donor embryo was from an all white breed: the Welsh Mountain breed. The recipients eggs were recovered from Scottish Blackface ewes. By micromanipulation the chromosomes were removed from the eggs before the nucleus of the donor cell was introduced by cell fusion. The electric current which is used to fuse the cells also triggers the egg to begin development. These new embryos were then transferred to recipient sheep to discover if they were able to develop to lambs. When the lambs were born they were all genetically identical females. They were all white, Welsh Mountain lambs, as it is the transferred nucleus which determines the characteristics of the offspring.

What is the key to this success?

We cannot be sure as the experiment has only been conducted once with one cell type and it seems likely

We cannot be sure as the experiment has only been conducted once with one cell type and it seems likely that several factors are involved. However, we suggest that the induction of a quiescent state in the donor cells may be one important factor. Early development is controlled by RNA and proteins that are produced in the unfertilised egg while it is still in the ovary. At a species specific stage of development these compounds are destroyed and products of the embryos own genes assume control of development. In a normal cell the chromosomes are very active and there is an open structure to some of the DNA to provide access to the cell machinery. When a nucleus from such a cell is transferred into an oocyte it is assumed that development depends upon changes to chromosomal structure to first of all inhibit activity from the chromosome and then to re-initiate activity at the appropriate stage of development. The nucleus in quiescent cells is comparatively inactive. We hypothesise that in this case the recipient egg is more readily able to "reprogramme" gene expression in the new embryos.

Why did so few of the embryos develop to lambs?

We do not know because the experiment has only been carried out once with one cell type. However, it should be appreciated that these results represent a very significant advance and this is a new approach to nuclear transfer. Improvements to the efficiency are to be expected as other experiments are carried out.

What is the biological significance of this research?

The fact that cells which had been in culture for a prolonged period and had begun to differentiate were able to support the development of lambs shows that they still retain all of the genetic material of the early embryo. Differentiation must reflect changes in gene expression, rather than the loss of specific regions of the chromosome.

What is the potential practical value of this new technique?

Two new opportunities will become available over a period of time. First, while the donor cells are in culture, it will be possible to introduce precise genetic changes before the cells are used as nuclear donors. The present methods for gene transfer are very primitive as they are only able to add a gene and they do this inaccurately. Sometimes the transferred genes interfere with existing genes. By contrast, "gene targeting" techniques are able to introduce a precise genetic change into an existing gene or to add genes in a precise way. After the change has been made, selection techniques would be applied so that only cells with the desired change would be used as donors of nuclei. Secondly, it will become possible to produce a number of genetically identical offspring from a population of cells. This would enable to a farmer to have a small group of identical sheep each with the same high level of performance. Uniformity of this kind would offer advantages to the farmer, as the animals will mature at a very similar rate, to the food processor, as they would have a more consistent product to sell, and to the consumer, as they could be more confident of purchasing a consistent, high quality product.

Are there any disadvantages to all of the animals being identical?

Yes, there would be a risk that the group might all prove to be susceptible to a particular infection. So it would never be anticipated that all of the animals on a farm would be from one clone. Rather the farmer would be advised to have several animals from a number of clones. In this way he would have the advantages of uniformity, without too great a risk.

What aspects of animal production might be genetically modified with this new technique?

It seems most likely that the first uses will be for biotechnology. Sheep and goats are already making in

their milk, proteins that are needed for the treatment of human disease. The new technique will make it possible to obtain proteins that are more like the human protein even than those that are being made at present. In addition, this route may provide a more practical means for introducing change in cattle. Some proteins are required in very large quantities and it would be useful to be able to produce these in cattle, with their larger milk yield, than in sheep or goats. However, in the longer term, as the techniques are improved, they may be used to modify many aspects of agricultural production. The changes may be aspects of current production or to provide novel agricultural products. Changes may be made to the composition of cows milk. Most of the fat in cows milk is saturated and this has implications for the health of the human consumer. The situation arises because of the activity of enzymes in the udder and it may be possible to reduce that activity and so have cows milk with more unsaturated fat. It would be important to show that this did not have any adverse consequences for the cow or her calves. At present our understanding is limited because only a small number of the genes in livestock have been identified. It is likely that the gene mapping projects will identify many other genes with significant influences on animal physiology. Similarly, research into the role of specific gene products or of the regulation of gene expression will reveal novel means to enhance animal health and performance. In the present situation it is unlikely that we can yet envisage many of the potential applications.

This experiment was carried out in sheep. Do you anticipate that similar results will be obtained with other livestock species?

There are differences between species in the mechanisms which regulate early development and these influence the response to nuclear transfer. We expect a very similar response in sheep and cattle as development in these two species is very similar. However, pig embryos are rather different and so their response may be different.

It has been suggested that some primates may be suitable organ donors. Do you expect similar responses in these species?

We would expect them to have the same basic responses as the embryos from livestock species and that the precise response will depend upon the regulation of early development in that species.

What other cell types will be suitable as nuclear donors?

We do not know. It is important that a variety of different cell types should be studied in order to establish the limits to the new technology.

Dr Soltor has suggested that it may be possible to clone adult animals?

We agree with him that this research represents a significant step in that direction, however, until donor cells have been taken from adults we will not know if this is yet possible.

Would it be possible to clone human beings?

We can see no clinical reason why that should be attempted. None of us would be interested in such experiments and in this country they would be considered unacceptable.

Page last edited: 11 March 1996
webmaster Chris Mungall

Human Embryo Research

C.R. 9 (P.L. 104-91) prohibits Federal funding for the "creation of a human embryo or embryos for research purposes..." and "for research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." The C.R. applies to funding for the entire FY 96. The first section codifies the President's directive of Dec. 2, 1994. The second section addresses research on all human embryos, regardless of source. NIH feels that the second part goes substantially further in prohibiting a much larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

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

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

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

Reconfirm - Fed fund not be used for human cloning; call upon private sector to adopt self-imposed. — ~~At~~ National discussion; at least as long as. —

Q & A —

— Legislation is not needed. —

Supporters: Morella, Frist, Mikulski. —

Bond - NIH groups
- Morella } authors
- Frist
- Dean
- Morella
- Frist
- Appropps.

Industry opinion leaders. —

- Henry ~~Trewitt~~ Feemor Jewett
- Al Johnson

CEO Genzyme
- Shapiro
- Bio
- var mals
- Religious Leader

Fame

industry, universities, ethics, religious leaders.

Build that

~~Frist~~ What's covered by prohibition - only human cloning?

Position we can articulate. —

~~Frist~~ - McGlaughlin - no rush to legislate

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release December 2, 1994

Statement by the President

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

-30-30-30-

Newell 6-6011

Marshall 6-6219

Cloning

Eli wrong cloning 6:5638

- Mac Reed -
  - ~~No funds would be~~ Direct Federal agencies ~~allocate~~ not to allocate any ~~resources~~ federal funds for human cloning

- HHS review remarks
  Maria Echeveste — religious leaders.
- Council —

Draft statement to

- Rosemary Hart
- Elena
- Phil Caplan
- Laura Graham

~~Cloning of human beings~~ — directive cleared by

~~Harriet Rabb~~ —

Vamus —

Zenora — Vita
— Harriette

Bill Marshall ✓
Elena ✓
Phil Caplan ✓
Rosemary Hart ✓

Welcome - Dickerson, Shalala

Marick Rachael [redacted]

Vannus 202-234-6741 home fax

Breakthroughs in human cloning. —

Call-Eli - remarks — ✓

memo to ✓ heads of Federal agencies ✓

- Conversation on remarks. —

March 7, 1997

FINAL DRAFT

NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC)

March 13, 1997
Watergate Hotel, Continental Chesapeake Extender Room
2650 Virginia Avenue, NW, Washington, DC
(202) 298-4466 (for messages)

AGENDA*/Day One

8:00 AM	**Welcome and Introduction** Dr. Harold Shapiro, Chair
8:15 AM	**Report of the Human Subjects Subcommittee** Dr. James Childress, Subcommittee Chair
9:15 AM	**Report of the Genetics Subcommittee** Dr. Thomas Murray, Subcommittee Chair
10:15 AM	**Coffee Break**
10:45 AM	**Discussion: Approach to the President's Request**
11:15 AM	**Lunch**
12:15 PM	**Science and Technology in Cloning** Dr. Shirley Tilghman, Princeton University
1:15 PM	**Discussion**
1:45 PM	**Coffee Break**
2:15 PM	**Religion-Based Perspectives on Cloning of Humans I** Protestantism: Dr. Gilbert Meilaender (Valparaiso University) Dr. Nancy Duff (Princeton Theological Seminary) Discussion Roman Catholicism: Dr. Lisa Cahill (Department of Theology, Boston College) ~~Dr. Richard Doerflinger~~ (National Conference of Catholic Bishops/ U.S. Catholic Conference) Discussion
3:45 PM	**Discussion**
4:15 PM	**Statements by the Public**
5:00 PM	**Adjournment for the Day**

* Please note: This agenda might be slightly revised before or at the meeting at the discretion of the Chair.

FINAL DRAFT

NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC)

March 14, 1997
Watergate Hotel, Continental Chesapeake Extender Room
2650 Virginia Avenue, NW, Washington, DC
(202) 298-4466 (for messages)

AGENDA*/Day Two

8:00 AM	**Welcome and Summary of Previous Day**
	Dr. Harold Shapiro, Chair
8:15 AM	**Religion-Based Perspectives on Cloning of Humans II**
	Judaism:
	Dr. Elliot Dorff (University of Judaism, Los Angeles)
	Dr. Moshe Tendler (Yeshiva University)
	Discussion
	Islam:
	Dr. Aziz Sachedina (University of Virginia)
	Discussion
9:45 AM	**Coffee Break**
10:00 AM	**Views on Cloning**
	Possible Benefits:
	Dr. John Robertson (University of Texas Law School)
	Dr. Ruth Macklin (Albert Einstein College of Medicine)
	Discussion
	Possible Risks:
	Dr. Leon Kass (University of Chicago)
	Dr. Jim Nelson (University of Tennessee)
	Discussion
11:30 AM	**Lunch**
12:30 PM	**Discussion**
2:00 PM	**Future Meetings**
2:15 PM	**Coffee Break**
2:30 PM	**Statements by the Public**
4:30 PM	**Adjournment**

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* Please note: This agenda might be slightly revised before or at the meeting at the discretion of the Chair.

THE WHITE HOUSE

WASHINGTON

Tim Newell Celebrity notes on POTUS briefing -

Vaccines — no need for ban as no scientists are interested in doing this

Gore — I bet right now there are people in other countries doing it — and the majority of the American people think it's wrong

Clinton - religious argument can't be what stops it. — Since every new life is a unique being...

Shapiro — I think we should call for ban and voluntary moratorium. -

- Beginning to write parts of the report - circulate
- Have introduction and science chapters.

Cover - one picture of her clone enrolling at Stanford and her clone enrolling at Princeton

Carol - scientific issues
- had circulated ~~this~~ to large # of (approx 60) societies to get their input on issues. - Hoping to get overview of where scientists come down
- summarized in draft report in views of scientific societies.

Alecia - survey of societies and associations.

- embryonic or adult nuclei
- basic dialogue bio in vitro
- potential cell based therapies
- cloned offspring

	prohibited entirely	limited	allowed freely	
1	3	2	14	7
2	3	2	14	7
3	2	5	12	
4	3	5	11	
5	13	1	4	
6	14	1	3	

\ cloned offspring for form of infertility

Defn. of cloning

"Cloning" - copying of biological material to produce identical genetic copies from a single entity (e.g. genes, cells, organism)

- Need clear defn. to avoid prohibiting right research.

"Human Nuclear transfer cloning"

- call to do as much research as possible in mice

No restrictions — cloning research to study basic dvlpt bio of cell-based therapies

- Oversight by sci com
- federal (Nat Bioethics adv), cloning an entire human being; and
- voluntary moratorium — cloning research

No support for fed or state legislation.

Shapiro — issue of defn is critical — in science chapter

Question is not somatic vs. embryonic cells.

Conclusion — Time's — baby making vs non-baby making research — w/in that — whether

AMA response on defn

May not be an ethical way to run clinical trials. —

Lo – is it unanimous we should clone humans in sci community? ~~SCNT~~ Somatic nuclear transfer with human cells – cavally

Carol – overwhelming, not unanimous. – Scientific reason?

→ No one came forward and said we need to do [somatic cell transfer] now in humans.
– but [?] – took case by case basis. –

Q. whether at this time there are ~~exp~~ scientific reasons to proceed with [somatic cell transfer] – contested issue.

Lo – if scientists don't distinguish btw animal and human – then need education.

David – not useful to say "just on the basis of the science – have to keep it together.

Alex. – on the witness stand – objection has to be based on science risk/danger rather than ethical threat.
– reason to believe that there would be self-restraint
– ~~because~~ it wouldn't meet standard of laws/world credit...

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Bernie —

Ethics bucket - fair to say there are differences among commissioners.

— safety an issue ⇒ inappropriate to proceed w/ banning baby-making

- remove safety considerations, disagreement.

- planning to lay out residual concerns in chapter, pro and con, not try to force agreement.

— want to focus on baby making. —

— will say a little but not much on cloning cell lines DNA, animals

— have to reach a decision on whether to reopen human embryo research debate.

- NIH report is done
- was not enacted in policy

- Question of presumption and starting pts.
- role of cases in chapter

~~Some~~ case

Whether to build policies on cases —
can we have both general rule and exceptions

Shapiro

Embryo research — not the time to revisit that. — wrong time to reengage that issue — Congress and President have decided.

Zeke — 3 views in ethics "bubble" — Warnock Commission
Non-neutrality of the position we adopt:
- re. right to reproductive freedom
↳ whether you think it falls under this right, depends on whether you think it's distinct from other technology

Distinguish how a few vs many acts in looking at whether it undermines "human dignity" (social practice)
- don't have to allow [illegible] and arguing for shoulder argument be about whether or not to allow it.

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mad scientists — What is the "higher goal" we're looking for

— not moratorium — we don't have to go one step beyond safety.

— Act vs. Practice — vs. preferred practice

— merely tolerate by changing policy —

"D. Honan conception of human flourishing."

		Single act.	Practice
a	Concerns about physical safety	✓	—
b	— psychological "	✓	—
c	— Defiance of natural order		✓
d	— Prospects for mass production and control		✓

moratorium vs. legislation — go to how important it is to protect against single act.

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Shapiro - don't know enough about
b,c,d to know "strength"
of our concern.
re. a. — moratorium means
real prohibition

LO - Starting question
- where should presumption lie
- liberty (not neutral) - won't forbid unless we have strong reasons.
- reproductive liberty
- essentially same as other
forms of ART.
(one difference is one parent)

Diane
- confidentiality, consent, etc. not covered
- chapter not focused enough on ethics
of research

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General Board of Church and Society
of The United Methodist Church

JAYDEE R. HANSON
Assistant General Secretary

Ministry of God's Creation
• Environmental Justice
• Peace with Justice

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Cloning technology is simple; ethical implications are not

Produced by United Methodist News Service, official news agency of the United Methodist Church, with offices in Nashville, Tenn., New York, and Washington.

CONTACT: Linda Bloom (Release #102) (212) 870-3803 Feb. 27, 1997

by Linda Bloom*
A UMNS Feature

Twenty-seven years ago, the cloning project that Robert Veatch worked on at the Hastings Center in New York didn't generate much excitement.

"Basically, we were told it was so much science fiction that nobody was interested in it," recalled Veatch, a United Methodist who now serves as a professor of medical ethics for the Kennedy Institute of Ethics at Georgetown University, Washington D.C.

With the Feb. 22 announcement of the successful cloning of a sheep -- a feat that has astounded some scientists as well as laypeople and generated endless debate -- science fiction has turned into fact.

The cloning was accomplished by Ian Wilmut, an embryologist from Scotland, who replaced the genetic content of one sheep's egg with the DNA from another adult sheep. The lamb that was born, named Dolly, is a genetic replica of that grown sheep.

While the technology used was relatively simple, the ethical and moral implications of its future applications are not, according to several United Methodists.

"With cloning, the theological questions are encamped right in the middle of things," said the Rev. Rebekah Miles, assistant professor of Christian ethics and director of United Methodist studies at Brite Divinity School, Texas Christian University, Fort Worth. "You can't take a step without tripping over them."

Cloning doesn't mean we're playing God, according to Miles, because God's creation values diversity, not sameness. It's more an issue of being too human.

"We human beings have a long track record of putting too much faith in our own technology and making ourselves the center of the world," she said. "It's called sin."

The technology for cloning now exists. Because of the agricultural interest in cloning, Veatch expects the techniques to be perfected quickly. Once developed, he said, "it will be very tempting to try it in very special human cases."

Veatch -- an ethics consultant for the United Methodist Association of Health and Welfare Ministries, which represents 400 health care and human service organizations and professionals -- believes the medical community would resist efforts to clone humans as a means of creating donor organs for transplant.

But there could be other cases, he said, "where the emotional appeal will be so great it will be very hard for physicians and others to resist."

An example, he said, would be a case where a couple with fertility problems hope to clone a dying child.

That type of cloning scenario raises "astounding questions about what it means to be a human, to love other humans, to live and die as humans," according to Miles.

"Mortality, loss and fragility are an inescapable part of our being," she said. "Of course, we applaud medical

advances that extend life. But we cannot manufacture or reproduce that distinctive person."

Jaydee Hanson, an executive with the United Methodist Board of Church and Society, came close to being a dying child. Born with a genetic disease, he was saved by surgical intervention. But he doesn't agree that genetic engineering is a solution.

Hanson advocates a moratorium on any commercial cloning of animals "until we have clear research guidelines in place" and a "straight prohibition on humans."

He said he doesn't even support animal cloning for the purpose of donor organs for human transplant. "I would rather the research money go to better prevention of diseases," he explained, citing diabetes as an example.

Hanson plans to ask Church and Society directors to adopt a policy advocating a cloning ban at the board's March 6-9 meeting in Washington.

Both Veatch and Miles said they are not totally opposed to animal cloning, but fear the possible consequences. Miles, who was a member of a denominational Genetic Science Task Force, opposes any research on human cloning and supports a temporary moratorium on animal cloning until "an international commission of scientists, ethicists, community leaders and lawmakers" can study the ethical implications.

"We should have put limits on the technology before it got this far," she declared. "We've been refusing to deal with the ethical implications because we didn't think mammal cloning was likely. We were wrong."

###

* Bloom is director of the United Methodist News Service office in New York.

NEWS RELEASE

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RELEASE TO BAPTIST PRESS

Society unprepared for problems of human cloning, scholars say

WASHINGTON (BP)--The report of the successful cloning of adult sheep in Scotland brings with it a host of ethical problems related to the potential cloning of human beings -- issues that the United States is not prepared for, Southern Baptist and evangelical scholars say.

The cloning of human beings jumped from science fiction to what some forecast as inevitable reality when Scottish researchers announced Feb. 22 they had successfully cloned a 6-year-old sheep. The genetic replica, named Dolly, was born in July in Edinburgh, Scotland. Eight other cloned lambs have been born since Dolly, all genetic copies of the adult from which they were cloned.

President Clinton instructed the National Bioethics Advisory Commission Feb. 24 to study the ethical and legal issues of cloning and to bring a report in 90 days.

Ian Wilmut, 52, an embryologist, and his fellow researchers at the Roslin Institute in Edinburgh said they were interested only in cloning farm animals, not human beings. Cloning people "would be ethically irresponsible," Wilmut said, according to The Washington Post.

It might be inevitable, however. While English law prohibits such research, there is no law in the United States preventing it as long as it is done with private funds. Even if such a law is enacted, there may be no way to prevent the cloning of human beings. And if it is legal, that certainly doesn't make it ethical, evangelical scholars say.

"While cloning animals probably doesn't violate any scriptural principles per se, it does open the Pandora's possibility of cloning human beings," said Ben Mitchell, assistant professor of Christian ethics at Southern Baptist Theological Seminary. "And frankly, there doesn't seem to be any likely way to prevent human cloning -- even though it would be unconscionable to do so. It's more a matter of when than if a person will be cloned.

"Since the U.S. has no laws against cloning a human being, it is imperative that lawmakers quickly pass a moratorium on human cloning," said Mitchell, also a biomedical ethics consultant for the Southern Baptist Christian Life Commission. "A comprehensive study of the ethical implications of human cloning needs to be done. A moratorium would

provide some time for ethical reflection.

"Nevertheless, almost assuredly, someone either clandestinely or outside the U.S. will attempt to clone a human being sooner rather than later. Once the technology is available, it will most certainly be used by someone."

The successful cloning of an adult mammal means there truly is "a brave new world upon us" that clashes with the teaching of Scripture, said Southern Seminary President R. Albert Mohler Jr.

"Cloning represents the attempt of the creature to be the Creator and to step outside the legitimate bounds of our creaturely power and responsibility," Mohler said. "I fear this will lead inevitably to attempts toward the development of a master race and a custom species.

"It also treads very near the sin of blasphemy," Mohler said, "because those who would tamper with the genetic code are acting as creator rather than creature. We should be extremely reluctant to tamper in any way with the reproductive process our Creator has put in place. To do otherwise is to risk not only intentional genetic mutation and its disastrous consequences for the human race, but to risk the coming of a very sinful and evil dark age in which human beings will seek to define themselves, clone themselves, make themselves, improve themselves and finally perfect themselves.

"Christians believe that human beings are the special creation of a loving and sovereign God who made human beings in his own image, not in the image of ourselves," Mohler said.

John Kilner, director of The Center for Bioethics and Human Dignity in suburban Chicago, said the news from Scotland "really comes as a wake-up call. Cloning human beings is not some futuristic issue that we don't have to take seriously."

While he, like Mitchell and Mohler, opposes human cloning, there are some practical ethical issues for a society which considers allowing such research, Kilner said.

"You can envision human lives being created with no responsible parties," Kilner said. "That's just horrendous. That's just irresponsible. ... (W)hat do you do with mistakes? Is it acceptable to just discard them?"

Other practical issues for the society, Mitchell said, include:

"Should human babies be cloned for 'replacement parts?' Are we really willing to produce exact duplicates of ourselves in an attempt toward immortality? The intuition that these things are wrong is not sentimentalism. Human life is sacred and must not be created and destroyed at will.

"We are simply not ready to tackle the thorny legal issues which would result from cloning human beings. For instance, one could easily conceive of a black market in 'good cells' so infertile couples could have the baby they've always wanted -- not just a baby but THE baby they've always wanted. And, if Dr. Wilmut or his lab owns the sheep he cloned, who will own cloned human beings?"

In addition, Kilner said, clones, as individuals or groups, would be produced "to serve as means for other people's purposes ... (T)hat's demeaning to human beings."

Would human clones have souls?

Mitchell and Kilner said they could not answer definitively without more information but they would assume so.

If not, "it would feed right into the whole utilitarian mind-set

that they are subhuman," Kilner said.

The Scottish researchers and others see the potential for benefit to human beings from the cloning of mammals. The potential medical and commercial impact includes such things as fighting diseases and old age and maximizing production in farm animals.

Wilmut and his colleagues achieved the first cloning of an adult mammal with a surprisingly simple method, according to news reports. They took a cell from the udder of a sheep and fused it with another sheep's unfertilized egg, its DNA nucleus having been removed. A spark of electricity in the lab started the egg dividing into an embryo. After a few days in a culture dish, the embryo was transplanted into the womb of a surrogate mother sheep.

"In just a few years, every university graduate student in biology will be able to clone a mammal," Mitchell said.

"This is clearly a momentous event. Whether it bodes good or ill, we'll have to wait to see. But one thing is certain: Without adequate ethical guidelines, monstrous results could well follow."

--30--

David Porter contributed to this article.

--30--

RELIGIOUS STATEMENT OPPOSING HUMAN AND ANIMAL PATENTS

WE, THE UNDERSIGNED RELIGIOUS LEADERS, OPPOSE THE PATENTING OF HUMAN AND ANIMAL LIFE FORMS. WE ARE DISTURBED BY THE U.S. PATENT OFFICE'S RECENT DECISION TO PATENT HUMAN BODY PARTS AND SEVERAL GENETICALLY ENGINEERED ANIMALS. WE BELIEVE THAT HUMANS AND ANIMALS ARE CREATIONS OF GOD, NOT HUMANS, AND AS SUCH SHOULD NOT BE PATENTED AS HUMAN INVENTIONS.

Joint Appeal Against Human and Animal Patenting

*Partial List Of Signatories To The Interfaith Appeal

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Faithful Witness on Today's Issues

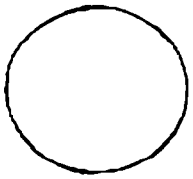
Genetic Science

Includes study guides and General Conference resolutions on:

- New Development in Genetic Science
- Organ and Tissue Donation

THE PRESIDENT HAS SEEN
3-10-97

3/12/97
– cc VP
– Interesting piece.
– Doesn't apply



ROBERT SCHULLER

March 4, 1997

Dear Mr. President:

I was listening to the morning news and heard your "call" for a moratorium request on "Cloning."

Thank you ... that is strong. protective leadership!

Just this past Sunday I said to my congregation, "The human being is not by nature humane."

I am enclosing a copy of an Op. Ed. piece I have just completed for the *Los Angeles Times* and wanted you to have a first look at it.

Yours with affection, respect and esteem,

Robert H. Schuller

President Bill Clinton
The White House
1600 Pennsylvania Avenue NW
East Wing, Room 214
Washington, DC 20500-2000

RHS/bh

Enclosure

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THE CRYSTAL CATHEDRAL
12141 LEWIS STREET, GARDEN GROVE, CALIFORNIA 92640

"YOU CAN'T CLONE THE HUMAN SOUL"

According to modern sages, genetics are the road map of human existence because they are said to explain not only what we are, but who we can be. Recently, when a team of Scottish scientists cloned a female sheep, shockwaves of awe and fear were sent throughout the world's scientific, religious and legal communities. Many wonder what the implications are if humans can be similarly duplicated.

The cloning of "Dolly," as the sheep is called, was important for two reasons. This was the first time a clone had been made from an adult creature. Thus its characteristics at maturity could be observed and selected. For many this is as close to a guaranteed product as anything. If two identical beings can be created, what are the implications for the human soul? If the body is made up of the same genetic material, what happens to the mind and soul?

If we agree, as seems to be the current fashion, that humans and other creatures in God's creation are merely the sum of their parts, then genetic engineering poses some real threats. A duplicate Adolf Hitler or a mass murderer would probably also commit genocide or mass murder.

But the fact is that human beings are more than the sum of their biological parts. The whole of each individual consists of the physical and spiritual nature.

Teilhard de Chardin says: *We are not human beings on a spiritual journey, rather we are spiritual beings on a human journey.* And the spirit cannot be cloned. Even if the biological material is the same, differences in spiritual makeup could also create differences in physical appearance.

Take for example two individuals who appear to be identical; one abstains from drugs, promiscuous sex, and other vices. He worships and has faith in God. The other disregards the Commandments of God, and pursues a reckless life of sin and self destruction. Can you picture the difference? Although similar, the two would develop drastically different personalities. Certainly once you got to know them, they would seem worlds apart.

From the time we are infants, and we begin to grow and make choices (or have choices made for us), our physical states undergo change. Thus, even with the same genetic material a cloned child would end up very different in "appearance" than the adult he or she was cloned from. We all become a collection of recorded experiences, which are not carried in human genes. And identical human spirits cannot be cloned. Bones, muscles, hair and blood may be cloned. But memory systems cloned? Never!

The soul has a profound influence on the appearance of an individual. Some would phrase this argument in terms of nature and nurture. If two identical twins were brought up by different parents, in different cultures and socio-economic circumstances, chances are they would see and make different choices in their lives.

This is very important. It is not our physical make-ups which most prominently mark our uniquenesses. It is our power to privately make personal choices. The evolving human personality can emerge into a person marked as either "kind" or "mean." One fact is irrefutable — you cannot inseminate and predetermine the "soul."

Choice. We have the choice to bring good or evil into existence for ourselves. The extent to which we choose either accounts for the only truly significant disparity in human nature. And the choices we make are based on the extent to which we try to civilize our souls and refine our character. This is an individual quest, and something that no scientist anywhere can ever recreate.

As scientists explore the unfathomable depths both within and outside the human body, they are often fascinated to find traces of the divine master plan. They call them, DNA, "The Theory of Relativity," "The Big Bang Theory," and other names. But these names are only metaphors, or useful lamp posts leading to the real nature of things. As such, they should not be mistaken for the deeper truths that lay beneath the surface.

As a person of faith, I would be interested to see how the cloned sheep develops under different environmental circumstances than its cloning parent. I'd avoid any milk or meat produced by a clone for now. But the question remains, should we lose sleep over men with God complexes trying to tinker with nature? As I ponder

this question, I take solace in the fact that science cannot transcend the human soul, because the human soul transcends science.

As the debate continues over whether or not humans are next to be cloned, the faithful should take heart. No matter how clever we become, we cannot have the power to control God's creation. Every person is endowed with the power to observe and select. And no two persons will be identical in all of their responses, reactions, choices and decisions. So we may be able to clone bodies — but the cloning of "persons" will be impossible. If science could possibly clone the personality, spirit, mind, soul and memory system, the end product would not be a "person" defined by the freedom to choose. Instead of a "person" we would have a "product," not a human soul.

March 7, 1997

FINAL DRAFT

NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC)

March 13, 1997
Watergate Hotel, Continental Chesapeake Extender Room
2650 Virginia Avenue, NW, Washington, DC
(202) 298-4466 (for messages)

AGENDA*/Day One

8:00 AM	**Welcome and Introduction** Dr. Harold Shapiro, Chair
8:15 AM	**Report of the Human Subjects Subcommittee** Dr. James Childress, Subcommittee Chair
9:15 AM	**Report of the Genetics Subcommittee** Dr. Thomas Murray, Subcommittee Chair
10:15 AM	**Coffee Break**
10:45 AM	**Discussion: Approach to the President's Request**
11:15 AM	**Lunch**
12:15 PM	**Science and Technology in Cloning** Dr. Shirley Tilghman, Princeton University
1:15 PM	**Discussion**
1:45 PM	**Coffee Break**
2:15 PM	**Religion-Based Perspectives on Cloning of Humans I** Protestantism: Dr. Gilbert Meilaender (Valparaiso University) Dr. Nancy Duff (Princeton Theological Seminary) Discussion Roman Catholicism: Dr. Lisa Cahill (Department of Theology, Boston College) Rev. Dr. Albert Moraczewski (National Conference of Catholic Bishops) Discussion
3:45 PM	**Discussion**
4:15 PM	**Statements by the Public**
5:00 PM	**Adjournment for the Day**

* Please note: This agenda might be slightly revised before or at the meeting at the discretion of the Chair.

FINAL DRAFT

NATIONAL BIOETHICS ADVISORY COMMISSION (NBAC)

March 14, 1997
Watergate Hotel, Continental Chesapeake Extender Room
2650 Virginia Avenue, NW, Washington, DC
(202) 298-4466 (for messages)

AGENDA*/Day Two

8:00 AM	**Welcome and Summary of Previous Day**
	Dr. Harold Shapiro, Chair
8:15 AM	**Religion-Based Perspectives on Cloning of Humans II**
	Judaism:
	Dr. Elliot Dorff (University of Judaism, Los Angeles)
	Dr. Moshe Tendler (Yeshiva University)
	Discussion
	Islam:
	Dr. Aziz Sachedina (University of Virginia)
	Discussion
9:45 AM	**Coffee Break**
10:00 AM	**Views on Cloning**
	Possible Benefits:
	Dr. John Robertson (University of Texas Law School)
	Dr. Ruth Macklin (Albert Einstein College of Medicine)
	Discussion
	Possible Risks:
	Dr. Leon Kass (University of Chicago)
	Dr. Jim Nelson (University of Tennessee)
	Discussion
11:30 AM	**Lunch**
12:30 PM	**Discussion**
2:00 PM	**Future Meetings**
2:15 PM	**Coffee Break**
2:30 PM	**Statements by the Public**
4:30 PM	**Adjournment**

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