

THE WHITE HOUSE

WASHINGTON

July 24, 1998

Cloning

MEMORANDUM FOR THE PRESIDENT

FROM: KERRI-ANN JONES, ACTING DIRECTOR, *K.A. Jones*
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
NEAL LANE, SCIENCE ADVISOR *K.A.J. 00*

SUBJECT: Cloning of Mice

On the front pages of yesterday's *Washington Post* and *New York Times* are reports of the successful cloning of adult mice by scientists at the University of Hawaii. This is the first time since the February 1997 report on cloning the sheep Dolly that a mammal has been cloned using genetic material derived from an adult cell. This is significant for the following reasons:

- First, this confirms the reality of Dolly. Some in the scientific community viewed Dolly as a fluke or questioned the rigor of the procedures used to obtain Dolly's genetic material. This recent work on mice proves unequivocally that this type of cloning is a biological reality.
- Second, the short generation time of mice, coupled with the advanced state of mouse genetics, will make the mouse an even more powerful experimental model to help scientists better determine the myriad functions of mouse genes and their human counterparts.
- Third, and perhaps most important from a policy and ethical perspective, is that the scientific community believes this work brings it closer to being able to successfully clone human beings. Cloning Dolly is a far cry from cloning a human. But cloning a mouse brings us closer to that possibility.

This announcement will surely elevate the debate on human cloning and result in a renewed attempt by the Congress to pass legislation banning such practices. Earlier this year, Senator Bond's overly broad measure was defeated by a comfortable margin (56-42). The key concern we have with previous legislative actions (e.g., the Bond and Ehlers bills) is the restrictive impact these bills would have on important biomedical research such as the development of cells and tissues for regeneration and transplantation of skin, nerve, or blood cells. The Kennedy-Feinstein bill is more consistent with your proposed bill and would not be detrimental to research. In the days ahead, Republicans could well be expected to attach a cloning amendment to the IHS appropriations bill.

The Administration and a coalition of scientific and industrial organizations are currently developing a two-pronged strategy to address this issue: 1) continue to support the Kennedy-Feinstein legislation and; 2) in the absence of legislation, clarify FDA's authority to regulate cloning procedures based on safety and efficacy, and explore establishing a new advisory structure similar to Recombinant DNA Advisory Committee. The RAC reviewed and approved early recombinant DNA experiments and performed the important function of assuring the public of the safety of the then-nascent technology. The cloning advisory committee would be charged to review proposed projects for their social and ethical implications. Your National Bioethics Advisory Commission does not have authority to review and approve individual proposals.

Date: 06/04/97 Time: 08:47

HCommission proposing guidelines for human embryo cloning

WASHINGTON (AP) A presidential commission will propose that Congress enact legislation allowing some researchers to create cloned human embryos, but ban use of the embryos to make human babies, The Washington Post reported today.

The 18-member National Bioethics Advisory Commission, appointed by President Clinton after the successful cloning of a sheep in Scotland, will make its recommendations at a meeting this weekend.

According to a draft report obtained by the Post and in interviews with its members, the commission will propose that privately funded scientists and doctors be allowed to make cloned human embryos for research, but not allow them to be implanted into women's wombs.

Clinton announced a moratorium on the use of federal funds for human embryo cloning in February and appointed the panel of experts in science, law and theology to make broad recommendations on the issue to Congress.

The commission was asked to find a common ground between those who see cloning as an option for infertile couples and those who see human cloning as unethical or immoral.

The panel has met five times at Clinton's request and delayed its final report by about two weeks in an effort to reach consensus.

"The most important thing is to get some rules about ethical conduct," said David R. Cox, a commission member and professor of genetics and pediatrics at Stanford University.

Some panel members told The Associated Press last month that scientific controls should be extended to "all research settings, whether in the public or private sector."

"Our concern here is that an in vitro fertilization doctor will say 'I'm not doing research, but using an innovative technique to help a couple with severe infertility,'" said panel member Bernard Lo, director of medical ethics at the University of California, San Francisco.

Historically, in vitro fertilization doctors have used this argument to avoid scientific oversight, Lo said.

APNP-06-04-97 0902EDT

Bruce -
FYI
Elena

Q&A on National Bioethics Advisory Commission Recommendations
June 4, 1997

Q. The Washington Post reported today that NBAC will recommend a legislative ban on creating a child using the cloning technology that created Dolly the sheep. But the Post reports that the Committee won't prohibit the creation of embryos using this technology. Where does the President stand? Does he think we should allow cloned embryos?

A. The President is very concerned about using this new technology to clone human beings. He is deeply troubled by the prospect that it might someday be possible to create a child from one's own genetic material. That is why he asked NBAC to review the issue.

The question of creating embryos for research -- as opposed to creating a child -- is a separate question that raises distinct scientific and ethical issues. The President has already acted in this area. In 1994 he directed the National Institutes of Health not to fund the creation of human embryos for research purposes. Congress has also placed restrictions on embryo research.

As you know, NBAC has not issued its final report, and the President has not yet reviewed their recommendations. We will have more to say about it after he has reviewed it.

in federal funding for

Bonus -

*I approved this,
w/ the one change*

E.

THE WHITE HOUSE

WASHINGTON

'97 JUN 8 AMB:28

May 29, 1997

MEMORANDUM FOR THE PRESIDENT

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

ELENA KAGAN
Deputy Assistant to the President for Domestic Policy

SUBJECT: CLONING POLICY OPTIONS

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

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

NBAC's Findings and Recommendations

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

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

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

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

National Legislation

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

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

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

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

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

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

Approve ___ Disapprove ___

Group of Eight Statement on Cloning

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

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

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

Approve ___ Disapprove ___

Cloning
THE PRESIDENT HAS SEEN
6-4-97

THE WHITE HOUSE
WASHINGTON

Copied to:
Kagan
Gibbons
Emanuel
Bowles

June 3, 1997

MEMORANDUM FOR THE PRESIDENT

FROM: TODD STERN *TDS*
PHIL CAPLAN *PC*

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

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

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

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

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

Approve Disapprove Discuss

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

Approve Disapprove Discuss