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MEMORANDUM FOR THE PRESIDENT

DRAFT

FROM:

SUBJECT: Cloning Legislative Options

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

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

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

I. Substantive Prohibition

A. Support existing language without changes

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

B. Refine current language

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

Current language:

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

Suggested modification:

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

Rationale

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

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

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

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

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

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

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

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

D. Adopt a more general prohibition

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

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

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

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

Recommendation:

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

Approve: _____ Disapprove: _____ Discuss: _____

II. Federal Pre-emption of State Regulation

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

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

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

Recommendation:

We recommend against adding a pre-emption clause.

Approve: _____ Disapprove: _____ Discuss: _____

Attachments:

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

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

copied
Kagan
Gibbons
COS

THE WHITE HOUSE
WASHINGTON

June 8, 1997

Cloning

Bruce -

FYI. What we gave to the President this weekend.

Elena

MEMORANDUM FOR THE PRESIDENT

THE PRESIDENT HAS SEEN
6/8/97

FROM: TODD STERN *TS*
SUBJECT: Proposed Cloning Legislation

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

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

Agree ☒

Disagree ☐

Discuss ☐

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

5-year sunset ☒

No sunset/but review (VP idea) ☐

No sunset or review ☐

Discuss ☐

THE WHITE HOUSE
WASHINGTON

'97 JUN 8 PM12:47

June 8, 1997

MEMORANDUM FOR THE PRESIDENT

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

Elena Kagan
Deputy Assistant to the President for Domestic Policy

SUBJECT: Cloning Policy Decisions

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

NBAC's Findings and Recommendations

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

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

Proposed Legislation

The legislation you will announce tomorrow, as currently written:

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

Key Legislative Issues

1. Embryo Research

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

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

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

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

2. Sunset Provision

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

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

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

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

Cloning
THE PRESIDENT HAS SEEN
6-4-97

THE WHITE HOUSE
WASHINGTON

June 3, 1997

Copied to:
Kagan
Gibbons
Emanuel
Bowles

MEMORANDUM FOR THE PRESIDENT

FROM: TODD STERN *TS*
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 ☐

THE WHITE HOUSE
WASHINGTON

'97 JUN 3 AM8:28

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 ____

File - cloning

THE WHITE HOUSE
WASHINGTON

March 3, 1997

MEMORANDUM FOR THE PRESIDENT

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

Bruce Reed *BR*
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:

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