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Cloning

THE WHITE HOUSE
WASHINGTON
June 8, 1997

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 TOS

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.

Office of the Commissioner
Office of Executive Secretariat
5600 Fishers Lane, HF-40
Rockville, Maryland 20857

Fax No. (301) 443-1863 Telephone No. (301) 827-4450

FACSIMILE TRANSMISSION RECORD

NUMBER OF PAGES (not including coversheet) - 4

TO: Tom Freedman
Domestic Policy Council

Fax No. 202-456-7431 Telephone No.

FROM: FDA per Bill Hubbard

MESSAGE: The "FDA's Newsletter" page was approved by the Dept. & should reach the Hill.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

April 16, 1998

FDA's Jurisdiction Over Human Cloning Activities

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

I. Background

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

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

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

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

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

II. Legal Authority

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

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

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

A. A Somatic Cell Clone is a Biological Product

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

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

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

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

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

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

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

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

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

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

B. A Somatic Cell Clone is a Drug

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

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

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

III. Previous FDA Guidance on Cellular Products

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

A. Regulatory Approach to Somatic Cell and Gene Therapy Products

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

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

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

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

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

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

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

IV. Prohibited and Permissible Acts

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

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

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

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

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

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

FDA

98 493
98 664

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 9 1998

Mr. Carl B. Feldbaum
President
Biotechnology Industry Organization (BIO)
1625 K Street, N.W., Suite 1100
Washington, D.C. 20006-1604

Dear Mr. Feldbaum:

Thank you for your two letters concerning human cloning. On behalf of the Department, I want to assure you that the Food and Drug Administration (FDA) has jurisdiction over experiments that would involve the cloning of humans and is prepared to exercise that jurisdiction. While FDA's authority does not address the larger question of whether or not creating a human being using cloning technology should be prohibited altogether, this authority will help ensure that such experimentation does not proceed until basic questions about safety are answered.

Creating a human being using cloning technology is subject to FDA regulation under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. Under these statutes and implementing FDA regulations, clinical research on the creation of a human being using cloning technology may proceed only when an investigational new drug application (IND) is in effect. As you know, criteria for approving an IND include a description of the research plan, obtaining authorization from an institutional review board, and obtaining informed consent from the individuals participating in the study. There are many unresolved safety questions with respect to human cloning. Until these questions are addressed appropriately, FDA would not allow a clinical investigation to proceed.

We appreciate your views and concerns, and we hope this information has been helpful. We are continuing to work with Congress on this issue.

Sincerely,

Donna E. Shalala

Senate Democrats Block Cloning Bill; Lott Seeks Cloture

Senate Democrats Thursday blocked GOP efforts to move a bill that would permanently ban human cloning.

HEALTH

Senate Majority Leader Lott late in the day filed a cloture petition on the motion to proceed to the bill, and announced a vote for Tuesday.

Lott said that vows made by Chicago physicist Richard Seed to seek to clone humans made it imperative for the Senate to act — even though the bill in question, introduced on Tuesday, has not yet been considered by committee.

"Clearly this is an issue that has the attention of the public," Lott said. "If we don't act, what could be the result? Do we want the possibility of human cloning to go forward?"

But Democrats, who objected to allowing the bill to be brought up, said Congress is rushing unnecessarily.

"It is not as if, despite the absurd publicity given to Richard Seed, a baby will be cloned tomorrow," said **Senate Labor and Human Resources ranking member Edward Kennedy**, D-Mass.

Kennedy, along with **Sen. Dianne Feinstein**, D-Calif., has introduced a bill that would place a 10-year moratorium on implantation of embryos created with the technique used by a Scottish scientist to clone a sheep in 1996.

"There is time for us to take a month or two and consider what approach to take," Feinstein said.

The key difference between the GOP bill, written by **Sens. Christopher (Kit) Bond**, R-Mo., and **Bill Frist**, R-Tenn., and the Democrats' bill is that the former would ban all use of the technology in question, "human somatic cell nuclear transfer."

The latter would permit use of the technology, but prohibit the implantation into a woman's uterus of an embryo created using the technique.

The debate is not just pitting Democrats against Republicans, however, but also medical research groups against abortion foes.

Research groups say the GOP bill, by blocking all creation of embryos, would sidetrack important medical research.

"The bill goes beyond the issue of cloning to make it a crime to use somatic cell nuclear transfer of a nucleus derived from normal sexual union of an egg and sperm, which is obviously not cloning," according to an analysis of the legislation performed by the Biotechnology Industry Organization.

The analysis goes on to say: "[The legislation] would also make it a crime to conduct some research seeking to generate stem cells to treat a wide range of deadly and disabling diseases, treatments which have nothing whatever to do with human cloning."

But anti-abortion groups say the Democrats' bill would encourage the creation of human embryos for the express purpose of experimenting on them and then killing them.

"Enactment of Kennedy-Feinstein would amount to a declaration by Congress that living human embryos are something other than human beings," the National Right to Life Committee charged in a letter circulated Thursday to senators.

"Under the Kennedy-Feinstein proposal, it would be perfectly legal to create cloned human embryos and use them as subjects for harmful experimentation, so long as they are killed before being implanted in a woman's womb," the letter added.

The NRLC letter also said the group intended to use a vote on the Democrats' bill as part of its annual scorecard of abortion-related votes.

Jennings Cautions GOP On Medicare Contracting Issue

Republicans are still pushing hard for legislation to rewrite a controversial provision of last year's budget reconciliation act allowing for limited private contracting between physicians and Medicare beneficiaries — but the Clinton administration is urging them to think again.

HEALTH

"Before you start changing the Balanced Budget Act, which was a very delicate compromise, you have to review all the implications of that," Chris Jennings, deputy assistant to the president for health policy, told *CongressDaily* in an interview Wednesday.

Sen. Jon Kyl, R-Ariz., author of the original language in the reconciliation bill that was changed at the insistence of the Clinton administration, is pushing a bill that would remove a requirement that physicians who privately contract for Medicare-covered services forgo all contact with the program for all patients for two years.

Kyl said on the floor Tuesday that his bill currently has 45 cosponsors and that companion legislation in the House has more than 150 cosponsors.

According to Kyl, hearings in the Senate Finance Committee are expected by the end of the month — and he expressed hopes of having a bill to the president "sometime in the early spring."

But Jennings said the administration remains concerned about both the substance of the measure and the precedent of reopening last year's legislation.

In particular, Jennings said, among the administration's concerns about physicians being allowed to privately contract for some patients but not others would be the difficulty of detecting fraud.

Jennings said the administration was concerned as well about potentially limiting access to physicians in rural or inner city areas if too many doctors were to stop accepting Medicare payment rates.

"Opening it up without considering all these other issues would seem imprudent right now," Jennings said.

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

List of Participants

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

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

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

March 25, 1998

MEMORANDUM FOR ELENA KAGAN

FROM: Jerry Mande

SUBJECT: Today's Cloning Meeting

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

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

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

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

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

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

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

Feinstein + Kennedy

Chris open it up & see where legis is →.

saw reaching - if biomedical community
saw further it was
Army extend to reintroduce bill
expectation that something w/ go thru House
bill being drafted in House Commerce
Cmte →

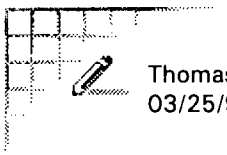
Chris - total ban on at state level?
Calif →
Calif bill is model for Kennedy
Feinstein bill

some prefer no legis
1) assure public concern
2) permit research
3) ban cloning human being
non-legis moratorium

Indeed Appreciate FDA's current pos →
- stay away from defining embryo

Issue: voluntary moratorium
need clones advisory cmte

who republicans support non legis
Mack, Greenlee (PA)
Specter, Hatch, Santorum
* apply std in legis & federal research



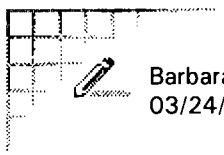
Thomas L. Freedman
03/25/98 12:12:38 PM

Record Type: Record

To: Mary L. Smith/OPD/EOP

cc:
Subject: List of Attendees - Cloning Meeting

---------- Forwarded by Thomas L. Freedman/OPD/EOP on 03/25/98 12:13 PM ----------



Barbara D. Woolley
03/24/98 05:59:54 PM

Record Type: Record

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

cc:
Subject: List of Attendees - Cloning Meeting

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

List of Participants

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

Scientific Organizations
David Korn, Senior Vice President, Association of American Medical Colleges

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

Industry
Barry Caldwell, Vice President, Federal affairs, PhRMA
Walter Moore, Senior Director, Genentech, Inc.
Eleanor Kerr, Senior Director, Government Relations, Smith Kline Beecham
Victoria Blatter, Director, Government Relations, Merck & Co.
Carl B. Feldbaum, Biotechnology Industry Organization
Nancy Bradish, Biotechnology Industry Organization
Amgen
Lisa Raines, Genzyme

Message Sent To:

Rachel E. Levinson/OSTP/EOP
Jerold R. Mande/OSTP/EOP
Thomas L. Freedman/OPD/EOP
Laura Emmett/WHO/EOP
Toby Donenfeld/OVP @ OVP

Essence P. Washington
02/26/98 03:34:50 PM

Record Type: Record

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

cc: Laura Emmett/WHO/EOP, Jessica L. Gibson/WHO/EOP
Subject: TIME CHANGED- Cloning Legislative Strategy MTG

The Meeting will be Tommorow at 2:00 p.m. in room 211 OEOB. Again, please call or send me an E-mail if you are unable to attend.

Thanks

---------- Forwarded by Essence P. Washington/OPD/EOP on 02/26/98 03:24 PM ----------

Mary L. Smith
02/26/98 10:02:18 AM

Record Type: Record

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

cc: Laura Emmett/WHO/EOP, Essence P. Washington/OPD/EOP
Subject: Cloning Legislative Strategy Meeting

There will be a cloning legislative strategy meeting on Friday, February 27 at 4p.m. in Room 211 OEOB. Please let me know if you cannot attend. Thanks, Mary

Message Sent To:

Elena Kagan/OPD/EOP
Thomas L. Freedman/OPD/EOP
Jerold R. Mande/OSTP/EOP
Janet Murguia/WHO/EOP
Lucia A. Wyman/WHO/EOP
Rachel E. Levinson/OSTP/EOP
William P. Marshall/WHO/EOP
Donald H. Gips/OVP @ OVP
Jeffrey M. Smith/OSTP/EOP

Message Sent To:

Elena Kagan/OPD/EOP
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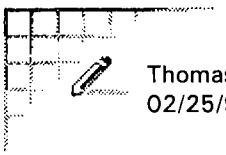
Donald H. Gips/OVP @ OVP
Jeffrey M. Smith/OSTP/EOP
Mary L. Smith/OPD/EOP



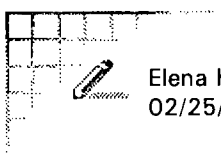
Thomas L. Freedman
02/25/98 01:44:15 PM

Record Type: Record

To: Mary L. Smith/OPD/EOP

cc:
Subject: Cloning

---------- Forwarded by Thomas L. Freedman/OPD/EOP on 02/25/98 01:44 PM ----------



Elena Kagan
02/25/98 12:31:58 PM

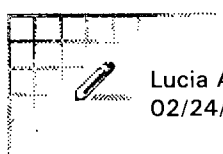
Record Type: Record

To: Lucia A. Wyman/WHO/EOP

cc: Jerold R. Mande/OSTP/EOP, Rachel E. Levinson/OSTP/EOP, Thomas L. Freedman/OPD/EOP
Subject: Cloning

yes -- let's meet friday when rachel gets back. Jerry or tom -- could you set this up -- Laura isn't here for the rest of the week. thanks.

---------- Forwarded by Elena Kagan/OPD/EOP on 02/25/98 12:31 PM ----------



Lucia A. Wyman
02/24/98 06:44:34 PM

Record Type: Record

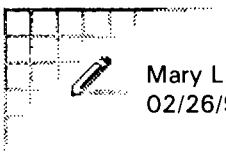
To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP, Jerold R. Mande/OSTP/EOP, Rachel E. Levinson/OSTP/EOP

cc:
Subject: Cloning

concerns
if we receive a bill that impedes research but has a grandfather clause or someother type of softener, do we sign? this would be a frist/bond bill w/changes. in a war of words, what is an embryo, we lose. when is an embryo an embryo (we lose). i'm beginning to think, if there is no middle ground and i don't think there is, we should consider a clean fight.

i keep hearing from the hill that the repubs are trying to peel off the research community. if this is the case, we need to regroup.

rachel levinson will be back on friday. can we regroup then? elena, what's a good time?



Mary L. Smith
02/26/98 10:02:18 AM

Record Type: Record

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

cc: Laura Emmett/WHO/EOP, Essence P. Washington/OPD/EOP
Subject: Cloning Legislative Strategy Meeting

There will be a cloning legislative strategy meeting on Friday, February 27 at 4p.m. in Room 211 OEOB. Please let me know if you cannot attend. Thanks, Mary

Message Sent To:

Elena Kagan/OPD/EOP
Thomas L. Freedman/OPD/EOP
Jerold R. Mande/OSTP/EOP
Janet Murguia/WHO/EOP
Lucia A. Wyman/WHO/EOP
Rachel E. Levinson/OSTP/EOP
William P. Marshall/WHO/EOP
Donald H. Gips/OVP @ OVP
Jeffrey M. Smith/OSTP/EOP

Thomas L. Freedman
02/25/98 01:44:15 PM

Record Type: Record

To: Mary L. Smith/OPD/EOP

cc:
Subject: Cloning

--------------------- Forwarded by Thomas L. Freedman/OPD/EOP on 02/25/98 01:44 PM ---------------------------

Don Gips / Secretary's
Rich Tarplin /
Bill ~~Rau~~ Raub
Lana Shirball
– Varmus

Elena Kagan
02/25/98 12:31:58 PM

Record Type: Record

To: Lucia A. Wyman/WHO/EOP

cc: Jerold R. Mande/OSTP/EOP, Rachel E. Levinson/OSTP/EOP, Thomas L. Freedman/OPD/EOP
Subject: Cloning

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--------------------- Forwarded by Elena Kagan/OPD/EOP on 02/25/98 12:31 PM ---------------------------

Lucia A. Wyman
02/24/98 06:44:34 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP, Jerold R. Mande/OSTP/EOP, Rachel E. Levinson/OSTP/EOP

cc:
Subject: Cloning

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rachel levinson will be back on friday. can we regroup then? elena, what's a good time?

Thomas L. Freedman
02/04/98 09:56:52 AM

Record Type: Record

To: Mary L. Smith/OPD/EOP

cc:
Subject: Telegram on Proposed Cloning Legislation

Unrelatedly: I think we'll need a tenative answer on alcohol and billboards today-- any chance?
---------- Forwarded by Thomas L. Freedman/OPD/EOP on 02/04/98 09:56 AM ----------

Rachel E. Levinson 02/04/98 09:55:34 AM

Record Type: Record

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

cc:
Subject: Telegram on Proposed Cloning Legislation

fyi
---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 02/04/98 09:54 AM ----------

hgarrison @ faseb.org
02/04/98 09:16:50 AM

Record Type: Record

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

cc: See the distribution list at the bottom of this message
Subject: Telegram on Proposed Cloning Legislation

During yesterday's Public Affairs Executive Committee (PAEC) conference call, the PAEC instructed us to send the following telegram to all members of the U.S. Senate:

"The Federation of American Societies for Experimental Biology (FASEB) urges the Senate to proceed extremely cautiously as it considers legislation regarding human cloning. While the Federation considers the cloning of a human being to be reprehensible, dangerous, and unethical, we are concerned that overly restrictive legislation could unintentionally preclude critical research of great benefit to the American people. We believe that S. 1599, currently pending consideration by

the Senate, would be damaging to worthwhile research. By flatly banning all use of human somatic cell nuclear technology for any purpose, this legislation would close off key areas of research which do not involve the creation of humans. We urge that the Senate not approve this legislation in its current form as it does not balance appropriate ethical considerations with the health needs of the American people."

The message was sent yesterday evening for delivery today.

Howard H. Garrison, Ph.D.
Director, Office of Public Affairs
Federation of American Societies for Experimental Biology
9650 Rockville Pike
Bethesda, MD 20814
voice: (301) 571-0657
fax: (301) 571-0686

Message Sent To: _____

baintond @ chanoff.ucsf.edu
rablab @ uci.edu
db8g @ virginia.edu
brinkley @ bcm.tmc.edu
brd @ virginia.edu
fisch @ med.cornell.edu
gierasch @ chem.umass.edu
joel.g.hardman @ mcmail.vanderbilt.edu
mjackson @ execofc.FASEB.org
JOLLIE @ Gems.vcu.edu
uncdgk @ med.unc.edu
kknight @ luc.edu
brian @ uoxray.uoregon.edu
mcmanus @ uthscsa.edu
newburgh @ faseb.org
ongde @ ctrvax.vanderbilt.edu
rmp @ nucleus.immunol.washington.edu
pedersen @ cgl.ucsf.edu
suttie @ biochem.wisc.edu
jim_schafer @ vesta.cmc.uab.edu
mike_sheetz @ cellbio.duke.edu
priley @ ucsd.edu
petevh @ morel.uoregon.edu
yount @ wsu.edu
chicago @ itsa.ucsf.edu
teitelbaum_s @ medicine.wustl.edu
tandersen @ ccgateway.amc.edu
csenecal @ urmc.rochester.edu
beckerle @ bioscience.biology.utah.edu
brinkley @ bcm.tmc.edu
haywood @ uthscsa.edu
ichow @ faseb.org
hugli @ scripps.edu
mjackson @ execofc.FASEB.org
rokelley @ medusa.unm.edu
richard-lynch @ uiowa.edu
schach @ socrates.Berkeley.EDU
mlokhandwala @ uh.edu
mstephens @ vsadc.com
shwhite @ uci.edu
yount @ wsu.edu
naider @ postbox.csi.cuny.edu
speicher @ wista.wistar.upenn.edu
partrinc @ wpogate.slu.edu

Message Copied To: _____

ahellers @ aps.faseb.org
litch @ faseb.org
pfarnham @ asbmb.faseb.org
fpwhite @ faseb.org
tleshan @ ascb.org
tlawless @ faseb.org
kwalsh @ aps.faseb.org
jwood @ faseb.org
mfrank @ aps.faseb.org
chancock @ asbmb.faseb.org
fpitlick @ pathol.faseb.org
rallison @ ain.faseb.org
mmhogan @ faseb.org
emarinco @ faseb.org
ccarrico @ faseb.org
olds @ faseb.org
newburgh @ faseb.org
ichow @ faseb.org
julia_janko @ sba.com
rkampman @ BIOPHYSICS.faseb.org
mstephens @ vsadc.com

Message Sent To:

Toby Donenfeld/OVP @ OVP
Wendy A. Taylor/OMB/EOP
gips_d @ a1.eop.gov @ inet
Clifford J. Gabriel/OSTP/EOP
Jeffrey M. Smith/OSTP/EOP
Lucia A. Wyman/WHO/EOP
Thomas L. Freedman/OPD/EOP
Jerold R. Mande/OSTP/EOP
William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

Laura Emmett 02/03/98 09:08:44 AM

Record Type: Record

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

cc: Jessica L. Gibson/WHO/EOP
Subject: Cloning Legislative Strategy Mtg.

The Cloning Legislative Strategy is now confirmed for 4:00 Wednesday in room 180 OEOB. Please let me know if you cannot attend. Thanks.

Participants
Elena Kagan, DPC
Tom Freedman, DPC
Jerold Mande, OSTP
Janet Murgia, Leg. Affairs
Lucia Wyman, Leg. Affairs
Mary Smith, DPC
Rachel Levinson, OSTP
Jeff Smith, OSTP
Rich Tarplin, HHS
Jim O'Hara, HHS
Bill Marshall, Counsel's

Message Sent To:

Janet Murguia/WHO/EOP
Lucia A. Wyman/WHO/EOP
Thomas L. Freedman/OPD/EOP
Jerold R. Mande/OSTP/EOP
Mary L. Smith/OPD/EOP
Rachel E. Levinson/OSTP/EOP
Jeffrey M. Smith/OSTP/EOP
William P. Marshall/WHO/EOP

Laura Emmett 02/02/98 03:24:29 PM

Record Type: Record

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

cc: Jessica L. Gibson/WHO/EOP
Subject: Cloning Legislative Strategy Mtg.

There will be a cloning legislative strategy meeting on Wednesday at 11:00AM in room 211 OEOB. Please let me know if you cannot attend. thanks.

Elena Kagan, DPC
Tom Freedman, DPC
Jerold Mande, OSTP
Janet Murgia, Leg. Affairs
Lucia Wyman, Leg. Affairs
Mary Smith, DPC
Rachel Levinson, OSTP
Jeff Smith, OSTP
Rich Tarplin, HHS
Jim O'Hara, HHS
Bill Marshall, Counsel's

Message Sent To:

Janet Murguia/WHO/EOP
Lucia A. Wyman/WHO/EOP
Thomas L. Freedman/OPD/EOP
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Rachel E. Levinson/OSTP/EOP
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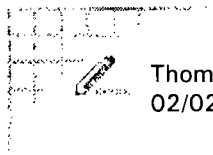
William P. Marshall/WHO/EOP



Thomas L. Freedman
02/02/98 05:38:31 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Jerold R. Mande/OSTP/EOP

cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP
Subject: bill analysis

NIH analysis of Feinstein bill and side by side.

---------- Forwarded by Thomas L. Freedman/OPD/EOP on 02/02/98 05:37 PM ----------

Rachel E. Levinson 02/02/98 04:18:14 PM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP

cc:
Subject: bill analysis

just got it.

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 02/02/98 04:17 PM ----------

SkirbolL @ od1tm1.od.nih.gov
02/02/98 03:27:06 PM

Record Type: Record

To: levinson

cc: wraub @ osaspe.dhhs.gov
Subject: bill analysis

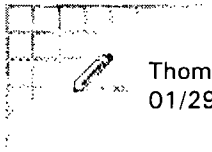
Here is our analysis of the Feinstein Bill and a side by side on all of the Bill be know about to date. (Bill the analysis of the Feinstein bill is slightly changed from the earlier version.) Please let us know if there is anything else you need.

lana

<<feinanalys.wpd>> <<Table4.wpd>>
Lana Skirboll, Ph.D.
NIH Associate Director for Science Policy

301-496-2122 (phone)
301-402-1759 (fax)

 - feinanalys.wpd  - Table4.wpd



Thomas L. Freedman
01/29/98 05:46:56 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP
Subject: attachment

Attched is OSTP's update to Leg Affairs about the status of cloning for a memo to Larry: do you have advice on which of the options (at the bottom of the memo) you want to pass on to him?
---------- Forwarded by Thomas L. Freedman/OPD/EOP on 01/29/98 05:43 PM ----------

Rachel E. Levinson 01/29/98 05:34:17 PM

Record Type: Record

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

cc:
Subject: attachment

Cloning Update

It appears that the Republicans will introduce a bill in the Senate next week to prohibit cloning human beings in the public and private sectors. Although the language has not been finalized, it is likely that the bill would seek to ban the creation of a zygote (a one-cell embryo) using somatic cell nuclear transfer cloning technology. This differs from our bill in that it would preclude research on the embryo prior to implantation, while our ban would start at introduction of the embryo into a woman's uterus. Currently, such research is allowed using private funds. It is not certain whether or not a sunset provision would be included. The plan is for the bill to go directly to the floor with the blessing of Senate leadership and others (Lott, Gregg, Bond, and Frist). Kennedy and Feinstein are poised to introduce a bill today that is close to the President's (draft attached).

We have at least five options: (1) try to work with the Senate majority on drafting a bill; (2) declare our support for the Kennedy/Feinstein bill; (3) issue a statement reiterating the principles in our bill in order to influence the drafting process; (4) wait until the Senate bill goes to the floor and then issue a SAP; or (5) do nothing and let the biotech industry and patient advocacy groups continue to fight against overly restrictive legislation. Should we choose to act prior to the floor debate, we will have to move quickly.

Message Sent To:

Lucia A. Wyman/WHO/EOP
Jeffrey M. Smith/OSTP/EOP
Jerold R. Mande/OSTP/EOP
Thomas L. Freedman/OPD/EOP
Clifford J. Gabriel/OSTP/EOP
Arthur Bienenstock/OSTP/EOP

Thomas L. Freedman
01/22/98 07:34:19 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Mary L. Smith/OPD/EOP, Laura Emmett/WHO/EOP
Subject: Cloning

CLONING.122 Attached is OSTP's draft of a memo that could be sent to the President on cloning. In general it is accurate: in meetings with OSTP (Rachel Levinson), VP (Gips), counsel (Marshall), Leg affairs, and DOJ we came up with four options-- the current approach, two refinements, or a generally worded approach recomended by some outside groups. It recomends in favor of one of the refinements and recommends against preemption. However, it is sloppy and not informative enough. We are meeting again tommorow morning to improve it. You are more familiar with the President's thinking on this issue, but here is what I think the memo should do better:

1. Explain what FDA can do. FDA has not formally announced it, but Bill Schultz thinks they have the authority to ban cloning for the time being on the basis of it not being safe. FDA thinks there is still a need for legislation that bans cloning on ethics grounds so that when it is a safe technology it remains a banned procedure.

2. Explain clearly the pros and cons of each option's effect on research. The option we chose (C) was supposed to be the most research friendly while still banning making human with cloning, that needs to be clearer.

3. I think we should list an option of not sending up a new bill. We've already said our principles and endorsed model legislation, we could offer to work with Feinstein or Kennedy to fix the problems we all see in our bill. The President could direct FDA to come up with a regulation, and leg. affairs could work with the the Senate to preserve embryo research but ban the making of humans via cloning (for instance by banning implanting in the womb using somatic cell nuclear transfer.) If you agree with this last point, I'm not sure we even need a special memo to the President but it could just be included in the Weekly.

Total Pages: 3

LRM ID: RJP187

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

URGENT

Thursday, February 5, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

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

DEADLINE: **10:00 a.m. Friday, February 6, 1998**

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

COMMENTS: ***REVISED*** **Statement of Administration Policy - incorporates changes received to date and has been reviewed and approved by HHS. HHS advises that the SAP should be held pending tonight's meeting on the cloning ban bill.**

DISTRIBUTION LIST

AGENCIES:
Executive Office of the President - EOP Review Only See Distribution -

EOP:
KAGAN_E
Thomas L. Freedman
Jerold R. Mande
JENNINGS_C
Joshua Gotbaum
Rachel E. Levinson
Robert G. Damus
Allison H. Eydt
Donald H. Gips
Barry T. Clendenin
Richard J. Turman
William P. Marshall
Alice E. Shuffield
James C. Murr
Janet R. Forsgren
Ellen J. Balis

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

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RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

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

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

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

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

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

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

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

DRAFT -- NOT FOR RELEASE

DRAFT

February 5, 1998
(Senate)

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

On June 9, 1997, the President transmitted to Congress legislation making it illegal for anyone to clone a human being. The President believes that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. The Administration, however, believes S. 1601 poses a significant threat to important biomedical research and, therefore, has concerns regarding passage of the bill in its current form. The Administration looks forward to working with the Congress to address these concerns. Specifically, the Administration supports amendments to S. 1601 that would:

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

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

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

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

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

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White House Press Release

REMARKS BY THE PRESIDENT ON CLONING

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release March 4, 1997

REMARKS BY THE PRESIDENT
ON **CLONING**

The Oval Office

9:25 A.M. EST

THE PRESIDENT: Good morning. I'm glad to be joined this morning by the Vice President, Secretary Shalala, Dr. Harold Varmus, the head of NIH; Dr. Harold Shapiro, the President of Princeton and the Chairman of our Bioethics Advisory Commission; and Dr. Jack Gibbons, the President's Advisor on Science and Technology, all of whom know a lot about and care a lot about this issue we are discussing today.

The recent breakthrough in animal **cloning** is one that could yield enormous benefits, enabling us to reproduce the most productive strains of crop and livestock, holding out the promise of revolutionary new 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.

Science often moves faster than our ability to understand its implications. That is why we have a responsibility to move with caution and care to harness the powerful forces of science and technology so that we can reap the benefit while minimizing the potential danger.

This new discovery 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 and spirituality as well.

My own view is that human **cloning** would have to raise deep concerns, given our most cherished concepts of faith and humanity. Each human life is unique, born of a miracle that reaches beyond laboratory science. I believe we must respect this profound gift and resist the temptation to replicate ourselves.

At the very least, however, we should all agree that we need a better understanding of the scope and implications of this most recent breakthrough. Last week, I asked our National Bioethics Advisory Commission, headed by President Harold Shapiro of Princeton, to conduct a thorough review of the legal and the ethical issues raised by this new **cloning** discovery, and to recommend possible actions to prevent its abuse, reporting back to me by the end of May.

In the meantime, I am taking further steps to prevent human **cloning**. The federal government currently restricts the use of federal funds for research involving human embryos. After reviewing these restrictions, our administration believes that there are loopholes that could allow the **cloning** of human beings if the technology were developed. Therefore, today I am issuing a directive that bans the use of any federal funds for any **cloning** of human beings.

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 and medical community, every foundation, every university, every industry that supports work in this area to heed the federal government's example. I'm asking for a voluntary moratorium on the **cloning** of human beings until our Bioethics Advisory Commission and our entire nation have had a real chance to understand and debate the profound ethical implications of the latest advances.

As we gain a fuller understanding of this technology, we must proceed not just with caution, but also with a conscience, by insisting that not a single taxpayer dollar supports human **cloning**. And by urging a moratorium on all private research in this area, we can ensure that as we move forward on this issue, we weigh the concerns of faith and family and philosophy and values, not merely of science alone. Thank you very much.

Q Mr. President, how do you think the Vice President did in his rebuttal yesterday, and do you agree with him that you two are in a separate category in terms of fundraising from federal property?

THE PRESIDENT: Well, I agree with -- number one, I thought he did very well and I agree with the statement he made and I agree that what he did was legal. But I also agree with the decision that he made.

I would remind you just that we knew that we had a very stiff challenge. We were fighting a battle not simply for our reelection, but over the entire direction of the country for years to come, and the most historic philosophical battle we've had in America in quite a long time -- over the direction of the budget, over our commitment to education, over whether we would dismantle large chunks of our environmental regulations and our public health regulations. It was a significant thing for America, and we knew that we were going to be outspent and outraced, but we knew we had to do everything we could to at least be competitive enough to get our message out.

In fact, that is what happened. We were outspent and outraised by more than $200 million; but thanks to the Vice President's efforts and those of thousands of others and a million small donors, we were able to get our message out.

Q But did you overdo it in a sense that now you're regretting, obviously -- you must be -- all the things that have happened since then?

THE PRESIDENT: The only thing I regret -- and I regret this very much as I have said -- is that a decision was made which I did not approve of or know about to stop the rigorous review of checks coming in to the Democratic Committee so that some funds were accepted which should not have been accepted. I regret that very much. And I have said that I feel, as the titular head of the Democratic Party I feel responsible for that; I think all of us in the line of command are. And I was very proud of Governor Romer and Mr. Grossman and the entire Democratic Committee when they made a full accounting; they went over all the checks, they did something as far as I know no party has done in modern history, and they gave back money that was not only clearly illegal, but that was questionable, and they're going on. I regret that very much, because that never should have happened in the first place.

For the rest, I think the Vice President said he thought that some changes were in order, but I don't regret the fact that we worked like crazy to raise enough money to keep from being rolled over by the biggest juggernaut this country had seen in a very long time. And I think it would have been a very bad thing for the American people if that budget had passed, if their plans to dramatically dismantle the environmental protections and the public health protections the country had passed, and I am glad we stood up to it. I'm glad we fought the battles of '95 and '96, and I'm glad it came out the way it did, and we had to be aggressive and strong within the law, and I'm very proud of what the Vice President did.

Q Don't you think it puts the Vice President in a vulnerable --

Q Mr. President, what is the extent of your order today? How much funds -- do you know how much funds were being spent toward this human **cloning**, if any?

THE PRESIDENT: We attempted previously to have a ban on this, going back to '94, I believe. The nature of the new discovery raised the prospect that the technology was not covered specifically by the nature of the ban. So as far as I know, nothing is going on in government-funded research. I just want to make sure that we keep it that way, because our research dollars are spread all across the country in different institutions.

With regard to the private sector, let me say that our staff here in the White House has been in touch with a number of people in the biotech industry, and they seem to be glad that we called and anxious to participate in a moratorium until we think through the implications of this.

I mean, I imagine a lot of you, not as journalists but in your own private homes have sat around talking about this discovery in the last few days; I know we have in our home. And I just think that we need the best minds that we can bring to bear and the distinguished people on the Bioethnics Advisory Committee to think through this, tell us about what we may be missing about if there's anything positive that could come from this, and also think

through the other implications.

How can we get the benefits of our deep desire to find any possible cure for any malady that's out there without raising the kind of ethical implications that, in effect, we're in the business where people are trying to play God, or to replicate themselves.

Q Mr. President, Democrats and Republicans are bogged down in Congress over whether to conduct hearings on the fundraising issue. Do you want to see that happen, and would you so tell your Democrats, you fellow Democrats up on the Hill?

THE PRESIDENT: My understanding is that the Democrats have no objection whatever to the hearings, they just believe that they ought not to go on forever and that they don't need to -- they're disputing whether $6.5 million needs to be spent. That's something that they need to work out among themselves.

I certainly have no objection to hearings. I've always assumed that they would occur, but I think that the American people are entitled to know that some prudence will be exercised in how much money is spent, because there's a lot of other things out there to be done, and we have the public's business to get on with as well -- a lot of other issues that need to be dealt with. And what I'm hoping that we can do is to just reconcile how this is going to be dealt with, and maybe spend some of that money to properly fund the Federal Election Commission so they can do the kind of audits they're supposed to do, and do the job that they actually have the power to do on the books right now, and get on with the big business, get on with balancing the budget, get on with passing the education program, get on with doing the other things that are out there for us to do. And so I'm going to do everything I can to facilitate that.

But it is a decision for the Senate and for the House, and the House to decide how these hearings with proceed and how they will be funded. But I don't think anybody objects to having hearings. We want them to be fair, we want them to be bipartisan, we want them to be balanced, and as I understand it, the big fight in the Senate is, will there be a date certain for ending and will there be a limit to how much is spent.

And let me say this: whatever the hearings produce, in the end, the only real question is, will they produce campaign finance reform. Whatever they produce, will they produce campaign finance reform. I still believe that the only way for the Congress to really deal with this and any questions from the past is to change the system. And we have the McCain/Feingold bill out there, it's a good vehicle, I have endorsed it, I would happily sign it the way it is, but they may want to debate that in some way or another. But the main thing that I want to say again is that there is no excuse for not voting on and passing a good bipartisan campaign finance reform bill this year. There is no excuse. That is the main issue.

THE PRESS: Thank you.

END 9:35 A.M. EST

To comment on this service: *feedback@www.whitehouse.gov*

2-10-98

Suggested Potus remarks on cloning for AAAS

This week Congress turned its attention to a vexing and complicated problem -- what steps should government take to prevent attempts to make a cloned child. No issue better illustrates the conflicting expectations we have for scientists.

On the one hand, we are counting on you to unravel for us the mysteries of human life. On the other hand we need you to preserve our sense that as human beings God has touched us in some indecipherable way. It is a delicate balance to strike.

I have called on Congress to pass legislation that would prohibit for 5 years, cloning experiments designed to produce a human being. But I have insisted that the legislation must be drafted to allow scientists to explore other uses of somatic cell nuclear transfer -- theprocedure used to clone Dolly the sheep last year. In our effort to prevent human cloning, we must not miss the opportunity to revolutionize treatments for diabetes, many cancers, burns, sickle cell anemia, and heart disease.

The Senate decided

Two days ago, in a significant victory for scientific reasoning, 54 Democratic and Republican Senators voted to delay legislation that would have banned all somatic cell nuclear transfer experiments. The fight is not over, and I need your help. I urge you to speak out publicly to provide a sound scientific foundation for this debate.

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I need you to help me do that

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DRAFT – NOT FOR RELEASE

February 4, 1998
(Senate)

SAP

Talk w/ them on Friday

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

On June 9, 1997, the President transmitted to Congress legislation making it illegal for anyone to clone a human being. The President believes that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. The Administration, however, opposes enactment of S. 1601 because it would have the ill-advised effect of permanently impeding significant scientific research in critical areas such as finding cures for diseases, enhancing treatments for infertility, and transplanting tissue and organs.

Instead, the Administration strongly supports enactment of the Feinstein/Kennedy amendment that will be offered as a substitue for S. 1601. The Feinstein/Kennedy amendment, which is based on the President's proposal, would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer, and protect important biomedical research.

Pay-As-You-Go Scoring

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

* * * * * * * * * *

Legislation to Ban Human Cloning
2/05/97

Senators Frist and Bond have drafted legislation that Lott has introduced that bans cloning of human beings. However, it defines an embryo as a single cell zygote, effectively banning all cloning experiments with human cells and blocking research that might someday be conducted to combat diseases such as diabetes and cancer. A number of biotechnology and health groups have objected to the legislation and are lobbying the Senate. We have met with the staffs of Senators Frist and Bond to encourage them to reach a compromise that allows for continued research, and Senators Kennedy and Feinstein have taken the lead with alternative research-friendly legislation. It seems likely that our best hope of compromise is in the Senate as the House position may be more intractable and could potentially involve right to life issues. Our goal is to produce legislation that you could sign. One option may be the addition of a sunset provision that bans human embryo research for a short time, but allows Congress to revisit the issue when scientists may actually be ready to take advantage of this technology for human research. Frist's bill also establishes a new bioethics commission appointed by Congress that would coexist with the one you set up.

2-04-98

COMPARISON OF PROPOSED CLONING LEGISLATION

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Title	Cloning Prohibition Act of 1997	Prohibition on Cloning of Human Beings Act of 1998	Human Cloning Research Prohibition Act	Human Cloning Prohibition Act	Human Cloning Prohibition Act of 1998	Human Cloning Prohibition Act
Sponsor	William Clinton (Not yet sponsored)	Dianne Feinstein (D-CA)	Vernon Ehlers (R-MI)	Vernon Ehlers (R-MI)	Christopher (Kit) Bond (R-MO) Lott	Ben Nighthorse Campbell (R-CO)
Findings	NBAC Report	NBAC Report	none	none	none	Congress finds that the Federal Govt has a moral obligation to the nation to prohibit the cloning of humans.
Purposes	To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and to provide for further review of the ethical and scientific issues associated with its use.	To prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and to provide for further review of the ethical and scientific issues associated with its use.	To prohibit the obligation or expenditure of Federal funds to conduct or support any project of research that includes the use of a human somatic cell nuclear transfer technology to produce an embryo.	To prohibit the cloning of humans.	To prohibit any attempt to create an embryo using human somatic cell nuclear transfer, protect research	To prohibit the cloning of humans.
Definitions	Cloning[1]; Somatic cell[2]; Somatic cell nuclear transfer[3]	Cloning[4], Nucleus[5], Oocyte[6], Somatic cell[7], Somatic cell nuclear transfer[8]	Human somatic cell nuclear transfer[9], Somatic cell[10]	none	Embryo[11], Human somatic cell nuclear transfer[12], Oocyte[13], Somatic cell[14]	Clone & Cloning[15]

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Prohibitions	Unlawful for any public or private individual or entity to perform or use somatic cell nuclear transfer with the intent of introducing the product into a woman's womb or in any other way creating a human being.	Unlawful for any person or other legal entity, public or private, to implant or attempt to implant the product of somatic cell nuclear transfer into a woman's uterus.	Prohibition against obligation or expenditure of Federal funds to conduct or support any project of research that includes the use of a human somatic cell nuclear transfer technology to produce an embryo.	Prohibition against the use of a human somatic cell for the process of producing a human clone.	Unlawful for any person or entity, public or private, to knowingly use human somatic cell nuclear transfer to produce an embryo or to knowingly purchase or sell an ovum, embryo, or fetus for that purpose, or obligate or expend Federal funds on research that includes that purpose.	Unlawful for any person to clone a human being or conduct research for the purpose of cloning a human being or otherwise creating a human embryo; no Federal funds may be obligated or expended to knowingly conduct or support any project of research for the above purposes.
Protected Research	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or the use of somatic cell nuclear transfer techniques to create animals.	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or the use of somatic cell nuclear transfer techniques to create animals.	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, other than human embryo cells, or tissues; or the use of somatic cell nuclear transfer techniques to create animals other than humans.	none	The use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, other than human embryo cells, or tissues; or the use of somatic cell nuclear transfer techniques to create animals other than humans.	none

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Preemption of State Laws	none	Preempt any state law which prohibits or limits research or practices regarding somatic cell nuclear transfer, human cloning, cloning of molecules, DNA, cells, or tissues, the use of somatic cell nuclear transfer techniques to develop animals, or related research.	none	none	none	none
Penalties Specified	Fines (the greater of $250,00 or 2X gross gain or loss), Civil Action by the AG, forfeiture of property derived from or used to commit act.	Fines (the greater of $250,00 or 2X gross gain or loss), Civil Action by the AG, forfeiture of property derived from or used to commit act.	none	Civil money penalty not to exceed $5,000.	Fines, up to 5 years in prison, forfeiture of property from or used to commit violation.	Civil money penalty not to exceed $5,000 for each violation; ineligibility for Federal funds for 5 years after violation.
Effective Date	Date of Enactment--Applies to acts performed within 5 years after that date.	Act is effective for the 10 year period after the its enactment and will terminate at the expiration of 10 years.	none mentioned	none mentioned	none mentioned	none mentioned

Bill Number	(White House)	(Feinstein)	HR 922	HR 923	S 368	S 1574
Provisions for Review	Review by NBAC 4 ½ years after enactment, on the state of the science of somatic cell nuclear transfer, the ethical and social issues associated with the potential use of this technology in humans, and advisability of continuing the prohibition established in the Act.	Review by NBAC 4 ½ years after enactment, on the state of the science of somatic cell nuclear transfer, the ethical and social issues associated with the potential use of this technology in humans, and advisability of continuing the prohibition established in the Act.	Review by NRC in agreement with the Director of NSF, not later than 5 years after the date of enactment, on the impact that the implementation of the Act has had on research and recommendations for any appropriate changes to the Act.	none	Review by Directors of NSF and NIH in agreement with NRC, not later than 5 years after enactment, on the impact that the implementation of the Act has had on research and recommendations for any appropriate changes to the Act.	None
Status	Legislative package was transmitted to Congress on June 9, 1997.		The bill was introduced on March 5, 1997, and jointly referred to the House Committees on Commerce, and Science. Hearings on substitution held July 22, 1997. Marked-up and passed out of the House Science Committee July 29, 1997.	The bill was introduced on March 5, 1997, and jointly referred to the House Committees on Commerce, and Science.		The bill was introduced on January 27, 1998 and referred to the Senate Committee on Labor and Human Resources.

PREPARED BY OSP

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

2. Somatic cell--any cell of the body other than germ cells (eggs or sperm.)

3. Somatic cell nuclear transfer--the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

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

5. Nucleus--the cell structure that houses the chromosomes, and thus the genes.

6.Oocyte–the female germ cell, the egg.

7.Somatic cell–a mature, diploid cell.

8.Somatic cell nuclear transfer–transferring the nucleus of a somatic cell of an existing or previously existing human child or adult into an oocyte from which the nucleus has been removed.

9. Human somatic cell nuclear transfer-- transferring the nucleus of a human somatic cell into an oocyte from which the nucleus has been removed or rendered inert.

10. Somatic cell--a cell of an embryo, fetus, child, or adult which is not and will not become a sperm or egg cell.

11. Embryo–The developing organism from the time of fertilization, or from the time of the single cell stage at the inception of growth and development of an organism, until significant differentiation has occurred.

12.Human somatic cell nuclear transfer–transferring the nucleus of a human somatic cell into an oocyte from which the nucleus has been removed or rendered inert.

13.Oocyte–the mature female germ cell, the egg.

14.Somatic cell–any cell of an embryo, fetus, child, or adult that is not a germ cell or is not destined to become a germ cell.

15.Clone & Cloning–the practice of creating or attempting to create a human being by transferring the nucleus from a human clel from whatever source into a human cell from which the nucleus has been removed for the purpose of, or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being.

Total Pages: 4

LRM ID: RJP190

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

URGENT

Monday, February 9, 1998

LEGISLATIVE REFERRAL MEMORANDUM

TO: Legislative Liaison Officer - See Distribution below

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

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

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

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

DISTRIBUTION LIST

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Janet R. Forsgren
OMB LA

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

RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM

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

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

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

FROM: _____ (Date)

_____ (Name)

_____ (Agency)

_____ (Telephone)

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

_____ Concur

_____ No Objection

_____ No Comment

_____ See proposed edits on pages _____

_____ Other: _____

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

DRAFT

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

Dear Senator Kennedy:

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

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

DRAFT

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

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

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

Sincerely,

Michael A. Friedman
Lead Deputy Commissioner
Food and Drug Administration