NLWJC - Kagan

DPC - Box 006 - Folder 018

Cloning [1]

Cloning
(and)
Health - stem cell research

BRITISH POLICY ON HUMAN CLONING
December 9, 1998

Context: *Today's Washington Post reports that a British scientific panel recommended that research into the cloning of human embryos be permitted in Britain. This follows in the wake of the new advances in culturing embryonic stem cells that dominated the news a few weeks ago, and led to a Senate hearing on the topic last week. The same ethical questions that we are facing on this issue, centering on the creation and destruction of embryos for research, are confronting the British. Britain has a limited ban on embryo research at the present, but does allow both privately and publicly funded research on embryos that are less than 14 days old. This is in contrast to US policy, which bans all public sector research on embryos completely. The British panel was careful to stress that reproductive cloning should never be permitted, but that therapeutic cloning (the production of a cloned embryo for the purpose of isolating stem cells to create replacement tissues) held such significant potential benefits that "it would not be right to rule out limited research" on human cloning techniques.*

General

A British advisory panel recommended that research be permitted into the cloning of human embryos for *therapeutic purposes only.* They recommended that reproductive cloning never be permitted.

The opening paragraph of the article suggests allowing this research could lead to a "genetic spare parts industry for damaged human bodies." This is an inflammatory and inaccurate phrase that infers that cloned human beings would be created as a source of organs. The panel limited its recommendation to permit research on the cloning of human embryos for the production of embryonic stem cells, and specifically stated that the cloned embryos not be used to reproduce a human being.

The article does not indicate how the British government will use the recommendation of the scientific advisory panel for developing policy.

Q. What do you think about the panel's recommendations?

A. The British scientific advisory panel addressed the same questions that the President's National Bioethics Advisory Commission is now considering. We believe that these are important issues from both a biomedical and ethical standpoint that deserve careful consideration, both here and in other nations throughout the world.

Q. Will research on cloning human embryos lead to creating a "genetic spare parts industry?"

A. That is a misleading description of the potential outcome of research on therapeutic cloning. The British panel recommended that research on cloning human embryos be permitted, as a means to generate stem cells that would then be used to generate replacement tissues. They clearly stated their opposition to the cloning of a human being as a source of organs.

Cloning

CLONING COWS
December 9, 1998

Context: *Today's Washington Post reports that Japanese scientists have succeeded in cloning 8 calves from one adult cow. The list of animals that have been cloned includes sheep, mice and now cows. The major newsworthy breakthrough in this report is the efficiency with which these calves were produced. This advance means that cloning animals for agricultural and pharmaceutical purposes is a more practical possibility than it was a year ago. The driving force behind the development of this technology is the desire to create genetically engineered cows that will produce human medicines in their milk.*

General

- Japanese scientists have succeeded in cloning calves from an adult cow using somatic cell nuclear transfer, the same technique that was used to produce Dolly.
- Their success rate was dramatically improved over that reported for Dolly, which brings cloning as a commercial technology much closer to reality.
- Cloning cows is highly desirable in the biotechnology industry as a means to produce large quantities of human medicines in the cow's milk.

Q: What's new in this report?

A: The cloning of cattle isn't new, but this is the first time it has been reported in the scientific literature. An important advance made by these Japanese scientists is the efficiency of their procedures. Where it took hundreds of attempts by Scottish scientists to generate Dolly the sheep, these scientists report success 8 times in 10 attempts. This level of efficiency dramatically opens the possibility of using this technology commercially.

Q: Does this bring us closer to being able to clone humans?

A: We don't know. These techniques might not be as successful for cloning other animals. There is a widely held view and consensus in the scientific community that producing a child using these cloning techniques is morally unacceptable. The president shares this view.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20852-1448

OCT 2 3 1998

Dr. Richard G. Seed
79 East Quincy
Riverside, Illinois 60546-2128

Dear Dr. Seed:

The purpose of this letter is to advise you that the Food and Drug Administration (FDA) has jurisdiction over clinical research using cloning technology to create a human being, and to inform you of the FDA regulatory process that is required before you or any other investigator can proceed with such a clinical investigation. You are receiving this letter because in a number of reports in the media, you are quoted as saying that you are actively pursuing the use of cloning technology to create human beings. As described more fully below, the appropriate mechanism to pursue such clinical investigation using cloning technology is the submission of an investigational new drug application (IND) to FDA.

Clinical research using cloning technology to create a human being is subject to FDA regulation under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. Under these statutes and FDA's implementing regulations, before such research may begin, you as the sponsor of the research are required to submit to FDA an IND describing the proposed research plan; to obtain authorization from a properly constituted institutional review board (IRB); and to obtain a commitment from the investigators to obtain informed consent from all human subjects of the research. Such research may proceed only when an IND is in effect. Since we believe that there are major unresolved safety questions pertaining to the use of cloning technology to create a human being, until those questions are appropriately addressed in the IND, FDA would not permit any such investigation to proceed.

FDA may prohibit a sponsor from conducting a study proposed in an IND application (often referred to as placing the study on "clinical hold") for a variety of reasons. If the Agency finds that "human subjects are or would be exposed to an unreasonable and significant risk of illness or injury," that would be sufficient reason to put a study on clinical hold. Other reasons listed in the regulations include "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."

The procedures and requirements governing the use of investigational new drugs, including those for the submission and review of INDs, are set forth in Title 21 of the Code of Federal Regulations (CFR), Part 312. Additional responsibilities of the sponsor of an IND include: selecting qualified investigators and overseeing the conduct of the investigators; ensuring that the

investigations are performed in accordance with the protocols of the IND; submitting adverse experience reports and annual reports; and other duties as outlined in the regulations. The responsibilities of an investigator include: ensuring that the study is conducted in accordance with the protocols; obtaining informed consent from study participants; and ensuring that an IRB that complies with the requirements of 21 CFR Part 56 reviews and approves the proposed clinical study and the informed consent form and procedures for obtaining informed consent, among other requirements specified in the regulations. Clinical investigators are encouraged to obtain a copy of the current "Information Sheets for IRBs and Clinical Investigators" (which contain useful information regarding clinical investigations) from FDA's Office of Health Affairs (301-827-1685) or FDA's home page on the world wide web (http://www.fda.gov/OHA/IRB/TOC.HTML).

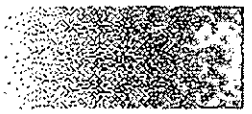
Enclosed is information on submitting an IND to FDA, along with relevant sections of 21 CFR, including Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application). We encourage you to meet with the Agency prior to submitting any IND application. Please contact Wendy Aaronson at 301-827-5101 at FDA's Center for Biologics Evaluation and Research within 14 days of receipt of this letter, to notify us of your intentions regarding the requirements outlined in this letter.

Sincerely,

for Jay Siegel, M.D.
Director
Office of Therapeutics Research
and Review
Center for Biologics Evaluation
and Research

Enclosures

cloning



Jerold R. Mande

07/24/98 03:15:17 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Laura Emmett/WHO/EOP
Subject: Draft cloning ltr.

Here is a draft Potus letter to Congress on cloning. I have included comments from Rachel Levinson in OSTP, and I sent copy to David Beier for his comments, which I will pass on when I receive them. The House is scheduled to take up the Labor, HHS approps bill on Wed.

WJCCLONE.

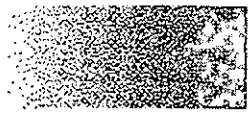
I am writing to ask you to work with me to enact into law this year restrictions that will prevent the cloning of a human being, without disrupting biomedical research. On June 9, 1997, I sent legislation to the Congress that would achieve these goals. My bill was carefully and narrowly crafted to prevent the cloning of a human being, but not interfere with important biomedical research that could lead to meaningful advances in treating illnesses such as cancer and diabetes. Reports this week of the cloning of more than 50 mice adds to the urgency of our task.

As you know, scientists, the public, and policymakers alike were stunned last year by reports that a scientist had cloned an adult sheep. Most experts had previously believed that it was not possible to reprogram the genes of an adult specialized cell. But as has happened so often, human ingenuity pierced old assumptions and provided a new understanding of what is possible. This technology holds great promise. Many scientists and doctors now believe cloning technology can be used to produce cell lines that could result in breakthrough treatments for many dreaded illnesses such as replacing a failing organ without the need for a donor or the risk of tissue rejection.

But the new technology also poses difficult moral questions. Scientific advancement should not occur in a moral vacuum. Technological developments divorced from values will not bring us one step closer to meeting the challenges of the next millennium. Virtually everyone agrees that the use of new cloning techniques to create a human being is untested, unsafe, and morally unacceptable.

This week's reports on the advances in cloning technology make it important that we set aside politics and send a clear message that cloning a child is not an acceptable endeavor. I am concerned that efforts to address other moral questions, such as when does human life begin, in cloning legislation are endangering our chances of passing a bill this year. We have the opportunity to pass cloning legislation in the next two months. But we will only succeed if we stay focused on prohibiting the cloning of human beings, and not try to resolve other moral conundrums.

Cloning



Jerold R. Mande

07/27/98 12:48:50 PM

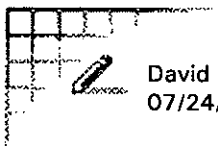
Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Re: Draft cloning ltr

fyi

---------- Forwarded by Jerold R. Mande/OSTP/EOP on 07/27/98 12:48 PM ----------



David W. Beier @ OVP
07/24/98 03:59:06 PM

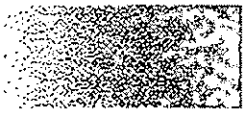
Record Type: Record

To: Jerold R. Mande/OSTP/EOP

cc:
Subject: Re: Draft cloning ltr

A couple of points. In my view the letter fails to identify the positives of biomedical research in this area (see the Jones memo to the President). Second, the letter fails to note or comment on the Kennedy Feinstein bill expressly, nor does it comment on the negatives associated with the other efforts and why they would be problematice. Finally, the letter is eliptical on the question of interfering with human embryo research. I know that there is a ban on the use of federal funds, but what is our view about the House effort to ban that conduct in the private sector.

Cloning



Jerold R. Mande

07/28/98 05:33:27 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP, Elena Kagan/OPD/EOP

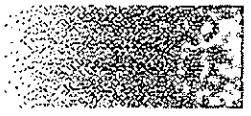
cc:

Subject: Cloning next steps.

I checked with Mike Friedman about FDA actions to support its April cloning jurisdiction statement. He is already exploring possible FDA next steps. He has a group looking at actions, such as writing to IRBs, professional societies, and individuals like Seed, to make certain FDA's requirements will be followed. He will let us know what he finds. Mike was also very confident in FDA's analysis of its cloning jurisdiction. He thought the Post's story questioning FDA's authority was flawed and easy to poke holes through.

One step we might take while we continue to monitor the Hill and while we see what Mike delivers, is to encourage our allies in the patient and biotech communities to remind Congressional leaders of their concerns with cloning legislation favored by many Rs.

Cloning



Jerold R. Mande

07/23/98 07:17:48 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Laura Emmett/WHO/EOP
Subject: Cloning update

I have monitored reaction to the Hawaiian mouse story. I spoke to experts usually contacted by the press on cloning stories, and I spoke to House D staff tracking cloning legislation. The story may not have legs. Even though it lead both the NYTs and WP, and Lee Silver's sensational quotes were everywhere, I was told press reaction is at least an order of magnitude calmer than when Dolly was news. Cloning did not come up in McCurry's briefing.

As for Congress, House Approps reported out the Labor, HHS bill earlier this week. It is a likely vehicle should the House leadership want to try something. I am checking on when it might come to the floor. One thing we should consider doing is urging the patient groups to remind Congressional leaders that they are still closely following this issue and will strongly object to legislation that restricts important biomedical research.

Do you want me to set up an internal meeting to discuss next steps and plan strategy, or should we wait until next week and see how the story plays? I will get you the draft letter in the morning.

cloning

DEPARTMENT OF HEALTH & HUMAN SERVICES

EK -
Background on
① How FDA Controls
Cloning

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

April 16, 1998

FDA's Jurisdiction Over Human Cloning Activities

② Letter by Shalala on current policy.

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

Cloning

Rachel E. Levinson 03/25/98 11:34:16 AM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: cloning meeting

Jerry tells me that you will be there and run the meeting. David Korn is hosting a meeting this morning to prepare for our meeting. They are discussing a proposal along the lines we had discussed earlier that combines FDA regulatory authority with case-by-case review by a body similar to NIH's Recombinant DNA Advisory Committee (RAC).

This morning I heard of a possible scenario involving attaching a cloning amendment to an NIH appropriations bill. In the worst case, there would be no tobacco money and a continuing resolution until the last minute when an unvetoable bill would come in with cloning attached. Sounds like business as usual.

Cloning

Rachel E. Levinson 03/24/98 03:35:31 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Cloning Meeting - Draft List, not final.

The cloning meeting is shaping up nicely. Are you planning to attend? Given the extensive cast of characters, I think it would be well if you could at least open the meeting. Other wise, Jerry and I will manage. There does not seem to be much action on cloning on the Hill. Although Armey had asked for a bill by Easter, I just heard that they have not made much progress. The Senate also does not seem anxious to move on a bill. Obviously, industry would be happier without a bill.

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 03/24/98 03:27 PM ----------

Barbara D. Woolley
03/23/98 07:46:27 PM

Record Type: Record

To: Rachel E. Levinson/OSTP/EOP, Jerold R. Mande/OSTP/EOP

cc:
Subject: Cloning Meeting - Draft List, not final.

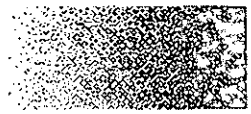
Any comments on the list, call me at 62155.

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

Cloning



Jerold R. Mande

03/10/98 08:14:53 PM

Record Type: Record

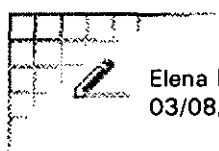
To: Elena Kagan/OPD/EOP
cc:
bcc:
Subject: Re: Cloning update.

We are trying to schedule the groups meeting. I told Barbara Woolley you would chair it. Barbara is waiting to get a time on your schedule. We are trying for next week.

Kennedy's staff see no movement in the Senate at this time. They are standing firm with their bill and waiting for the Rs to come to them.

In the House there are rumors of an Armey bill, but no details. House D staff also don't expect movement soon.

I am working with my contacts among bioethicists to find religious leaders who would be willing to speak up on our side.
Elena Kagan



Elena Kagan
03/08/98 01:37:30 PM

Record Type: Record

To: Jerold R. Mande/OSTP/EOP

cc:
Subject: Re: Cloning update.

what happened to this meeting?
amything else I should know about?
what's the most recent legislative gossip?

Cloning

3/11/98

Elena:

I want to give you a heads up about a March 26 National Health Council forum in which I will participate entitled, "Cloning: What it Means for Patients." I will be on the last panel with congressional staff, NIH and FDA. My intent is to:

- discuss the President's charge to NBAC, their deliberations and resulting report;
- describe the elements of the President's draft legislation (banning the creation of human beings through somatic cell nuclear transfer cloning technology, protecting research, encouraging further public discussion through the sunset); and
- note that there is more than one way to skin a cat (not in so many words!) and that we look forward to continuing to work with Congress to reach the best possible means for promoting the principles stated above.

Please let me know if you have any suggestions about my presentation, which I expect to be very brief (under 15 minutes).

The National Health Council is a private, nonprofit association of more than 100 national health care organizations, but the forum audience will be limited to patient-based organizations. The Council is one of the groups we hope to have at our meeting with cloning stakeholders.

Incidentally, I will be out town next week on Wed. through Friday. I understand that Barbara Woolley is working to set up our meeting and hope that my schedule won't interfere with my participation. I would suggest that IIHS also be invited.

Rachel

NATIONAL HEALTH COUNCIL

1730 M Street, NW
Suite 500 • Washington, D.C. 20036-4505
(202) 785-3910 • Fax (202) 785-5923

"Cloning: What it Means for Patients"

March 26, 1998

Current advances in medical research are, for the first time, holding true promise of curing some of the most well-known diseases: cancer, diabetes, and paralysis. Cloning, the duplication of scientific material, such as cells or genes, has allowed scientists to more efficiently study biological processes. The novel technique used to create the sheep Dolly may hold the key not only to understanding the function of human cells but also lead to new avenues to repair damaged cells, effectively curing disease. Combined with gene therapy, cloning may make it possible to eliminate the transmission of such inherited diseases as Cystic Fibrosis.

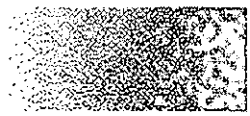
However, the emergence of this new technology has raised important questions. For example, what are the ethical issues relating to cloning? What role has the media played in the recent debate? How will anti-cloning legislation impact the development of potential treatments and cures for those with serious disease?

To answer these questions, the National Health Council will hold a one-day forum for representatives of patient-related organizations. The forum, **"Cloning: What It Means For Patients,"** will feature researchers, biocthicists, journalists, and policy makers. While there is near unanimous consensus in the United States that we do not want to clone human beings, there is controversy about how to express this consensus in ways that do not negatively affect the ability of biomedical researchers to find cures for diseases and conditions such as diabetes, cancer, Huntington's Disease, AIDS and others.

The National Health Council's membership reflects the breadth of the health care community. The Council's core membership includes over 40 of the nation's leading patient organizations, including the American Cancer Society, American Heart Association, Arthritis Foundation, Juvenile Diabetes Foundation International, and American Autoimmune Related Diseases Association. Other members include provider organizations, biopharmaceutical and medical device companies and managed care companies. It is the Council's mission to encourage and assist its membership to work together to improve the health of all Americans, particularly those with chronic diseases and/or disabilities.

The Council is uniquely positioned to bring together all segments of the health care community to address key issues. This event will be an important step in resolving some of the critical issues relating to cloning.

Cloning



Jerold R. Mande

01/30/98 08:30:16 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Thomas L. Freedman/OPD/EOP
Subject: Cloning

Our goal on cloning should be to ensure the President receives a bill he can sign. The legislative strategy I recommend we pursue to reach our goal is to work with the Senate Republican leadership to develop a cloning bill the President can publicly support. Currently, the House Republican leadership appears set on using cloning legislation to score points with the religious right. They will pass an irresponsible bill that prohibits all embryo research, send it to the Senate and let the Senate fix it. The Senate Republican leadership is currently working with Bond and Frist and could end up introducing an irresponsible bill. But given Frist's medical background and the presence of moderate Republicans such as Jeffords, Chafee, Collins, and Snowe, there is some chance that our efforts, along with a concerted effort by the biotech industry, could convince the Senate Rs to take a more moderate path.

Substantively, there are two approaches we should consider for producing a compromise with the Senate Republican leadership: sunset and exemptions. At issue is human cloning research that involves creating an embryo that will not be implanted. This research is scientifically important because it could help scientists develop exciting new therapies for a number of diseases. For example, it may be possible to cure diabetes using somatic cell nuclear transfer (SCNT). This could be done by taking a somatic cell from a diabetic patient, using SCNT to return the cell to its unspecialized state, correcting the genetic error, growing new pancreas cells, and transplanting them into the patient. Because the replacement cells would be genetically identical to the patient (since they were cloned), there would be no problem with rejection -- the reason most current organ and tissue transplants fail.

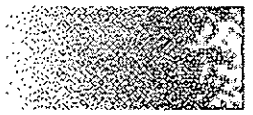
Sunset -- This approach preserves important avenues of scientific research by buying us time until animal research provides us a better sense of the value of the technology. As long as the prohibition is limited in time we can accept more onerous restrictions, possibly even a total prohibition, since scientists must do a lot more animal research before human research would be valdable. Five years is probably the right length for the moratorium, although Feinstein has publicly talked about ten.

Exemptions -- This approach preserves important avenues of scientific research by exempting potentially life-saving research. Creating a SCNT embryo would be prohibited unless the research was designed to treat or prevent a serious or life-threatening disease. The problem with this approach is that we may miss an important exemption and would need an act of Congress to provide it.

We need to do more work to figure out which approach works best -- substantively and politically.

Regardless of the approach we take, we should reach out to the Senate Rs asap. If nothing else it may slow down the introduction of their bill, and provide industry and science groups more time to press their case.

Cloning



Jerold R. Mande

03/02/98 03:12:37 PM

Record Type: Record

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

cc:

Subject: Cloning update.

I spoke to an industry representative about recent cloning-related events, especially events on the Hill, and here is what I was told. There was a meeting between Republican leadership staff and representatives from the pharmaceutical and biotechnology industry. Republican staff complained loudly about the industry's efforts to defeat Republican sponsored cloning legislation. As a result of that meeting, and because industry staff had not yet had a chance to confer with their boards, industry staff were unusually quiet during sessions that had been previously scheduled with House and Senate Democratic staff. Industry staff did then meet with their boards and the bottom line was that there would be no sea change in their opposition to current cloning legislation. Industry staff were instructed to be more respectful in their opposition.

Several other points: 1) Industry representatives who have been working the Hill don't perceive a rush at this point by Republicans to bring up cloning legislation. In fact, House Republican's who are trying to craft legislation are struggling with what should be prohibited. 2) It would be helpful if we held a meeting with our allies to shore up our base (because of scheduling conflicts, we are now trying to set up a meeting for next week). 3) Genentech's CEO asked the President about cloning while the President was in SF. The President said he supported the Feinstein/Kennedy approach, but urged the industry to reach out to Frist (have we heard from our people what was said in this conversation?). 4) The industry is interested in the advisory committee approach to oversee reasearch. This approach would be modeled after NIH's recombinant-DNA committee that oversees gene therapy research and it would be combined with FDA regulation.

Message Sent To:

Elena Kagan/OPD/EOP
Donald H. Gips/OVP @ OVP
Rachel E. Levinson/OSTP/EOP
Jeffrey M. Smith/OSTP/EOP
Lucia A. Wyman/WHO/EOP
William P. Marshall/WHO/EOP

Cloning

① Le Her
② FASEB Caution on leg.
③ Bio's bill analysis

Rachel E. Levinson 02/04/98 01:23:21 PM

Record Type: Record

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

cc:

Subject: draft cloning letter for discussion at 4 today

I commend you on your introduction of S. 1602 the "Prohibition on Cloning of Human Beings Act of 1998." If enacted, this bill 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. The bill, which closely parallels the bill I submitted last June, also follows the findings and recommendations presented to me by my National Bioethics Advisory Commission. I said then and reaffirmed this belief in my January 10 radio address that using somatic cell nuclear transfer cloning techniques to clone a human being is untested, unsafe, and morally unacceptable. I called on Congress to enact legislation making it illegal for anyone to clone a human being at this time. I am pleased to see your response to my challenge.

Trying to draft a bill that walks the fine line between defining the unacceptable act of producing a child that is the genetic replica of another person, while protecting biomedical and agricultural research is a formidable task. My bill offered one way to achieve those dual goals; your bill clearly reaches for the same result. In this case, imprecise wording carries the threat of impeding research that might one day offer hope to those suffering from spinal cord injury, Parkinson's disease, diabetes or AIDS. We must not make such a mistake in our haste to close the doors to those who would subvert this promising new technology by using it for unethical purposes.

I am also pleased that you have heeded my proposal to put a time limit on this prohibition. The sunset provision ensures a continuing examination of the risks and benefits of this technology, while we are free from worry that someone will use it prematurely.

Society shouldn't make decisions about the application of a specific technology without first understanding its full potential, both good and bad. Asking the National Bioethics Advisory Commission to return to this complex issue in four and one-half years will promote a deeper awareness of the power we hold to alleviate the burden of human illness and a broader debate on the ethical and moral limits we ought to impose on exercising that power. We are not ready to answer these enormously challenging questions today.

That is why we must act now to reassure the public that this government will not tolerate anyone using somatic cell nuclear transfer to create a child. I thank you for your efforts on

behalf of the American people and look forward to signing this bill.

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

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

Rachel E. Levinson 02/03/98 04:35:24 PM

Record Type: Record

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

cc:
Subject: BIO's analysis

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 02/03/98 04:34 PM ----------

cludlam @ mail.bio.org
02/03/98 02:31:57 PM

Record Type: Record

To: levinson

cc:
Subject: analysis

ANALYSIS OF BOND/FRIST/GREGG
HUMAN CLONING BILL

First Issue: The Bond/Frist/Gregg human cloning bill bans the act of "producing an embryo (including a preimplantation embryo)" through the use of a specified technology (somatic cell nuclear transfer). It would ban the production of this embryo even if the production of such an embryo is for purposes completely unrelated to the cloning of a human being.

The bill, therefore, would effectively ban some research to generate stem cells for the following types of treatments:

cardiac muscle cells to treat heart attack victims and degenerative heart disease;

skin cells to treat burn victims;

spinal cord neuron cells for treatment of spinal cord trauma and paralysis;

neural cells for treating those suffering from neurodegenerative diseases;

pancreas cells to treat diabetes;

blood cells to treat cancer anemia, and immunodeficiencies;

neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS);

cells for use in genetic therapy to treat 5,000 genetic diseases, including Cystic Fibrosis,

Tay-Sachs Disease, schizophrenia, depression, and other diseases;
blood vessel endothelial cells for treating atherosclerosis;
liver cells for liver diseases including hepatitis and cirrhosis;
cartilage cells for treatment of osteoarthritis;
bone cells for treatment of osteoporosis;
myoblast cells for the treatment of Muscular Dystrophy;
respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer;
adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration;
modified cells for treatment of various genetic diseases; and
other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions.
To be precise, the bill would ban the generation of stem cells for these purposes where the stem cells have nuclear DNA from a "human somatic cell" -- see critical discussion below and somatic cell nuclear transfer technology was used.

It would not ban stem cell research where the stem cell is generated without the use of somatic cell nuclear transfer or does not involve nuclear DNA from a "human somatic cell" -- again, see the critical discussion below.

If the legislation is limited to somatic cells with nuclear DNA identical to that of an existing or previously exisiting human being -- again, see critical discussion below -- the specific type of stem cells research which is banned is "customized" stem cell research. A researcher or doctor might want to create a human zygote with DNA identical to that of an existing or previously existing person through the use of somatic cell nuclear transfer -- the act prohibited in the Bond/Frist/Gregg bill -- in order to create a customized stem cell line to treat the individual from whom the DNA was extracted. By using the same DNA the stem cell would be more likely to be compatible and not rejected by the person when the stem cell is transferred (back) to the person for the treatment.

The statement released by Senators Bond/Frist/Gregg about the impact of their bill on biomedical research is technically accurate but highly misleading. The title of the document is "CURRENT RESEARCH UNTOUCHED BY THE BOND/FRIST/GREGG LEGISLATION" and it is followed by a list of such research, including "In Vitro Fertilization," "Stem Cell Research," "Gene Therapy," "Cloning of Cells, Tissues, Animals and Plants," "Cancer," "Diabetes," "Birth Defects," "Arthritis," "Organ Failure," "Genetic Disease," "Severe Skin Burns," "Multiple Sclerosis," "Muscular Dystrophy," "Spinal Cord Injuries," "Alzheimer's Disease," "Parkinson's Disease," and "Lou Gehrig's Disease." The title to this document includes a critical qualification -- an asterisk. The asterisk qualification states, "The Bond/Frist/Gregg bill would not prohibit any of this research, even embryo research, as long as it did not involve the use of a very specific technique (somatic cell nuclear transfer) to create a live cloned human embryo."

This qualification swallows the list. It acknowledges that the bill would, in fact, ban some types of stem cell research and other research, as explained above. Given the importance of the asterisk, the title to the document and the list of protected research are highly misleading.

The statement of Senators Bond/Frist/Gregg is a challenge to patient disease groups to seek to include in the legislation a specific guarantee that research on the diseases they list is not, in fact, stifled. Such an exemption might read as follows:

"NOTHING IN THIS ACT shall apply where the acts or research are for the purpose of producing or generating stem cells to treat or diagnose deadly or disabling diseases and other medical conditions including the following: cardiac muscle cells to treat heart attack victims and degenerative heart disease; skin cells to treat burn victims; spinal cord neuron cells for treatment of spinal cord trauma and paralysis; neural cells for treating those suffering from neurodegenerative diseases; pancreas cells to treat diabetes; blood cells to treat anemia, immunodeficiencies, and cancer; neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS); cells for use in genetic therapy to treat 5,000 genetic diseases, including Cystic Fibrosis, Tay-Sachs Disease, schizophrenia, depression, and other diseases; blood cells for use in treating patients with cancer, anemia, or immunodeficiency diseases; blood vessel endothelial cells for treating atherosclerosis; liver cells for liver diseases including hepatitis and cirrhosis; cartilage cells for treatment of osteoarthritis; bone cells for treatment of osteoporosis; myoblast cells for the treatment of Muscular Dystrophy; respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer; adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration; modified cells for treatment of various genetic diseases; and other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions; or for the purpose of conducting scientific research into the mechanisms of interaction between the genes and their intracellular and extracellular environments in order to control and redirect the specialization of somatic cells into novel treatments or diagnostic products for deadly or disabling diseases and other medical conditions."

If Senators Bond/Frist/Gregg are, in fact, determined to protect this research, they could not object to including this explicit guarantee in their bill.

The stem cell technology is exciting and potentially revolutionary. Scientists are developing an entirely new approach for treating human diseases that depend not on drugs like antibiotics but on living cells that can differentiate into blood, skin, heart, or brain cells and potentially treat cancers, spinal cord injuries, or heart disease. This research -- called stem cell research -- holds the potential to develop and improve cancer treatments by gaining a more complete understanding of cell division and growth and the process of metastasis. This could also lead to a variety of cancer treatment advances.

The kinds of cells that make up most of the human body are differentiated, meaning that they have already achieved some sort of specialized function such as blood, skin, heart or brain cells. The precursor cells that led to differentiated cells come from the embryo. They are called stem cells because functions stem from them like the growth of a plant. Stem cells have the capacity for self-renewal, meaning that they can produce more of themselves, and differentiation, meaning that they can specialize into a variety of cell types with different functions. In the last decade, scientists studying mice and other laboratory animals have discovered powerful new approaches involving cultured stem cells. Studies of such cells obtained from mouse stem cells show that they are capable of differentiating in vitro or in vivo into a wide variety of specialized cell types. Stem cells have been derived by culturing cells of non-human primates and promising efforts to obtain human stem cells have also recently been reported.

Stem cell research has been hailed as the "[m]ost tantalizing of all" research in this field. The reason for this is because adults do not have many stem cells. Most cells are fully differentiated into their proper functions. When differentiated cells are damaged, such as cardiac muscle when someone suffers a heart attack, the adult cells do not have the ability to regenerate. If stem cells could be derived from human sources and induced to

differentiate in vitro, they could potentially be used for transplantation and tissue repair.

Using the heart attack sufferer as an example, we might be able to replace damaged cardiac cells with healthy stem cells that could differentiate into cardiac muscle. Research with these stem cells could lead to the development of "universal donor cells" of invaluable benefit to patients. Stem cell therapy could make it possible to store tissue reserves that would give health care providers a wholly new and virtually endless supply of the cells listed above. The use of stem cells to create these therapies would lead to great medical advances. We have to be sure that nothing we do in this legislation concerning human cloning would obstruct in any way this vital research.

Second Issue: The bill bans the use of somatic cell nuclear to transfer a "human somatic cell" but it does not state that this is limited to somatic cell which contains nuclear DNA identical to that of an existing or previously existing person. This means that the bill is not limited to cloning (creating a person or embryo with nuclear DNA identical to that of someone else), but would also apply to the use of somatic cell nuclear transfer of nuclear DNA which is not identical. It would, in fact, prohibit the use of somatic cell nuclear transfer where the nuclear DNA is the product of normal, sexual reproduction -- that is the opposite of cloning. It would also prohibit the use of somatic cell nuclear transfer where the somatic cell had been modified in some way prior to the use of somatic cell nuclear transfer. In short, the bill prohibits a broad range of uses of somatic cell nuclear transfer having nothing whatever to do with cloning, such as use of this technology to treat mitochondrial disease.

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
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William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

Rachel E. Levinson 02/03/98 03:53:58 PM

Record Type: Record

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

cc:
Subject: Bond bill

I have copies of the Bond bill available in Room 436. It is unclear in intent but appears to prohibit a much broader range of activities than our June draft. It has internal inconsistencies that would appear to make it difficult to determine if any research involving the use of human cells in somatic cell nuclear transfer might be carried out. The bulk of the language is devoted to establishing a Commission to promote a national dialogue on bioethics.

I hope to get a draft letter on Kennedy-Feinstein around shortly. That bill will dropped "shortly" but probably not today.

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
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William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

Cloning

SCIENTIFIC ANALYSIS OF CLONING BILL PROPOSED BY SENATOR FEINSTEIN

A BILL

To prohibit any attempt to create a human being using somatic cell nuclear transfer, to provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in human beings, and for other purposes.

The phrase "attempt to create a human being" could be interpreted by certain factions as an attempt to create an embryo, although this distinction is cleared up in the prohibitions section.

SECTION 1. Short Title

This Act may be cited as the "Prohibition on Cloning of Human Beings Act of 1998".

This title is succinct and accurate, unlike the titles of other bills, such as the "Human Cloning Prohibition Act" which could imply prohibition of inadvertent twinning of some infertility treatments.

SEC. 2. Findings

This section accurately recounts the findings of the NBAC on cloning.

SEC. 3. Purposes.

It is the purpose of this Act to–

(1) prohibit any attempt to create a human being using somatic cell nuclear transfer cloning; and

(2) provide for further review of the ethical and scientific issues associated with the use of somatic cell nuclear transfer in humans.

Once again, the phrase "attempt to create a human being" could be interpreted by certain factions as an attempt to create an embryo.

SEC. 4. Definitions.

In this Act:

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

Some scientists might argue that cloning is not a "precise" genetic copy, due to the invariable mistakes made in replicating DNA, and some would argue that a human is an animal, but this definition does not pose any negative implications for research.

(2) Nucleus– the cell structure that houses the chromosomes, and thus the genes.

Accurate for the purposes of this Act, but there are genes outside of the nucleus (mitochondrial genes.)

(3) Oocyte–the female germ cell, the egg.

Would this definition include immature oocytes? If it did not, this could possibly allow somatic cell nuclear transfer to create a human being to take place with an immature oocyte.

(4) Somatic cell–a mature, diploid cell.

Not entirely clear what "mature" means. If it means "differentiated" this would allow somatic cell nuclear transfer to create a human being using an undifferentiated embryo cell, which could allow for treatment of infertility due to mitochondrial diseases.

(5) 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.

This language could allow (if one does not consider an embryo an existing human child) the use of this technology to treat infertility due to mitochondrial defects. Perhaps a small point of semantics, but does "transferring the nucleus of a somatic cell" include the fusion of a somatic cell with an oocyte? This is how Dolly was created. Perhaps could clarify by adding "or fusion of a somatic cell with an oocyte from which the nucleus..."

SEC. 5. Prohibition.

It shall be 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.

This prohibition clearly states the scientific intent of the legislation, and avoids the question of when life begins or what "creating a human being" really means. It also clearly prohibits an act or an attempt at action, which is easy to assess, rather than an "intent" to act. This would protect researchers and others from being second-guessed about their intentions. This would allow the private sector to use somatic cell nuclear transfer technology to develop therapeutic cell lines for the treatment of many disorders via tissue transplantation. If the definition of somatic cell is interpreted as a differentiated diploid cell, and if "existing human child" is not interpreted to include an embryo, this would also allow the use of this technology to treat infertility due to mitochondrial diseases. One possible concern is that this would not prohibit attempts to implant such a product to an animal's uterus.

SEC. 6. Protected Biomedical Research.

Nothing in this Act shall be construed to restrict areas of biomedical and agricultural research or

practice not expressly prohibited in this Act, including research or practices that involve–

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals.

The inclusion of the phrase "or practices" protects activities such as animal husbandry or IVF that may not be considered research. Allowing the use of this technology "to clone molecules, DNA, cells, and tissues" would allow the private sector to pursue this technology to develop therapeutic tissues as mentioned above. Allowing the use of this technology to create animals will allow the continuation of a thriving research base in animal husbandry and transgenic animals for the production of therapeutic products and animal models. However, as mentioned previously, one could argue that a human being is an animal.

SEC. 7. Penalties.

(a) In General–Any person who intentionally violates the provision of section 5 shall be fined the greater of $250,000 or 2 times the gross pecuniary gain or loss resulting from the violation.

(b) Civil Actions–If a person is violating or about to violate the provisions of section 5, the Attorney General may commence a civil action in an appropriate Federal district court to enjoin such violation.

(c) Forfeiture–any property, real or personal, derived from or used to commit a violation or attempted violation of the provisions of section 5, or any property traceable to such property, shall be subject to forfeiture to the United States in accordance with the procedures set forth in chapter 46 of title 18, U.S. Code.

(D) Authority–The Attorney General shall have exclusive, nondelegable enforcement authority under this Act.

(E) Advisory Opinions–The Attorney General shall, upon request, render binding advisory opinions regarding the scope, applicability, interpretation, and enforcement of this Act with regard to specific research projects or practices.

This section uses phrases such as "attempted violation." The prohibition already includes the attempt to implant the product to a uterus. Would this then allow civil actions or forfeitures of "attempts at attempts" and would this lead to the difficult question of intentions on a researcher's part?

SEC. 8. Cooperation with Foreign Countries.

It is the sense of Congress that the President should cooperate with foreign countries to enforce mutually supported restrictions on the activities prohibited under section 5.

SEC. 9. National Bioethics Advisory Commission Report.

Not later than 4 ½ years after the date of enactment of this Act, the National Bioethics Advisory Commission shall prepare and submit to the President a report concerning–

(1) the state of the science of somatic cell nuclear transfer;

(2) the ethical and social issues associated with the potential use of this technology in

humans; and

(3) the advisability of continuing the prohibition established in the Act.

The Commission is authorized to continue for the 10-year period described in section 12 to prepare such a report and for other purposed as established in Executive order 122975 and subsequent amendments to such Order.

Suggest adding provisions for additional review by NBAC after the initial report, particularly since the first report may still find insufficient scientific evidence of safety. Language could state "Not later than 4 ½ years after the date of enactment of this Act, and at intervals after that as necessary,..." Perhaps could broaden the nature of the report to include the state of the science of cell and tissue therapies to further investigate the potential for this technology. "Executive order 122975" may include a typo–NBAC's Website states the EO number as 12975.

SEC. 10. Right of Action.

Nothing in this Act shall be construed to give any individual or person a private right of action.

SEC. 11. Preemption of State Law.

The provisions of this Act shall 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.

This would prohibit poorly written State laws from prohibiting the cloning of DNA, cells or tissues (as a recent Florida bill would have done) or from prohibiting the private sector from investigating this technology for the development of therapeutic tissues or cells.

SEC. 12. Effective Date.

This Act shall be effective for the 10 year period beginning on the date of enactment of this Act. The prohibitions contained in this Act shall terminate at the expiration of such10-year period.

Cloning

Rachel E. Levinson 02/11/98 01:08:09 PM

Record Type: Record

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

cc:
Subject: Varmus Qs and As

HHS has asked for our assistance in preparing answers for two questions Varmus may get a the House Commerce hearing tomorrow.

1. Why does the Administration's bill call for civil and not criminal penalties?

Bill - could you take a crack at this and e:mail me a response?

2. How does the Administration reconcile allowing the creation of embryos for research purposes in the private sector, but not using Federal funds?

One option for answering this question could be the following:

The Administration bill does not address the issue of embryo research. It prohibits the use of somatic cell nuclear transfer to create a human being. We will not resolve the debate over embryo research in the immediate future, but we do want to move to ensure that cloning technology is not use prematurely to create a child.

However, there are scientific applications of somatic cell nuclear transfer that are worth pursuing, as described in Dr. Varmus' testimony. Depending on one's definition of an embryo, some may feel that this research would, indeed, entail the creation of embryos.

We do not have a consensus in this country on whether or not it is acceptable to create embryos for research purposes. Therefore, in 1994, the President issued a statement directing the National Institutes of Health not to fund research involving the creation of human embryos. However, the government does not have a compelling reason to prohibit such activities if they are done using private funds. Therefore, if a couple wants to pursue a novel method for treating their infertility problems, and has the means to do so, they are free to pay for such services in a private clinic[, subject to appropriate FDA regulation].
This is similar to the way we treat alcohol. Many people have a strong belief that alcohol consumption is forbidden. Those people do not buy alcohol and, out of respect for that belief, we do not use taxpayers' dollars for the purchase of alcohol. However, the beliefs of some are not cause for the government to issue a broad prohibition against the sale and consumption of alcohol by others. We do not restrict liberty without a strong compelling reason to do so. It appears that we do have a consensus against using cloning technology to create human beings and our proposed ban supports that sentiment.

The SAP speaks in support of stem cell research which might be interpreted to include creating embryos for research purposes. Also, the Bond bill does not distinguish between public and private

activities. Therefore, we might ask Harold Varmus to clarify by saying that the SAP does not trump the 1994 statement and that the ban on using Federal funds to create embryos still stands.

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

Cloning

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

Cloning

Rachel E. Levinson 02/04/98 06:46:30 PM

Record Type: Record

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

cc:
Subject: Adhoc: Cloning Legislation

here's an example of mobilizing the forces
---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 02/04/98 06:45 PM ----------

owner-adhoc @ aamcinfo.aamc.org
02/04/98 04:20:00 PM

Record Type: Record

To: Rachel E. Levinson

cc:
Subject: Adhoc: Cloning Legislation

Colleagues:

I am writing to bring everyone up to speed on the status of the anti-cloning legislative proposals, and to ask for help. Please note that while I am borrowing the Ad Hoc Group's List Serve capacity, I am not speaking for the Ad Hoc Group.

Senators Feinstein and Kennedy have introduced a bill (S 1602) as has Senator Bond (S 1599). Bonds has been re-introduced with Sen. Lott as main sponsor (S. 1601) in order to make it a leadership bill.

The Bond bill prohibits the use of somatic cell nuclear transfer technology. It prohibits the use of this technology to produce an embryo from the earliest stages, but it does not define the term somatic cell anywhere.

The Kennedy/Feinstein Bill contains clear definitions, has a federal preemption, has a sunset in 10 years, and it makes illegal any attempt to implant an embryo produced from cloning into a woman's uterus.

We think the Bond bill is very dangerous for the medical research community. It makes the use of a specific technology in medical research a federal crime, punishable by 10 years in prison.

Its broad prohibition and imprecise wording endanger many areas of medical research including gene therapy and stem cell research. It also

poses risks for several promising infertility treatments.

We expect an attempt to bring the Bond (now the Lott) bill to the floor of the Senate as early as Thursday, and certainly by early next week.

I hope that regardless of where you or your organization stand on cloning or cloning legislation, you will at least object to the bringing this measure to the floor in such a hurry. I would urge you to contact members of the Senate and ask them to avoid acting on this with such haste and instead deal with this matter in the serious deliberative manner it deserves.

Please feel free to contact me with questions or comments.

Sean Tipton
American Society for Reproductive Medicine
202-863-2494

Cloning

DRAFT – NOT FOR RELEASE

February 4, 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, 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.

****

1) has concerns about?

2) 5-yr ?

Cloning

(

Is it there? try to find it?

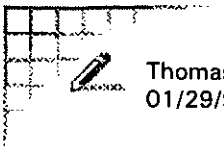
→ [Substantive solution – that can pass pol muster?

OR: keep a procedural issues – smart, more of all

cloning to create a l.b.

Smart people → Talk to our legislature or anyone else around up?

Cloning



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.

Clinins

Rachel E. Levinson 02/04/98 05:20:54 PM

Record Type: Record

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

cc:
Subject: amendments

Possible amendments include:

- Adding sunset (preferably 5 years as in Administration bill)
- Adding a list of exceptions like the following:

["( ) Subsection [( )] and [( )] shall not apply where the creation of the embryo is for the purpose of producing or generating stem cells to treat or diagnose deadly or disabling diseases and other medical conditions including the following: cardiac muscle cells to treat heart attack victims and degenerative heart disease; skin cells to treat burn victims; spinal cord neuron cells for treatment of spinal cord trauma and paralysis; neural cells for treating those suffering from neurodegenerative diseases; pancreas cells to treat diabetes; blood cells to treat anemia, immunodeficiencies, and cancer; neural cells to treat Parkinson's, Huntington's and amyotrophic lateral sclerosis (ALS); cells for use in genetic therapy to treat 5,000 genetic diseases, including cystic fibrosis, Tay-Sachs disease, schizophrenia, depression, and other diseases; blood cells for use in treating patients with cancer, anemia, or immunodeficiency diseases; blood vessel endothelial cells for treating atherosclerosis; liver cells for liver diseases including hepatitis and cirrhosis; cartilage cells for treatment of osteoarthritis; bone cells for treatment of osteoporosis; myoblast cells for the treatment of Muscular Dystrophy; respiratory epithelial cells for the treatment of cystic fibrosis and lung cancer; adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration; modified cells for treatment of various genetic diseases; and other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions; or for the purpose of conducting scientific research into the mechamisms of interaction between the genes and their intracelluar and extracellular enviroments in order to control and redirect the specializiation of somatic cells into novel treatments or diagnostic products for deadly or disabling diseases and other medical
conditions.]

- Penalties--delete criminal and insert the following:

(c) Any property, real or personal, derived from or used to commit a violation or attempted violation of Section 5, or any property traceable to such property, is subject to forfeiture to the United States in accordance with the procedure set forth in Chapter 46 of Title 18 of the United States Code.

- Delete reference to establishment of Commission

Clinton

Rachel E. Levinson 02/03/98 03:53:58 PM

Record Type: Record

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

cc:
Subject: Bond bill

I have copies of the Bond bill available in Room 436. It is unclear in intent but appears to prohibit a much broader range of activities than our June draft. It has internal inconsistencies that would appear to make it difficult to determine if any research involving the use of human cells in somatic cell nuclear transfer might be carried out. The bulk of the language is devoted to establishing a Commission to promote a national dialogue on bioethics.

I hope to get a draft letter on Kennedy-Feinstein around shortly. That bill will dropped "shortly" but probably not today.

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
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William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

Cloning

Rachel E. Levinson 02/03/98 04:35:24 PM

Record Type: Record

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

cc:
Subject: BIO's analysis

---------- Forwarded by Rachel E. Levinson/OSTP/EOP on 02/03/98 04:34 PM ----------

cludlam @ mail.bio.org
02/03/98 02:31:57 PM

Record Type: Record

To: levinson

cc:
Subject: analysis

ANALYSIS OF BOND/FRIST/GREGG
HUMAN CLONING BILL

First Issue: The Bond/Frist/Gregg human cloning bill bans the act of "producing an embryo (including a preimplantation embryo)" through the use of a specified technology (somatic cell nuclear transfer). It would ban the production of this embryo even if the production of such an embryo is for purposes completely unrelated to the cloning of a human being.

The bill, therefore, would effectively ban some research to generate stem cells for the following types of treatments:

cardiac muscle cells to treat heart attack victims and degenerative heart disease;

skin cells to treat burn victims;

spinal cord neuron cells for treatment of spinal cord trauma and paralysis;

neural cells for treating those suffering from neurodegenerative diseases;

pancreas cells to treat diabetes;

blood cells to treat cancer anemia, and immunodeficiencies;

neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS);

cells for use in genetic therapy to treat 5,000 genetic diseases, including Cystic Fibrosis,

Tay-Sachs Disease, schizophrenia, depression, and other diseases;
blood vessel endothelial cells for treating atherosclerosis;
liver cells for liver diseases including hepatitis and cirrhosis;
cartilage cells for treatment of osteoarthritis;
bone cells for treatment of osteoporosis;
myoblast cells for the treatment of Muscular Dystrophy;
respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer;
adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration;
modified cells for treatment of various genetic diseases; and
other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions.

To be precise, the bill would ban the generation of stem cells for these purposes where the stem cells have nuclear DNA from a "human somatic cell" -- see critical discussion below and somatic cell nuclear transfer technology was used.

It would not ban stem cell research where the stem cell is generated without the use of somatic cell nuclear transfer or does not involve nuclear DNA from a "human somatic cell" -- again, see the critical discussion below.

If the legislation is limited to somatic cells with nuclear DNA identical to that of an existing or previously exisiting human being -- again, see critical discussion below -- the specific type of stem cells research which is banned is "customized" stem cell research. A researcher or doctor might want to create a human zygote with DNA identical to that of an existing or previously existing person through the use of somatic cell nuclear transfer -- the act prohibited in the Bond/Frist/Gregg bill -- in order to create a customized stem cell line to treat the individual from whom the DNA was extracted. By using the same DNA the stem cell would be more likely to be compatible and not rejected by the person when the stem cell is transferred (back) to the person for the treatment.

The statement released by Senators Bond/Frist/Gregg about the impact of their bill on biomedical research is technically accurate but highly misleading. The title of the document is "CURRENT RESEARCH UNTOUCHED BY THE BOND/FRIST/GREGG LEGISLATION" and it is followed by a list of such research, including "In Vitro Fertilization," "Stem Cell Research," "Gene Therapy," "Cloning of Cells, Tissues, Animals and Plants," "Cancer," "Diabetes," "Birth Defects," "Arthritis," "Organ Failure," "Genetic Disease," "Severe Skin Burns," "Multiple Sclerosis," "Muscular Dystrophy," "Spinal Cord Injuries," "Alzheimer's Disease," "Parkinson's Disease," and "Lou Gehrig's Disease." The title to this document includes a critical qualification -- an asterisk. The asterisk qualification states, "The Bond/Frist/Gregg bill would not prohibit any of this research, even embryo research, as long as it did not involve the use of a very specific technique (somatic cell nuclear transfer) to create a live cloned human embryo."

This qualification swallows the list. It acknowledges that the bill would, in fact, ban some types of stem cell research and other research, as explained above. Given the importance of the asterisk, the title to the document and the list of protected research are highly misleading.

The statement of Senators Bond/Frist/Gregg is a challenge to patient disease groups to seek to include in the legislation a specific guarantee that research on the diseases they list is not, in fact, stifled. Such an exemption might read as follows:

"NOTHING IN THIS ACT shall apply where the acts or research are for the purpose of producing or generating stem cells to treat or diagnose deadly or disabling diseases and other medical conditions including the following: cardiac muscle cells to treat heart attack victims and degenerative heart disease; skin cells to treat burn victims; spinal cord neuron cells for treatment of spinal cord trauma and paralysis; neural cells for treating those suffering from neurodegenerative diseases; pancreas cells to treat diabetes; blood cells to treat anemia, immunodeficiencies, and cancer; neural cells to treat Parkinson's, Huntington's and Amyotrophic Lateral Sclerosis (ALS); cells for use in genetic therapy to treat 5,000 genetic diseases, including Cystic Fibrosis, Tay-Sachs Disease, schizophrenia, depression, and other diseases; blood cells for use in treating patients with cancer, anemia, or immunodeficiency diseases; blood vessel endothelial cells for treating atherosclerosis; liver cells for liver diseases including hepatitis and cirrhosis; cartilage cells for treatment of osteoarthritis; bone cells for treatment of osteoporosis; myoblast cells for the treatment of Muscular Dystrophy; respiratory epithelial cells for the treatment of Cystic Fibrosis and lung cancer; adrenal cortex cells for the treatment of Addison's disease; retinal pigment epithelial cells for age-related macular degeneration; modified cells for treatment of various genetic diseases; and other cells for use in the diagnosis, treatment and prevention of other deadly or disabling diseases or other medical conditions; or for the purpose of conducting scientific research into the mechanisms of interaction between the genes and their intracellular and extracellular environments in order to control and redirect the specialization of somatic cells into novel treatments or diagnostic products for deadly or disabling diseases and other medical conditions."

If Senators Bond/Frist/Gregg are, in fact, determined to protect this research, they could not object to including this explicit guarantee in their bill.

The stem cell technology is exciting and potentially revolutionary. Scientists are developing an entirely new approach for treating human diseases that depend not on drugs like antibiotics but on living cells that can differentiate into blood, skin, heart, or brain cells and potentially treat cancers, spinal cord injuries, or heart disease. This research -- called stem cell research -- holds the potential to develop and improve cancer treatments by gaining a more complete understanding of cell division and growth and the process of metastasis. This could also lead to a variety of cancer treatment advances.

The kinds of cells that make up most of the human body are differentiated, meaning that they have already achieved some sort of specialized function such as blood, skin, heart or brain cells. The precursor cells that led to differentiated cells come from the embryo. They are called stem cells because functions stem from them like the growth of a plant. Stem cells have the capacity for self-renewal, meaning that they can produce more of themselves, and differentiation, meaning that they can specialize into a variety of cell types with different functions. In the last decade, scientists studying mice and other laboratory animals have discovered powerful new approaches involving cultured stem cells. Studies of such cells obtained from mouse stem cells show that they are capable of differentiating in vitro or in vivo into a wide variety of specialized cell types. Stem cells have been derived by culturing cells of non-human primates and promising efforts to obtain human stem cells have also recently been reported.

Stem cell research has been hailed as the "[m]ost tantalizing of all" research in this field. The reason for this is because adults do not have many stem cells. Most cells are fully differentiated into their proper functions. When differentiated cells are damaged, such as cardiac muscle when someone suffers a heart attack, the adult cells do not have the ability to regenerate. If stem cells could be derived from human sources and induced to

differentiate in vitro, they could potentially be used for transplantation and tissue repair.

Using the heart attack sufferer as an example, we might be able to replace damaged cardiac cells with healthy stem cells that could differentiate into cardiac muscle. Research with these stem cells could lead to the development of "universal donor cells" of invaluable benefit to patients. Stem cell therapy could make it possible to store tissue reserves that would give health care providers a wholly new and virtually endless supply of the cells listed above. The use of stem cells to create these therapies would lead to great medical advances. We have to be sure that nothing we do in this legislation concerning human cloning would obstruct in any way this vital research.

Second Issue: The bill bans the use of somatic cell nuclear to transfer a "human somatic cell" but it does not state that this is limited to somatic cell which contains nuclear DNA identical to that of an existing or previously existing person. This means that the bill is not limited to cloning (creating a person or embryo with nuclear DNA identical to that of someone else), but would also apply to the use of somatic cell nuclear transfer of nuclear DNA which is not identical. It would, in fact, prohibit the use of somatic cell nuclear transfer where the nuclear DNA is the product of normal, sexual reproduction -- that is the opposite of cloning. It would also prohibit the use of somatic cell nuclear transfer where the somatic cell had been modified in some way prior to the use of somatic cell nuclear transfer. In short, the bill prohibits a broad range of uses of somatic cell nuclear transfer having nothing whatever to do with cloning, such as use of this technology to treat mitochondrial disease.

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
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Jerold R. Mande/OSTP/EOP
William P. Marshall/WHO/EOP
Arthur Bienenstock/OSTP/EOP
Rachel E. Levinson/OSTP/EOP
Elena Kagan/OPD/EOP

Cloning

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

STATEMENT OF ADMINISTRATION POLICY

TO: **LARRY STEIN**
JOHN PODESTA
SYLVIA MATHEWS
BRUCE REED
ELENA KAGAN
JERRY MANDE
RACHEL LEVINSON
LUCIA WYMAN
CHARLES BROWN
TOM FREEDMAN
PAUL WEINSTEIN
JASON GOLDBERG

CC: **JACK LEW**
CHARLES KIEFFER

FROM: **Alice Shuffield**

DATE: **February 9, 1998**

SUBJECT: **FOR YOUR CLEARANCE --**
SAP on S. 1601 -- Human Cloning Prohibition Act

Attached is our draft SAP on S. 1601, the Human Cloning Prohibition Act. On Thursday (2/5), the Senate debated the motion and filed cloture on the bill. The cloture vote will occur on Tuesday (2/10).

Position: **The Administration does not support passage of the bill in its current form.**

Timing: We aim to send to the Hill as soon as possible on Monday.

Background: HHS and White House staff have been working with Congress to amend the bill as described in our SAP. NIH Director Harold Varmus met with Senator Frist on Thursday afternoon to encourage amendment to the bill. The Agency reports that the Senator was receptive in the meeting. The Administration has been working to delay consideration of the bill in an effort to incorporate these amendments.

*Please contact Alice Shuffield (5-4790) by **noon today** with your clearance or your concerns.*

DRAFT -- NOT FOR RELEASE

February 9, 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 morally unacceptable. The Administration, however, believes S. 1601, as introduced, is too far-reaching because it would prohibit important biomedical research aimed at preventing and treating serious and life-threatening diseases. Therefore, the Administration does not support 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 would ensure a continuing examination of the risks and benefits of this technology ~~[for purposes other than cloning a human being]~~, while being free from the concern 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.

-- Strike 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.

-- Strike the bill's provisions establishing a new Commission to Promote a National Dialogue on Bioethics. The new Commission would needlessly 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.

* * * * * * * * * *

(Do Not Distribute Outside Executive Office of the President)

This Statement of Administration Policy was developed by the Legislative Reference Division (Pellicci) in consultation with OSTP (Levinson), DPC (Kagan/Mande), and HLTH (Turman/ Garufi). Executive Associate Director Gotbaum has approved the proposed position. The Department of Health and Human Services (per Assistant Secretary for Legislation Tarplin) concurs in the proposed position. The Departments of Agriculture (Wachs) and Veterans Affairs (Prudhomme), and NASA (Costanzo), and NSF (Ashley) have no objection to the proposed position. The Department of Justice did not respond to our request for views.

OMB/LA Clearance:

Background

Both S.1601 and the Feinstein/Kennedy substitute bill (S. 1602) were introduced on February 3rd. Neither bill was the subject of committee hearings or markups. On June 9, 1997, the President transmitted to Congress legislation that would prohibit any attempt - public or private - to create a human being using somatic cell nuclear transfer technology, the method that was used to create Dolly the sheep. A cloture vote will occur on Tuesday, February 10th, on the motion to proceed with Senate consideration of S. 1601.

Summary of Legislation

S. 1601 - the "Human Cloning Prohibition Act (Lott)

S. 1601 would permanently ban the use of human somatic cell nuclear transfer technology for the purpose of creating an embryo. According to HHS, although the term embryo is not defined, the fact that the bill states "including a preimplantation embryo" suggests that embryo would include the single cell egg with a full complement of DNA. S. 1601 would impose the same penalties as those for illegally using fetal tissue -- a maximum of 10 years in prison and a $250,000 fine.

S. 1601 would also establish within the Institute of Medicine a Commission to Promote a National Dialogue on Bioethics to serve as an "independent forum for broad public participation and discourse concerning important bioethical issues, including cloning . . . ." The new Commission would be required to report to Congress annually beginning no later than December 31, 1999. The Commission would have 25 members, representative of the fields of law, theology, philosophy or ethics, medicine, science, and society. Of the 25 members, six would be appointed by the Majority Leader of the Senate; six by the Minority Leader of the Senate; six by the Speaker of the House; and six by the Minority Leader of the House. The Senate Majority Leader and the Speaker of the House would select the Chairperson of the Commission. S. 1601 would authorize such sums as may be necessary for the establishment and operation of the Commission.

S. 1602 - the "Prohibition on Cloning of Human Beings Act of 1998" (Feinstein/Kennedy)

The major provisions of S. 1602 are based on the President's proposal. Like the Administration's legislation, S. 1602 would prohibit any attempt to create a human being using somatic cell nuclear transfer technology. Unlike S. 1601, the Feinstein/Kennedy bill would permit cloning research until the implementation stage. For example, the bill would allow the use of cloning technologies (including embryo research) to seek cures for cancer, diabetes, burns, spinal cord injuries, infertility, birth defects, and other human illnesses. The ban on human cloning would be effective for 10 years from the date of the bill's enactment. (The Administration's bill included a five-year ban.) S. 1602 would provide for fines, civil actions, and forfeiture of property for violations of the Act.

Consistent with the Administration's proposal, S. 1602 would also require the National Bioethics Advisory Commission to report to the President and Congress in four and a half years and nine and a half years, and recommend whether the ban should continue. It would also preempt any State law affecting somatic cell nuclear transfer, human cloning, and related activities.

Pay-As-You-Go Scoring

According to BASD (Balis) and HLTH (Garufi), S. 1601 could affect receipts because the bill provides for criminal fines and civil monetary penalties for violations of the Act. Therefore, S. 1601 is subject to the pay-as-you-go requirement of the Omnibus Budget Reconciliation Act of 1990. OMB's preliminary scoring of S. 1601 is zero.

Clinton

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

February 12, 1998

The Honorable Michael Bilirakis
Chairman
Subcommittee on Health
and Environment
Committee on Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

As you know, the Administration witness for today's hearing on technology and human cloning will not be able to attend due to the inability of the Subcommittee to honor long-standing bipartisan precedent concerning testimony by senior Administration officials.

President Clinton and Secretary Shalala strongly support a ban on human cloning. It was because of our strong desire to work with you on this issue that our representative, Dr. Harold Varmus, Director of the National Institutes of Health, agreed to participate in the hearing with very short notice to alter his schedule and prepare testimony. It was subsequent to this that we learned the Subcommittee would be unable to afford Dr. Varmus the courtesy routinely extended to senior Executive branch witnesses by this and other committees.

We are pleased, however, to submit our testimony for the record. Despite this regrettable incident, we look forward to working with you and other members of your Subcommittee to work through the complex scientific and ethical issues that surround human cloning and medical research. We commend you for holding this timely hearing that will help focus public debate and highlight issues of concern. In addition, the Administration would be eager to testify at any future time on this issue under the standard hearing format for Administration witnesses.

Sincerely,

Rich

Richard Tarplin
Assistant Secretary for Legislation

cc: The Honorable Sherrod Brown

Cloning

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, has a number of concerns about S. 1601 and 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 the creation of an embryo for the purpose of producing or generating stem cells to treat or diagnose deadly or disabling diseases and other medical conditions, including the treatment of cancer, diabetes, genetic diseases, and spinal cord injuries.

-- 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.

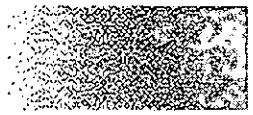
The President's proposal, which in many ways is reflected in S. 1602 sponsored by Senators Feinstein and Kennedy, would prohibit any attempt to create a human being using somatic cell nuclear transfer, provide for further review of the ethical and scientific issues associated with the use of somatic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

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.

* * * * * * * * * *

Cloning



Jerold R. Mande

02/10/98 01:10:25 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Lucia A. Wyman/WHO/EOP, Thomas L. Freedman/OPD/EOP

cc: Bruce N. Reed/OPD/EOP
Subject: Cloning Update

Good news! I have received word from industry lobbyists that the leadership has decided to put off the cloture vote and ask the Judiciary Committee to review the Bond/Frist and Feinstein/Kennedy bills (although technically the bills will remain on the calendar and not be referred to committee). The leadership made this move after the most recent vote count showed they had lost 10 Rs and the Ds were united. I am checking with HHS to see if they agree with this intelligence.

Next Hurdle -- there is a House Judiciary Committee hearing on Thursday at 11am and we still haven't decided who we are sending. Varmus would seem the obvious choice, but HHS has some reservations. The hearing is already stacked against us. Armey, Bond, and Ehlers are testifying. There is also a panel of pseodo-scientists who will present the right-to-life view point. It is critical we send a scientist with stature to make our case.

Closing

THE WHITE HOUSE

OFFICE OF LEGISLATIVE AFFAIRS
HOUSE LIAISON
--FAX COVER SHEET--

DATE: 2/11

TO: Podesta, B. Reed, Stein, Bowen, Murguia, Kagan, Emanuel, Smith, JS, Mande, L. Freedman

FAX #:

FROM:

- ___ JANET MURGUIA
- ___ AL MALDON
- ✓ DAN TATE
- ✓ LUCIA WYMAN
- ✓ PETER JACOBY
- ✓ STACEY RUBIN
- ___ ANDY BLOCKER
- ___ JEFF FORBES
- ___ ELISA MILLSAP
- ___ JESSICA GIBSON
- ___ PETER GREENBERGER

(202)456-6620 (TELEPHONE)
(202)456-2604 (FAX)

SUBJECT: Closing Cloture Vote

NUMBER OF PAGES:

02/12/98 THU 03:43 FAX

001

FEB 1 1 1998
(Date)

Roll Call Vote

10:02 am

Legislative

NO. 10

SUBJECT. MOTION TO INVOKE.....
.....CLOTURE ON MOTION TO....
.....PROCEED TO CONSIDER.....
S. 1601

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	Ashcroft	
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	Cleland	
	Coats	
	Cochran	
	Collins ABS.	
	Conrad	
	Coverdell	
	Craig	
	D'Amato	
	Daschle	
	DeWine	
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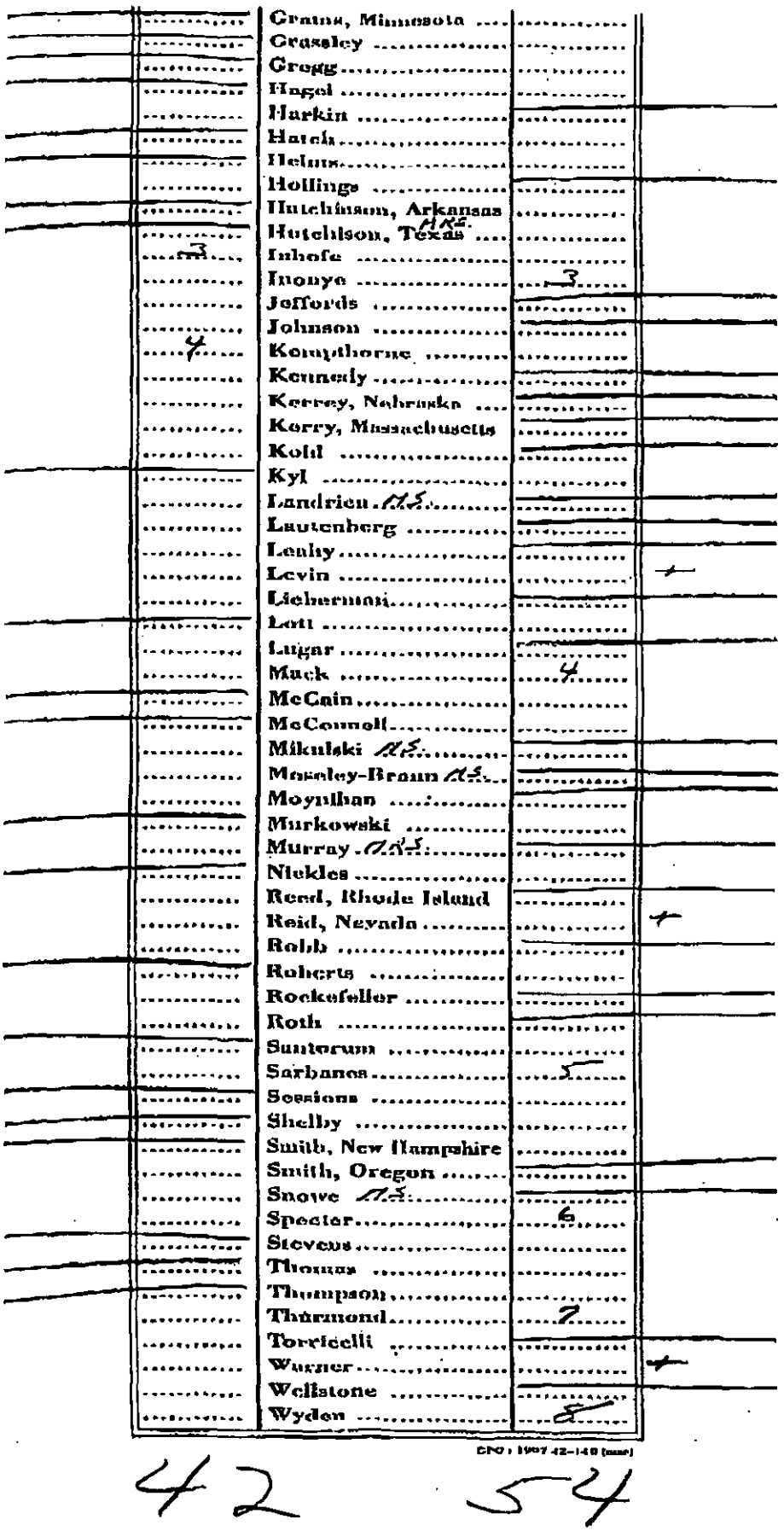
	Glenn	
	Gorton	
	Graham, Florida	
	Gramm, Texas	
	Grams, Minnesota	
	Grassley	
	Gregg	
	Hagel	
	Harkin	
	Hatch	
	Helms	



cloning

Rachel E. Levinson 02/10/98 03:44:14 PM

Record Type: Record

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

cc:
Subject: House cloning bill

FYI -

Harold Varmus is scheduled to testify at House Commerce hearing on cloning, Thursday, February 12. Ehlers, Bond and Armey are also on the list.

below is the text of HR 3133 a cloning bill (actually its a research bill) brought by Stearns and Wicker. I think the definition they use might be of some use.

"(a) Prohibition.--None of the funds made available in any Federal law may be obligated or expended to conduct or support any project of research that includes the use of human somatic cell nuclear transfer technology to produce an oocyte that is undergoing cell division toward development of a fetus.

(b) Definitions.--For purposes of this section--

(1) the term ``human somatic cell nuclear transfer'' means transferring the nucleus of a human somatic cell into an oocyte from which the nucleus has been removed or rendered inert; and

(2) the term ``somatic cell'' means a cell of an embryo, fetus, child, or adult which is not and will not become a sperm or egg cell."

Obviously, I don't like saying embryonic cells are somatic cells, however, the phrase "toward development of a fetus" might give us some wiggle room. We could argue we are not interested in development towards a fetus, only towards bone marrow, or skin or whatever.

Since Stearns and Wicker are both pretty solid with the Chrisitan Coalition, the fact that the language started with them might be helpful as well.

Sean Tipton
ASRM

<PRE>[DOCID: f:h3133ih.txt]

105th CONGRESS
2d Session

H. R. 3133

To prohibit the expenditure of Federal funds to conduct or support research on the cloning of humans, and to express the sense of the
Congress that other countries should establish substantially equivalent restrictions.

IN THE HOUSE OF REPRESENTATIVES

January 28, 1998

Mr. Stearns (for himself and Mr. Wicker) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Science, for a period to be subsequently determined by the
Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

---

A BILL

To prohibit the expenditure of Federal funds to conduct or support research on the cloning of humans, and to express the sense of the
Congress that other countries should establish substantially equivalent restrictions.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ``Human Cloning Research Prohibition Act''.

SEC. 2. PROHIBITION AGAINST EXPENDITURE OF FEDERAL FUNDS FOR RESEARCH ON CLONING HUMANS.

(a) Prohibition.--None of the funds made available in any Federal law may be obligated or expended to conduct or support any project of research that includes the use of human somatic cell nuclear transfer technology to produce an oocyte that is undergoing cell division toward development of a fetus.

(b) Definitions.--For purposes of this section--

(1) the term ``human somatic cell nuclear transfer'' means transferring the nucleus of a human somatic cell into an oocyte from which the nucleus has been removed or rendered inert; and

(2) the term ``somatic cell'' means a cell of an embryo, fetus, child, or adult which is not and will not become a sperm or egg cell.

SEC. 3. REVIEW.

The Director of the National Science Foundation shall enter into an agreement with the National Research Council for a review of the implementation of this Act. Not later than 5 years after the date of the enactment of this Act, the Director shall transmit to the Congress a report containing the results of that review, including the conclusions of the National Research Council on--

(1) the impact that the implementation of this Act has had on research; and

(2) recommendations for any appropriate changes to this Act.

SEC. 4. PROTECTED SCIENTIFIC RESEARCH.

Nothing in this Act shall restrict other areas of scientific research not specifically prohibited by this Act, including important and promising work that involves--

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells other than human embryo cells, or tissues; or

(2) the use of somatic cell nuclear transfer techniques to create animals other than humans.

SEC. 5. SENSE OF CONGRESS REGARDING INTERNATIONAL PROHIBITION.

It is the sense of the Congress that each foreign country should establish a prohibition substantially equivalent to the prohibition established in section 2(a).

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

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)	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]

Cloning

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.

Clouing

Rachel E. Levinson 02/10/98 05:06:16 PM

Record Type: Record

To: William P. Marshall/WHO/EOP

cc: See the distribution list at the bottom of this message
Subject: Re: senate

The Senate leadership cancelled their cloture vote once they determined that they didn't have enough votes to pull it off. According to Jerry, both bills will remain on the calendar and no hearings have been scheduled. Technically, both Labor and Judiciary have standing.

Lucia, Jerry and HHS staff met with Bond and Frist staff late on Thursday. I am told that Frist's person stood firm on the National Commission. Jerry pushed on the sunset there seemed to be some possibility of movement on that issue. I saw a a report that Varmus talked to Frist but can't confirm it. I do know that Frist spoke to people from Vanderbilt and U. TN over the weekend and learned something about the science.

The National Bioethics Advisory Commission wrote to POTUS on Friday and reiterated their June recommendations and concerns over pending legislation. Let me know if you want a copy of their letter.

Message Copied To:

Toby Donenfeld/OVP @ OVP
Wendy A. Taylor/OMB/EOP
gips_d @ a1.eop.gov
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

Cloning

DRAFT

Noon, 2/11/98
Not cleared by Dr. Varmus

Mr. Chairman and Members of the Subcommittee, I am Harold Varmus, Director of the National Institutes of Health. I am here today to discuss somatic cell nuclear transfer and the potential benefits from this technology. This issue was first brought to public attention when Ian Wilmut and his colleagues at the Roslin Institute, Edinburgh, published in the February 27, 1997 issue of *Nature*, the results of their cloning experiments in sheep. The true benefits from these studies are the contributions to animal husbandry and medical research. But the importance of these contributions has been dwarfed by the public's fascination with Dolly, a lamb cloned from the cell of an adult sheep. Successfully cloning an adult sheep sharply focused public attention on the possibility of cloning a person.

The President, recognizing the ethical and societal implications of the Dolly experiment, requested the National Bioethics Advisory Committee to examine this issue and report recommendations within 90 days. The Committee concluded "that there should be imposed a period of time in which no attempt is made to create a child using somatic cell nuclear transfer." They further cautioned that "Any regulatory or legislative actions undertaken to effect the foregoing prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere with other important areas of scientific research." Their final suggestion was to formally re-evaluate this issue in three to five years. Subsequently, over 67,000 scientists involved in reproduction biology signed a voluntary moratorium on the cloning of a human.

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This hearing is a continuation of the public discourse on this issue. It is imperative that this discourse be informed and comprehensive. I will briefly discuss the science as it exists and as it was used to create Dolly, and I will also describe the scientific and medical promises of this technology.

SOMATIC CELL NUCLEAR TRANSFER–WHAT IS IT?

I am certain that everyone here has heard of somatic cell nuclear transfer. I am also certain that there is much confusion and misunderstanding. In order to understand this technology, it is necessary to briefly review normal reproduction.

In sexual reproduction, an egg and sperm join to create a fertilized egg which develops into an embryo and ultimately an individual. In this situation, the progeny receives genetic material from both the mother and father. After fertilization, the egg initially divides into a number of identical unspecialized cells. Each of these early embryonic cells are totipotent, meaning they are *totally potent* in that they have the capacity to form any type of cell in the body - a muscle cell, a liver cell, a blood cell. At the appropriate time, these totipotent cells must begin to specialize into specific types of cells; this process is triggered when specific genes are turned on. It had long been thought that the process of cell specialization was strictly a one way street. But this dogma was challenged by the experiment that produced Dolly.

Dolly, a sheep cloned from a specialized adult sheep cell, was created using the technology of somatic cell nuclear transfer. Unlike the normal process of sexual reproduction in which an egg

DRAFT

and a sperm each contribute genetic material, somatic cell nuclear transfer is asexual. Before proceeding, let me remind you that a somatic cell is any cell of the body except the egg cells or sperm cells. Human somatic cells contain the full complement of DNA -- 46 chromosomes. In contrast an egg or a sperm contain 23 chromosomes.

The process of somatic cell nuclear transfer is done in the following way. I will use the sheep as an example. First a normal sheep egg cell is taken from a ewe (see diagram). The nucleus (which is the cell structure containing the genes or DNA) is removed. The end result is an egg cell containing only the egg fluid which has the nutrients and other energy producing materials that are essential for embryo development. Next, a somatic cell is isolated--in the case of Dolly, a cell grown in cell culture from the mammary tissue of an adult sheep. Under very specific laboratory conditions, the somatic cell, in this example, the mammary cell, is placed next to the egg from which the nucleus had been removed, an electrical stimulus is applied and the two cells fuse. The result is a cell which contains genetic material only from the somatic cell and the nutrient environment of an egg cell. This is not sexual reproduction. There is no sperm involved. The egg provides the environment for growth. The resultant APT cells or asexually produced totipotent cells begin to divide. In the case of Dolly, after a number of cell divisions, these cells were placed into the uterus of a sheep and eventually a lamb was born.

The birth of a lamb cloned from an adult sheep was dramatic. But we must be cautious. This was only one successful experiment - in fact, Dolly was the first success after 276 failed attempts. Before somatic cell nuclear transfer should even be considered as a true cloning

DRAFT

technique, the Dolly experiment must be repeated numerous times. At this point I would like to reiterate that the interest of the scientific world focuses on somatic cell nuclear transfer as a technology for animal husbandry and for medical research. Let me described the reasons for this enthusiasm.

POTENTIAL BENEFITS FROM SOMATIC CELL NUCLEAR TRANSFER TECHNOLOGY

The experiment that created Dolly demonstrated that, when appropriately manipulated and exposed to the correct environment, the genetic material of somatic cells can regain full potential or totipotent status. Medical researchers realized that if the genetic material of a somatic cell could be stimulated to return to a totipotent state, with the potential to become any kind of cell, the potential uses of this technology for the study and treatment of disease were remarkable. Medical researchers are focused on the possibility of creating cells and tissues for transplantation and research, they are not focused on cloning a human.

Let me elaborate for a moment. Remember that the totipotent cells have the capacity to become any type of cell in response to specific gene activation. Researchers are now working to understand how different genes are turned on. Once this is known, it would be possible to take totipotent cells and direct them to specialize into a specific type of cell, for example a skin cell or a muscle cell. These cells could then be used for cell and tissue transplantation.

Somatic cell nuclear transfer research offers the potential for developing individualized cell and tissue therapies that *cannot* be developed using current methods. Medical practitioners and

DRAFT

researchers are currently transplanting cells to replace damaged or diseased cells in humans. But these procedures require a donor from whom cells can be taken. With the exception of cells from an identical twin, donor cells are genetically different from the recipient. When they are placed into the patient, the patient's immune system sees these cells as foreign and tries to reject them from the body. In order to prevent this rejection, drugs are used to suppress the normal immune response. Unfortunately, these drugs are not always effective for preventing rejection and they have serious toxicities including malignancy and even death. An additional problem with transplant medicine is the shortage of donors: the supply of replacement cells and tissue is inadequate.

Somatic cell nuclear transfer could overcome many of these obstacles. Using this technology a patient's own cells from any part of the body could be used to generate the needed therapeutic cells or tissue in adequate amounts. Because these cells would be a genetic match, rejection should not occur and the need for anti-rejection drugs would be minimal. In addition, the shortage of cell and tissue donors would no longer be a problem. Treatment could be revolutionized for patients with diseases such as diabetes, leukemia, burns, sickle cell anemia, muscular dystrophy, heart disease and liver disease to name a few.

Somatic cell nuclear transfer technology also holds hope for patients with neurologic injury and disease. Because mature, specialized nerve cells do not reproduce, it has been virtually impossible to create cultures of replicating nerve cells. If with somatic cell nuclear transfer we were able to take a totipotent cell and direct it to produce different types of nerve cells, this

would be a major breakthrough for patients with spinal cord injury, Parkinson's disease, Lou Gehrig's disease, multiple sclerosis and Alzheimer's disease.

Animal Cloning

As Dolly showed the world, an additional benefit of somatic cell nuclear transfer includes animal cloning. The advantage of this process would be the genetic duplication of an animal. In traditional breeding practices, the offspring of an animal are sexually reproduced from genetically different parents and, therefore, may not share all of the characteristics that made the parents valuable. In conventional breeding, it takes years to produce many animals with similar genetic characteristics. Cloning could speed up this process and could allow the production of genetically identical animals.

This technique would be particularly valuable for research. The use of genetically identical animals could dramatically reduce the numbers of animals needed for experiments. For the first time, researchers could be sure that differences in responses to drugs and other interventions are due to the interventions, not to genetic differences between animals.

Cloning could also contribute to animal husbandry and medical research by facilitating transgenic technology. A transgenic animal is one that is genetically altered by inserting a new gene with the desired attributes into the DNA of a fertilized egg. Transgenic animals are valuable for a number of reasons. They can be engineered to have decreased susceptibility to bacterial infection, to have increased milk production, and to have the ability to produce

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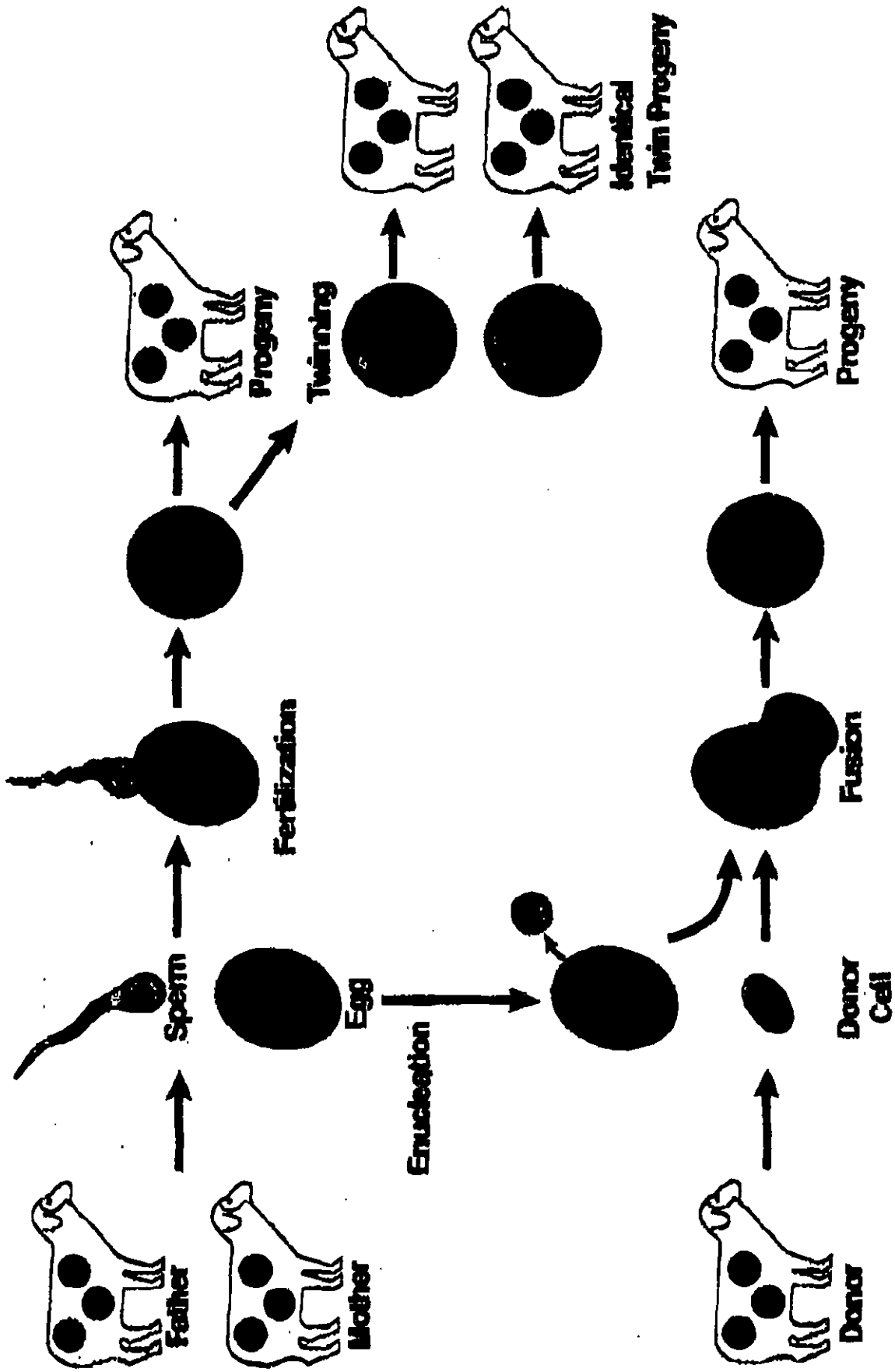
pharmaceutically important proteins in their milk. Recently, calves were cloned with the gene that enabled them to produce in their milk human clotting factors for the treatment of hemophilia. Future advances may also allow the development of animal clones with tissues and organs that are compatible for human transplantation purposes. Cloning the animal that incorporated the gene of interest would be much faster than selective breeding and would decrease the amount of time required to produce transgenic animals.

CONCLUSION

In sum, somatic cell nuclear transfer holds many diverse and important possibilities to significantly prevent, treat and maybe cure disease. All of these possibilities can be accomplished without using this technology to create a human being. While these possibilities are, for now, scientific conjecture, they reflect previous advances in the fields of tissue culture, genetics, molecular and cell biology and transplantation. The promise of these advances for the development of therapeutics will be significantly slowed, if not unrealized, absent the continued development of somatic cell nuclear transfer technology.

This concludes my testimony. I would be happy to respond to any questions that you or other Members of the Subcommittee may have.


Identical Twin Progeny
Progeny
Twinning
Progeny
Fertilization
Fusion
Sperm
Egg
Enucleation
Donor Cell
Father
Mother
Donor

Man and Woman
In Vitro Fertilization
Somatic Cell
Nuclear Transfer
Specialized
Cells
New Human
Being
Therapeutic
Tissue

Donor
Donor
Sexually Produced Totipotent Cells (SPT)
Specialized Cells
Therapeutic Tissue
Patient
Donor
Patient
Somatic Cell Nuclear Transfer
Asexually Produced Totipotent Cells (APT)
Specialized Cells
Customized Therapeutic Tissue
Patient

Closing

Chris → Mike

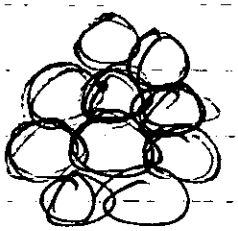
Dan Feinstein -

Says he will veto
Board - First.
- K-Feinstein -

Don't see how we cannot get cloture
Port so complicated.

Pt to Lite - becoming involved over weekend.

Veto -



Closing

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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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

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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

Clinton

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

February 9, 1998
(Senate)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

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 create a human being through cloning. The President believes that using somatic cell nuclear transfer cloning techniques to create a human being is untested, unsafe, and morally unacceptable. The Administration, however, believes S. 1601, as introduced, is too far-reaching because it would prohibit important biomedical research aimed at preventing and treating serious and life-threatening diseases. Therefore, the Administration would not support 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 would ensure a continuing examination of the risks and benefits of this, while being free from the concern 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 prevent and treat serious and life-threatening 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.

- Strike 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.

- Strike the bill's provisions establishing a new Commission to Promote a National Dialogue on Bioethics. The new Commission would needlessly 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.

****

Cloning

National Bioethics Advisory Commission

6100 Executive Boulevard • Suite 5B01
Rockville, MD 20892-7508
Telephone: (301) 402-4242
Facsimile: (301) 480-6900

February 6, 1998

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

Last February, in the wake of the startling announcement that researchers in Scotland had apparently succeeded in creating a genetic copy of an adult sheep through somatic cell nuclear transfer, you asked the National Bioethics Advisory Commission to review the legal and ethical issues that would arise from the use of this technology to clone human beings.

The Commission immediately began a series of meetings and consultations. We heard not only from physicians and scientists but from religious leaders, ethicists, lawyers, and members of the public in an effort to understand the full range of views on this controversial and multifaceted subject. Of course, given the need for a prompt report, we recognized that while we might resolve some of the issues, many would remain for which we could supply a road map but not ourselves reach final conclusions.

In *Cloning Human Beings,* the report that we presented to you at the White House on June 9, 1997, we concluded that the use of this new technique to create a child would entail unacceptable risks and ought not to be attempted now by anyone. Beyond the issues of safety, we found that concerns relating to the potential harms to children and effects on the moral, religious, and cultural values of society merit further reflection and deliberation. We therefore recommended that no attempt be made at this time to create a child using somatic cell nuclear transfer.

You immediately transmitted to Congress a bill embodying our recommendations. Despite hearings in both houses, Congress did not adopt legislation on human cloning in 1997. As you recognized last week in the State of the Union address, recent developments make clear that such legislation is needed. Some legislators have called for enacting a permanent ban not just on the creation of children by cloning but on studies with embryonic cells, even though such research could offer an important means of finding a cure for cancer and other lethal diseases.

We continue to believe that sweeping legislation would be a mistake, and we urge you to work with Congress to ensure that any legislation follows the basic points of the bill you sent to Congress last June, namely to:

- stop anyone in the private as well as the public sector from using somatic cell

nuclear transfer techniques to create a child at this time,

- clearly distinguish the area of concern (the attempt to create a human child using these techniques) from the cloning of human DNA, genes, or cells in the laboratory, and

- place a time limit on the ban. The major reasons for a moratorium—concerns about safety and unresolved social, legal and ethical issues—all need to be reexamined as scientific research and public discussion move forward.

We would be pleased to provide whatever help we can to achieve the adoption of public policies on human cloning that attain an appropriate balance among competing goals and values.

Sincerely,

Harold T. Shapiro

Harold T. Shapiro
Chair

cloning

Rachel E. Levinson 02/17/98 09:46:44 AM

Record Type: Record

To: Jerold R. Mande/OSTP/EOP, ls25d @ nih.gov @ inet, wraub @ osaspe.dhhs.gov @ inet

cc: Elena Kagan/OPD/EOP
Subject: cloning

Elena Kagan has asked that we form a small group to develop options for possible legislative language on cloning. Our assignment is to look at the various prohibitions that have already been floated, along with views that may have been expressed in meetings with Hill staff or other parties, and see if we can identify a bright line that would be agreeable to a broad group (including Hill leadership).

We can meet here, at Humphrey, or by phone, but I would very much like to schedule this for Wed. or Thursday this week so that we can respond to Elena quickly.

Please let me know your time and place preferences (by e:mail) ASAP. Thanks

Cleaning

Total Pages: 11

LRM ID: RJP199

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

URGENT

Friday, February 20, 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 FDA's jurisdiction over human cloning activities**

DEADLINE: **NOON Monday, February 23, 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: The attached document would be provided to congressional staff upon request. **CLOSE HOLD OF DOCUMENT IS NECESSARY.**

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RESPONSE TO
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MEMORANDUM

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Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ **(Date)**

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_____ **(Agency)**

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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:** _____

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DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

DRAFT

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.

Following the announcement of the cloned sheep, President Clinton directed that federal funds should not be used for cloning a

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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.

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 Celise v. United States, 217 F. 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

[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.

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 98-4263 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 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

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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).

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.

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

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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.

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, injunctions, and criminal prosecution).

Cloning

Rachel E. Levinson 02/27/98 03:40:26 PM

Record Type: Record

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

cc:

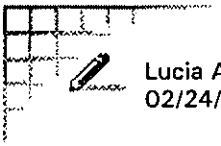
Subject: BIO's current position on cloning

Carl Feldbaum assures me that BIO has not changed their position and would continue to object to a Bond-like bill that limits cloning research. BIO would support Feinstein's bill without the forfeiture clause, and would prefer that the sunset be shortened to 5 years. Although he may make conciliatory noises to the Majority, he says that should not be interpreted as a softening of their position. I have a call in to PhRMA

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
jhorvath @ os.dhhs.gov @ inet

Cloning



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

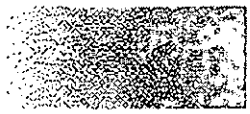
cc:
Subject: Cloning

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?

Cloning



Jerold R. Mande

02/24/98 03:30:28 PM

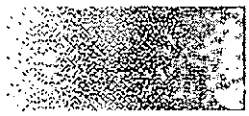
Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Laura Emmett/WHO/EOP, Lucia A. Wyman/WHO/EOP
Subject: Cloning update.

I had sent this note while you were away.

---------- Forwarded by Jerold R. Mande/OSTP/EOP on 02/24/98 03:24 PM ----------



Jerold R. Mande

02/18/98 04:34:52 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Cloning update.

I want to revisit a decision we made last week not to reach out to groups. I have heard that the Rs are hard at work. In meetings, they have made it clear they will bring cloning up again as soon as they can regroup. The Rs have also begun leaning on the groups that worked our side of the issue and reminding them who controls the fate of the rest of the groups' legislative agendas. I recommend that we convene a meeting of the groups to rally continued support and brief them on issues such as FDA jurisdiction. Let me know if you agree, and I will work with OPL to set this up. Thanks.

Cloning

Genentech, Inc.

460 Point San Bruno Boulevard
South San Francisco, CA 94080
(415) 225-1107
FAX: (415) 225-2929

Arthur D. Levinson, Ph.D.
President and
Chief Executive Officer

February 9, 1998

The Honorable Connie Mack
SH-517 Hart Senate Office Building
Washington, DC 20510

Dear Senator Mack:

I am writing with regard to legislative proposals currently pending in the Senate relating to cloning entire human beings. This vexing topic needs to be put into a larger perspective before the Senate votes on a bill, S. 1601, which was introduced only last week.

The biotechnology and research community has been very open and public about its support for the President's request for a voluntary moratorium on activities that could lead to the cloning of entire human beings. This exercise of responsibility in science is consistent with our long history of restraint in the pursuit of basic biomedical research. We do not plan or seek to clone entire human beings. In addition, we fully recognize the existence of various federal laws setting out the jurisdiction of the Food and Drug Administration which, when taken together, would bar the commercialization of cloning of entire human beings. Because of this moratorium and existing legal limitations on action, it is possible to deliberate and exercise caution and restraint in legislating this issue.

The reality of modern biomedical research is that it is difficult to predict in advance exactly how specific, even esoteric, areas of research will produce breakthroughs. As Michael Bishop (cancer researcher, Nobel laureate in medicine and my colleague from the University of California, San Francisco) spoke of this issue recently, in 1968 his work with Dr. Harold Varmus, and Professor Herb Boyer would have never been foreseen as leading to breakthroughs in recombinant DNA research and cancer genetics. Similarly, work done in the 1980s on transgenic animals by Dr. Phil Leder, of Harvard, and others, would not have easily been understood as being essential to the development of animal models that could facilitate dramatic advances in our ability to test new AIDS therapies.

It is also the case that with virtually every scientific advance there are voices that seek to delay legitimate, if misunderstood, advances in science. In the early 1970s, some government officials sought to bar virtually all recombinant DNA research out of exaggerated fears about the safety of the technology. Researchers and companies voluntarily adopted a moratorium on some research until more information was obtained. Fortunately, the calls for more radical local or federal regulation were rejected. The self-regulatory efforts by industry and the research community worked, and there were no significant safety issues to arise out of that research.

In the 1980s some critics advocated bans on transgenic animal research out of fear of science. These requests for a halt to research were often based on assertions of pseudoscience. Again, we are fortunate that Congress did not act to bar the creation of transgenic animals, which are now so commonly used in drug development, especially in AIDS research. IN addition, transgenic animals may someday be used for the actual production of pharmaceutical compounds. This hope for pure protein production at a lower cost is yet to be realized, but if Congress had acted in the 1980s to end research, patients would have had that hope foreclosed.

Now Congress is faced with difficult decisions about how to react to a single experiment in sheep. Each side of the current debate has sincere motivations and convictions about its legislative approach. Senators Bond, Frist and others have bona fide concerns about cloning human beings and hope that their bill would not affect biomedical research. Yet, determining how to prohibit the act of cloning an entire human being has proven to be a daunting task. For a set of reasons outlined below, we prefer the approach taken in the bill, S. 1602, to that found in the bill currently pending, S. 1601.

Most importantly, in considering restrictions on scientific research in the private sector (as opposed to previously enacted limitations on the expenditure of federal funds), great care must be exercised. In addition to the legal rights of persons to free expression and inquiry in the private market, there is little precedent for imposing limitations on research except for reasons of safety or other narrowly crafted circumstances.

In this instance, there are multiple possibilities of promising research with somatic cells. Our hope in the research community is that this branch of research will lead to discoveries that permit us to develop new cures and treatments for serious and unmet medical needs. Some of our colleagues in academe have already begun exploring questions of how to turn on and off these somatic cells so that new biological material could be generated for transplantation and for other therapeutic purposes. At this point in the discovery process, it is not known exactly how to accomplish this therapeutic goal, but one possible way is to use the technique known as somatic nuclear cell transfer. Such research could, in some circumstances, involve conduct that would be permitted under S. 1602 and would be criminalized under S. 1601. This difference (among others noted below) is the reason we prefer your bill.

There seems to be little dispute within the Congress about the current inappropriateness of using somatic nuclear cell transfer technology to create an embryo which is implanted into the uterus, with the goal being reproductive in nature. On the other hand, it is hard to understand why scientists should become criminals if they pursue legitimate new therapies for heart disease, cancer, diabetes, and other diseases, and if their research has no prospect or intent of creating an entire cloned human being.

Given our current state of knowledge, there is no reasonable prospect for creating a new human being unless an embryo is implanted into the uterus of a woman. Thus, the approach should be to adopt a bill that effectively bars what the political consensus wants to prohibit, while simultaneously retaining the option of research that is aimed at new therapies, not at reproductive ends.

There are several other reasons to support the approach taken in S. 1602:

- S. 1602 preempts inconsistent state laws. Given the rush to judgment in various states, the high likelihood for overlapping and inconsistent standards, and the clearly negative effect on interstate commerce, a federal standard is appropriate.

- S. 1602, unlike S. 1601, uses a civil penalty structure that will be sufficient to deter unwanted conduct. If criminal penalties or asset forfeiture are threatened for research activities, there is likely to be a chilling effect on research in this entire area. Moreover, there are additional sanctions available under the Food, Drug and Cosmetic Act to address human cloning.

- S. 1602 appropriately requires that Congress should review these limitations on research after a set period of time. This review could be facilitated if, using carefully drawn criteria, there was a balanced review of this area of research by a nonpolitical entity.

- The suggestion in S. 1602 for international cooperation on this topic is welcome, as is the ratification of the authority of the jurisdiction of the Food and Drug Administration.

One final point, S. 1601 would establish a commission that could approach the bioethics questions associated with certain limited new somatic cell nuclear transfer technologies. This concept is worthy of serious consideration. As we approach scientific advances, it is important that we make sure that science reflects our basic human and ethical values.

The work done by existing entities, such as the Recombinant DNA Advisory Committee of the NIH, and the NIH-DOE Working Group on Ethical, Legal, and Social Implications of Human Genome Research, has advanced the public discussion. In this regard, the work already done by the President's Commission on the topic of cloning entire human beings has materially assisted the national debate on this topic. We leave to the political process questions of whether any such bioethics commission should be situated in the Executive Branch and who should exercise the appointment authority.

There are several caveats worth noting, however:

- Past history, here and in Europe, suggests that there is a real risk that any such commission could inadvertently begin to function as a new regulatory entity and serve to delay the approval of new treatments for patients. This temptation should be avoided at all costs by explicitly limiting the role of the commission.

- There is a risk that any new commission will be led by other political agendas into discussions that do not advance progress on improving human health. This temptation should also be avoided by narrowly circumscribing the commission's charter.

- The composition of any commission should broadly reflect the best available thinking in science, law, and ethics. The mere prohibition on political officials serving on such a panel is not likely sufficient to prevent the politicization of the appointment process. There are, I understand, precedents that permit certain relevant professional societies to offer lists of nominees to an appointing authority. This approach would appear to mitigate the risk of an overly political appointment process.

In closing, let me thank you for having the special sensitivity and commitment to biomedical research to ask for greater deliberation and for crafting a more precise bill that seeks a uniform consensus about how to ban the cloning of entire human beings.

The issue before the Senate is: Can we simultaneously advance science and the search for cures for serious diseases while also barring the cloning of entire human beings? We believe that to foster further dialogue and deliberation can help achieve that common goal.

Sincerely,

Art Levinson

Cloning

Rachel E. Levinson 01/23/98 03:19:12 PM

Record Type: Record

To: Elena Kagan/OPD/EOP, Thomas L. Freedman/OPD/EOP, Jerold R. Mande/OSTP/EOP, Arthur Bienenstock/OSTP/EOP

cc: See the distribution list at the bottom of this message
Subject: cloning memo


DECMEM.1

Tom and Jerry have raised the question of whether or not a decision memo is needed, now that we have come to agreement on changes that leave the boundaries relatively intact, although more clear than the current draft bill.

We are not bound to a decision memo. I believe that we have reached consensus on the need to refine and clarify our current draft bill and to pursue some legislative strategy that encourages the development of a bill that could be signed. We do, however, still need a decision on language that could be shared with friendly colleagues on the Hill. As Jerry suggested yesterday, having specific language in our pockets will encourage its adoption. We also need to plan for the possibility of getting a bill that can't be signed, making it even more important that we send clear signals right now while bills are in development.

Message Copied To:

Clifford J. Gabriel/OSTP/EOP
Jeffrey M. Smith/OSTP/EOP
Lucia A. Wyman/WHO/EOP
Wendy A. Taylor/OMB/EOP
William P. Marshall/WHO/EOP
gips_d @ a1.eop.gov @ inet
Toby Donenfeld/OVP @ OVP

DRAFT MEMORANDUM FOR THE PRESIDENT

FROM:

SUBJECT: Cloning: Legislative Options

Interest in cloning legislation was renewed by reports that a Chicago physicist plans to attempt to use this technology to create a child. Your January 10 radio address challenged Congress to enact a ban on private sector activities like the one you have imposed on the use of public funds. Congressional staff inquiries indicate that your challenge will be accepted. Both critics and supporters of your draft bill agree that this issue raises complex drafting problems. You have the opportunity at this juncture to stay with existing language or, alternatively, propose new wording that clarifies your position. Given the strong possibility that Congressional measures may deviate from the principles outlined in your draft bill, it may be desirable to assert your leadership and encourage your allies by providing more specific language.

Your June 9, 1997 draft legislation (Tab A): 1) prohibits the production of a child using somatic cell nuclear transfer, 2) protects valuable research, especially embryo research conducted without the use of Federal funds, 3) provides no new incentives for abortion, and 4) establishes a sunset provision. We believe these principles should underpin any cloning legislation. The prohibition wording options presented below are designed to clarify our position.

Whichever option you choose, you will have to struggle with the dichotomy between allowing most embryo research in the private sector, while maintaining a ban on the use of Federal funds with which much valuable science might be conducted. You addressed this issue in developing the current draft bill and might refer to the June 8 decision memorandum for useful discussion (Tab B). It is probable that cloning legislation will viewed by some members of Congress as a vehicle for extending a more permanent, broad ban on embryo research.

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

I. Prohibition Wording Options

A. Support current language without changes

Current language:

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

Your bill has been praised by the biomedical industry and professional societies for its narrow focus on the act of creating a human being through somatic cell nuclear transfer--the technology used to create Dolly the sheep--and the absence of any mention of embryo research. These groups also applaud your protection of noncontroversial biomedical research and the 5-year sunset provision. Current language maintains the status quo with respect to freedom to carry out embryo research in the private sector under existing (albeit limited) Federal oversight, and does not affect nor address the ban on Federal funding for a much broader class of embryo research.

The biotechnology industry and fertility research community have identified three problems with this language: (1) it appears to equate introduction into the womb with creating a human being, (2) the meaning of the word "intent" is ambiguous, and (3) the meaning of the phrase "or in any other way" is unclear. Option B describes a solution for these problems, while continuing to uphold the principles expressed in your draft bill .

B. Refine current language

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

This language is an improvement in that it makes it clear that violation would occur at the time of introduction into the womb of the product of cloning. However, the phrase "in order to create child" carries with it two problems: (1) defining a child and when life begins, and (2) "in order to" still implies intent. Option C avoids these pitfalls/difficulties.

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

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

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

or fetus. Therefore, we would suggest that "in order to create a child" be deleted.

This clear language means that during the time this law is in effect, no one in the public or private sectors may perform somatic cell nuclear transfer and implant the resulting product in a woman's uterus. Today, this is legal in the private sector, although it may be possible to exert some regulatory oversight, as discussed in the background attachment. Some fertility research would be precluded under this option, although it is difficult to determine how much because efforts are generally made to sustain a pregnancy after implantation, not to perform experiments with the intention of aborting. Your National Bioethics Advisory Commission recommended a temporary ban on the use of somatic cell nuclear transfer to create child only after hearing testimony that a 3-5 year prohibition would not impede medical research progress, as long as animal cloning experiments were permitted. We have been told that the fertility research community would not object to this approach.

The right-to-life community has criticized your bill based on their interpretation that it would allow the creation of embryos for research purposes using private funds as long as those embryos were aborted subsequently. Option C still permits the creation of embryos, but removes the incentive for abortion. While the scientific and medical communities supported your earlier version, it is likely that you will retain their support even with this change in view of the larger threats that Congress might impose on research. However, it does make retention of the **sunset clause** all the more crucial. Sen. Bond, Rep. Ehlers, and others will oppose a sunset clause.

D. Adopt a more general prohibition

Your bill is intended to prevent anyone from creating a child who is a genetically identical copy of an existing or previously existing person. Somatic cell nuclear transfer is one way of accomplishing this feat and you endorsed the recommendation of your National Bioethics Advisory Commission in limiting the scope of your bill to the use of such technology to create a child. However, other groups including the American Society for Reproductive Medicine and Council of Europe have proposed more general, non-technology specific bans. One example might be the following:

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

We oppose this approach because it raises many of the same problems addressed in Options A and B; namely, defining a child and when life begins. It would also bar reproductive technology currently in use in the U.S.

Recommendation:

We propose that you select Option C so as to: maintain a narrowly focused prohibition, thus protecting the widest possible range of biomedical research while not creating any new incentives for abortion.

Approve: _____ Disapprove: _____ Discuss: _____

II. Federal Pre-emption of State Regulation

The industry is strongly advocating that the Administration use this bill to pre-empt state laws restricting cloning research. The industry cites the California Bill as an example of the type of provision that would prohibit appropriate biomedical research on cloning and they fear that the political climate would likely pressure states to adopt unduly restrictive measures.

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

Recommendation:

We recommend against adding a pre-emption clause.

Approve: _____ Disapprove: _____ Discuss: _____

III. Legislative Strategy

Because the amendment process is difficult to control and extreme amendments may make ultimate support of transmitted Administration legislation

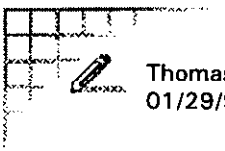
undesirable, we recommend encouraging our allies in Congress to incorporate your improved language into their legislation. Senator Diane Feinstein is currently drafting legislation and might be receptive.

Cloning legislation already introduced:
HR 922 by Ehlers - prohibition of Federal funds to conduct or support research on the cloning of humans. Passed out of House Science Committee. Jurisdiction claimed by House Commerce. No hearing date set.
HR 923 by Ehlers - prohibition on cloning humans. House Judiciary Committee. No hearing date.
S 368 by Bond - prohibition of use of Federal funds for human cloning research. No action to date.

Tabs:

A. June 9, 1997 draft Administration bill
B. June 8, 1997 Decision memorandum
C. Discussion of Impact of FDA Regulatory Authority on Legislative Strategy

Cloning



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.

Cloning

Wed. morning –

Thomas L. Freedman
02/02/98 09:05:05 AM

Record Type: Record

To: Laura Emmett/WHO/EOP

cc:
Subject: MONDAY'S CONFERENCE CALL

---------------------- Forwarded by Thomas L. Freedman/OPD/EOP on 02/02/98 09:04 AM ---------------------------

Repubs not introduced yet – "once they get into it" not finished yet ← Frist/Bond – try to work w/ us –

Essence P. Washington
01/30/98 05:04:13 PM

Record Type: Record

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

cc:
Subject: MONDAY'S CONFERENCE CALL

Subject: **Conference Call on Cloning**
Time: **1:30 PM**
Date: **Febuary 2 1998**
Participants calling on line 6-6755 code 7979

Elena Kagen
Mary Smith
Tom Freedman
Jerold Mande
Janet Murgia
Lucia Wyman

Participants calling on line 6-6766 code 7979

Rachel Levinson
Jeff Smith
Rich Tarplin
Bill Marshall

tomorrow afternoon new bill – available at that time

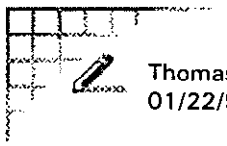
Rich T – longer time it takes, better off we are + if we take time to sit down w/ them, poss of working something out

Difficult with fighting ~~mes~~/ – but rhetoric not favorable – should try eve. to work out.

Message Sent To:

Schedule mtg for late in week – use as delaying tactic.

Cloning



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.1 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.

DRAFT MEMORANDUM FOR THE PRESIDENT

FROM:

SUBJECT: Cloning Legislative Options

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

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

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

I. Substantive Prohibition

A. Support existing language without changes

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

B. Refine current language

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

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

Rationale

There is greater agreement on the definition of a child than there is on a human being, thus avoiding some, but not all of the embryo research and abortion debate.

The term "or in any other way" created unnecessary confusion.

"Intent" was included as protection for a defendant, but industry and medical practitioners suggested deleting it.

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

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

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

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

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

The right-to-life community criticized your bill for allowing the creation of embryos for research purposes using private funds, as long as those embryos were aborted subsequently. This modification still permits the creation of embryos but removes the incentive for abortion. While the scientific and medical communities supported your earlier version, it is likely that you will retain their support even with this change in view of the larger threats to research emanating from Congress. However, it does make the sunset clause all the more crucial. We have been told that the fertility research community would not object to this approach.

D. Adopt a more general prohibition

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

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

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

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

Recommendation:

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

Approve: _____ Disapprove: _____ Discuss: _____

II. Federal Pre-emption of State Regulation

The industry is strongly advocating that the Administration use this bill to pre-empt state laws restricting cloning research. The industry cites the California Bill as an example of the type of provision that would prohibit appropriate biomedical research on cloning and they fear that the political climate would likely pressure states to adopt unduly restrictive measures.

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

Recommendation:

We recommend against adding a pre-emption clause.

Approve: _____ Disapprove: _____ Discuss: _____

Attachments:

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

B. H.R. 922 - Bill Introduced By Rep. Vernon Ehlers to prohibit the expenditure of Federal