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

Discuss: 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.

Note The problem with this approach is discussed below

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

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

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

Recommendation:

We recommend against adding a pre-emption clause.

Approve: _____ Disapprove: _____ Discuss: _____

Attachments:

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

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

Fil-cloning

THE WHITE HOUSE

WASHINGTON

March 3, 1997

MEMORANDUM FOR THE PRESIDENT

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

Bruce Reed
Assistant to the President for Domestic Policy

SUBJECT: Background and Suggested Presidential Statement on Cloning

As you know, the February 27 issue of *Nature*, a renowned scientific journal, contains an account of the first successful cloning of an adult sheep. Hypothetically, similar techniques could be used to clone humans. Because of the ethical concerns human cloning would present, on February 24 you asked your National Bioethics Advisory Commission (NBAC) to review the legal and ethical issues involved and to report back within 90 days on possible federal actions

We recommend that you: (1) issue a statement on cloning to assure the public that federal funds will not be used to clone humans; and (2) call on the scientific community to voluntarily refrain from human cloning while NBAC and the nation distinguish the facts from the hype and consider its ethical implications.

Background

Most scientists believe that human cloning faces major scientific barriers. For complicated scientific reasons, sheep may be more easily cloned than humans and other animals, and all attempts to clone other mammals such as mice starting with cells from mature animals have failed. The majority of experts believe that any prospect of successfully applying this new cloning method to human beings in the near future is extremely remote.

Human cloning research also faces funding barriers. On December 2, 1994, you issued a statement barring the use of federal funds to create human embryos for research purposes. Appropriations bills for FY96 and FY97 codified this policy and expanded it to cover HHS research in which human embryos are "destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." (The Administration has opposed addressing the issue through legislation and has supported repealing this provision). Senator Bond (R-MO) has begun to draft legislation making permanent the current ban on federal funding for human embryo research

News reports have indicated that the Congressional ban prohibits using federal funds for human cloning, and no one in Congress has taken issue with this understanding. But the language is not as tight as it could be. It does not explicitly bar federally-supported scientists from creating human

embryos they intend to implant -- it only prohibits them from creating embryos they will discard. In addition, the Congressional ban only covers HHS-funded research.

Privately funded facilities are free to engage in human cloning research under current law. There is a booming business in all forms of reproduction technology to assist infertile couples. Human cloning is not likely to be pursued in this context -- at least until it has a chance of competing successfully against existing technology -- but it cannot be definitively ruled out.

Congress has scheduled fact-finding hearings on human cloning March 5 (Technology Subcommittee, House Science Committee) and March 12 (Senate Subcommittee on Science, Technology and Space). NIH Director Harold Varmus has been asked to testify at both upcoming hearings. On February 26, in testimony before the House Appropriations Subcommittee on Labor and Health and Human Services, Dr. Varmus stated that the idea of human cloning was "repugnant." He went on to say that he "would be concerned about a rush to legislate" a prohibition since legislation could also restrict related work that offers important medical, economic, and scientific benefits.

Rushed attempts to ban cloning could easily result in unintended harmful effects on important research. For example, Dr. Varmus has noted that sheep cloning might inform new methods for producing human proteins, creating model organisms to study human diseases, and possibly reprogramming human cells for treatment of cancer, burns, and other disorders. Therefore, any restraints on human cloning should be worded carefully to avoid unintended consequences on a broader sphere of biomedical and agricultural research.

A consensus is emerging, however, that researchers should not pursue human cloning at least until the nation has more thoroughly considered the ethical implications of the technology. The current restrictions do not assure this outcome for two reasons. First, as noted above, the current ban on using federal funds to create embryos for research does not explicitly prohibit all human cloning -- it only covers cloning of embryos that will be discarded (not implanted), and only covers HHS-funded research. Second, the restrictions apply to federally-supported human embryo research only, not privately-funded activities.

You could urge the non-federally funded scientific community to declare a self-imposed moratorium on human cloning. Some in science will question the need for this approach because they do not believe our ability to clone humans is imminent.. Some also believe that it would be inappropriate for you to take action before NBAC reports back to you with recommendations (your referral of the issue to NBAC received enthusiastic, bipartisan support at NIH's February 26 appropriations hearing). On the other hand, your calling for a moratorium might deter restrictive, ill-advised legislation, reassure the public, and strengthen the nation's resolve to consider ethical questions carefully before advancing human cloning. The scientific community favors a voluntary moratorium over a Congressional ban, and key scientists including Dr. Varmus would understand your calling for it.

Suggested Presidential Statement

We recommend that you issue a statement to:

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

Senate Democrats Block Cloning Bill; Lott Seeks Cloture

HEALTH

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Jennings Cautions GOP On Medicare Contracting Issue

HEALTH

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

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

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

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

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

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

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

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

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

shall be ineligible to receive any contract or subcontract made with funds made available in this Act, pursuant to the debarment, suspension, and ineligibility procedures described in sections 9.400 through 9.409 of title 48, code of Federal Regulations.

SEC. 507. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

[SEC. 508. None of the funds appropriated under this Act shall be expended for any abortion except when it is made known to the Federal entity or official to which funds are appropriated under this Act that such procedure is necessary to save the life of the mother or that the pregnancy is the result of an act of rape or incest.][1]

SEC. [509] *508.* Notwithstanding any other provision of law—

(1) no amount may be transferred from an appropriation account for the Departments of Labor, Health and Human Services, and Education except as authorized in this or any subsequent appropriation Act, or in the Act establishing the program or activity for which funds are contained in this Act;

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

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

[SEC. 510. None of the funds made available in this Act may be used for the expenses of an electronic benefit transfer (EBT) task force.]

SEC. [510] *509.* Not to exceed 1 percent of any discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act, as amended) which are appropriated for the current fiscal year for titles I, II, and III of this Act may be transferred between appropriations, but no such appropriation shall be increased by more than 3 percent by any such transfer: Provided, That such transfers may be made only between appropriations within each title: Provided further, That the Public Health and Social Services Emergency Fund appropriation under title II of this Act shall not be subject to the 3 percent limitation of this section.

SEC. [511] *510.* None of the funds made available in this Act may be used to enforce the requirements of section 428(b)(1)(U)(iii) of the Higher Education Act of 1965 with respect to any lender when it is made known to the Federal official having authority to obligate or expend such funds that the lender has a loan portfolio under part B of title IV of such Act that is equal to or less than $5,000,000.

[SEC. 512. (a) None of the funds made available in this Act may be used for—

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

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term "human embryo or embryos" include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.][2]

SEC. [513] *511.* (a) LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES.—None of the funds made available in this Act may be used for any activity when it is made known to the Federal official having authority to obligate or expend such funds that the activity promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812)

(b) EXCEPTIONS.—The limitation in subsection (a) shall not apply when it is made known to the Federal official having authority to obligate or expend such funds that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that Federally-sponsored clinical trials are being conducted to determine therapeutic advantage.

[SEC. 514. (a) DENIAL OF FUNDS FOR PREVENTING ROTC ACCESS TO CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps (in accordance with section 654 of title 10, United States Code, and other applicable Federal laws) at the covered educational entity; or

(2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

(b) DENIAL OF FUNDS FOR PREVENTING FEDERAL MILITARY RECRUITING ON CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or

(2) access by military recruiters for purposes of Federal military recruiting to the following information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity:

(A) student names, addresses, and telephone listings; and

(B) if known, student ages, levels of education, and majors.

(c) EXCEPTIONS.—The limitation established in subsection (a) or (b) shall not apply to a covered educational entity if the Secretary of Defense determines that—

(1) the covered educational entity has ceased the policy or practice described in such subsection;

(2) the institution of higher education involved has a longstanding policy of pacifism based on historical religious affiliation; or

(3) the institution of higher education involved is prohibited by the law of any State, or by the order of any State court, from allowing Senior Reserve Officer Training Corps activities or Federal military recruiting on campus, except that this paragraph shall apply only during the one-year period beginning on the effective date of this section.

(d) NOTICE OF DETERMINATIONS.—Whenever the Secretary of Defense makes a determination under subsection (a), (b), or (c), the Secretary—

(1) shall transmit a notice of the determination to the Secretary of Education and to the Congress; and

(2) shall publish in the Federal Register a notice of the determination and the effect of the determination on the eligibility of the covered educational entity for contracts and grants.

(e) SEMIANNUAL NOTICE IN FEDERAL REGISTER.—The Secretary of Defense shall publish in the Federal Register once every 6 months a list of each covered educational entity that is currently ineligible for contracts and grants by reason of a determination of the Secretary under subsection (a) or (b).

(f) COVERED EDUCATIONAL ENTITY.—For purposes of this section, the term "covered educational entity" means an institution of higher education, or a subelement of an institution of higher education.

(g) EFFECTIVE DATE.—This section shall take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act, by which date the Secretary of Defense shall have published final regulations in consultation with the Secretary of Education to carry out this section.]

[2] The Administration proposes to delete this provision and does not support addressing this issue in legislation.

Human Embryo Research

Continuing Resolution 9 (P.L. 104-91) prohibited Federal funding for the "creation of a human embryo or embryos for research purposes..." and "for research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." The C.R. applied to funding for the entire FY 96. Identical language was placed in FY 97 DHHS Appropriations language (P.L.104-208). The President's FY 97 and 98 budgets proposed deleting the the second provision and did not support addressing this issue in legislation. The first section codifies the President's directive of Dec. 2, 1994. The second section addresses research on all human embryos, regardless of source. The second part goes substantially further in prohibiting a much larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

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

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

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

CHRISTOPHER S. BOND
MISSOURI

COMMITTEES
APPROPRIATIONS
SMALL BUSINESS
BUDGET
ENVIRONMENT AND
PUBLIC WORKS

Health

United States Senate

WASHINGTON, DC 20510-2503

January 9, 1998

Dear Colleague:

Please join me as a cosponsor of the "Human Cloning Prohibition Act". I intend to introduce the measure when the Senate reconvenes at the end of this month.

Reports this week that a Chicago-based scientist is prepared to move forward with human cloning experimentation forces an immediate debate on how far out on the moral cliff we are willing to let science proceed before we as a nation insist on some meaningful constraints. My legislation will send a strong message that this type of research is clearly unethical and unacceptable by placing an emergency ban on human cloning research.

Plant and animal cloning, and research taking place at the Human Genome Center offer great hope in addressing how to prevent, diagnose, and treat many devastating diseases. However, we must draw the line at human cloning. The belief that all human beings are unique and created by God is shared by billions of us around the world. Human cloning, or man's attempt to play God, would change the very meaning of life, of what it is to be human. Are we ready for that? Hardly.

The United States should show the moral courage and follow the example of several other countries by banning and criminalizing all human cloning research, whether public or private. Recent news accounts show that we no longer have the luxury of waiting for this morally reprehensible act to occur.

If you would like to join me, or if you have any questions, please call me or have your staff contact Joe Pierle of my staff at 4-5721.

Sincerely,

Kit Bond

Christopher S. Bond

(R) MO

DIANNE FEINSTEIN
CALIFORNIA

COMMITTEES ON FOREIGN RELATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEE ON RULES AND ADMINISTRATION

United States Senate

WASHINGTON, DC 20510-0504

Heath

January 15, 1998

Dear Colleague:

I am writing to invite you to join me in cosponsoring legislation to prohibit human cloning, whether funded publicly or privately.

According to recent press reports, Dr. G. Richard Seed, a Chicago-area physicist, announced that he intends to clone a human being and that eight people have already volunteered to be cloned.

I agree with the recommendation of the National Bioethics Advisory Commission, that ". . . at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning." The Commission concluded that this technique is not safe to use in humans and that it raises "serious ethical concerns . . . which require much more widespread and careful public deliberation before this technology may be used."

Commendably, President Clinton on March 4, 1997, directed federal agencies not to use federal funds for the cloning of human beings. This prohibition, however, does not extend to privately-funded research and on June 10, the President proposed the Cloning Prohibition Act to cover both the public and private sector.

The legislation I will introduce will make it unlawful, for ten years, for any person or other legal entity, public or private, to use cloning to create human beings. It will also require the National Bioethics Advisory Commission to report to the President and the Congress on the (1) state of the science of somatic cell nuclear transfer and (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 by the bill.

I hope you will join me in cosponsoring this bill and working for its prompt enactment. If you have any questions, please feel free to call me or Glenda Booth or Richard Pfohl at 4-3841 on my staff.

Sincerely,

Dianne Feinstein
U. S. Senator

DF:gb

JUDD GREGG
NEW HAMPSHIRE

CHIEF DEPUTY WHIP

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99 PEASE BOULEVARD
PORTSMOUTH, NH 03801
(603) 431-2171

January 14, 1998

Dear Colleague:

When we return for the second session of the 105th Congress, there is an issue that will require our immediate action: the cloning of human beings. I firmly believe that there needs to be an outright prohibition on the possible development of this procedure. Current law prohibits federal funds going toward human embryo research, but we must clearly now extend the ban to private activities as well. That is why I will be introducing legislation upon our return to ban human embryo creation by the process of cloning.

It has been almost 12 months since the world learned that, after 276 unsuccessful attempts, Dr. Ian Wilmut of the Roslin Institute in Scotland had actually managed to clone a sheep that became known as "Dolly." Since that time, the debate has gone from the theoretical to the possible implications of this ability to clone living beings. However, the overwhelming consensus has been that while cloning may hold some important scientific promise for producing therapies where they may not exist -- such as growing skin from skin cells for burn victims -- as well as potential for important agricultural and botanical advances, there is little tolerance for those who entertain the notion of reproducing human "carbon copies."

My legislation is modeled on a law that was enacted last year in the State of California, that became effective January 1, 1998. Similar to the California law, my bill makes the cloning of a human being unlawful. My bill differs from the California law, however, in that it outlaws human embryo creation even for the purpose of research. My proposal does allow certain genetic research that does not involve cloning human embryos to continue. This legislation sets up a system of penalties for the violation of this law that will serve as a deterrent for such activities in either the public or the private sector.

I hope that you will join me as a cosponsor of this legislation, which I will circulate shortly. I do not believe that we here in the Senate have the luxury of time on this issue. I hope to see this legislation considered expediently upon our return. If you are interested in being a cosponsor, please contact Kimberly Spaulding or Alan Gilbert of my staff at 4-0136.

Sincerely,

Judd Gregg
U.S. Senator

(R) NH

Discussion:
This is a very straightforward statement but is burdened by implications regarding abortion.

Implications:
- Violation occurs at the time of birth (unless one believes that a child is created before birth) and so allows anything up to that point including creating an embryo via SCNT and introducing it into a woman's uterus
- Would require abortion at some point before birth
- Would allow embryo research (using private funds), regardless of whether or not the embryo was transferred to a woman for gestation, thus permitting fertility and other biomedical research

D. Council of Europe Position

Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.

Invites definitional issue of when a human being is created. May prohibit blastomere or embryo splitting; a reproductive technique currently in use in this country, depending on definition of human being. The word "seeking" is vague leaving open possibility of inhibiting a range of research involving other forms of cloning.

III. OTHER: DEFINITIONS AND BACKGROUND

(a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.
(b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).
(c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

OSTP Discussion:
"Somatic cell" (See alternative definition below.) While ours differs from others, it is a reasonable, accurate lay language definition of a technical term. The goal of groups such as ASRM and BIO is to create a more narrow set of definitions in order to protect a rather broad class of research. Ours is not so encumbered, leaving out any oblique references to embryo research.

American Society for Reproductive Medicine
"somatic cell means a mature, diploid cell."

Discussion:
Diploid corresponds to our definition; mature is an addition intended to permit certain

types of infertility or other biomedical research. For example, under this definition research might be carried out to improve the efficiency of in vitro fertilization and other treatments for infertility using cells taken from an embryo.

Research of more general interest might be done using cells not yet deemed to be mature, or so-called stem cells, cells which have not yet differentiated into their final form. Embryonic stem cells are cells from an early embryo that can go on to form any cell of the organism. Embryonal stem cells from mice have been grown in culture and can be stimulated to form precursors of blood, nerve and muscle cells. Human embryonal stem cells could be cultured similarly and engineered to prevent transplant rejection.

"'the creation of a human child' means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth."

Discussion:
ASRM's intent is to prohibit the birth of a child created using SCNT technology but their definition is unclear with respect to the act of implantation.

IV. OTHER SECTIONS: PROTECTED RESEARCH AND PREEMPTION

SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:
(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.

Sen. Feinstein's staff suggested that we include reference to medical practice in this section as follows:

SECTION 6. PROTECTED BIOMEDICAL RESEARCH AND MEDICAL PRACTICE.__Nothing in this Act shall restrict other areas of biomedical and agricultural research and medical practice, including important and promising work that involves:

STATE PREEMPTION

BIO and ASRM would like to see a Federal law preempt state laws such as that enacted in California. They believe that the California law is an example of the difficulty in crafting language that does not impinge on non-controversial, beneficial research. We are investigating the California law.

DRAFT BACKGROUND ON CLONING

I. CENTRAL ISSUES

A. Action to Take. Whether to send up a bill, announce a statement of principles, do this as a regulatory matter, or do regulatory and legislative actions.

B. Protecting Research. There is on-going privately funded embryo research. Blanket bans on using this technology for any research satisfy the urge to stop cloning of humans but meet opposition from researchers who want to use this technology. They claim the technique may be of use for work on immune systems, burn victims, bone marrow, diabetes, leukemia and liver damage. Using federal resources to do this research is prohibited at its earliest stages under the federal ban on creating embryos for research purposes using federal money. (1994)

II. POLICY OPTIONS

A. FDA AUTHORITY

* FDA has not reached a formal determination as to whether it has the authority to ban cloning research.

* However, they are very likely to reach the conclusion that they do have such authority, and could forbid such research on the grounds of safety.

* They say that whether or not they issue this determination it will not eliminate the need for legislation as after a few years cloning research may be safe and would then need a ban based on ethical considerations.

B. CURRENT ADMINISTRATION POSITION

Administration Bill (June 9, 1997)
SECTION 5. PROHIBITION. 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.

This bill has not been introduced. Counsel's office feels the "Or in any other way creating a human being" phrase is unclear. It can be interpreted to mean creating a human being in any way other than by using somatic cell nuclear

transfer (SCNT), or, as we intended, creating a human being through extra-uterine gestation, a technology that is unlikely to become available prior to significant development of SCNT. There is also the question of when does someone become a human being.

C. Possible Revision I

> "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 in order to create a child."

Implications:
Violation begins at time of introduction of the product of SCNT into a woman's uterus. That would have to happen within 14 days of differentiation.

- Would allow creation of an embryo (only with private funding) using SCNT, as long as transfer to woman's uterus does not occur.
- Would maintain status quo for private sector IVF research
- Would be consistent with current public sector ban on embryo research, precluding opportunity to capitalize on SCNT for research into treatment for spinal cord and other nerve cell regeneration, AIDS, skin grafts, and replacement organs

D. POSSIBLE REVISION II

It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer when the product of that transfer is introduced into a woman's womb [in order to create a child].

Implications:

- Violation begins at time of introduction of the product of SCNT into a woman's uterus.
- Would allow creation of an embryo (only with private funding) using SCNT, as long as transfer to woman's uterus does not occur.
- Would maintain status quo for private sector IVF research
- Would be consistent with current public sector ban on embryo research, precluding opportunity to capitalize on SCNT for research into treatment for spinal cord and other nerve cell regeneration, AIDS, skin grafts, and replacement organs

<u>American Society for Reproductive Medicine</u>

It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.

BACKGROUND ON CLONING

I. CENTRAL ISSUES

A. Action to Take. Whether to send up a bill, announce a statement of principles, do this regulatorily, or do regulatory and legislative actions.

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(c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

Discussion:

"Somatic cell" (See alternative definition below.) While ours differs from others, it is a reasonable, accurate lay language definition of a technical term. The goal of groups such as ASRM and BIO is to create a more narrow set of definitions in order to protect a rather broad class of research. Ours is not so encumbered, leaving out any oblique references to embryo research.

American Society for Reproductive Medicine

"somatic cell means a mature, diploid cell."

Discussion:
Diploid corresponds to our definition; mature is an addition intended to permit certain types of infertility or other biomedical research. For example, under this definition research might be carried out to improve the efficiency of in vitro fertilization and other treatments for infertility using cells taken from an embryo.

Research of more general interest might be done using cells not yet deemed to be mature, or so-called stem cells, cells which have not yet differentiated into their final form. Embryonic stem cells are cells from an early embryo that can go on to form any cell of the organism. Embryonal stem cells from mice have been grown in culture and can be stimulated to form precursors of blood, nerve and muscle cells. Human embryonal stem cells could be cultured similarly and engineered to prevent transplant rejection.

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Discussion:
ASRM's intent is to prohibit the birth of a child created using SCNT technology but their definition is unclear with respect to the act of implantation.

OTHER COMMENTS

SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:

(1) the use of somatic cell nuclear transfer or other cloning technologies to clone molecules, DNA, cells, and tissues; or
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Sen. Feinstein's staff suggested that we include reference to medical practice in this section as follows:

SECTION 6. PROTECTED BIOMEDICAL RESEARCH AND MEDICAL PRACTICE.__Nothing in this Act shall restrict other areas of biomedical and agricultural research and medical practice, including important and promising work that involves:

STATE PREEMPTION

BIO and ASRM would like to see a Federal law preempt state laws such as that enacted in California. They believe that the California law is an example of the difficulty in crafting language that does not impinge on non-controversial, beneficial research.

IMPACT OF FDA AUTHORITY ON CLONING OPTIONS

Recent reports notwithstanding, FDA is still in the process of developing a determination of its authority to regulate the use of somatic cell nuclear transfer (SCNT) for the purpose of creating a child. Assuming for the moment that FDA **does** have this authority, how would that effect our strategy with respect to legislation?

The Food, Drug and Cosmetic Act gives FDA authority to regulate products and procedures on the basis of safety and efficacy--not ethics. Our bill would prohibit any attempt to create a child using SCNT and provide for further review of the ethical and scientific. FDA's likely authority takes care of the former, for some period of time, but does not address the need for public discourse. Therefore, there is still a need to pursue legislative options.

The issues of greatest concern [to scientists and industry] are what is prohibited and how the prohibited act(s) is(are) defined

Prohibitions, part 2

possible revision II	ASRM	Council of Europe
It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer when the product of that transfer is introduced into a woman's womb [in order to create a child].	It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.	Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
	•This is a very straightforward statement but is burdened by implications regarding abortion.	Does not mention any specific type of cloning technology, which may be desirable. Invites definitional issue of when a human being is created.
Violation begins at time of introduction of the product of SCNT into a woman's uterus	Violation occurs at the time of birth (unless one believes that a child is created before birth) and so allows anything up to that point including creating an embryo via SCNT and introducing it into a woman's uterus	The word "seeking" is vague leaving open possibility of inhibiting a range of research involving other forms of cloning.
Would allow creation of an embryo (only with private funding) using SCNT, as long as transfer to woman's uterus does not occur.	Would require abortion at some point before birth	Similar to ASRM prohibition above.
Would maintain status quo for private sector IVF research	Would allow embryo research (using private funds), regardless of whether or not the embryo was transferred to a woman for gestation, thus permitting fertility and other biomedical research	Could be used to proscribe a broad range of research involving other forms of cloning
Would be consistent with current public sector ban on embryo research, precluding opportunity to capitalize on SCNT for research into treatment for spinal cord and other nerve cell regeneration, AIDS, skin grafts, and replacement organs.		May prohibit blastomere or embryo splitting; a reproductive technique currently in use in this country, depending on definition of human being.

Definitions	Administration	ASRM	ASRM
wording	SECTION 4. DEFINITIONS. (a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human. (b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm). (c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.	"somatic cell means a mature, diploid cell."	"the creation of a human child" means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth."
discussion	"Somatic cell" – See alternative definition below. While ours differs from others, it is a reasonable, accurate lay language definition of a technical term. The goal of groups such as ASRM and BIO is to create a more narrow set of definitions in order to protect a rather broad class of research. Ours is not so encumbered, leaving out any oblique references to embryo research.	"Diploid" corresponds to our definition; mature is an addition intended to permit certain types of infertility or other biomedical research. For example, under this definition research might be carried out to improve the efficiency of in vitro fertilization and other treatments for infertility using cells taken from an embryo.	ASRM's intent is to prohibit the birth of a child created using SCNT technology but their definition is unclear with respect to the act of implantation.
		Research of more general interest might be done using cells not yet deemed to be mature, or so-called stem cells, cells which have not yet differentiated into their final form. Embryonic stem cells are cells from an early embryo that can go on to form any cell of the organism. Embryonal stem cells from mice have been grown in culture and can be stimulated to form precursors of blood, nerve and muscle cells. Human embryonal stem cells could be cultured similarly and engineered to prevent transplant rejection.	

OTHER	Administration	possible revision (suggested by Sen. Feinstein's staff)
wording	SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:	SECTION 6. PROTECTED BIOMEDICAL RESEARCH AND MEDICAL PRACTICE.—Nothing in this Act shall restrict other areas of biomedical and agricultural research and medical practice, including important and promising work that involves:
discussion		Includes reference to medical practice.

shall be ineligible to receive any contract or subcontract made with funds made available in this Act, pursuant to the debarment, suspension, and ineligibility procedures described in sections 9.400 through 9.409 of title 48, code of Federal Regulations.

SEC. 507. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

[SEC. 508. None of the funds appropriated under this Act shall be expended for any abortion except when it is made known to the Federal entity or official to which funds are appropriated under this Act that such procedure is necessary to save the life of the mother or that the pregnancy is the result of an act of rape or incest.][1]

SEC. [509] *508.* Notwithstanding any other provision of law—

(1) no amount may be transferred from an appropriation account for the Departments of Labor, Health and Human Services, and Education except as authorized in this or any subsequent appropriation Act, or in the Act establishing the program or activity for which funds are contained in this Act;

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

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

[SEC. 510. None of the funds made available in this Act may be used for the expenses of an electronic benefit transfer (EBT) task force.]

SEC. [510] *509.* Not to exceed 1 percent of any discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act, as amended) which are appropriated for the current fiscal year for titles I, II, and III of this Act may be transferred between appropriations, but no such appropriation shall be increased by more than 3 percent by any such transfer: Provided, That such transfers may be made only between appropriations within each title: Provided further, That the Public Health and Social Services Emergency Fund appropriation under title II of this Act shall not be subject to the 3 percent limitation of this section.

SEC. [511] *510.* None of the funds made available in this Act may be used to enforce the requirements of section 428(b)(1)(U)(iii) of the Higher Education Act of 1965 with respect to any lender when it is made known to the Federal official having authority to obligate or expend such funds that the lender has a loan portfolio under part B of title IV of such Act that is equal to or less than $5,000,000.

[SEC. 512. (a) None of the funds made available in this Act may be used for—

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

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term "human embryo or embryos" include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.][2]

SEC. [513] *511.* (a) LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES.—None of the funds made available in this Act may be used for any activity when it is made known to the Federal official having authority to obligate or expend such funds that the activity promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812).

(b) EXCEPTIONS.—The limitation in subsection (a) shall not apply when it is made known to the Federal official having authority to obligate or expend such funds that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that Federally-sponsored clinical trials are being conducted to determine therapeutic advantage.

[SEC. 514. (a) DENIAL OF FUNDS FOR PREVENTING ROTC ACCESS TO CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps (in accordance with section 654 of title 10, United States Code, and other applicable Federal laws) at the covered educational entity; or

(2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

(b) DENIAL OF FUNDS FOR PREVENTING FEDERAL MILITARY RECRUITING ON CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or

(2) access by military recruiters for purposes of Federal military recruiting to the following information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity:

(A) student names, addresses, and telephone listings; and

(B) if known, student ages, levels of education, and majors.

(c) EXCEPTIONS.—The limitation established in subsection (a) or (b) shall not apply to a covered educational entity if the Secretary of Defense determines that—

(1) the covered educational entity has ceased the policy or practice described in such subsection;

(2) the institution of higher education involved has a longstanding policy of pacifism based on historical religious affiliation; or

(3) the institution of higher education involved is prohibited by the law of any State, or by the order of any State court, from allowing Senior Reserve Officer Training Corps activities or Federal military recruiting on campus, except that this paragraph shall apply only during the one-year period beginning on the effective date of this section.

(d) NOTICE OF DETERMINATIONS.—Whenever the Secretary of Defense makes a determination under subsection (a), (b), or (c), the Secretary—

(1) shall transmit a notice of the determination to the Secretary of Education and to the Congress; and

(2) shall publish in the Federal Register a notice of the determination and the effect of the determination on the eligibility of the covered educational entity for contracts and grants.

(e) SEMIANNUAL NOTICE IN FEDERAL REGISTER.—The Secretary of Defense shall publish in the Federal Register once every 6 months a list of each covered educational entity that is currentiy ineligible for contracts and grants by reason of a determination of the Secretary under subsection (a) or (b)

(f) COVERED EDUCATIONAL ENTITY.—For purposes of this section, the term "covered educational entity" means an institution of higher education, or a subelement of an institution of higher education.

(g) EFFECTIVE DATE.—This section shall take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act, by which date the Secretary of Defense shall have published final regulations in consultation with the Secretary of Education to carry out this section.]

[2] The Administration proposes to delete this provision and does not support addressing this issue in legislation.

Human Embryo Research

Continuing Resolution 9 (P.L. 104-91) prohibited Federal funding for the "creation of a human embryo or embryos for research purposes..." and "for research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." The C.R. applied to funding for the entire FY 96. Identical language was placed in FY 97 DHHS Appropriations language (P.L.104-208). The President's FY 97 and 98 budgets proposed deleting the the second provision and did not support addressing this issue in legislation. The first section codifies the President's directive of Dec. 2, 1994. The second section addresses research on all human embryos, regardless of source. The second part goes substantially further in prohibiting a much larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

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

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

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

CHRISTOPHER S. BOND
MISSOURI

COMMITTEES
APPROPRIATIONS
SMALL BUSINESS
BUDGET
ENVIRONMENT AND
PUBLIC WORKS

United States Senate

WASHINGTON, DC 20510-2503

Health
Will introduce new bill. No Action

January 9, 1998

Dear Colleague:

Please join me as a cosponsor of the "Human Cloning Prohibition Act". I intend to introduce the measure when the Senate reconvenes at the end of this month.

Reports this week that a Chicago-based scientist is prepared to move forward with human cloning experimentation forces an immediate debate on how far out on the moral cliff we are willing to let science proceed before we as a nation insist on some meaningful constraints. My legislation will send a strong message that this type of research is clearly unethical and unacceptable by placing an emergency ban on human cloning research.

Plant and animal cloning, and research taking place at the Human Genome Center offer great hope in addressing how to prevent, diagnose, and treat many devastating diseases. However, we must draw the line at human cloning. The belief that all human beings are unique and created by God is shared by billions of us around the world. Human cloning, or man's attempt to play God, would change the very meaning of life, of what it is to be human. Are we ready for that? Hardly.

The United States should show the moral courage and follow the example of several other countries by banning and criminalizing all human cloning research, whether public or private. Recent news accounts show that we no longer have the luxury of waiting for this morally reprehensible act to occur.

If you would like to join me, or if you have any questions, please call me or have your staff contact Joe Pierle of my staff at 4-5721.

Sincerely,

Kit Bond

Christopher S. Bond

(R) MO

DIANNE FEINSTEIN
CALIFORNIA

COMMITTEES ON FOREIGN RELATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEES ON RULES AND ADMINISTRATION

United States Senate

WASHINGTON, DC 20510-0504

Heath

January 15, 1998

Dear Colleague:

I am writing to invite you to join me in cosponsoring legislation to prohibit human cloning, whether funded publicly or privately.

According to recent press reports, Dr. G. Richard Seed, a Chicago-area physicist, announced that he intends to clone a human being and that eight people have already volunteered to be cloned.

I agree with the recommendation of the National Bioethics Advisory Commission, that ". . . at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning." The Commission concluded that this technique is not safe to use in humans and that it raises "serious ethical concerns . . . which require much more widespread and careful public deliberation before this technology may be used."

Commendably, President Clinton on March 4, 1997, directed federal agencies not to use federal funds for the cloning of human beings. This prohibition, however, does not extend to privately-funded research and on June 10, the President proposed the Cloning Prohibition Act to cover both the public and private sector.

The legislation I will introduce will make it unlawful, for ten years, for any person or other legal entity, public or private, to use cloning to create human beings. It will also require the National Bioethics Advisory Commission to report to the President and the Congress on the (1) state of the science of somatic cell nuclear transfer and (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 by the bill.

I hope you will join me in cosponsoring this bill and working for its prompt enactment. If you have any questions, please feel free to call me or Glenda Booth or Richard Pfohl at 4-3841 on my staff.

Sincerely,

Dianne Feinstein
U. S. Senator

DF:gb

- 10 year limit
- similar to ours

JUDD GREGG
NEW HAMPSHIRE

CHIEF DEPUTY WHIP

COMMITTEES:
BUDGET
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LABOR AND HUMAN RESOURCES

United States Senate

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BERLIN, NH 03570
(603) 752-2604

99 PEASE BOULEVARD
PORTSMOUTH, NH 03801
(603) 431-2171

January 14, 1998

Dear Colleague:

When we return for the second session of the 105th Congress, there is an issue that will require our immediate action: the cloning of human beings. I firmly believe that there needs to be an outright prohibition on the possible development of this procedure. Current law prohibits federal funds going toward human embryo research, but we must clearly now extend the ban to private activities as well. That is why I will be introducing legislation upon our return to ban human embryo creation by the process of cloning.

It has been almost 12 months since the world learned that, after 276 unsuccessful attempts, Dr. Ian Wilmut of the Roslin Institute in Scotland had actually managed to clone a sheep that became known as "Dolly." Since that time, the debate has gone from the theoretical to the possible implications of this ability to clone living beings. However, the overwhelming consensus has been that while cloning may hold some important scientific promise for producing therapies where they may not exist -- such as growing skin from skin cells for burn victims -- as well as potential for important agricultural and botanical advances, there is little tolerance for those who entertain the notion of reproducing human "carbon copies."

My legislation is modeled on a law that was enacted last year in the State of California, that became effective January 1, 1998. Similar to the California law, my bill makes the cloning of a human being unlawful. My bill differs from the California law, however, in that it outlaws human embryo creation even for the purpose of research. My proposal does allow certain genetic research that does not involve cloning human embryos to continue. This legislation sets up a system of penalties for the violation of this law that will serve as a deterrent for such activities in either the public or the private sector.

I hope that you will join me as a cosponsor of this legislation, which I will circulate shortly. I do not believe that we here in the Senate have the luxury of time on this issue. I hope to see this legislation considered expediently upon our return. If you are interested in being a cosponsor, please contact Kimberly Spaulding or Alan Gilbert of my staff at 4-0136.

Sincerely,

Judd Gregg
U.S. Senator

CLONING

LEGISLATIVE OPTIONS

BACKGROUND

Cloning

Cloning means making a precise copy of a molecule (such as a gene), a cell, or an individual plant or animal. It is done routinely in laboratories and clinics around the world in order to understand how proteins work in an organism, to construct new drugs with fewer side effects, to engineer foods with better nutritional characteristics, or to produce animals as models for human disease. Forensic experts clone DNA to identify crime perpetrators, cartilage cells are cloned to repair damaged knees and a few of the more than 5,000 genetic defects are being treated by inserting properly functioning cloned genes into the patient's cells.

Dolly reviewed

Dolly was news because she is thought to be a replica of an adult sheep. We already have human replicas, or twins, which occur naturally and through assisted reproductive technology known as blastomere splitting. However, identical twins are born at the same time and have no identical forebears. Dolly was the product of somatic cell nuclear transfer (SCNT), a technique that may have applications ranging from reconstituting an AIDS patient's own immune system or producing skin cells for burn victims, bone marrow cells for cancer patients, insulin-producing cells to treat diabetes, leukemia and liver damage. Much of this research is prohibited at its earliest stages under the Federal ban on creating embryos for research purposes.

Embryo research

Federal funding for the creation of human embryos for research purposes is banned under a December 2, 1994 Presidential directive and other embryo research is also prohibited via restrictions on DHHS appropriations. (See Attachment A for further discussion.) Embryo research in support of improvements in assisted reproductive medicine is carried out in the private sector with virtually no Federal regulation.

We must assess the need to engage in the issue of embryo research in the context of a cloning bill and follow closely other legislative initiatives.

LEGISLATION

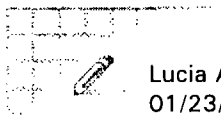
The issues of greatest concern [to scientists and industry] are what is prohibited and how the prohibited act(s) is(are) defined. (See Attachment B for discussion of options)

IMPACT OF FDA AUTHORITY ON CLONING OPTIONS

Recent reports notwithstanding, FDA is still in the process of developing a determination of its authority to regulate the use of somatic cell nuclear transfer (SCNT) for the purpose

of creating a child. Assuming for the moment that FDA **does** have this authority, how would that effect our strategy with respect to legislation?

The Food, Drug and Cosmetic Act gives FDA authority to regulate products and procedures on the basis of safety and efficacy—not ethics. Our bill would prohibit any attempt to create a child using SCNT and provide for further review of the ethical and scientific. FDA's likely authority takes care of the former, for some period of time, but does not address the need for public discourse. Therefore, there is still a need to pursue legislative options.



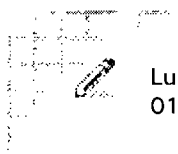
Lucia A. Wyman
01/23/98 11:44:45 AM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP

cc:
Subject: cloning statement

---------- Forwarded by Lucia A. Wyman/WHO/EOP on 01/23/98 11:40 AM ----------



Lucia A. Wyman
01/23/98 10:09:16 AM

Record Type: Record

To: Jeffrey M. Smith/OSTP/EOP, Rachel E. Levinson/OSTP/EOP

cc:
Subject: cloning statement

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 our improved language into their legislation. Senator Diane Feinstein is currently drafting legislation and would be receptive.

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

shall be ineligible to receive any contract or subcontract made with funds made available in this Act, pursuant to the debarment, suspension, and ineligibility procedures described in sections 9.400 through 9.409 of title 48, code of Federal Regulations.

SEC. 507. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

[SEC. 508. None of the funds appropriated under this Act shall be expended for any abortion except when it is made known to the Federal entity or official to which funds are appropriated under this Act that such procedure is necessary to save the life of the mother or that the pregnancy is the result of an act of rape or incest.][1]

SEC. [509] *508.* Notwithstanding any other provision of law—

(1) no amount may be transferred from an appropriation account for the Departments of Labor, Health and Human Services, and Education except as authorized in this or any subsequent appropriation Act, or in the Act establishing the program or activity for which funds are contained in this Act;

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

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

[SEC. 510. None of the funds made available in this Act may be used for the expenses of an electronic benefit transfer (EBT) task force.]

SEC. [510] *509.* Not to exceed 1 percent of any discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act, as amended) which are appropriated for the current fiscal year for titles I, II, and III of this Act may be transferred between appropriations, but no such appropriation shall be increased by more than 3 percent by any such transfer: Provided, That such transfers may be made only between appropriations within each title: Provided further, That the Public Health and Social Services Emergency Fund appropriation under title II of this Act shall not be subject to the 3 percent limitation of this section.

SEC. [511] *510.* None of the funds made available in this Act may be used to enforce the requirements of section 428(b)(1)(U)(iii) of the Higher Education Act of 1965 with respect to any lender when it is made known to the Federal official having authority to obligate or expend such funds that the lender has a loan portfolio under part B of title IV of such Act that is equal to or less than $5,000,000.

[SEC. 512. (a) None of the funds made available in this Act may be used for—

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

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term "human embryo or embryos" include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.][2]

SEC. [513] *511.* (a) LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES.—None of the funds made available in this Act may be used for any activity when it is made known to the Federal official having authority to obligate or expend such funds that the activity promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812).

(b) EXCEPTIONS.—The limitation in subsection (a) shall not apply when it is made known to the Federal official having authority to obligate or expend such funds that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that Federally-sponsored clinical trials are being conducted to determine therapeutic advantage.

[SEC. 514. (a) DENIAL OF FUNDS FOR PREVENTING ROTC ACCESS TO CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps (in accordance with section 654 of title 10, United States Code, and other applicable Federal laws) at the covered educational entity; or

(2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

(b) DENIAL OF FUNDS FOR PREVENTING FEDERAL MILITARY RECRUITING ON CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or

(2) access by military recruiters for purposes of Federal military recruiting to the following information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity:

(A) student names, addresses, and telephone listings; and

(B) if known, student ages, levels of education, and majors.

(c) EXCEPTIONS.—The limitation established in subsection (a) or (b) shall not apply to a covered educational entity if the Secretary of Defense determines that—

(1) the covered educational entity has ceased the policy or practice described in such subsection;

(2) the institution of higher education involved has a longstanding policy of pacifism based on historical religious affiliation; or

(3) the institution of higher education involved is prohibited by the law of any State, or by the order of any State court, from allowing Senior Reserve Officer Training Corps activities or Federal military recruiting on campus, except that this paragraph shall apply only during the one-year period beginning on the effective date of this section.

(d) NOTICE OF DETERMINATIONS.—Whenever the Secretary of Defense makes a determination under subsection (a), (b), or (c), the Secretary—

(1) shall transmit a notice of the determination to the Secretary of Education and to the Congress; and

(2) shall publish in the Federal Register a notice of the determination and the effect of the determination on the eligibility of the covered educational entity for contracts and grants.

(e) SEMIANNUAL NOTICE IN FEDERAL REGISTER.—The Secretary of Defense shall publish in the Federal Register once every 6 months a list of each covered educational entity that is currently ineligible for contracts and grants by reason of a determination of the Secretary under subsection (a) or (b).

(f) COVERED EDUCATIONAL ENTITY.—For purposes of this section, the term "covered educational entity" means an institution of higher education, or a subelement of an institution of higher education.

(g) EFFECTIVE DATE.—This section shall take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act, by which date the Secretary of Defense shall have published final regulations in consultation with the Secretary of Education to carry out this section.]

[2] The Administration proposes to delete this provision and does not support addressing this issue in legislation.

Human Embryo Research

Continuing Resolution 9 (P.L. 104-91) prohibited Federal funding for the "creation of a human embryo or embryos for research purposes..." and "for research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." The C.R. applied to funding for the entire FY 96. Identical language was placed in FY 97 DHHS Appropriations language (P.L.104-208). The President's FY 97 and 98 budgets proposed deleting the the second provision and did not support addressing this issue in legislation. The first section codifies the President's directive of Dec. 2, 1994. The second section addresses research on all human embryos, regardless of source. The second part goes substantially further in prohibiting a much larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

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

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

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

CHRISTOPHER S. BOND
MISSOURI
COMMITTEES
APPROPRIATIONS
SMALL BUSINESS
BUDGET
ENVIRONMENT AND
PUBLIC WORKS

Health

United States Senate

WASHINGTON, DC 20510-2503

January 9, 1998

Dear Colleague:

Please join me as a cosponsor of the "Human Cloning Prohibition Act". I intend to introduce the measure when the Senate reconvenes at the end of this month.

Reports this week that a Chicago-based scientist is prepared to move forward with human cloning experimentation forces an immediate debate on how far out on the moral cliff we are willing to let science proceed before we as a nation insist on some meaningful constraints. My legislation will send a strong message that this type of research is clearly unethical and unacceptable by placing an emergency ban on human cloning research.

Plant and animal cloning, and research taking place at the Human Genome Center offer great hope in addressing how to prevent, diagnose, and treat many devastating diseases. However, we must draw the line at human cloning. The belief that all human beings are unique and created by God is shared by billions of us around the world. Human cloning, or man's attempt to play God, would change the very meaning of life, of what it is to be human. Are we ready for that? Hardly.

The United States should show the moral courage and follow the example of several other countries by banning and criminalizing all human cloning research, whether public or private. Recent news accounts show that we no longer have the luxury of waiting for this morally reprehensible act to occur.

If you would like to join me, or if you have any questions, please call me or have your staff contact Joe Pierle of my staff at 4-5721.

Sincerely,

Kit Bond

Christopher S. Bond

(R) MO

DIANNE FEINSTEIN
CALIFORNIA

COMMITTEES ON FOREIGN RELATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEES ON RULES AND ADMINISTRATION

Health

United States Senate

WASHINGTON, DC 20510-0504

January 15, 1998

Dear Colleague:

I am writing to invite you to join me in cosponsoring legislation to prohibit human cloning, whether funded publicly or privately.

According to recent press reports, Dr. G. Richard Seed, a Chicago-area physicist, announced that he intends to clone a human being and that eight people have already volunteered to be cloned.

I agree with the recommendation of the National Bioethics Advisory Commission, that ". . . at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning." The Commission concluded that this technique is not safe to use in humans and that it raises "serious ethical concerns . . . which require much more widespread and careful public deliberation before this technology may be used."

Commendably, President Clinton on March 4, 1997, directed federal agencies not to use federal funds for the cloning of human beings. This prohibition, however, does not extend to privately-funded research and on June 10, the President proposed the Cloning Prohibition Act to cover both the public and private sector.

The legislation I will introduce will make it unlawful, for ten years, for any person or other legal entity, public or private, to use cloning to create human beings. It will also require the National Bioethics Advisory Commission to report to the President and the Congress on the (1) state of the science of somatic cell nuclear transfer and (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 by the bill.

I hope you will join me in cosponsoring this bill and working for its prompt enactment. If you have any questions, please feel free to call me or Glenda Booth or Richard Pfohl at 4-3841 on my staff.

Sincerely,

Dianne Feinstein
U. S. Senator

DF:gb

JUDD GREGG
NEW HAMPSHIRE

CHIEF DEPUTY WHIP

COMMITTEES:
BUDGET
APPROPRIATIONS
LABOR AND HUMAN RESOURCES

Health

United States Senate

WASHINGTON, DC 20510-2904
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125 N. MAIN STREET
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3 GLEN AVENUE
BERLIN, NH 03570
(603) 752-2604

99 PEASE BOULEVARD
PORTSMOUTH, NH 03801
(603) 431-2171

January 14, 1998

Dear Colleague:

When we return for the second session of the 105th Congress, there is an issue that will require our immediate action: the cloning of human beings. I firmly believe that there needs to be an outright prohibition on the possible development of this procedure. Current law prohibits federal funds going toward human embryo research, but we must clearly now extend the ban to private activities as well. That is why I will be introducing legislation upon our return to ban human embryo creation by the process of cloning.

It has been almost 12 months since the world learned that, after 276 unsuccessful attempts, Dr. Ian Wilmut of the Roslin Institute in Scotland had actually managed to clone a sheep that became known as "Dolly." Since that time, the debate has gone from the theoretical to the possible implications of this ability to clone living beings. However, the overwhelming consensus has been that while cloning may hold some important scientific promise for producing therapies where they may not exist -- such as growing skin from skin cells for burn victims -- as well as potential for important agricultural and botanical advances, there is little tolerance for those who entertain the notion of reproducing human "carbon copies."

My legislation is modeled on a law that was enacted last year in the State of California, that became effective January 1, 1998. Similar to the California law, my bill makes the cloning of a human being unlawful. My bill differs from the California law, however, in that it outlaws human embryo creation even for the purpose of research. My proposal does allow certain genetic research that does not involve cloning human embryos to continue. This legislation sets up a system of penalties for the violation of this law that will serve as a deterrent for such activities in either the public or the private sector.

I hope that you will join me as a cosponsor of this legislation, which I will circulate shortly. I do not believe that we here in the Senate have the luxury of time on this issue. I hope to see this legislation considered expediently upon our return. If you are interested in being a cosponsor, please contact Kimberly Spaulding or Alan Gilbert of my staff at 4-0136.

Sincerely,

Judd Gregg
U.S. Senator

(R) NH

Prohibitions, Part 1

Prohibition	Administration	possible revision I
wording	Administration Bill (June 9, 1997) SECTION 5. PROHIBITION.–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.	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 in order to create a child.
discussion	**"Or in any other way creating a human being"**—The meaning of this phrase is unclear. It can be interpreted to mean creating a human being in any way other than by using SCNT, or, as we intended, creating a human being through extra-uterine gestation, a technology that is unlikely to become available prior to significant development of SCNT.	**"intent"**—Questions for the legal scholars – is intent a term associated only with criminal statutes? Would its inclusion make this language more difficult to enforce? What does it add? Does it make sense in reference to a legal entity? Is "other legal entity" necessary?
discussion	**"human being"**--We have not and probably would prefer not to attempt to define: a human being, the means for creating a human being, nor the definitive act that results in the creation of a human being. Therefore, one option is to substitute "child" in place of "human being," as the National Bioethics Advisory Commission chose to do. While this leaves open the question of when a fetus becomes a child, there is greater agreement on this point, i.e., at birth, than on when life begins.	
implication		
implication		
implication		

Prohibitions, part 2

possible revision II	ASRM	Council of Europe
It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer when the product of that transfer is introduced into a woman's womb [in order to create a child].	It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.	Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
	This is a very straightforward statement but is burdened by implications regarding abortion.	Does not mention any specific type of cloning technology, which may be desirable. Invites definitional issue of when a human being is created.
Violation begins at time of introduction of the product of SCNT into a woman's uterus.	Violation occurs at the time of birth (unless one believes that a child is created before birth) and so allows anything up to that point including creating an embryo via SCNT and introducing it into a woman's uterus	The word "seeking" is vague leaving open possibility of inhibiting a range of research involving other forms of cloning.
Would allow creation of an embryo (only with private funding) using SCNT, as long as transfer to woman's uterus does not occur.	Would require abortion at some point before birth	Similar to ASRM prohibition above.
Would maintain status quo for private sector IVF research	Would allow embryo research (using private funds), regardless of whether or not the embryo was transferred to a woman for gestation, thus permitting fertility and other biomedical research	Could be used to proscribe a broad range of research involving other forms of cloning.
Would be consistent with current public sector ban on embryo research, precluding opportunity to capitalize on SCNT for research into treatment for spinal cord and other nerve cell regeneration, AIDS, skin grafts, and replacement organs.		May prohibit blastomere or embryo splitting, a reproductive technique currently in use in this country, depending on definition of human being

Definitions	Administration	ASRM	ASRM
wording	SECTION 4. DEFINITIONS. (a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human. (b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm). (c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.	"somatic cell means a mature, diploid cell."	"the creation of a human child" means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth."
discussion	"Somatic cell" – See alternative definition below. While ours differs from others, it is a reasonable, accurate lay language definition of a technical term. The goal of groups such as ASRM and BIO is to create a more narrow set of definitions in order to protect a rather broad class of research. Ours is not so encumbered, leaving out any oblique references to embryo research.	"Diploid" corresponds to our definition; mature is an addition intended to permit certain types of infertility or other biomedical research. For example, under this definition research might be carried out to improve the efficiency of in vitro fertilization and other treatments for infertility using cells taken from an embryo.	ASRM's intent is to prohibit the birth of a child created using SCNT technology but their definition is unclear with respect to the act of implantation.
		Research of more general interest might be done using cells not yet deemed to be mature, or so-called stem cells, cells which have not yet differentiated into their final form. Embryonic stem cells are cells from an early embryo that can go on to form any cell of the organism. Embryonal stem cells from mice have been grown in culture and can be stimulated to form precursors of blood, nerve and muscle cells. Human embryonal stem cells could be cultured similarly and engineered to prevent transplant rejection.	

OTHER	Administration	possible revision (suggested by Sen. Feinstein's staff)
wording	SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:	SECTION 6. PROTECTED BIOMEDICAL RESEARCH AND MEDICAL PRACTICE.—Nothing in this Act shall restrict other areas of biomedical and agricultural research and medical practice, including important and promising work that involves:
discussion		Includes reference to medical practice.

shall be ineligible to receive any contract or subcontract made with funds made available in this Act, pursuant to the debarment, suspension, and ineligibility procedures described in sections 9.400 through 9.409 of title 48, code of Federal Regulations.

SEC. 507. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state (1) the percentage of the total costs of the program or project which will be financed with Federal money, (2) the dollar amount of Federal funds for the project or program, and (3) percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

[SEC. 508. None of the funds appropriated under this Act shall be expended for any abortion except when it is made known to the Federal entity or official to which funds are appropriated under this Act that such procedure is necessary to save the life of the mother or that the pregnancy is the result of an act of rape or incest.][1]

SEC. [509] *508.* Notwithstanding any other provision of law—

(1) no amount may be transferred from an appropriation account for the Departments of Labor, Health and Human Services, and Education except as authorized in this or any subsequent appropriation Act, or in the Act establishing the program or activity for which funds are contained in this Act;

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

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

[SEC. 510. None of the funds made available in this Act may be used for the expenses of an electronic benefit transfer (EBT) task force.]

SEC. [510] *509.* Not to exceed 1 percent of any discretionary funds (pursuant to the Balanced Budget and Emergency Deficit Control Act, as amended) which are appropriated for the current fiscal year for titles I, II, and III of this Act may be transferred between appropriations, but no such appropriation shall be increased by more than 3 percent by any such transfer: Provided, That such transfers may be made only between appropriations within each title: Provided further, That the Public Health and Social Services Emergency Fund appropriation under title II of this Act shall not be subject to the 3 percent limitation of this section.

SEC. [511] *510.* None of the funds made available in this Act may be used to enforce the requirements of section 428(b)(1)(U)(iii) of the Higher Education Act of 1965 with respect to any lender when it is made known to the Federal official having authority to obligate or expend such funds that the lender has a loan portfolio under part B of title IV of such Act that is equal to or less than $5,000,000.

[SEC. 512. (a) None of the funds made available in this Act may be used for—

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

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term "human embryo or embryos" include any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.][2]

SEC. [513] *511.* (a) LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES.—None of the funds made available in this Act may be used for any activity when it is made known to the Federal official having authority to obligate or expend such funds that the activity promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812).

(b) EXCEPTIONS.—The limitation in subsection (a) shall not apply when it is made known to the Federal official having authority to obligate or expend such funds that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that Federally-sponsored clinical trials are being conducted to determine therapeutic advantage.

[SEC. 514. (a) DENIAL OF FUNDS FOR PREVENTING ROTC ACCESS TO CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps (in accordance with section 654 of title 10, United States Code, and other applicable Federal laws) at the covered educational entity; or

(2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

(b) DENIAL OF FUNDS FOR PREVENTING FEDERAL MILITARY RECRUITING ON CAMPUS.—None of the funds made available in this or any other Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act for any fiscal year may be provided by contract or by grant (including a grant of funds to be available for student aid) to a covered educational entity if the Secretary of Defense determines that the covered educational entity has a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents—

(1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or

(2) access by military recruiters for purposes of Federal military recruiting to the following information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity:

(A) student names, addresses, and telephone listings; and

(B) if known, student ages, levels of education, and majors.

(c) EXCEPTIONS.—The limitation established in subsection (a) or (b) shall not apply to a covered educational entity if the Secretary of Defense determines that—

(1) the covered educational entity has ceased the policy or practice described in such subsection;

(2) the institution of higher education involved has a longstanding policy of pacifism based on historical religious affiliation; or

(3) the institution of higher education involved is prohibited by the law of any State, or by the order of any State court, from allowing Senior Reserve Officer Training Corps activities or Federal military recruiting on campus, except that this paragraph shall apply only during the one-year period beginning on the effective date of this section.

(d) NOTICE OF DETERMINATIONS.—Whenever the Secretary of Defense makes a determination under subsection (a), (b), or (c), the Secretary—

(1) shall transmit a notice of the determination to the Secretary of Education and to the Congress; and

(2) shall publish in the Federal Register a notice of the determination and the effect of the determination on the eligibility of the covered educational entity for contracts and grants.

(e) SEMIANNUAL NOTICE IN FEDERAL REGISTER.—The Secretary of Defense shall publish in the Federal Register once every 6 months a list of each covered educational entity that is currently ineligible for contracts and grants by reason of a determination of the Secretary under subsection (a) or (b).

(f) COVERED EDUCATIONAL ENTITY.—For purposes of this section, the term "covered educational entity" means an institution of higher education, or a subelement of an institution of higher education.

(g) EFFECTIVE DATE.—This section shall take effect upon the expiration of the 180-day period beginning on the date of the enactment of this Act, by which date the Secretary of Defense shall have published final regulations in consultation with the Secretary of Education to carry out this section.]

[2] The Administration proposes to delete this provision and does not support addressing this issue in legislation.

Human Embryo Research

Continuing Resolution 9 (P.L. 104-91) prohibited Federal funding for the "creation of a human embryo or embryos for research purposes..." and "for research in which a human embryo or embryos would be destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero." The C.R. applied to funding for the entire FY 96. Identical language was placed in FY 97 DHHS Appropriations language (P.L.104-208). The President's FY 97 and 98 budgets proposed deleting the the second provision and did not support addressing this issue in legislation. The first section codifies the President's directive of Dec. 2, 1994. The second section addresses research on all human embryos, regardless of source. The second part goes substantially further in prohibiting a much larger class of research that has implications for treating infertility, preventing birth defects, understanding oncogenes and studying embryonic stem cells.

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

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

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

CHRISTOPHER S. BOND
MISSOURI
COMMITTEES
APPROPRIATIONS
SMALL BUSINESS
BUDGET
ENVIRONMENT AND
PUBLIC WORKS

Health

United States Senate

WASHINGTON, DC 20510-2503

January 9, 1998

Dear Colleague:

Please join me as a cosponsor of the "Human Cloning Prohibition Act". I intend to introduce the measure when the Senate reconvenes at the end of this month.

Reports this week that a Chicago-based scientist is prepared to move forward with human cloning experimentation forces an immediate debate on how far out on the moral cliff we are willing to let science proceed before we as a nation insist on some meaningful constraints. My legislation will send a strong message that this type of research is clearly unethical and unacceptable by placing an emergency ban on human cloning research.

Plant and animal cloning, and research taking place at the Human Genome Center offer great hope in addressing how to prevent, diagnose, and treat many devastating diseases. However, we must draw the line at human cloning. The belief that all human beings are unique and created by God is shared by billions of us around the world. Human cloning, or man's attempt to play God, would change the very meaning of life, of what it is to be human. Are we ready for that? Hardly.

The United States should show the moral courage and follow the example of several other countries by banning and criminalizing all human cloning research, whether public or private. Recent news accounts show that we no longer have the luxury of waiting for this morally reprehensible act to occur.

If you would like to join me, or if you have any questions, please call me or have your staff contact Joe Pierle of my staff at 4-5721.

Sincerely,

Christopher S. Bond

(R) MO

DIANNE FEINSTEIN
CALIFORNIA

COMMITTEES ON FOREIGN RELATIONS
COMMITTEE ON THE JUDICIARY
COMMITTEES ON RULES AND ADMINISTRATION

United States Senate

WASHINGTON, DC 20510-0504

Heath

January 15, 1998

Dear Colleague:

I am writing to invite you to join me in cosponsoring legislation to prohibit human cloning, whether funded publicly or privately.

According to recent press reports, Dr. G. Richard Seed, a Chicago-area physicist, announced that he intends to clone a human being and that eight people have already volunteered to be cloned.

I agree with the recommendation of the National Bioethics Advisory Commission, that ". . . at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning." The Commission concluded that this technique is not safe to use in humans and that it raises "serious ethical concerns . . . which require much more widespread and careful public deliberation before this technology may be used."

Commendably, President Clinton on March 4, 1997, directed federal agencies not to use federal funds for the cloning of human beings. This prohibition, however, does not extend to privately-funded research and on June 10, the President proposed the Cloning Prohibition Act to cover both the public and private sector.

The legislation I will introduce will make it unlawful, for ten years, for any person or other legal entity, public or private, to use cloning to create human beings. It will also require the National Bioethics Advisory Commission to report to the President and the Congress on the (1) state of the science of somatic cell nuclear transfer and (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 by the bill.

I hope you will join me in cosponsoring this bill and working for its prompt enactment. If you have any questions, please feel free to call me or Glenda Booth or Richard Pfohl at 4-3841 on my staff.

Sincerely,

Dianne Feinstein

Dianne Feinstein
U. S. Senator

DF:gb

JUDD GREGG
NEW HAMPSHIRE

CHIEF DEPUTY WHIP

COMMITTEES:
BUDGET
APPROPRIATIONS
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Heal Th

United States Senate

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99 PEASE BOULEVARD
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January 14, 1998

Dear Colleague:

When we return for the second session of the 105th Congress, there is an issue that will require our immediate action: the cloning of human beings. I firmly believe that there needs to be an outright prohibition on the possible development of this procedure. Current law prohibits federal funds going toward human embryo research, but we must clearly now extend the ban to private activities as well. That is why I will be introducing legislation upon our return to ban human embryo creation by the process of cloning.

It has been almost 12 months since the world learned that, after 276 unsuccessful attempts, Dr. Ian Wilmut of the Roslin Institute in Scotland had actually managed to clone a sheep that became known as "Dolly." Since that time, the debate has gone from the theoretical to the possible implications of this ability to clone living beings. However, the overwhelming consensus has been that while cloning may hold some important scientific promise for producing therapies where they may not exist -- such as growing skin from skin cells for burn victims -- as well as potential for important agricultural and botanical advances, there is little tolerance for those who entertain the notion of reproducing human "carbon copies."

My legislation is modeled on a law that was enacted last year in the State of California, that became effective January 1, 1998. Similar to the California law, my bill makes the cloning of a human being unlawful. My bill differs from the California law, however, in that it outlaws human embryo creation even for the purpose of research. My proposal does allow certain genetic research that does not involve cloning human embryos to continue. This legislation sets up a system of penalties for the violation of this law that will serve as a deterrent for such activities in either the public or the private sector.

I hope that you will join me as a cosponsor of this legislation, which I will circulate shortly. I do not believe that we here in the Senate have the luxury of time on this issue. I hope to see this legislation considered expediently upon our return. If you are interested in being a cosponsor, please contact Kimberly Spaulding or Alan Gilbert of my staff at 4-0136.

Sincerely,

Judd Gregg
U.S. Senator

(R) NH

Prohibitions, Part 1

Prohibition	Administration	possible revision I
wording	Administration Bill (June 9, 1997) SECTION 5. PROHIBITION.-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.	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 in order to create a child.
discussion	**"Or in any other way creating a human being"**—The meaning of this phrase is unclear. It can be interpreted to mean creating a human being in any way other than by using SCNT, or, as we intended, creating a human being through extra-uterine gestation, a technology that is unlikely to become available prior to significant development of SCNT.	**"intent"**—Questions for the legal scholars – is intent a term associated only with criminal statutes? Would its inclusion make this language more difficult to enforce? What does it add? Does it make sense in reference to a legal entity? Is "other legal entity" necessary?
discussion	**"human being"**--We have not and probably would prefer not to attempt to define: a human being, the means for creating a human being, nor the definitive act that results in the creation of a human being. Therefore, one option is to substitute "child" in place of "human being," as the National Bioethics Advisory Commission chose to do. While this leaves open the question of when a fetus becomes a child, there is greater agreement on this point, i e., at birth, than on when life begins.	
implication		
implication		
implication		

Prohibitions, part 2

possible revision II	ASRM	Council of Europe
It shall be unlawful for any person or other legal entity, public or private, to perform or use somatic cell nuclear transfer when the product of that transfer is introduced into a woman's womb [in order to create a child].	It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.	Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.
	This is a very straightforward statement but is burdened by implications regarding abortion.	Does not mention any specific type of cloning technology, which may be desirable. Invites definitional issue of when a human being is created.
Violation begins at time of introduction of the product of SCNT into a woman's uterus.	Violation occurs at the time of birth (unless one believes that a child is created before birth) and so allows anything up to that point including creating an embryo via SCNT and introducing it into a woman's uterus	The word "seeking" is vague leaving open possibility of inhibiting a range of research involving other forms of cloning.
Would allow creation of an embryo (only with private funding) using SCNT, as long as transfer to woman's uterus does not occur.	Would require abortion at some point before birth	Similar to ASRM prohibition above.
Would maintain status quo for private sector IVF research	Would allow embryo research (using private funds), regardless of whether or not the embryo was transferred to a woman for gestation, thus permitting fertility and other biomedical research	Could be used to proscribe a broad range of research involving other forms of cloning
Would be consistent with current public sector ban on embryo research, precluding opportunity to capitalize on SCNT for research into treatment for spinal cord and other nerve cell regeneration, AIDS, skin grafts, and replacement organs.		May prohibit blastomere or embryo splitting; a reproductive technique currently in use in this country, depending on definition of human being.

Definitions	Administration	ASRM	ASRM
wording	SECTION 4. DEFINITIONS. (a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human. (b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm). (c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.	"somatic cell means a mature, diploid cell."	"the creation of a human child" means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth."
discussion	"Somatic cell" – See alternative definition below. While ours differs from others, it is a reasonable, accurate lay language definition of a technical term. The goal of groups such as ASRM and BIO is to create a more narrow set of definitions in order to protect a rather broad class of research. Ours is not so encumbered, leaving out any oblique references to embryo research.	"Diploid" corresponds to our definition; mature is an addition intended to permit certain types of infertility or other biomedical research. For example, under this definition research might be carried out to improve the efficiency of in vitro fertilization and other treatments for infertility using cells taken from an embryo.	ASRM's intent is to prohibit the birth of a child created using SCNT technology but their definition is unclear with respect to the act of implantation.
		Research of more general interest might be done using cells not yet deemed to be mature, or so-called stem cells, cells which have not yet differentiated into their final form. Embryonic stem cells are cells from an early embryo that can go on to form any cell of the organism. Embryonal stem cells from mice have been grown in culture and can be stimulated to form precursors of blood, nerve and muscle cells. Human embryonal stem cells could be cultured similarly and engineered to prevent transplant rejection.	

OTHER	Administration	possible revision (suggested by Sen. Feinstein's staff)
wording	SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:	SECTION 6. PROTECTED BIOMEDICAL RESEARCH AND MEDICAL PRACTICE.—Nothing in this Act shall restrict other areas of biomedical and agricultural research and medical practice, including important and promising work that involves:
discussion		Includes reference to medical practice.

Prohibitions, Part 1

Prohibition	Administration	possible revision I
wording	Administration Bill (June 9, 1997) SECTION 5. PROHIBITION.-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. Keep away from embryo's.	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 in order to create a child.
discussion	**"Or in any other way creating a human being"**—The meaning of this phrase is unclear. It can be interpreted to mean creating a human being in any way other than by using SCNT, or, as we intended, creating a human being through extra-uterine gestation, a technology that is unlikely to become available prior to significant development of SCNT.	**"intent"**—Questions for the legal scholars – is intent a term associated only with criminal statutes? Would its inclusion make this language more difficult to enforce? What does it add? Does it make sense in reference to a legal entity? Is "other legal entity" necessary?
discussion	**"human being"**--We have not and probably would prefer not to attempt to define: a human being, the means for creating a human being, nor the definitive act that results in the creation of a human being. Therefore, one option is to substitute "child" in place of "human being," as the National Bioethics Advisory Commission chose to do. While this leaves open the question of when a fetus becomes a child, there is greater agreement on this point, i.e., at birth, than on when life begins	
implication		
implication		
implication		
	Could just do principles.	

CLONING

LEGISLATIVE OPTIONS

BACKGROUND

Cloning

Cloning means making a precise copy of a molecule (such as a gene), a cell, or an individual plant or animal. It is done routinely in laboratories and clinics around the world in order to understand how proteins work in an organism, to construct new drugs with fewer side effects, to engineer foods with better nutritional characteristics, or to produce animals as models for human disease. Forensic experts clone DNA to identify crime perpetrators, cartilage cells are cloned to repair damaged knees and a few of the more than 5,000 genetic defects are being treated by inserting properly functioning cloned genes into the patient's cells.

Dolly reviewed

Dolly was news because she is thought to be a replica of an adult sheep. We already have human replicas, or twins, which occur naturally and through assisted reproductive technology known as blastomere splitting. However, identical twins are born at the same time and have no identical forebears. Dolly was the product of somatic cell nuclear transfer (SCNT), a technique that may have applications ranging from reconstituting an AIDS patient's own immune system or producing skin cells for burn victims, bone marrow cells for cancer patients, insulin-producing cells to treat diabetes, leukemia and liver damage. Much of this research is prohibited at its earliest stages under the Federal ban on creating embryos for research purposes.

Embryo research

Federal funding for the creation of human embryos for research purposes is banned under a December 2, 1994 Presidential directive and other embryo research is also prohibited via restrictions on DHHS appropriations. (See Attachment A for further discussion.) Embryo research in support of improvements in assisted reproductive medicine is carried out in the private sector with virtually no Federal regulation.

We must assess the need to engage in the issue of embryo research in the context of a cloning bill and follow closely other legislative initiatives.

LEGISLATION

The issues of greatest concern [to scientists and industry] are what is prohibited and how the prohibited act(s) is(are) defined. (See Attachment B for discussion of options)

IMPACT OF FDA AUTHORITY ON CLONING OPTIONS

Recent reports notwithstanding, FDA is still in the process of developing a determination of its authority to regulate the use of somatic cell nuclear transfer (SCNT) for the purpose

of creating a child. Assuming for the moment that FDA **does** have this authority, how would that effect our strategy with respect to legislation?

The Food, Drug and Cosmetic Act gives FDA authority to regulate products and procedures on the basis of safety and efficacy—not ethics. Our bill would prohibit any attempt to create a child using SCNT and provide for further review of the ethical and scientific. FDA's likely authority takes care of the former, for some period of time, but does not address the need for public discourse. Therefore, there is still a need to pursue legislative options.

Draft3 1-13-98
ASRM

CLONING PROHIBITION AND RESEARCH PROTECTION ACT

SECTION 1. PROHIBITION. It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.

SECTION 2. DEFINITIONS. For the purposes of this section, the following definitions apply:

(a) "somatic cell nuclear transfer" means 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;
(b) "the creation of a human child" means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth;
(c) "somatic cell" means a mature, diploid cell;
(d) "oocyte" means the female germ cell, the egg;
(e) "nucleus" means cell structure that houses the chromosomes, and thus the genes; and
(f) "gestation" means the period during which an embryo develops, inside the uterus, into a fetus that is ready to be born.

SECTION 3. PREEMPTION OF STATE LAWS. This law shall preempt any state law that imposes on individuals or institutions any limitations with respect to nuclear transfer, human cloning, cloning of molecules, DNA, cells, and tissues, or the use of nuclear transfer techniques to develop animals, or to related research.

SECTION 4. PROTECTED BIOMEDICAL RESEARCH. Nothing in this Act shall restrict other areas of biomedical and agricultural research, including but not limited to important and promising work that involves:

(a) the use of somatic cell nuclear transfer or other cloning technologies, to clone molecules, DNA, cells, and tissues; or
(b) the use of somatic cell nuclear transfer techniques to develop animals.

SECTION 5. EFFECTIVE DATE. This Act shall apply to somatic cell nuclear transfer performed after the date of its enactment.

SECTION 6. REAUTHORIZATION. The prohibition in this legislation shall expire five years from the effective date.

SECTION 7. NATIONAL BIOETHICS ADVISORY COMMISSION REPORT. No later than four and one-half years after the enactment of this Act, the National Bioethics Advisory Commission shall report to the President on

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

(b) the ethical and social issues associated with the potential use of this technology in humans; and

(c) the advisability of continuing the prohibition established by this Act. The Commission is authorized to continue for five years from the date of enactment for this purpose and for other purposes as established in Executive Order 12975 and subsequent amendments to this order.

SECTION 8. RIGHT OF ACTION. Nothing in this Act shall be construed to give any individual or person a private right of action.

SECTION 9. PENALTIES.

(a) Any person who intentionally violates Section 1 shall be fined the greater of $250,000 or two times the gross gain or loss from the offense.

OUTLINE OF WHITE HOUSE STATEMENT

In fashioning a law to ban human cloning, we have to be extremely careful to ensure that we do not inadvertently ban research which is vital to developing cures and therapies for deadly diseases.

Let me outline the key principles which should guide us in drafting a law:

1. The law should ban the act of cloning of a human being. It should not ban "research" because that might chill scientists in the conduct of vital basic biomedical research.

2. The law should focus only on the issue addressed by the National Bioethics Advisory Commission (NBAC). NBAC did not review and made no recommendations regarding embryo research, which is already subject to a ban on federally funded research.

> "We do not revisit either the question of the cloning of humans by embryo-splitting or the issues surround embryo research. The latter issue has, of course, recently received careful attention by the National Institutes of Health panel, the Administration, and the Congress." Letter of Harold Shapiro, NBAC Chairman (June 9, 1997).

3. Violation of the ban would be determined based on objective activities, not the "intent" or "purpose" of the scientists. We need to give scientists objective standards to define the prohibited acts. Focusing on their "intent" or "purpose" is open to interpretation and misinterpretation and does not permit scientists to predict how the statute will be enforced.

4. We need a national ban on human cloning. The national law should govern and we need to avoid the enactment of multiple and different state laws. This was one of the recommendations of NBAC.

> "The advantage to federal legislation -- as opposed to state-by-state laws -- lies primarily in its comprehensive coverage and clarity....Besides ensuring interstate uniformity, a federal law would relieve the need to rely on the cooperation of diverse medical and scientific societies, or the actions of diverse IRBs, to achieve the policy objective. As an additional benefit, federal legislation could displace the varied state legislative efforts now ongoing, some of which suffer from ambiguous drafting that could inadvertently prohibit the important cellular and molecular cloning research described...in this report." NBAC report at 100.

5. We need to enact the law for a five year period with a mandatory review at that time to determine whether the ban should be extended.

> "It is notoriously difficult to draft legislation at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science. Some mechanism, therefore, such as a sunset provision, is absolutely needed to ensure an opportunity to re-examine any judgment made today about the implications of somatic

cell nuclear transfer cloning of human beings. As scientific information accumulates and public discussion continues, a new judgment may develop and we, as a society, need to retain the flexibility to adjust our course in this manner. A sunset provision...ensures that the question of cloning will be revisited by the legislature in the future, when scientific and medical questions have been clarified, possible uses have been identified, and public discussion of the deeper moral concerns about this practice have matured." NBAC report at 101.

6. We need to make sure the bill sets penalties which will absolutely deter any violations. The penalties should be civil fines in large amounts and we should not threaten the existence of a entire research firm.

7. We need to include a findings section and a explicit list of protected medical research to help ensure that the law does not have unintended consequences in inhibiting biomedical research.

8. Finally, we need to ensure that the Department of Justice enforces the law, not private individuals. We need to prevent the filing of frivolous or harassment law suits.

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.

* * * * * * * * * *

KEY DRAFTING ISSUES

Ban act of cloning

-- No ban "research"

Do not ban embryo research

Violation should be determined based on objective facts, not "intent" or "purpose"

-- "intent" and "purpose" are criminal law concepts, unpredictable, subjective

Federal preemption -- NBAC recommendation

-- Florida bill would have banned cloning of cells and genes!

Sunset -- NBAC recommendation

Penalties -- fines vs. confiscation

Protected medical research -- findings

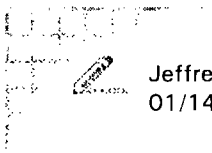
No private right of action -- Clinton bill

California Law Penalties

(a) If the violator is a corporation, firm, clinic, hospital, laboratory, or research facility, by a civil penalty of not more than one million dollars ($1,000,000) or the applicable amount under subdivision (c), whichever is greater.

(b) If the violator is an individual, by a civil penalty of not more than two hundred fifty thousand dollars ($250,000) or the applicable amount under subdivision (c), whichever is greater.

(c) If any violator derives pecuniary gain from a violation of this section, the violator may be assessed a civil penalty of not more than an amount equal to the amount of the gross gain multiplied by two.



Jeffrey A. Forbes
01/14/98 02:39:11 PM

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To: Bruce N. Reed/OPD/EOP

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

Barry just called because there is a storu in the Bloomberg report where Hatch and McCain are complaining that we are not working with them on Tobacco -- McCurry has been saying we have been dealing with them -- When I told Barry you had tried to call Hatch's guy but that we have not really done anything and we are waiting for the Congressional working group to gather before we proceed, Barry got mad because he feels Mike is out on a limb -- the long and short of it is I have very little idea what is going on but am being held somewhat accountable -- can you briefly let me know what has happened since we met w/ the Industry guys and they said we need to get Gingrich more involved (that is my last contact). Also -- when can we get on the horn w/ Tarplin and figure out where we are going congressionally.

let me know

THANKS!

Forbes

We need to protect our farms [illegible]

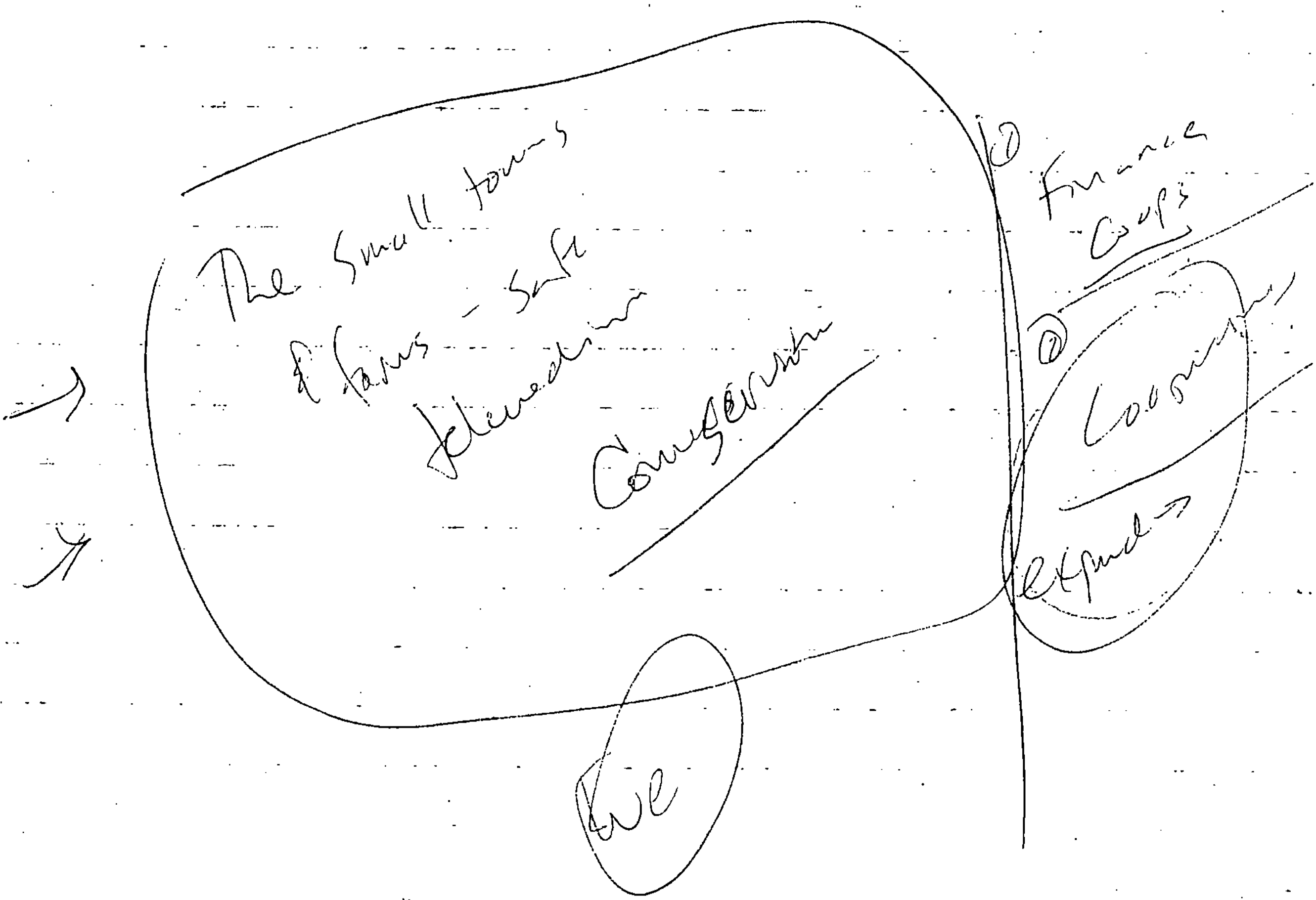
The economy has moved to protect private agriculture

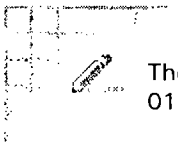
risk management tools,

safety net

We need to protect American

Urban areas - participating →


The small towns
& farms - Safe
Finance
Corps
expand
We



Thomas L. Freedman
01/14/98 03:25:37 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

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

I went to the meeting you forwarded the invite to on cloning where the Biotech industry laid out its concerns on proposed cloning legislation; they are worried it will inadvertently ban embryo research etc..

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Everyone, including Bill, felt more info was required on the effects of the different approaches. Rachel Levinson from OSTP will circulate a draft options memo on the scientific approaches and their implications for research, and right to life issues.

The basic issue centers on: how do you define what type of research is banned? The WH version bans all entities from using "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." That would seem to not ban experimentation with cloned embryos and would have right to life implications. The Biotech industry language: "it shall be unlawful for any person to use federal funds to create a human child identical in terms of DNA to an existing or previously existing individual using somatic cell nuclear transfer technology." Doesn't effect private sector, doesn't deal with experimentation and right to life. The reproductive society says "It shall be unlawful for any person to create a human child using somatic cell nuclear transfer." (applies to all, protects research specifically in separate section).

There is also a preemption issue.

DRAFT BACKGROUND ON CLONING

I. CENTRAL ISSUES

A. Action to Take. Whether to send up a bill, announce a statement of principles, do this as a regulatory matter, or do regulatory and legislative actions.

B. Protecting Research. There is on-going privately funded embryo research. Blanket bans on using this technology for any research satisfy the urge to stop cloning of humans but meet opposition from researchers who want to use this technology. They claim the technique may be of use for work on immune systems, burn victims, bone marrow, diabetes, leukemia and liver damage. Using federal resources to do this research is prohibited at its earliest stages under the federal ban on creating embryos for research purposes using federal money. (1994)

II. POLICY OPTIONS

A. FDA AUTHORITY

* FDA has not reached a formal determination as to whether it has the authority to ban cloning research.

* However, they are very likely to reach the conclusion that they do have such authority, and could forbid such research on the grounds of safety.

* They say that whether or not they issue this determination it will not eliminate the need for legislation as after a few years cloning research may be safe and would then need a ban based on ethical considerations.

B. CURRENT ADMINISTRATION POSITION

Administration Bill (June 9, 1997)
SECTION 5. PROHIBITION. 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.

This bill has not been introduced. Counsel's office feels the "Or in any other way creating a human being" phrase is unclear. It can be interpreted to mean creating a human being in any way other than by using somatic cell nuclear

transfer (SCNT), or, as we intended, creating a human being through extra-uterine gestation, a technology that is unlikely to become available prior to significant development of SCNT. There is also the question of when does someone become a human being.

C. Possible Revision I

> "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 in order to create a child."

Implications:
Violation begins at time of introduction of the product of SCNT into a woman's uterus. That would have to happen within 14 days of differentation.

- Would allow creation of an embryo (only with private funding) using SCNT, as long as transfer to woman's uterus does not occur.
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D. POSSIBLE REVISION II

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<u>American Society for Reproductive Medicine</u>

It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.

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American Society for Reproductive Medicine

It shall be unlawful for any person to create a human child using somatic cell nuclear transfer.

Discussion:
This is a very straightforward statement but is burdened by implications regarding abortion.

Implications:
- Violation occurs at the time of birth (unless one believes that a child is created before birth) and so allows anything up to that point including creating an embryo via SCNT and introducing it into a woman's uterus
- Would require abortion at some point before birth
- Would allow embryo research (using private funds), regardless of whether or not the embryo was transferred to a woman for gestation, thus permitting fertility and other biomedical research

D. Council of Europe Position

Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.

Invites definitional issue of when a human being is created. May prohibit blastomere or embryo splitting; a reproductive technique currently in use in this country, depending on definition of human being. The word "seeking" is vague leaving open possibility of inhibiting a range of research involving other forms of cloning.

III. OTHER: DEFINITIONS AND BACKGROUND

(a) "Cloning" means the production of a precise genetic copy of a molecule (including DNA), cell, tissue, plant, animal, or human.
(b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).
(c) "Somatic cell nuclear transfer" means the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

OSTP Discussion:
"Somatic cell" (See alternative definition below.) While ours differs from others, it is a reasonable, accurate lay language definition of a technical term. The goal of groups such as ASRM and BIO is to create a more narrow set of definitions in order to protect a rather

broad class of research. Ours is not so encumbered, leaving out any oblique references to embryo research.

American Society for Reproductive Medicine
"somatic cell means a mature, diploid cell."

Discussion:
Diploid corresponds to our definition; mature is an addition intended to permit certain types of infertility or other biomedical research. For example, under this definition research might be carried out to improve the efficiency of in vitro fertilization and other treatments for infertility using cells taken from an embryo.

Research of more general interest might be done using cells not yet deemed to be mature, or so-called stem cells, cells which have not yet differentiated into their final form. Embryonic stem cells are cells from an early embryo that can go on to form any cell of the organism. Embryonal stem cells from mice have been grown in culture and can be stimulated to form precursors of blood, nerve and muscle cells. Human embryonal stem cells could be cultured similarly and engineered to prevent transplant rejection.

"'the creation of a human child' means implanting into the uterus the product of somatic cell nuclear transfer technology for gestation and subsequent birth."

Discussion:
ASRM's intent is to prohibit the birth of a child created using SCNT technology but their definition is unclear with respect to the act of implantation.

IV. OTHER SECTIONS: PROTECTED RESEARCH AND PREEMPTION

SECTION 6. PROTECTED BIOMEDICAL RESEARCH.—Nothing in this Act shall restrict other areas of biomedical and agricultural research, including important and promising work that involves:
(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.

Sen. Feinstein's staff suggested that we include reference to medical practice in this section as follows:

SECTION 6. PROTECTED BIOMEDICAL RESEARCH AND MEDICAL PRACTICE.__Nothing in this Act shall restrict other areas of biomedical and agricultural research and medical practice, including important and promising work that involves:

STATE PREEMPTION

BIO and ASRM would like to see a Federal law preempt state laws such as that enacted in California. They believe that the California law is an example of the difficulty in crafting language that does not impinge on non-controversial, beneficial research. We are investigating the California law.

OTHER COMMENTS

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IMPACT OF FDA AUTHORITY ON CLONING OPTIONS

Recent reports notwithstanding, FDA is still in the process of developing a determination of its authority to regulate the use of somatic cell nuclear transfer (SCNT) for the purpose of creating a child. Assuming for the moment that FDA **does** have this authority, how would that effect our strategy with respect to legislation?

The Food, Drug and Cosmetic Act gives FDA authority to regulate products and procedures on the basis of safety and efficacy--not ethics. Our bill would prohibit any attempt to create a child using SCNT and provide for further review of the ethical and scientific. FDA's likely authority takes care of the former, for some period of time, but does not address the need for public discourse. Therefore, there is still a need to pursue legislative options.

BIO
BIOTECHNOLOGY
INDUSTRY
ORGANIZATION

News Release

1625 K Street, N.W. · Suite 1100 · Washington, D.C. 20006 · (202) 857-0244 · FAX: (202) 857-0237

Tim -
Does The FDA have jurisdiction?
Has it asserted jurisdiction?
What could/
should it do?
Elena

FOR IMMEDIATE RELEASE

CONTACT:
Dan Eramian
Libby Mikesell
202-857-0244

BIO Calls For FDA To Assert Its Authority On Cloning

(WASHINGTON, D.C., January 13, 1998)...Carl B. Feldbaum, president of the Biotechnology Industry Organization (BIO) sent the attached letter to Health and Human Services Secretary Donna Shalala asking her to assert the Food and Drug Administration's (FDA) authority and jurisdiction over any possible attempts to clone a human being:

"It is clear that society is not ready for the cloning of a human being. We need to listen carefully, and analyze thoughtfully the ethical, moral and safety issues that have been raised.

"Recognition and assertion of the FDA's regulatory power over human cloning will protect biomedical advances and at the same time will give everybody some breathing room to debate this issue. Bioethics issues will occur with further advances in science. We need to be certain, before we move ahead, that advances will clearly benefit human kind and not set us back into some new age of uncertainty about our values and the quality of human life."

The Biotechnology Industry Organization (BIO) represents over 745 biotechnology companies, academic institutions, and state biotechnology centers in 46 states and more than 25 nations. BIO members are involved in the research and development of health care, agricultural and environmental biotechnology products.

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BIO

BIOTECHNOLOGY INDUSTRY ORGANIZATION

January 13, 1998

The Honorable Donna E. Shalala, Ph.D.
Secretary,
Department of Health and Human Services
615F Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Dear Secretary Shalala:

The recent announcement from Dr. Richard Seed regarding his proposal to establish a clinic for the cloning of human beings has caused significant controversy. BIO supports President Clinton's and the National Bioethics Advisory Commission's (NBAC) moratorium on the cloning of a human being. Cloning a human being poses major ethical and moral questions, as well as deeply troubling medical safety issues. The experience with "Dolly," in which there were 276 unsuccessful attempts before an apparently healthy sheep was born, points to the experimental nature of this technology in animals. It is plainly inappropriate to attempt to apply this technology to human beings. While these questions remain unresolved, government and public opposition to the cloning of a human being remains strong. Society needs to be heard and respected on this issue.

Several members of Congress have recently expressed interest in legislation that would ban the cloning of human beings. They may not be aware that the Food and Drug Administration (FDA) has broad authority to regulate biological products. Last February, FDA published a regulatory framework for the regulation of cellular and tissue-based products. The level of FDA oversight is dictated by the degree of human manipulation of cells or tissues. Those products which are subject to a low level of oversight are those which are defined as 'minimal manipulation' when the processing does not alter the biological characteristics of the cells or tissue.

But in those cases where there is more than 'minimal manipulation,' FDA has stated its intent to subject such products to formal regulatory review including the investigational new drug (IND) regulations and license review regulations.

[illegible]

BIO believes that the Dr. Seed's proposal to clone humans using nuclear transfer technology is much more than minimal manipulation as the original function of the egg cell is unmistakably altered by the removal of the parental haploid DNA and insertion of DNA from a somatic cell from another person. Thus, any such research along these lines should be subject to the IND regulations that require patient informed consent, review by an institutional review board (IRB) where the research is being conducted, and FDA review under 21 CFR Part 312.

In addition to raising profound ethical issues, nuclear transfer technology has not been reliably proven to work in animal models and raises serious safety issues. We believe that for the foreseeable future, FDA should issue a clinical hold on any IND submission to proceed with such experiments.

A public statement by senior officials within HHS as to the regulatory status of nuclear transfer technology would be welcomed and useful as the public debate continues.

Sincerely,

Carl B. Feldbaum /ag

Carl B. Feldbaum
President

CBF:ag

cc: Michael Friedman, MD. Food and Drug Administration

Rachel E. Levinson 01/21/98 11:50:18 AM

Record Type: Record

To: Thomas L. Freedman/OPD/EOP

cc:
Subject: cloning

CLONING

LEGISLATIVE OPTIONS

BACKGROUND

Cloning

Cloning means making a precise copy of a molecule (such as a gene), a cell, or individual plant or animal. It is done routinely in laboratories and clinics around the world in order to understand how proteins work in an organism, to construct new drugs with fewer side effects, to engineer foods with better nutritional characteristics, or to produce animals as models for human disease. Forensic experts clone DNA to identify crime perpetrators, cartilage cells are cloned to repair damaged knees, and a few of the more than 5,000 genetic defects are being treated experimentally by inserting properly functioning cloned genes the patient's cells.

Dolly reviewed

Dolly was news because she is thought to be a replica of an adult sheep. We already have human replicas, or twins, which occur naturally and through assisted reproductive technology known as blastomere splitting. However, identical twins are born at the same time and have no identical forebears. Dolly was the product of somatic cell nuclear transfer (SCNT), a technique that may have applications ranging from reconstituting an AIDS patient's own immune system or producing skin cells for burn victims, bone marrow cells for cancer patients, insulin-producing cells to treat diabetes, leukemia and liver damage. Much of this research is prohibited at its earliest stages under the Federal ban on creating embryos for research purposes.

Embryo research

Federal funding for the creation of human embryos for research purposes is banned under a December 2, 1994 Presidential directive and other embryo research is also prohibited via restrictions on DHHS appropriations. See Attachment A for further discussion. Embryo research in support of improvements in assisted reproductive medicine is carried out in the private sector with virtually no Federal regulation.

We must assess the need (if it exists) to engage in the issue of embryo research in the context of a cloning bill and follow closely other legislative initiatives.

LEGISLATION

The issues of greatest concern [to scientists and industry] are what is prohibited and how the prohibited act(s) is(are) defined

Prohibition

Administration Bill (June 9, 1997)
SECTION 5. PROHIBITION. 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.

Discussion:
"Or in any other way creating a human being"--The meaning of this phrase is unclear. It can be interpreted to mean creating a human being in any way other than by using SCNT, or, as we intended, creating a human being through extra-uterine gestation, a technology that is unlikely to become available prior to significant development of SCNT.

"human being"--We have not and probably would prefer not to attempt to define: a human being, the means for creating a human being, nor the definitive act that results in the creation of a human being. Therefore, one option is to substitute "child" in place of "human being," as the National Bioethics Advisory Commission chose to do. While this leaves open the issue of when a fetus becomes a child, there is greater agreement on this point, i.e., at birth, than on when life begins.

Possible Revision I

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 in order to create a child.

"intent"--Questions for the legal scholars-- is intent a term associated only with criminal statutes? Would its inclusion make this language more difficult to enforce? What does it add? Does it make sense in reference to a legal entity? Is "other legal entity" necessary?

Possible Revision II

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Implications:

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Council of Europe

Any intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited.

Discussion:
Does not mention any specific type of cloning technology, which may be desirable. Invites definitional issue of when a human being is created.

May prohibit blastomere or embryo splitting; a reproductive technique currently in use in this country, depending on definition of human being.

The word "seeking" is vague leaving open possibility of inhibiting a range of research involving other forms of cloning.

Implications:

- Similar to ASRM prohibition above.
- Could be used to proscribe a broad range of research involving other forms of cloning

Definitions

Administration bill

SECTION 4. DEFINITIONS.

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

(b) "Somatic cell" means any cell of the body other than germ cells (eggs or sperm).

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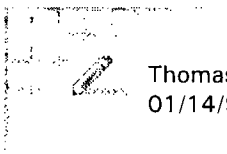

Thomas L. Freedman
01/14/98 03:25:37 PM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc: Laura Emmett/WHO/EOP, Mary L. Smith/OPD/EOP
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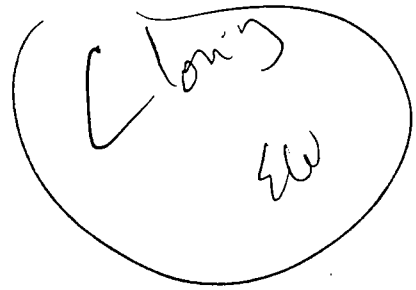
There is also a preemption issue.



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There is also a preemption issue.

Cloning

Jordan Tamagni
01/07/98 11:19:17 AM

Record Type: Record

To: Elena Kagan/OPD/EOP

cc:
Subject: Cloning

It shouldn't be too much trouble to produce a draft quickly on cloning. My only question is to what extent are we refering to the Chicago scientist who is publicizing his plan to clone human beings?

Dr. Seed (that's really his name) just did an interview on CNN in which he said he was "an independent thinker," who "disagreed with the President." I'd love to use this a little (e.g., "this is not independent thinking -- it is science independent of ethics" or something.) He sounds quite aged and not terribly sharp. He is a PhD, working with a medical doctor who has said that he will not go forward until he receives permission from the American Society of Reproductive Physicians.

Other issues:

Progress of President's Bioethics Advisory Board?
Status of Legislation banning human cloning?

Let me know where you want me to go with this. Thanks.

Tom –

Pls check up w/ OSTP and find out what we are or should be doing to ~~encourage~~ our cloning legislative (as opposed to the other various out there). Also, find out what the real status of any of these legislative proposals is.

Elena