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MEMORANDUM

To: Michelle Peterson
From: Christina S. Tsai
Re: Cloning; News Highlights

I was requested to gather information on the status of the debate and development of human cloning in the United States. The following is a summary of the major scientific and political developments in the area of human cloning within the last few years.

On February 22, 1997, Ian Wilmut announced that a lamb named Dolly had been born as a result of cloning an adult sheep. Through the use of somatic cell nuclear transfer technology Wilmut and his colleagues at the Roslin Institute in Scotland had cloned the first mammal in history. This process of nuclear transfer technology involved taking the udder cell of one sheep and transferring it into another sheep's egg cell whose DNA had been removed. After an electric current was administered, the egg cell became an embryo and was transplanted into a surrogate mother sheep. As the embryo grew, the genetic material from the udder cell directed the embryo to grow into a clone of the first sheep from which the udder cell was derived. Thus, Dolly was born as a genetic clone of the first sheep.

The announcement of this scientific breakthrough quickly led to discussion about possibility of cloning humans. Scientists speculated that a nuclear transfer technique to clone humans would be available anywhere from one to ten years.[1]

Regardless of whether human cloning was truly feasible, leaders in Washington moved quickly to respond to the announcement of Dolly's birth. On March 4, 1997, President Bill Clinton announced a ban on federal funds for use in human cloning and called for a voluntary moratorium on human cloning by the private sector. He then asked the National Bioethics Advisory Commission (NBAC) to examine the issue and prepare a report. The NBAC reviewed the scientific, religious, ethical and legal issues raised by the possibility of using somatic cell nuclear transfer to implant a human embryo into a woman's uterus and bring it to term. The NBAC concluded that "at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or a clinical setting, to attempt to create a child using . . cloning "[2] The report also urged federal legislation to prohibit anyone from, "attempting to create a child through somatic cell nuclear transfer techniques" in both research

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[1] David Masci, *Cloning Humans Sparks Debate Advisory Panel to Report Thursday on Issues and Give Guidelines*, Pitt. Post-Gazette, May 25, 1997, at A15.

[2] NBAC, "Cloning Human Beings," June 6, 1997.

and clinical settings, so that privately funded infertility researchers would not attempt to create clonal human embryos for implantation in women.

Legislation

a. Federal

In response to the NBAC Report, on June 9, 1997, the President submitted the Cloning Prohibition Act of 1997.[3] One of its key provisions prohibited public or private entities from using the cloning technology (NTT) to place the embryo into a woman's womb with the intent to create a child. The language of the Act was careful not to restrict biomedical research that involved the cloning of molecules, DNA cells, tissues or animals. The legislation also included a sunset provision for five years after its enactment. Despite hearings in both houses however, Congress did not adopt this legislation.

Then in January 1998, just after the commotion over cloning began to settle down, Richard Seed announced that he intended to establish a clinic to clone humans.[4]

The response from Congress was immediate. Senate Majority Leader Trent Lott (R-Miss.) rushed an emergency measure onto the floor for a Republican anti-cloning bill. Although the measure appeared to be a shoo-in, congressional support for the legislation quickly

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[3] The key provision reads:

> "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. 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."

[4] Richard Seed returned to the spotlight in September 1998, when he announced that the first person he would try to clone was himself. His wife Gloria has agreed to carry the embryo that would grow into a clone of Richard Seed if carried to term. Seed states: "I have decided to clone myself first to defuse the criticism that I'm taking advantage of desperate women with a procedure that's not proven." Richard Saltus, *Would-Be Cloner Plans to Start With Himself; Says Wife Will Carry Test-Tube Embryo*, Boston Globe, Sept. 6, 1998, A6.

evaporated.

After the Lott emergency measure, several different proposals emerged. In the lead was the **Human Cloning Prohibition Act** sponsored by Sens. Lott, Christopher S. Bond (R-Mo.) and Bill Frist (R-Tenn.). First introduced on February 3, 1998, this legislation outlawed cloning of embryos and children. It was defeated a week later in the Senate. Another proposal that garnered attention was sponsored by Democratic Reps. Dianne Feinstein (D-Calif.) and Edward M. Kennedy (D-Mass.). Entitled the **Alternative Human Cloning Prohibition Act**, it banned the cloning of people, but not human embryos for research purposes. Presently, this bill languishes in the Senate Labor and Human Resources Committee. Finally, Rep. Vernon Ehler (R-Mich.) presented another alternative with the **Prohibition of Federal Funds for Human Embryo Cloning**. This proposal was approved by the House Science Committee in July 1997, but waits in the Commerce Committee which has yet to place the bill on its agenda. As the sponsors of the various bills suspected, human cloning did not make it to the floor before the fall elections and end of the year's session.

The sudden halt in cloning legislation is attributed mainly to various patient advocacy groups and the biotechnology industry. They argued that federal anti-cloning legislation was far too broad in its language and scope, curtailing a larger sphere of activities commonly used in biomedical and agricultural research. Even before any legislation was proposed, Dr. Harold Varmus, Director of the National Institutes of Health, urged lawmakers to be cautious in drafting legislation:

> " I am worried . . . that in rejecting one aspect of these experiments that all of us find repugnant, that is, the idea of cloning human beings, that we end up with legislation, be it State or Federal that restricts the experimental possibilities that will be beneficial to all. . . .It's worth exploring some of the deeper aspects of these experiments with respect to gene regulation before we throw the baby out with the bath water."[5]

As written, the proposals would have prohibited important research to cure disease. The Bond bill, for instance, would have halted efforts to "teach" embryonic mouse cells to produce organs to be used in transplants. Even the NBAC, which suggested federal cloning legislation, wrote to the President stating, "We believe that sweeping legislation would be a mistake . . ."[6]

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[5] Questions and Answers Regarding NBAC Following Dr. Varmus' Statement At the February 26 House Appropriations Hearing.

[6] NBAC Letter to the President, Feb. 6, 1998.

b. State

Over 25 states have attempted to pass some form of human cloning regulation. State attempts to regulate human cloning have fared better than tries at the national level. Presently, California, Michigan and Missouri are the only states to have passed legislation on human cloning.

FDA Regulation

Around the same time the federal bills began to lose support, the Biotechnology Industry Organization (BIO) wrote a letter to Health and Human Services Secretary Donna Shalala asking her to assert the FDA's authority and jurisdiction over any possible attempts to clone a human being. Soon after, the Food and Drug Administration claimed its jurisdiction over human cloning issues and announced that any party wanting to clone a person would have to apply for permission from that agency.

The FDA has authority to regulate biological products and has published a regulatory framework for the regulation of cellular tissue-based products. The level of FDA oversight is determined by the degree of human manipulation of the cells or tissues. For example, the FDA does not always require prior approval for research on cells that will only be "minimally manipulated." On the other hand, if cloned cells are considered "more than minimally manipulated," the research may be subject to formal regulatory FDA regulation.

FDA officials assert that cloning is more than minimal manipulation. Cloning cells involves gutting the egg cell of its genetic material and injecting the nucleus from another cell into it. FDA officials believe that such procedures produce a highly manipulated cell. Critics note however, that in vitro fertilization and other fertility techniques even more aggressive than IVF, has not been regulated by the FDA. Given the complexities of this subject, the FDA established a working group to look into such questions.

Subsequent Cloning Development

Dolly's birth has led other attempts to clone by other scientists. In one case, clones of rhesus monkey embryos were born after nuclear transfer from undifferentiated embryo cells.[7] Another company in Wisconsin reported pregnancies in cows, but no births from those pregnancies have occurred.[8] A Massachusetts company cloned calves from the fetal cells of

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[7] See Robert Cooke, *Monkeys, Too: Cloning Creates Identical Primates Helpful in Research*, Newsday, Mar. 3, 1997, at A5.

[8] See Gina Kolata, *10 Cloned Cows Soon to Be Born, Company Reports, Duplicating a Lamb Experiment*, N.Y. Times, Aug. 8, 1997, at A10.

cows, using a variation on the Wilmut technique.[9]

On July 22, 1998, biologists at the University of Hawaii announced that they had produced more than 50 cloned mice, including clones of clones, and had developed a process for mass cloning. Using a new and relatively simple technique, Teruhiko Wakayama created Cumulina, the first cloned mouse to survive to adulthood.[10]

Most recently, scientists in Japan cloned eight calves from cells of another cow's slaughterhouse entrails.[11] This recent development may have far ranging impact on the biomedical research, as cows with human medicines in their milk may be cloned.[12] Also, the ability to clone cows may be worth billions of dollars to the agricultural industry.

Benefits of Human Cloning / Cloning Research

Aside from ethical concerns with human cloning, proponents of the technology cite the following as potential benefits:

- creating cells that the body needs and cannot produce: bone marrow transplants for cancer patients, burn victims, degenerative diseases, spinal cord injuries, Alzheimer's disease
- greater knowledge for how genes are turned on and off: treatment of sickle-cell disease, diabetes- reactivate pancreas development of missing cell types
- human cloning may be safer than IVF because it involves little risk of passing on a

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[9] Carey Goldberg & Gina Kolata, *Scientists Announce Birth of Cows Cloned in New Way*, N.Y. Times, Jan. 21, 1998, at A14.

[10] Wakayama's new technique involves three steps slightly dissimilar from the one used for creating Dolly. First, the DNA is removed from the egg cell. Second, cumulus cells are collected from the ovaries. (In contrast, Dolly was cloned from an udder cell.) Third, the DNA from the cumulus cell is injected into the gutted egg cell. (With Dolly, the entire udder cell was fused with the egg cell by an electrical jolt.) Finally, chemicals are added to the re-combined cell to start division into an embryo in a laboratory dish and eventually transferred to the womb of a surrogate mother mouse. Rick Weiss, *Scientists Clone Adult Lab Mice; Process May Hurry Human Application*, The Washington Post, July 23, 1998, A1.

[11] Gina Kolata, *8 Cows Cloned in Japan From Scrapped Entrails; Breakthrough Event Follows Lamb and Mice*, N.Y. Times, Dec. 9, 1998, at A8.

[12] Rick Weiss, *Japanese Clone 8 Calves From Cow; New Process Shows Commercial Potential*, Washington Post, Dec. 9, 1998, at A1.

communicable disease.

- animals in medical research; proteins in milk, acceptable anitgens on organs for transplantation, disease models
- agricultural husbandry; self-fertilization of corn, generation of in-bred strains of animals or the twinning of cattle