

Prepared Witness Testimony

The Committee on Energy and Commerce

W.J. "Billy" Tauzin, Chairman

Issues Raised by Human Cloning Research

Subcommittee on Oversight and Investigations

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2123 Rayburn House Office Building

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Mr. Chairman and Members of the Committee, I am Kathryn C. Zoon, Ph.D., Director of the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration (FDA or the Agency). I can assure the members of this Committee and the American public that FDA views the use of cloning technology to clone a human being as a cause for public health concern. I appreciate the opportunity to discuss FDA's role with respect to this issue. Because of unresolved safety questions on the use of cloning technology to clone a human being, FDA would not permit the use of cloning technology to clone a human being at this time.

Very recently, there have been numerous press articles on individuals and groups expressing interest in cloning a human being by cloning technology. We have heard that people have incorrectly stated that there are no legal controls in place in the United States governing the use of cloning technology to clone a human being. My hope today is to clarify FDA's role in regulating the use of cloning technology to clone a human being and to discuss the significant scientific concerns regarding safety that would lead us at this time to disallow any such activities. It is important to note that FDA's role in assessing the use of cloning technology to clone a human being is a scientific one. As recognized by the National Bioethics Advisory Commission, there are additional unresolved issues including the broader social and ethical implications of the use of cloning technology to clone a human being. Because of the profound moral, ethical, and scientific issues, the Administration is unequivocally opposed to the cloning of human beings.

To give you a better understanding of cloning technology, the Statement for the Record submitted by Dr. Harold Varmus, then Director of the National Institutes of Health, to the House Committee on Commerce, Subcommittee on Health and Environment, (February 12, 1998 hearing, "Oversight Hearing Regarding Cloning: Legal, Medical, Ethical, and Social Issues") is helpful:

In order to understand this technology, it is necessary to briefly review normal sexual reproduction in mammals. . . Normally, an egg and sperm join to create a fertilized egg, which develops into an embryo and ultimately a newborn animal. In this situation, the progeny receives genetic material from both the mother and father.

In the Dolly experiment, a lamb was produced using the technology of somatic cell nuclear transfer. Unlike the normal process of sexual reproduction in which an egg and a sperm each contribute genetic material, somatic cell

nuclear transfer is asexual. A somatic cell is any cell except the egg cells or sperm cells. Somatic cells contain the full complement of chromosomes. In contrast, an egg or a sperm contains half that number.

Somatic cell nuclear transfer is done in the following way . . . using sheep as an example. First a normal sheep egg cell is taken from a ewe and the nucleus (the cell structure containing the chromosomes) is removed, yielding an egg cell containing the nutrients and other energy producing materials that are essential for embryo development, but not the chromosomes. Next, a somatic cell is isolated--in the case of Dolly, a cell grown in cell culture from the mammary tissue of an adult sheep. Under certain conditions, the somatic cell (in this example, the mammary cell) is placed next to the egg from which the nucleus had been removed, an electrical stimulus is applied, and the two cells fuse. The result is a cell that contains the nutrient environment of an egg cell and genetic material only from the donated somatic cell. This is not sexual reproduction, since genetic material is derived from only one, not two, individuals. There is no sperm involved. The egg provides only the environment for growth. After a number of cell divisions, these cells are placed into the uterus of a sheep. In the case of Dolly, a lamb was born - an identical twin of the original donor, only born later.

This technology did not readily result in the birth of a lamb cloned from an adult sheep. It took 276 failed attempts before Dolly was born. Since the time of Dolly, additional animals have been cloned. However, the success rate remains low and numerous abnormalities in the offspring and safety risks to the mother have been observed. These facts raise serious concerns regarding the use of cloning technology to clone a human being.

FDA has the authority to regulate medical products, including biological products, drugs, and devices. The use of cloning technology to clone a human being would be subject to both the biologics provisions of the Public Health Service (PHS) Act and the drug and device provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act.

In response to questions about cellular products, in

October 1993, FDA published a notice in the Federal Register, 58 FR 53248 (October 14, 1993), clarifying the application of FDA's statutory authorities to human somatic cell therapy and gene therapy products. The notice stated that somatic cell therapy products are biological products under the PHS Act as well as drugs under the FD&C Act and are subject to investigational new drug (IND) application requirements. In the notice, FDA defined somatic cell therapy products as "autologous (i.e., self), allogeneic (i.e., intra-species), or xenogeneic (i.e. inter-species) cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics ex vivo to be administered to humans . . ."

Subsequently, in March 1997, the Agency proposed a more comprehensive regulatory approach for cellular and tissue-based products that includes somatic cell therapy products

(62 FR 9721 March 4, 1997). In January 2001, after issuing and reviewing comments on a proposed rule, FDA issued a final rule that establishes the regulatory approach for human cells, tissue, cellular and tissue-based products and requires establishments to register with the Agency and list their

products.

Clinical research using cloning technology to clone a human being is subject to FDA regulation under the PHS Act and the FD&C Act. Before such research could begin, the researcher must submit an IND request to FDA, which FDA would review to determine if such research could proceed. FDA believes

that there are major unresolved safety questions on the use of cloning technology to clone a human being and therefore would not permit any such investigation to proceed at this time.

The following briefly describes the established FDA process in overseeing clinical research. A researcher may not conduct a clinical study unless an IND is in effect. Sponsors are required to submit to FDA an IND describing the proposed research plan and other pertinent scientific information, to obtain authorization from an independent Institutional Review Board, and to obtain the informed consent from all participating individuals. The sponsor must wait at least 30 days after submitting its proposal to FDA before beginning any study. During this time, FDA may take action to prohibit a sponsor from conducting the study by placing the study on "clinical hold" for a variety of reasons, including but not limited to, situations where the Agency finds that "human subjects are or would be exposed to unreasonable and significant risk of illness or injury" or that "the IND does not contain sufficient information required . . . to assess the risks to subjects of the proposed studies." (Title 21, Code of Federal Regulations § 312.42.)

Following the reports about the cloning of Dolly, the sheep, there were reports in the media that scientists were contemplating using cloning technology to clone human beings. FDA notified professional organizations, Institutional Review Boards, and several individuals professing an interest in using somatic cell nuclear transfer to clone a human being. This "Dear Colleague" letter, which is available on FDA's website: www.fda.gov/oc/oha/irbletr.html reiterated FDA jurisdiction over the use of cloning technology to clone a human being. The letter notified researchers that clinical research could proceed only when an IND is in effect. The letter stated that until significant safety issues are appropriately addressed, FDA would not permit any such investigation to proceed. Since the 1998 "Dear Colleague" letter was issued, circumstances have not changed to warrant a change in FDA's position.

FDA has further communicated regarding its jurisdiction with individuals or entities that expressed an intention to pursue the use of cloning technology to clone a human being. FDA continues to monitor information, as it becomes available, with regard to individuals or entities that express an intention to use cloning technology to clone a human being. We can assure you that the Agency will continue to inform such individuals and entities of the laws and regulations governing such research and take appropriate enforcement action as warranted to protect the health and safety of the public.

The Agency's regulatory approach encourages research and innovation, while at the same time helping to ensure that safeguards are in place to protect the public from unreasonable risks that may be associated with clinical trials. Because of the unresolved safety questions pertaining to the use of cloning technology to clone a human being, FDA would not permit any such investigation to proceed at this time.

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Feedback