

Qs and As on NBAC's Report on Cloning

Q. 1 How would you summarize the Commission's recommendations?

- A. The Commission supports a continuation of the current moratorium on federal funding of any attempt to create a child by cloning, using the somatic cell nuclear transfer technique, the same technology that made possible the creation of "Dolly". NBAC is also asking the private sector for voluntary compliance with this moratorium. Furthermore, the Commission recommends enactment of legislation to prohibit anyone in either the public or private sector from attempting to create a child, using this technology, in either a research or clinical setting. Such legislation must include a "sunset" provision to ensure that this issue is reviewed by Congress after a specified time period to determine whether there is a continuing need for this prohibition.

Because there are various ethical and religious perspectives on the cloning of humans, NBAC also recommended that the Federal Government and other appropriate organizations encourage widespread and continuing public dialogue on these issues to further understand the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding the use of this technology.

Q. 2 Why is there need for a "sunset" provision?

- A. Our base of scientific knowledge expands over time and public attitudes and concerns often shift to reflect these changes. A sunset provision takes this into account and ensures that, at a specified point in time prior to the expiration of the legislation, an appropriate advisory body will evaluate and report on the status of somatic cell nuclear transfer technology and on the ethical and social implications of its use with human beings in the context of public attitudes at that time.

Q. 3 Why ban the cloning of humans?

- A. The Commission finds it morally unacceptable for anyone in either the public or private sector to attempt this type of cloning on the grounds that there is no information on the safety and effectiveness of this method in humans. Knowing that "Dolly" was the only successful case in 277 attempts, there is no doubt that there would be substantial risk to the potential child and birth mother. In addition to the safety concerns, there are other serious ethical considerations raised by the possibilities that we could replicate ourselves that require broader and more thoughtful public deliberation.

Q. 4 Why not ban all cloning? What are the potential benefits of cloning research?

- A. There are legitimate and beneficial applications of cloning cells, DNA, tissues, and animals: in animal husbandry to create herds with desirable traits; to develop animal models for biomedical research, to the production of important drugs in the milk of

animals, and to further our knowledge about developmental biology that may one day lead to such advances as regeneration of tissue in severe burns and spinal cord injuries.

Q. 5 Why is any additional legislation necessary? Why not extend the President's moratorium?

A. The President's moratorium covers only federally funded activities. In March, President Clinton called for a voluntary ban on privately funded activities. Legislation is necessary, however, to ensure that the privately funded research and clinical centers comply with the proposed prohibition on cloning of humans using the somatic cell nuclear transfer technique.

Q. 6 Would the NBAC recommendations, if followed, stop anyone from producing another "Dolly" or a cloned human being? If we prohibit cloning of humans in the U.S., will it not be done somewhere else?

A. There is no intention to prohibit anyone from cloning animals as long as such practices are subject to existing regulations regarding the humane use of animals. However, NBAC's recommendations, if implemented, will make it a violation of federal law for anyone to attempt to clone a human being using somatic cell nuclear transfer technology. Most countries in Europe have already placed a ban on such cloning.

Q. 7 Does the President agree with all the Commission's recommendations? Could there be instances in which cloning of humans would be acceptable?

A. Yes, the President endorses all of NBAC's recommendations. At this time neither the safety considerations nor the state of the science can justify any attempt to use this cloning technique for creating human beings. Furthermore, even if safety concerns were to be met someday, any serious consideration of applying this technology to create humans must be preceded by extensive public debate on the various ethical concerns associated with this issue. As a nation, we need to understand the ethical and social implications of this technology before it is ever used to create human beings.

Q. 8 With the proposed legislation, are we interfering with people's reproductive freedom?

A. Currently we do not have the science base to create a child by somatic cell nuclear transfer. Thus, what is being prohibited is currently not possible to do. Yes, the proposed legislation does restrict the reproductive freedom of individuals but in only limited ways. This narrow curb on reproductive freedom is necessary because we do not have the science to ensure that the risks to the resulting baby can be either eliminated or reduced to an acceptable level.

Q. 9 Since the "Dolly" experiment has not been replicated yet, are we overreacting? It took over 270 tries to produce "Dolly."

- A. The fact that 276 attempts to clone a sheep failed and that the experiment has been successful so far only in sheep are precisely the reasons to continue the moratorium, and to make it even stronger.

Q. 10 How will the recommendations and legislation affect research?

- A. NBAC found that a ban on human cloning will not impede any important research at this time. Basic research in such areas as animal husbandry and drug development will continue. Similarly, basic research using somatic cell nuclear transfer technology to study, for instance, the potential for regenerating tissues and organs will continue. However, under current federal restrictions, human embryo research using federal funds will remain prohibited.

Q. 11 Why would you support a total ban on cloning people, but not on creating embryos using cloning technology for research?

- A. The proposed ban on creating children using somatic cell nuclear transfer rests primarily on the fact that no information is available regarding the safety and effectiveness of this method in humans. Indeed, the technique clearly has many imperfections and uncertainties insofar as animal husbandry uses are concerned. As reported by the scientists in Scotland, out of 277 nuclear transfers involving cells from adult sheep, only one led to a live birth (Dolly).

Creation of human embryos for research through in vitro fertilization or somatic cell nuclear transfer is a separate question. NBAC did not speak to this issue, but the President has already acted on it. In 1994, the President imposed a prohibition on creating embryos for research; and the Congress included similarly restrictive provisions in the appropriations statutes for the Department of Health and Human Services for Fiscal Years 1996 and 1997. The prohibition applies irrespective of the technology used to create the human embryos.

Neither the President nor the Congress heretofore has placed restrictions on privately funded activities that involve creation of human embryos, whether for assisted reproduction or research.

Q. 12 If human embryo research is bad, why not ban it in the private sector as well? If human embryo research is good, why prohibit federally funded investigators from doing it?

- A. Americans hold a range of views with respect to human embryo research, in vitro fertilization, or other methods of assisted human reproduction. Both the President and the Congress have determined that such activities are not appropriate uses for federal funds. Private sector restrictions raise difficult questions. They could impede, for example, in vitro fertilization as a method of assisted human reproduction for infertile couples who

desire children that are genetically related to them. The Administration opposed addressing the issue through legislation.

Q. 13 How does the Federal Government oversee privately funded research with human embryos? If a privately funded program were to use somatic cell nuclear transfer technology to create human embryos for research purposes, what regulatory oversight would that research receive?

A. Privately funded research with human embryos is subject to regulation the FDA. If it is part of an effort to develop a drug, biologic, or medical device, the research is subject to regulation by the Food and Drug Administration. Otherwise, it is unregulated. However, many research institutions also voluntarily subject all privately funded research projects to the same human subjects protections that they are required to apply to federally funded research.

Q. 14 Pro-life groups are opposed to the use of human embryos for research. How do you explain the (Commission's position) (legislative proposal) to them?

A. Neither the Commission's report nor the President's legislative proposal alters the nature or the scope of current restrictions on research with human embryos. NBAC's recommendations do not address this area of research because the commission chose to focus on issues raised by creating a child, and did not speak to the issue of embryos..

Q. 15 What happens to human embryos created for research? If they are not implanted, isn't that tantamount to abortion, or even murder?

A. Creation of human embryos for research is a prohibited use of federal funds. The extent of such research under private sponsorship is unknown; therefore, we have no reliable information on the fate of human embryos used in this way.

Q. 16 How will this affect childless couples who see cloning as their only chance to have genetically related offspring?

A. Continuing the President's moratorium and strengthening it with penalties will have little practical effect on such couples. Currently neither the science base nor safety considerations make it possible to produce a child by somatic cell nuclear transfer.

Q. 17 Is the United States acting unilaterally on this issue? Are we treating this issue any differently than other countries?

A. Some European countries have already established legal prohibitions on the cloning of humans. To the extent that there are common aspects to our respective policies, we will certainly cooperate with these nations regarding enforcement.