

Ethical and Policy Issues of Human Cloning

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The idea that humans might someday be cloned from a single adult somatic cell without sexual reproduction moved further away from science fiction and closer to a genuine possibility when scientists at the Roslin Institute in Scotland announced the successful cloning of a sheep (1) by a new technique that had never before been fully successful in mammals. The technique involved transplanting the genetic material of an adult sheep, apparently obtained from a well-differentiated somatic cell, into an egg from which the nucleus had been removed. The resulting birth of the sheep, named Dolly, on 5 July 1996, was different from prior attempts to create identical offspring because Dolly contained the genetic material of only one parent and was therefore a "delayed" genetic twin of a single adult sheep.

This cloning technique, which I will refer to as "somatic cell nuclear transfer," is an extension of research that had been going on for over 40 years with nuclei derived from nonhuman embryonic and fetal cells. The further demonstration that nuclei from cells derived from an adult animal could be "reprogrammed," or that the full genetic complement of such a cell could be reactivated well into the chronological life of the cell, is what sets the results of this experiment apart from prior work. At the same time, several serious scientific uncertainties remain that could have a significant impact on the potential ability of this new technique to create human beings. Examples of such uncertainties include the impact of genetic imprinting, the nature of currently unknown species differences, and the effects of cellular aging and mutations.

The initial public response to this news, here and abroad, was primarily one of concern. In some cases, these concerns were amplified by largely fictional and mistaken accounts of how this new technology might dramatically reshape the future of our society. The sources of these feelings were complex, but usually centered around the basic fact that this technique would permit human procreation in an asexual manner, would allow for an unlimited number of genetically identical offspring, and would give us the capacity for complete control over the genetic profile of our children.

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Ethical and Legal Issues

Within days of the published report, President Clinton instituted a ban on federal funding related to attempts to clone human beings in this manner. In addition, the president asked the recently appointed National Bioethics Advisory Commission (NBAC) to report within 90 days on the ethical and legal issues that surround the potential cloning of human beings (2).

This was an unusually challenging assignment for many reasons. These issues are complex and difficult, and many scientific uncertainties remain. Conflicting values are at stake, and Americans disagree on the implications of this new technology for the social and cultural values they hold dearest. It is difficult to decide if and when our liberties, including the freedom of scientific inquiry, should be restricted. Finally, the commission was given an ambitious timetable.

Nonetheless, NBAC made every effort to consult widely with ethicists, theologians, scientists, scientific societies, physicians, and others in initiating an analysis of the many scientific, legal, religious, ethical, and moral dimensions of the issue. This included a careful consideration of the potential risks and benefits of using this technique to create children and a review of the potential constitutional challenges that might be raised if new legislation were to restrict the creation of a child through somatic cell nuclear transfer cloning.

The commission focused its attention on the new and distinctive ethical issues that would be raised by the use of this technique for the purpose of creating an embryo genetically identical to an existing (or previously existing) person that would then be implanted in a woman's uterus and brought to term. Although the creation of embryos for research purposes alone always raises serious ethical questions, these issues have recently received extensive analysis and deliberation in our country, and the use of somatic cell nuclear transfer to create embryos raises no new issues in this respect. The unique and distinctive ethical issues raised by the use of somatic cell nuclear transfer to create children relate to serious safety concerns and to a set of questions about what it means to be human; questions that go to the heart of the way we think

about families and relationships between generations, our concept of individuality, and the potential for treating children as objects, as well as issues of constitutional law that might be involved in the area of procreation.

Concerns

In its deliberations, NBAC reviewed the scientific developments that preceded the Roslin announcement, as well as those likely to follow in its path, and the many moral and legal concerns raised by the possibility that this technique could be used to clone human beings. Although some of the initial negative response arose from fictional accounts of cloning human beings, more thoughtful concerns revealed fears about harm to the children who may be created in this manner, particularly psychological harm associated with a possibly diminished sense of individuality and personal autonomy. Others expressed concern about a degradation in the quality of parenting and family life.

In addition to concerns about specific harms to children, people have frequently expressed fears that the widespread practice of somatic cell nuclear transfer cloning would undermine important social values by opening the door to a form of eugenics or by tempting some to manipulate others as if they were objects instead of persons. These are concerns worthy of widespread and intensive debate, but arrayed against these concerns are other vitally important social and constitutional values, such as protecting the widest possible sphere of personal choice, particularly in matters pertaining to procreation and child rearing; maintaining privacy; protecting the freedom of scientific inquiry; and encouraging the possible development of new biomedical breakthroughs.

To arrive at its recommendations, NBAC also examined longstanding religious traditions and found that religious positions on human cloning are pluralistic in their premises, modes of argument, and conclusions. Some religious thinkers argue that the use of somatic cell nuclear transfer cloning to create a child would be intrinsically immoral and thus could never be morally justified. Other religious thinkers contend that human cloning to create a child could be morally justified under some circumstances but believe that it should be strictly regulated to prevent abuses.

Public Policies

The public policies that NBAC recommended with respect to the creation of a child by means of somatic cell nuclear transfer reflected the commission's attempt to balance the various interests at stake and to apply its

best judgments about the ethics of attempting such an experiment at this time as well as its view of U.S. constitutional traditions regarding limitations on individual actions in the name of the common good. We concluded that, at present, the use of this technique to create a child would be a premature experiment that would expose the fetus and the developing child to unacceptable risks. In our judgment, this in itself might be sufficient to justify a prohibition on using this new technique to clone human beings at this time, even if such efforts were to be characterized as the exercise of a fundamental right to attempt to procreate. Beyond the issue of the safety of the procedure, however, NBAC found that concerns relating to potential psychological harm to children and effects on the moral, religious, and cultural values of society merit further reflection and deliberation. Whether upon such further deliberation our nation will conclude that the use of this new cloning technique to create children should be allowed or permanently banned is, for the moment, an open question. Fortunately, time is an ally in this regard, allowing for the accrual of further data from animal experimentation, an assessment of the prospective safety and efficacy of the procedure in humans, and a period of fuller national debate on ethical and social concerns.

The commission therefore concluded that a period of time should be imposed in which no attempt is made to create a child using somatic cell nuclear transfer.

Conclusions and Recommendations

Within this overall framework, the commission's full set of conclusions and recommendations was as follows:

1) The commission concluded 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. We reached a consensus on this point because current scientific information indicates that this technique is not safe to use in humans at this time. Indeed, we believe that it would violate important ethical obligations were clinicians or researchers to attempt to create a child using these particular technologies, which are likely to involve unacceptable risks to the fetus or potential child. Moreover, in addition to safety concerns, many other serious ethical concerns have been identified that require much more widespread and careful public deliberation before this technology may be used.

The commission therefore recommended the following: (i) A continuation of the

current moratorium on the use of federal funding to support any attempt to create a child by somatic cell nuclear transfer. (ii) An immediate request to all firms, clinicians, investigators, and professional societies in the private and nonfederally funded sectors to comply voluntarily with the intent of the federal moratorium. Professional and scientific societies should make clear that any attempt to create a child by somatic cell nuclear transfer and implantation into a woman's body would at this time be an irresponsible, unethical, and unprofessional act.

2) The commission further recommended that federal legislation should be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through cloning by somatic cell nuclear transfer. It is critical, however, that such legislation include a sunset clause to ensure that Congress will review this issue after a specified period of time (3 to 5 years) to decide whether the prohibition continues to be needed. If state legislation is enacted, it should also contain such a sunset provision. Any such legislation or associated regulation should require that at some point before the expiration of the sunset period, an appropriate oversight body will evaluate and report on the current status of somatic cell nuclear transfer technology and on the ethical and social issues that its potential use to create human beings would raise in the light of public understandings at that time.

3) The commission also concluded that (i) any regulatory or legislative actions undertaken to effect the foregoing prohibition should be carefully written so as not to interfere with other important areas of scientific research. In particular, we believe that no new regulations are required regarding the cloning of human DNA sequences and cell lines, because neither activity raises the scientific and ethical issues that arise from the attempt to create children through somatic cell nuclear transfer, and these fields of research have already provided important scientific and biomedical advances. Likewise, research on cloning animals by this technique does not raise the same issues as attempting to use it for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and to review by institution-based animal protection committees. (ii) If a legislative ban is not enacted, or is enacted but later lifted, clinical use of somatic cell nuclear transfer techniques to create a child should be preceded by research trials that are governed by the twin protections of independent review and informed consent, which is consistent with existing norms of human subjects protection. (iii) The U.S. government should co-

operate with other nations and international organizations to enforce any common aspects of their respective policies on the cloning of human beings.

4) The commission concluded that different ethical and religious perspectives and traditions are divided on many of the important moral issues that surround this topic. Therefore, it recommended that the federal government and all interested and concerned parties encourage widespread and continuing deliberation on these issues to further our understanding of the ethical and social implications of this technology and to enable society to produce appropriate long-term policies should the time come when present concerns about safety have been addressed.

5) Finally, because scientific knowledge is essential for all citizens to participate in a full and informed fashion in the governance of our complex society, the commission recommended that federal departments and agencies concerned with science should cooperate in seeking out and supporting opportunities to provide information and education to the public in the area of genetics and about other developments in the biomedical sciences, especially where they affect important cultural practices, values, and beliefs.

NBAC hopes that the sections of its report that outline the scientific, religious, ethical, and legal issues associated with human cloning will form a useful basis for the widespread deliberations and broad public education we believe are so essential. We believe that this kind of deliberation and education are especially critical in a society where individuals hold various religious and moral perspectives. As I have already noted, issues related to human cloning in this novel manner go to the very nature of what it means to be human and to the very heart of what people think of as their families and their individuality. These are issues worthy of intensive and widespread debate.

Once again, however, time is an ally, allowing for the accumulation of more scientific data from animal studies as well as granting an opportunity for fuller national debate on ethical and moral concerns. Through such deliberation, we can, as a society, improve not only our understanding of the scientific issues but our prospects for achieving moral agreement where that is possible, or mutual respect where such agreement cannot be achieved.

REFERENCES AND NOTES

1. I. Wilmut, A. E. Schnieke, J. McWhir, A. J. Kind, K. H. S. Campbell, *Nature* **385**, 810 (1997).
2. The full report will be posted on the NBAC home page at <http://www.nih.gov/nbac/nbac.htm>