



# NATIONAL BIOETHICS ADVISORY COMMISSION

Harold T. Shapiro, Ph.D.  
Chair

September 26, 2001

Patricia Backlar

The President  
The White House  
Washington, DC 20500

Arturo Bratto, M.D.

Alexander Morgan Capron, LL.B.

Eric J. Casell, M.D.

Dear Mr. President:

R. Alta Charo, J.D.

James F. Childress, Ph.D.

I am writing to you as the chair of the National Bioethics Advisory Commission (NBAC). In the six years that we have had the honor to provide advice to the White House, the Commission has issued six reports on various issues relating to ethics and research. We had planned to hold a final meeting on September 19 to discuss outstanding issues that could be addressed by a national ethics and public policy advisory body. Due to the recent tragic events, we canceled the meeting.

David R. Cox, M.D., Ph.D.

Rhetaugh G. Damas, Ph.D., R.N.

Carol W. Greider, Ph.D.

Steven H. Holtzman

Bette O. Kramer

The purpose of the meeting was to articulate a set of bioethics issues that we believe require serious and sustained discussion at the federal level. Among the issues we anticipated discussing were assisted reproductive technologies, horizontal gene transfer, property issues concerning the human body, research involving children, population-based research, and human cloning. Many of these issues are currently being debated and have been long-standing concerns of this Commission.

Bernard Lo, M.D.

Lawrence H. Mink, M.D., J.D.

Thomas H. Murray, Ph.D.

William C. Oldaker, LL.B.

Diane Scott-Jones, Ph.D.

Attached is a brief summary of the issues. At your request, we could provide you with background materials on any of them. I am happy to offer my assistance as you continue to consider important bioethics issues.

Sincerely,

Harold T. Shapiro  
Chair

Enclosures

## **Outstanding Ethical and Public Policy Issues**

### Assisted Reproductive Technologies

The methods and frequency of use of assisted reproductive technologies are increasing. Oversight of these technologies in the United States is limited, and there is little distinction between the development and experimental use of a new assisted reproductive technology and its use as a proven clinical treatment. Key issues for consideration are the need and type of required oversight when assisted reproductive technologies are used in research or practice, identifying and assessing risks of these technologies, whether the motivations behind their use are relevant to determining acceptability, and whether there should be eligibility criteria for use of such technologies.

### Horizontal Gene Transfer

Horizontal gene transfer is the insertion of new genetic material or material from another species into human beings. When horizontal gene transfer is initiated by humans (as opposed to being unplanned such as through viral infection) it raises issues about whether it should be permitted and if so, with what protections. In other words, we must be able to anticipate horizontal gene transfer applications and evaluate safety and efficacy. At a more fundamental level, horizontal gene transfer may alter an individual's humanness, especially when this involves making inheritable genetic changes.

### Body as Property

Research and commercial uses of human tissues are increasing while relatively little federal or state law addresses the transfer of human tissue. The interplay of property law and personal control over one's body raises a number of questions. Should the body, in whole or in part, be treated as the property of the person who inhabits or inhabited the body? If so, questions include whether it can be disposed of by will or other testamentary measures after death, and what effect treating the body as property has on efforts to ensure the autonomy and dignity of individuals and to regulate the human tissue market.

### Research Involving Children

There is an increasing recognition of the value of including children as participants in research, and inclusion is encouraged by recent regulatory and legal changes. However, children can be particularly vulnerable in research. Only a few federal agencies have regulations addressing research involving children. Questions have been raised as to whether current regulations are adequate to protect children, under what circumstances healthy children should be involved in research, and the role of the child's age in determining participation in research.

### Population-Based Research

There has been increasing recognition of the need to respect and protect communities or groups of people in research. Federal regulations are focused on protecting individuals, so researchers have little guidance on how to identify risks to communities and provide

appropriate protections. Community issues arise even when a population is not necessarily being studied. Consideration should be given as to when and how to involve communities in planning and conducting research and in reporting research findings.

#### Cloning Human Beings

In 1997, NBAC recommended a prohibition on somatic cell nuclear transfer to create a child and noted that more debate on the ethical, social, and legal aspects of cloning would be necessary if safety concerns were ever resolved in the future. Today, serious safety issues remain. However, consideration should be given to the ethical, social, and legal issues associated with human cloning in the event that the risks to the fetus and mother were someday to be considered acceptable.