

National Bioethics Advisory Commission



1996-1997 Annual Report

National Bioethics Advisory Commission

Rockville, Maryland

March 1998

1996-1997 Annual Report

National Bioethics Advisory Commission

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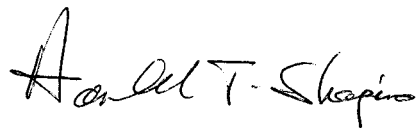
Preface

The purpose of this report is to make available to the public a brief description of the work of the National Bioethics Advisory Commission during 1996-1997, and its ongoing agenda.

The National Bioethics Advisory Commission, appointed by President Clinton in the later half of 1996, has had a rather eventful first year. Our initial agenda, which focused both on the protection of human subjects and the ethical issues surrounding the use of an individual's genetic information, perhaps drawn from existing tissue banks, was "interrupted" or temporarily displaced by a new, urgent request from President Clinton. This Presidential request, prompted by the apparent success of the "Dolly Experiment"—the cloning of an animal from an adult or specialized cell using somatic cell nuclear transfer technique—and the resulting widespread public excitement, fear, concern, and awe—effectively put our initial agenda on hold for a number of months. We turned our attention instead to the challenge of providing, in ninety days, advice on the ethical and legal issues involved if using this technique to clone human beings. Our report on this issue was delivered to the President in early June 1997, after which we returned to the items on our initial agenda. These items and the ongoing work of the Commission are more fully described in this report.

Finally, I would like to take this occasion to extend my appreciation to all the Commissioners for their dedication to the work of the Commission, to our small but very hard working staff, the many scholars who responded to our request for help, the leadership of the Department of Health and Human Services, and the Office of Science and Technology Policy, which in many ways supported the work of the Commission. I would also like to thank Dr. William F. Raub for his leadership and guidance as Acting Executive Director during 1997, which he provided in addition to his full time duties as Deputy Assistant Secretary for Science Policy at the Department of Health and Human Services. As Dr. Raub's day-to-day responsibilities come to a close, NBAC welcomes Dr. Eric M. Meslin as its new Executive Director, beginning February 1998.

Harold T. Shapiro, Chair

A handwritten signature in cursive script that reads "Harold T. Shapiro". The signature is written in black ink and is positioned below the printed name.

March 1998

Roster of NBAC Members (1996-1997)

Harold T. Shapiro, Ph.D. — *Chair*

President

Princeton University
Princeton, New Jersey

Patricia Backlar

Research Associate Professor of Bioethics
Department of Philosophy
Portland State University
Senior Scholar
Center for Ethics in Health Care
Oregon Health Sciences University
Portland, Oregon

Arturo Brito, M.D.

Assistant Professor of Clinical Pediatrics
University of Miami School of Medicine
Miami, Florida

Alexander M. Capron, LL.B.

Henry W. Bruce Professor of Law
University Professor of Law and Medicine
Co-Director, Pacific Center for
Health Policy and Ethics
University of Southern California
Los Angeles, California

Eric J. Cassell, M.D.

Clinical Professor of Public Health
Cornell University Medical College
New York, New York

R. Alta Charo, J.D.

Associate Professor of Law and Medical Ethics
School of Law and Medicine
University of Wisconsin
Madison, Wisconsin
(From Jan. 1, 1998 to Aug. 1, 1998)
Senior Fellow
Program in Genomics, Ethics, and Society
Stanford Center for Biomedical Ethics
Palo Alto, California)

James F. Childress, Ph.D.

Kyle Professor of Religious Studies
Professor of Medical Education
Department of Religious Studies
University of Virginia
Charlottesville, Virginia

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

Professor of Genetics and Pediatrics
Stanford University School of Medicine
Department of Genetics
Stanford, California

Rhetaugh Graves Dumas, Ph.D., R.N.

Vice Provost Emerita and Dean Emerita
Lucille Cole Professor of Nursing
The University of Michigan
Ann Arbor, Michigan

Ezekiel J. Emanuel, M.D., Ph.D.
Associate Professor of Medical Ethics
Department of Social Medicine
Harvard Medical School
Boston, Massachusetts
(resigned February 1998)

Laurie M. Flynn
Executive Director
National Alliance for the Mentally Ill
Arlington, Virginia

Carol W. Greider, Ph.D.
Associate Professor
Department of Molecular Biology and Genetics
Johns Hopkins University School of Medicine
Baltimore, Maryland

Steven H. Holtzman
Chief Business Officer
Millennium Pharmaceuticals Inc.
Cambridge, Massachusetts

Bette O. Kramer
Founding President
Richmond Bioethics Consortium
Richmond, Virginia

Bernard Lo, M.D.
Director
Program in Medical Ethics
University of California, San Francisco
San Francisco, California

Lawrence H. Miike, M.D., J.D.
Director
State Department of Health
Honolulu, Hawaii

Thomas H. Murray, Ph.D.
Director, Center for Biomedical Ethics
School of Medicine
Case Western Reserve University
Cleveland, Ohio

Diane Scott-Jones, Ph.D.
Professor
Department of Psychology
Temple University
Philadelphia, Pennsylvania

NBAC Staff (1997)

Executive Director, Acting

William F. Raub, Ph.D

Deputy Executive Director

Henrietta D. Hyatt-Knorr, M.A.

Senior Consultants

Kathi Hanna, M.S., Ph.D.

Jonathan Moreno, Ph.D.

Research Staff

William L. Freeman, M.D., M.P.H.

Sheri Alpert, M.A., M.P.A.

Emily C. Feinstein

E. Randolph Hull, Jr.

Sean A. Simon

Robert Tanner

Joel Mangel, J.D.

Administrative Staff

Patricia Norris

Margaret C. Quinlan

LaShell Gaskins

Robin Dorsey

*Includes full-time, part-time and volunteer staff in 1997;
for current (1998) staff, please see Appendix A*

Executive Order 12975 of October 3, 1995

Federal Register: October 5, 1995 (Volume 60, Number 193) Page 5206352065

Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Review of Policies and Procedures.

(a) Each executive branch department and agency that conducts, supports, or regulates research involving human subjects shall promptly review the protections of the rights and welfare of human research subjects that are afforded by the department's or agency's existing policies and procedures. In conducting this review, departments and agencies shall take account of the recommendations contained in the report of the Advisory Committee on Human Radiation Experiments.

(b) Within 120 days of the date of this order, each department and agency that conducts, supports, or regulates research involving human subjects shall report the results of the review required by paragraph (a) of this section to the National Bioethics Advisory Commission, created pursuant to this order. The report shall include an identification of measures that the department or agency plans or proposes to implement to enhance human subject protections. As set forth in section 5 of this order, the National Bioethics Advisory Commission shall pursue, as its first priority, protection of the rights and welfare of human research subjects.

(c) For purposes of this order, the terms "research" and "human subject" shall have the meaning set forth in the 1991 Federal Policy for the Protection of Human Subjects.

Sec. 2. Research Ethics.

Each executive branch department and agency that conducts, supports, or regulates research involving human subjects shall, to the extent practicable and appropriate, develop professional and public educational programs to enhance activities related to human subjects protection, provide forums for addressing ongoing and emerging issues in human subjects research, and familiarize professionals engaged in nonfederally-funded research with the ethical considerations associated with conducting research involving human subjects. Where appropriate, such professional and educational programs should be organized and conducted with the participation of medical schools, universities, scientific societies, voluntary health organizations, or other interested parties.

Sec. 3. Establishment of National Bioethics Advisory Commission.

(a) There is hereby established a National Bioethics Advisory Commission ("NBAC"). NBAC shall be composed of not more than 15 members to be appointed by the President. NBAC shall be subject to the Federal Advisory Committee Act, as amended (5 U.S.C. App.).

(b) The President shall designate a Chairperson from among the members of NBAC.

Sec. 4. Functions.

(a) NBAC shall provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding the following matters:

1. the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior; and
2. applications, including the clinical applications, of that research.

(b) NBAC shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles.

(c) NBAC shall not be responsible for the review and approval of specific projects.

(d) In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council.

Sec. 5. Priorities.

(a) As a first priority, NBAC shall direct its attention to consideration of: protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information, including but not limited to, human gene patenting.

(b) NBAC shall consider four criteria in establishing the other priorities for its activities:

1. the public health or public policy urgency of the bioethical issue;
2. the relation of the bioethical issue to the goals for Federal investment in science and technology;
3. the absence of another entity able to deliberate appropriately on the bioethical issue; and
4. the extent of interest in the issue within the Federal Government.

Sec. 6. Administration.

(a) The heads of executive departments and agencies shall, to the extent permitted by law, provide NBAC with such information as it may require for purposes of carrying out its functions.

(b) NBAC may conduct inquiries, hold hearings, and establish subcommittees, as necessary. The Assistant to the President for Science and Technology and the Secretary of Health and Human Services shall be notified upon establishment of each subcommittee, and shall be provided information on the name, membership (including chair), function, estimated duration, and estimated frequency of meetings of the subcommittee.

(c) NBAC is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on NBAC, the Secretary of Health and Human Services may contract for the services of nongovernmental consultants who may conduct analyses, prepare reports and background papers, or prepare other materials for consideration by NBAC, as appropriate.

(d) Members of NBAC shall be compensated in accordance with Federal law. Members of NBAC may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. 57015707).

(e) To the extent permitted by law, and subject to the availability of appropriations, the Department of Health and Human Services shall provide NBAC with such funds as may be necessary for the performance of its functions. The Secretary of Health and Human Services shall provide management and support services to NBAC.

Sec. 7. General Provisions.

(a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to NBAC, except that of reporting annually to the Congress, shall be performed by the Secretary of Health and Human Services, in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) NBAC shall terminate two years from the date of this order unless extended prior to that date.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit, trust, or responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

WILLIAM J. CLINTON

The White House

October 3, 1995

Amending Executive Order No. 12975

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to add 3 members to the National Bioethics Advisory Commission, it is hereby ordered that the number “15” in the second sentence of section 3(a) of Executive Order No. 12975 is deleted and the number “18” is inserted in lieu thereof.

WILLIAM J. CLINTON

The White House

September 16, 1996

Further Amending Executive Order No. 12975, Extension National Bioethics Advisory Commission

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to extend the term of the National Bioethics Advisory Commission, it is hereby ordered that section 7(b) of Executive Order No. 12975 further is amended to read, “NBAC shall terminate on October 3, 1999, unless extended by the President prior to that date.”

WILLIAM J. CLINTON

The White House

May 16, 1997

Introduction

The National Bioethics Advisory Commission (NBAC) was established by Executive Order 12775 in October 1995 to advise the National Science and Technology Council and other appropriate government entities regarding bioethical issues arising from research on human biology and behavior. NBAC's first priority, as directed in its Charter, was to "consider the protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information." The Charter encouraged NBAC to identify other bioethical issues for the purpose of providing advice and recommendations. This Annual Report will describe the establishment of the National Bioethics Advisory Commission, briefly recount the history of federal bioethics commissions in the United States, and offer a summary of NBAC's activities in its first year, including the activities of the two subcommittees and the publication of the Commission's first report, *Cloning Human Beings*.

Establishment of the National Bioethics Advisory Commission

In the Fall of 1993, the White House Office of Science and Technology Policy (OSTP) was approached by the National Institutes of Health (NIH), the Department of Energy (DOE), and other research-oriented agencies to consider supporting many longstanding calls for the United States to establish a standing, expert, national commission on bioethics. The proposal stemmed in part from a congressional request that NIH and DOE establish an advisory committee on genetic privacy, but was also responsive to a growing chorus of voices suggesting the need for such a commission to address a wide and growing range of other unsettled issues in the area of bioethics. One recommendation, which came directly from the Advisory Committee on Human Radiation Experiments (ACHRE), called for the creation of a committee to address more broadly the ethics of research involving human subjects¹. As a result, OSTP expressed a need for a high-level group to serve as a shared resource to address a broad set of ethical issues, including genetic privacy and the protection of human subjects in research, and to complement specialized committees and boards already supported by the various mission agencies.

Other than a short-lived advisory committee appointed by Congress in the late 1980's, no such standing body for addressing bioethical issues had existed in the United States since 1983. Indeed, the United States stood virtually alone among industrialized nations in not having established a permanent standing commission to address evolving bioethical issues. Instead, this country has relied on the work of highly qualified but time-limited commissions, which have deliberated about specific topics. For example, ACHRE was responsible for reviewing the protections of U.S. citizens involved in radiation experiments several

decades ago, including American soldiers who were intentionally exposed to radiation during atmospheric nuclear tests. Three ongoing issues were raised by ACHRE: the need for a continuing public forum on the interpretation and application of ethics rules and principles for the conduct of human subjects research; the need to maintain consistency in ethical standards for human subjects research across the federal agencies and departments that support such efforts; and finally the need to review the current Institutional Review Board (IRB) system. The first of these concerns provided some of the initial impetus to create NBAC.

In August 1994, OSTP published in the *Federal Register* a draft charter for a National Bioethics Advisory Commission (NBAC) to provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities on relevant bioethical issues. The NBAC charter that was signed by John H. Gibbons, the Assistant to the President for Science and Technology Policy, on July 26, 1996, reflected public comments received as well as bipartisan input from Congress. In addition to establishing NBAC, the President also charged the executive branch agencies that conduct, support, or regulate research involving human subjects to review their policies and procedures for protection of research subjects. This directive was a direct response to the recommendations contained in the ACHRE report. The President's Executive Order 12975 of October 3, 1995, required federal agencies to report the results of their review to NBAC, which was to pursue, as its first priority, protection of the rights and welfare of human research subjects.

¹ Advisory Committee on Human Radiation Experiments, Final Report (Washington, DC: U.S. Government Printing Office, October 1995), pg. 817.

The charter requires that NBAC consider “issues in the management and use of genetic information, including but not limited to human gene patenting.” The Commission also may consider additional issues suggested by executive branch agencies, Congress, and the public, or issues which originate within the Commission itself.

NBAC is not a regulatory body and does not review or approve individual projects. Rather, it is designed to identify broad overarching principles to govern the ethical conduct of research.

It is an 18-person body, appointed by the President, the membership of which is drawn from the fields of ethics, philosophy, law, medicine, theology, economics, psychology, science, and the public. Meetings of NBAC are public and are announced 15 working days in advance in the *Federal Register*. These meetings provide an opportunity for the public to comment either in person (see Appendix D) or by submitting written testimony. These and other specific requirements are described in the Federal Advisory Committee Act (FACA)² to which NBAC adheres.

A Brief History of U.S. Bioethics Commissions

In the decades since the end of World War II, advances in biomedical science increasingly focused attention on both the opportunities and challenges posed by biomedical research and medical practice. As a nation, the United States has enjoyed great success in utilizing innovative technologies for medical purposes. However, technology and the needs of medical researchers have, at times, found themselves in juxtaposition with deeply held social values, such as respect for human dignity, and the right to privacy. Just as complex ethical, legal, and social issues motivated society’s interest in decision making at the end of life, equitable access to health care, and the use of medically assisted reproduction, we now find a similar motivation arising, for example, from research in the Human Genome Project—the international effort to determine our genetic blueprint. Consideration of research ethics continues to be an important part of public policy in a system in which the Federal Government has a direct responsibility for the research activities it conducts, sponsors or regulates.

In the past, American society has found it useful to promote a national discussion of those complex

bioethical issues that have arisen and to develop appropriate public policies where necessary. To carry out this task, the Federal Government has, in the last three decades, convened a number of bioethics commissions to promote national deliberation. Indeed, the United States took the lead in developing a forum for “public bioethics.” These government commissions have functioned as mechanisms to develop public policies, to articulate common values, and to foster understanding in the face of growing cultural and religious heterogeneity, evolving moral sensibilities and the rapidly advancing scientific frontier. The establishment of these deliberative bodies signaled the increasing importance of medical and biological technologies in our national life and the pressing need for the global consideration of these issues in a public forum. The work of these commissions has been used by courts, legislatures, academic and research institutions, and the public media, each helping to shape and inform public dialogue.

NBAC was established more than a decade after the expiration of the last federal bioethics commission, the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical

²Federal Advisory Committee Act, Pub. L. 92-463, Oct. 6, 1972, 86 Stat. 770

and Behavioral Research. To date, Congress has created five deliberative bodies devoted to bioethics. In order to understand the challenges and opportunities facing it, NBAC's contribution to a national (and indeed international) dialogue on bioethics issues must be seen in the context of the four national bioethics commissions that preceded it. NBAC is part of an important history of federal bioethics commissions in the United States.³

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) (1974-1978) was established under the National Research Act (Public Law 93-348), following a congressional debate dating back to 1968 concerning the protection of human research participants. A series of controversial cases, including the Tuskegee syphilis study and the Willowbrook hepatitis experiments, signaled a need for some form of additional national oversight and review of human subjects research.

Congress created the National Commission as part of the then Department of Health, Education, and Welfare and gave it a specific task-to articulate the principles of ethics to guide research involving human subjects, and to use those principles to recommend actions by the Federal Government. The Commission issued 10 reports, many of which were later translated by the Department into what remain today the core regulations for research involving human subjects (45 CFR 46). In perhaps its most influential and enduring report, the *Belmont Report*, the Commission articulated three basic principles to guide research with human subjects: respect for persons, beneficence, and justice. These principles have been adopted by research ethic statements and codes in many parts of the world. *The Belmont Report* placed an emphasis on autonomy, elaborated and extended the notion of informed consent, recognized the vulnerability of specific populations (children, prisoners, those institutionalized as mentally infirm), and fleshed

out details of review by the Institutional Review Boards (IRBs) now embodied in federal research regulations.

Based upon the first set of recommendations from the National Commission, the Department announced in 1975 that no proposal for research on human embryos or on in vitro fertilization (IVF) of human eggs would be funded until it was reviewed and approved by a Federal ethics advisory board. In 1978, the Secretary of HEW appointed an **Ethics Advisory Board (EAB)** which issued a report on in vitro fertilization in May 1979 that stipulated several criteria for approval of such experiments. The Office of the Secretary has never responded to the EAB's report on IVF research, thus resulting in a de facto moratorium on human IVF research. The EAB was dissolved in 1980, because the Secretary concluded it had become redundant due to the appointment of a new bioethics commission.

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (President's Commission) (1980-1983) was authorized in 1978 by Section III of Public Law 95-622. The language of the statute specified several tasks, but also gave the President's Commission the authority to undertake studies at the request of the President or upon its own initiative. The President's Commission issued 11 reports. It continued some of the work of the National Commission in several reports on the federal regulations of research with human subjects and compensation for research injuries. Its report *Defining Death* became the foundation for statutory changes adopted by a majority of U.S. states. The Commission addressed "whistleblowing" in biomedical research, and issued prescient reports on genetic screening and counseling. The Commission also confronted controversies about termination of treatment in its reports on making health care decisions, and even more directly in *Deciding to Forego Life-Sustaining Treatment*. Another report, *Securing Access to*

³U.S. Congress, Office of Technology Assessment, *Biomedical Ethics in U.S. Public Policy-Background Paper*, OTA-BP-BBS-105 (Washington, DC: U.S. Government Printing Office, June, 1993.)

Health Care was a foray into mainstream American health policy, addressing a central issue, equitable access to health care. *Splicing Life* emphasized the distinction between genetically altering somatic cells, which would not lead to inherited changes, and germ cells (sperm, egg cells, and their precursors), which would induce inherited changes.

The Biomedical Ethics Advisory Committee (BEAC) (1988-1989) was a 14-member group whose membership was appointed by the Biomedical Ethics Board (BEB), comprised of 12 Members of Congress — three each from the majority and minority parties of the House and Senate. It took almost a year for the four party leaders of the House and Senate to appoint the 12 members of the

congressional Board, which then took on the responsibility of appointing the 14 members of BEAC, the operational arm. BEAC met for the first time in September 1988, less than a week before its authorization expired. BEAC was required to prepare at least three reports on specified topics, as well as to provide annual reports. The first mandated report concerned the implications of human genetic engineering. The deadline for the second report, on fetal research, expired before BEAC members were appointed. The third mandate, feeding and nutrition of dying patients, also was not addressed. Caught in political crossfire within BEB, BEAC was ordered to cease meeting after its second session and closed its doors in October 1989, having issued no reports.

NBAC's First Year: 1996-1997

NBAC met for its inaugural meeting on October 4, 1996. Following this initial meeting, two subcommittees were formed to address the two mandated issues of human subjects protections and issues in the management and use of genetic information⁴. They were named the Human Subjects Subcommittee (HSSC) and the Human Genetics Subcommittee (HGSC). The subcommittees were established to allow the Commission to work more efficiently. On most occasions, the subcommittees met on or within one day of the full Commission's meeting, and then would convene jointly as a full Commission. There were 17 meetings held between October 1996 and December 1997. Of those, seven were devoted to the Human Subjects Subcommittee, and seven were devoted to the Human Genetics Subcommittee. NBAC met as a full commission eight times (see Appendix C).

In November 1996, NBAC sponsored an International Summit on bioethics in conjunction with the III. World Congress of Bioethics held by the International Association of Bioethics in San Francisco. Representatives of 25 nations gathered to discuss organized bioethics activities in their countries (see Table 1). There are bioethics commissions and institutes in the Americas, Africa, Asia, Australia, and Europe. Existing commissions vary in their scope and sponsorship. Several have been formed in response to concerns about human rights. Although drawn to what they do because of a common concern about the course of modern science in society, the international commissions reflect diversity in moral beliefs based on nationality, culture, history, and religious tradition.

Beginning in December 1997, the Subcommittees met independently to advance their work on the use

⁴ Memo to John H. Gibbons, *Assistant to the President for Science and Technology*, signed November 6, 1996 by F. William Dommel, Jr., J.D., *Executive Director* (Acting)

of genetic information and human subjects protection. These subcommittees functioned as semi-independent working groups that reported their progress and ideas to the full commission at each joint meeting. This enabled the work of the commission as a whole to progress more rapidly. The subcommittees each commissioned papers on subjects germane to their deliberations, and invited

testimony from both experts and members of the public. Meetings were open to the public and announced in the Federal Register as required by FACA. Despite the existence of these distinct subcommittees, NBAC issues all of its reports as a full commission; all conclusions and recommendations come before the entire group for discussion and vote.

Table 1

**International Bioethics Organizations Attending November 1996 Summit
of National Bioethics Advisory Bodies, San Francisco, California**

Association of Bioethics, Brazil
Association for Bioethics, Japan
Comision Nacional de Bioetica, Mexico
Comite Consultatif National d’Ethique, France
Committee of Medical Ethics and Health Law, Health Council of the Netherlands
Consejo Asesor de Sanidad, Spain
Council of Ethics, Denmark
East Asian Association for Bioethics
Escuela Latinamericana de Bioetica, Argentina
Ethics Committee of the Human Genome Organization
European Commission on Ethical Implications of Biotechnology
Groupe de Conseillers, Italy
Health Ethics Committee, Australia
International Associations of Bioethics
Japan Society of Bioethics
Law Commission for the Family Code and Transsexualism, Croatia
National Council on Bioethics in Human Research, Canada
National Committee for Medical Ethics, Slovenia
Nuffield Council on Bioethics, United Kingdom
Program in Bioethics, Chinese Academy of Social Sciences
Russian National Committee on Bioethics
Swiss Academy of Medical Sciences, Switzerland
The International Bioethics Committee, UNESCO
The Steering Committee on Bioethics, Council of Europe

Activities of the Human Subjects Subcommittee

James F. Childress, Ph.D., *Chair*
Arturo Brito, M.D.
Alexander M. Capron, LL.B.
Eric J. Cassell, M.D.
R. Alta Charo, J.D.
Rhetaugh Graves Dumas, Ph.D., R.N.
Laurie M. Flynn
Diane Scott-Jones, Ph.D.

Federal Agency Compliance with Rules Governing Research with Human Subjects

The first task of the Human Subjects Subcommittee was to review the federal agency reports on human subjects protections, required by Executive Order 12975. In response to those reports, NBAC undertook a survey of the federal agencies to determine the extent to which agencies protect human subjects according to the Common Rule, the name given to the regulations promulgated jointly by relevant federal departments and agencies in 1991 to govern the conduct of federally supported research involving human subjects (45 CFR 46). Once this study is complete, the Commission will recommend actions to be taken to ensure that all federal agencies conducting or supporting research with human subjects understand and implement the regulations. The Commission will likely issue its findings as part of a more comprehensive report on federal oversight of human subjects research.

Federal Oversight of Research

In the course of its deliberations, the Commission recognized the importance of understanding the oversight functions exercised by the Office for Protection from Research Risks and the extension

of this oversight only to federally funded research. The Commission devoted some of its meeting time to this subject, and intends to pursue this more thoroughly in 1998 and 1999. The subcommittee commissioned three papers on this subject in 1997 (see Table 2). It heard testimony from 6 experts and 10 members of the public, and discussed the topic at 6 meetings.

Research Involving Subjects with Disorders Affecting Decisionmaking Capacity

The ethical conduct of research with persons who suffer from disorders affecting their decision making capacity presents a significant challenge for public policy. The National Commission's Report *Research Involving Those Institutionalized as Mentally Infirm* (1978) identified many of these challenges, but limited its focus to those persons who were patients in mental health facilities. This report, unlike others focusing on potential subjects whose ability to consent was limited in some way, was never translated into federal regulation. Recent discussions about research conducted with these individuals has been stimulated by several incidents, including the tragic suicide of a former subject in a schizophrenia relapse study conducted at the University of California, Los Angeles and a court case regarding the legality of restrictions on the participation of subjects with decisional incapacity issued by the Office of Mental Health in New York. Several organizations and individuals have proposed additional guidance for research with persons with decisional impairments, because of concern about unclear areas in current regulations or about perceived abuses. Although the Commission does not have the authority to investigate specific complaints, it was persuaded that

there is substantial public concern about actual, perceived, or potential failures to protect those with decisional impairments in research. The Subcommittee commissioned three papers on this subject in 1997 (see Table 2) and heard

testimony from 10 experts and 13 members of the public. The subject was discussed at all 7 HSSC meetings. NBAC's report and recommendations on this topic will be issued in 1998.

Table 2

Papers Commissioned by the Human Subjects Subcommittee

Decisional Impairment

*Research Involving Persons With Mental Disabilities:
A Review of Policy Issues and Proposals*

Rebecca Dresser, J.D., Case Western Reserve University

Relational Ethics and Research with Vulnerable Populations

Celia B. Fisher, Ph.D., Fordham University

Critical Issues Concerning Research Involving Decisionally Impaired Persons

Jonathan Moreno, Ph.D., SUNY Health Science at Brooklyn

Oversight of Federal Research

Examination of the Location of the Office for Protection from Research Risks

John C. Fletcher, Ph.D., University of Virginia

Standard Models for Human Subjects Oversight

C. K. Gunsalus, J.D., Associate Provost, University of Illinois, Urbana-Champaign

Examination of the Location of the Office for Protection from Research Risks

Charles R. McCarthy, Ph.D., Georgetown University

Activities of the Human Genetics Subcommittee

Thomas H. Murray, Ph.D., *Chair*
Patricia Backlar
David R. Cox, M.D., Ph.D.
Ezekiel Emanuel, M.D., Ph.D.
Carol W. Greider, Ph.D.
Steven H. Holtzman
Bette O. Kramer
Bernard Lo, M.D.
Lawrence H. Miike, M.D., J.D.

In response to its charge, NBAC formed the Human Genetics Subcommittee to address issues in the management and use of genetic information. The subcommittee met for the first time in December 1996 to set priorities for 1997. It decided to pursue three topics: the use of tissue samples in DNA analysis; genetic privacy and genetic discrimination; and gene patenting.

The use of tissue samples in genetic research was chosen as the first topic because the issue is well-defined, clearly important, and a matter of considerable current interest to professional organizations, government agencies, and the research community.

The Research of Human Biological Materials

NBAC estimates that there are more than 282 million human tissue samples in storage in hospitals and research facilities in the United States⁵. Many important advances made in medical science would have been impossible were it not for the analysis of collected and stored human tissues. However, the increasingly common practice of

performing genetic analyses on these materials is triggering a renewed interest in examining how these samples have been (and will be) collected, stored, used, and shared, and how the results of the research performed will be disseminated. A matter of concern is how to handle consent for the use of samples collected in the past for diagnostic or research purposes, especially when the research purposes for which the samples might be used was not foreseen.

An additional concern centers on the relationship between a person who provides a sample for research and the particular community of which the person may be a member. Research conducted on an individual identified as belonging to an ethnic community is sometimes conducted or presented in a way that suggests the community shares certain genetic traits. The findings of the research may thus have repercussions for the whole community that must be considered before returning to previously collected samples for analyses. There has been ongoing discussion within the scientific community as to whether consent can and should be obtained to use human samples that have been previously collected and stored (in some instances for decades). At issue is whether the samples were collected with identifiers that would link the sample to the person from which it came. The subcommittee recognized that one of the difficulties in resolving this issue is the lack of consensus regarding the concept of anonymity. For example, if samples can be collected with certain personal identifiers (e.g., aspects of the medical record), is the ability to “anonymize” these tissues sufficient protection from risk to the donor to waive the requirement to obtain informed consent?

⁵ Elisa Eiseman, Ph.D., *Stored Tissue Samples: An Inventory of Sources in the United States*, RAND, MR-954.0-CTI, December 1997

The subcommittee commissioned 6 papers to inform its deliberations (see Table 3) and one report summarizing seven “mini-hearings” across the country to ascertain the views of the American public about uses of samples, the ethical obligations of those who may learn significant health risk information from samples, and privacy protections. NBAC will issue its report on this topic in 1998.

The Human Genetics Subcommittee met 7 times (including meetings that involved the full Commission) and heard testimony from 19 experts and from 8 members of the public.

Table 3

Papers and Report Commissioned by the Genetics Subcommittee

Privacy and the Analysis of Stored Tissues

Sheri Alpert, M.A., M.P.A.

Research on Human Tissue: Religious Perspectives

Courtney Campbell, Ph.D., Oregon State University

Stored Tissue Samples: An Inventory of Sources in the United States

Elisa Eiseman, Ph.D., and Jennifer Brower,
Critical Technologies Institute, Rand Corporation

Evaluation of Tissue Sample Storage Focus Group Methodology

Regina Kenen, Ph.D., M.P.H., The College of New Jersey

Genetic Tissue Storage: International, Comparative Positions

Bartha M. Knoppers, LL.D., University of Montreal

The Ongoing Debate about Stored Tissue Samples and Informed Consent

Robert Weir, Ph.D., University of Iowa

Report of National Mini Hearings on Issues in Genetic Tissue Storage

James Wells, Ph.D., Center for Health Policy Studies

Response to the President's Request: *Cloning Human Beings*

In February 1997, the work of the Commission was diverted toward an unexpected development. Within days of the published report by Dr. Ian Wilmut and his colleagues of the apparently successful cloning of a sheep⁶ using a technique called somatic cell nuclear transfer President Clinton instituted a ban on federal funding for research directed at cloning human beings. In addition, the President asked NBAC to address the ethical and legal issues raised by cloning human beings and to report back within ninety days with recommendations on what steps should be taken to prevent the abuse of this technology. The Commission quickly commissioned eight papers on the scientific, legal, ethical, religious, and policy aspects of the prospect of human cloning (see Table 4) and met five times over the following three months. It delivered its report, *Cloning Human Beings: Report and Recommendations of the National Bioethics Advisory Commission*, to the President at a White House ceremony on June 9, 1997.

NBAC recognized that resolution of the ethical, scientific and legal issues associated with the cloning of human beings would be difficult to achieve, particularly because they evoked many deeply held beliefs and values. Nevertheless, NBAC attempted to consolidate its assessment of the risks and benefits of this new technology and the public's concerns regarding the moral acceptability of the practice into a cohesive set of recommendations that could serve the scientific community, the public, and policy makers. Due to the diversity and intensity of opinions heard and held by the Commission, and the limited time period in which

it had to reach conclusions, the Commission made recommendations that it hoped would serve as the foundation for further deliberation. NBAC recommended that the Federal Government take advantage of this opportunity to encourage a continuing public deliberation of the issues. Copies of the Executive Summary, the full report (Vol. I), and the commissioned papers (Vol. II) are available on the NBAC website (<http://www.bioethics.gov>).

⁶ I. Wilmut, A.E. Schnieke, J. McWhir, A.J. Kind & K.H.S. Campbell Roslin Institute (Edinburgh), Roslin, Midlothian EH25 9PS, UK PPL Therapeutics, Roslin, Midlothian EH25 9PP, UK; "Viable offspring derived from fetal and adult mammalian cells" *Nature*, Volume 385, 810-813, February 27, 1997

Table 4

Papers Commissioned for the Report: *Cloning Human Beings*

Legal Status of Cloning in the United States

Lori B. Andrews, J.D., Chicago-Kent College of Law

Cloning Human Beings: An Assessment of the Ethical Issues Pro and Con

Dan W. Brock, Ph.D., Brown University

Religious Perspectives on Human Cloning

Courtney S. Campbell, Ph.D., Oregon State University

Do Research Moratoria Work? A Review of Fetal Research, Gene Therapy, and Recombinant DNA Research

Robert Mullan Cook-Deegan, M.D.

Views of Scientific Societies and Professional Associations on Human Nuclear Transfer Cloning Research

Elisa Eiseman, Ph.D., Critical Technologies Institute, Rand Corporation

Cloning: An International Comparative Overview

Bartha M. Knoppers, LL.D., University of Montreal

Animal Cloning and Related Embryo Research: Implications for Medicine

Stuart H. Orkin, M.D., Dana Farber Cancer Institute

The Science of Animal Cloning

Janet Rossant, Ph.D., Mount Sinai Hospital, Toronto

Plans for 1998 and Beyond

As 1997 came to a close, NBAC devoted portions of two meetings to discussions of the research activities in which it will engage. The Commission will prepare the reports requested within the Executive Order No. 12975, including the “protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information, including but not limited to, human gene patenting.”⁷ The Commission has identified several important topics to which it intends to turn its attention in 1998 including the scope of federal oversight of human subjects research; Institutional Review

Boards; and ethical and legal issues in international research. NBAC also recognizes that an important opportunity exists to reflect on how the research paradigm, so effectively articulated in the National Commission’s *Belmont Report*, has been used and interpreted over the past two decades. One commissioned paper has already been developed on this subject, by Dr. Charles Weijer. Following further consultation with the National Science and Technology Council, the Congress and the public, the Commission will publish its research agenda for 1998.

Further Information About NBAC

Early in 1998, the NBAC homepage was updated at <http://www.bioethics.gov>. Eventually, all NBAC reports, documents, agendas, and transcripts will be available at this site. For other requests, contact NBAC at (301) 402-4242 (telephone) or (301) 480-6900 (facsimile).

⁷ Executive Order 12975 of October 3, 1995, Sec. 5 (a)

Appendix A: NBAC Staff (1998)

Executive Director

Eric M. Meslin, Ph.D.

Deputy Executive Director

Henrietta D. Hyatt-Knorr, M.A.

Senior Consultants

Kathi Hanna, M.S., Ph.D.

Jonathan Moreno, Ph.D.

Research Staff

William L. Freeman, M.D., M.P.H.

Melissa Goldstein, J.D.

Debra McCurry

Emily Feinstein

Everson R. Hull, Jr.

Sean Simon

Robert Tanner

Joel Mangel, J.D.

Administrative Staff

Patricia Norris

Margaret Quinlan

Evadne Hammett

LaShell Gaskins

Emma Codrington

Claudia Ansah

Includes full-time, part-time and volunteer staff.

Appendix B:

Executive Summary: *Cloning Human Beings*

The idea that humans might someday be cloned—created from a single somatic cell without sexual reproduction—moved further away from science fiction and closer to a genuine scientific possibility on February 23, 1997. On that date, *The Observer* broke the news that Ian Wilmut, a Scottish scientist, and his colleagues at the Roslin Institute were about to announce the successful cloning of a sheep by a new technique which had never before been fully successful in mammals. The technique involved transplanting the genetic material of an adult sheep, apparently obtained from a differentiated somatic cell, into an egg from which the nucleus had been removed. The resulting birth of the sheep, named Dolly, on July 5, 1996, was different from prior attempts to create identical offspring since Dolly contained the genetic material of only one parent, and was, therefore, a “delayed” genetic twin of a single adult sheep.

This cloning technique is an extension of research that had been ongoing for over 40 years using nuclei derived from non-human embryonic and fetal cells. The 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. In this report we refer to the technique, first described by Wilmut, of nuclear transplantation using nuclei derived from somatic cells other than those of an embryo or fetus as “somatic cell nuclear transfer.”

Within days of the published report of Dolly, 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 address within ninety days the ethical and legal issues that surround the subject

of cloning human beings. This provided a welcome opportunity for initiating a thoughtful analysis of the many dimensions of the issue, including a careful consideration of the potential risks and benefits. It also presented an occasion to review the current legal status of cloning and the potential constitutional challenges that might be raised if new legislation were enacted to restrict the creation of a child through somatic cell nuclear transfer cloning.

The Commission began its discussions fully recognizing that any effort in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term. Ethical concerns surrounding issues of embryo research have recently received extensive analysis and deliberation in our country. Indeed, federal funding for human embryo research is severely restricted, although there are few restrictions on human embryo research carried out in the private sector. Thus, under current law, the use of somatic cell nuclear transfer to create an embryo solely for research purposes is already restricted in cases involving federal funds. There are, however, no current federal regulations on the use of private funds for this purpose.

The unique prospect, vividly raised by Dolly, is the creation of a new individual genetically identical to an existing (or previously existing) person—a “delayed” genetic twin. This prospect has been the source of the overwhelming public concern about such cloning. While the creation of embryos for research purposes alone always raises serious ethical questions, 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, for example, serious safety concerns, individuality,

family integrity, and treating children as objects. Consequently, the Commission focused its attention on the use of such techniques for the purpose of creating an embryo which would then be implanted in a woman's uterus and brought to term. It also expanded its analysis of this particular issue to encompass activities in both the public and private sector.

In its deliberations, NBAC reviewed the scientific developments which preceded the Roslin announcement, as well as those likely to follow in its path. It also considered the many moral concerns raised by the possibility that this technique could be used to clone human beings. Much of the initial reaction to this possibility was negative. Careful assessment of that response revealed fears about harms to the children who may be created in this manner, particularly psychological harms 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. Arrayed against these concerns are other important social values, such as protecting the widest possible sphere of personal choice, particularly in matters pertaining to procreation and child rearing, maintaining privacy and the freedom of scientific inquiry, and encouraging the possible development of new biomedical breakthroughs.

To arrive at its recommendations concerning the use of somatic cell nuclear transfer techniques to create children, NBAC also examined longstanding religious traditions that guide many citizens' responses to new technologies 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 hold that it should be strictly regulated in order to prevent abuses.

The public policies recommended with respect to the creation of a child using somatic cell nuclear transfer reflect the Commission's best judgments about both the ethics of attempting such an experiment and our view of traditions regarding limitations on individual actions in the name of the common good. 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. This in itself might be sufficient to justify a prohibition on cloning 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 the potential psychological harms to children and effects on the moral, religious, and cultural values of society merited further reflection and deliberation. Whether upon such further deliberation our nation will conclude that the use of cloning techniques to create children should be allowed or permanently banned is, for the moment, an open question. Time is an ally in this regard, allowing for the accrual of further data from animal experimentation, enabling an assessment of the prospective safety and efficacy of the procedure in humans, as well as granting a period of fuller national debate on ethical and social concerns. The Commission therefore concluded that there should be imposed a period of time in which no attempt is made to create a child using somatic cell nuclear transfer.⁸

Within this overall framework the Commission came to the following conclusions and recommendations.

Recommendation One

The Commission concludes 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 have reached a consensus on this point because current scientific information indicates that this technique is not safe to use in humans at this point. Indeed, we believe 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 and/or potential child. Moreover, in addition to safety concerns, many other serious ethical concerns have been identified, which require much more widespread and careful public deliberation before this technology may be used.

The Commission, therefore, recommends the following for immediate action:

A continuation of the current moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer.

An immediate request to all firms, clinicians, investigators, and professional societies in the private and non-federally 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.

Recommendation Two

Federal legislation should be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning. It is critical, however, that such legislation include a sunset clause to

ensure that Congress will review the issue after a specified time period (three to five years) in order 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 also ought to require that at some point prior to 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 light of public understandings at that time.

Recommendation Three

Any regulatory or legislative actions undertaken to effect the foregoing prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere with other important areas of scientific research. In particular, no new regulations are required regarding the cloning of human DNA sequences and cell lines, since 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 somatic cell nuclear transfer does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees.

If a legislative ban is not enacted, or if a legislative ban is ever 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, consistent with existing norms of human subjects protection.

⁸ The Commission also observes that the use of any other technique to create a child genetically identical to an existing (or previously existing) individual would raise many, if not all, of the same non-safety-related ethical concerns raised by the creation of a child by somatic cell nuclear transfer.

The United States Government should cooperate with other nations and international organizations to enforce any common aspects of their respective policies on the cloning of human beings.

Recommendation Four

The Commission also concludes that different ethical and religious perspectives and traditions are divided on many of the important moral issues that surround any attempt to create a child using somatic cell nuclear transfer techniques. Therefore, we recommend that:

The federal government, and all interested and concerned parties, encourage widespread and continuing deliberation on these issues in order to further our understanding of the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding this technology should the time come when present concerns about safety have been addressed.

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 recommends 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 on other developments in the biomedical sciences, especially where these affect important cultural practices, values, and beliefs.

Recommendation Five

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 recommends 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 on other developments in the biomedical sciences, especially where these affect important cultural practices, values, and beliefs.

Appendix C: Meeting Dates of the Commission, 1996-1997

1. **October 4, 1996**
Full Commission
Inaugural Meeting
Bethesda, Maryland
2. **November 21, 1996**
Full Commission
International Bioethics Summit
San Francisco, California
3. **December 13, 1996**
Genetics Subcommittee
Bethesda, Maryland
4. **December 16, 1996**
Human Subjects Subcommittee
Bethesda, Maryland
5. **January 9, 1997**
Full Commission
Washington, D.C.
and
January 10, 1997
Genetics Subcommittee
Washington, D.C.
and
January 10, 1997
Human Subjects Subcommittee
Washington, D.C.
6. **February 24, 1997**
Human Subjects Subcommittee
Bethesda, Maryland
7. **March 5, 1997**
Genetics Subcommittee
Bethesda, Maryland
8. **March 13-14, 1997**
Full Commission
Washington, D.C.
9. **April 12, 1997**
Human Subjects Subcommittee
Arlington, Virginia
and
April 13, 1997
Full Commission
Arlington, Virginia
10. **May 2, 1997**
Full Commission
Arlington, Virginia
11. **May 17, 1997**
Full Commission
Arlington, Virginia
12. **June 7, 1997**
Full Commission
Arlington, Virginia
13. **July 14, 1997**
Genetics Subcommittee
Bethesda, Maryland
and
July 15, 1997
Human Subjects
Subcommittee
Bethesda, Maryland
14. **September 18, 1997**
Human Subjects
Subcommittee
Bethesda, Maryland
and
Genetics Subcommittee
Bethesda, Maryland
and
September 19, 1997
Genetics Subcommittee
Bethesda, Maryland
15. **October 19, 1997**
Human Subjects
Subcommittee
and
Genetics Subcommittee
Bethesda, Maryland
16. **November 23, 1997**
Genetics Subcommittee
Bethesda, Maryland
17. **December 9, 1997**
Genetics Subcommittee
Arlington, Virginia

Appendix D: Expert and Public Testimony Presented to NBAC, 1996-1997

Expert Testimony for the National Bioethics Advisory Commission

October 4, 1996

John H. Gibbons, Assistant to the President for Science and Technology
Francis S. Collins, National Center on Human Genome Research
Gary B. Ellis, Office for Protection from Research Risks
Aaron Meinkoff, Legislative Assistant to Sen. Mark O. Hatfield
Leonard Weiss, Minority Staff Director, U.S. Senate Committee on Governmental Affairs
Michelle Russell-Einhorn, National Institutes of Health

November 21, 1996*

Jean-Pierre Changeux, President, Comite Consultatif National d' Ethique, France
Michael Abrams, Steering Committee on Bioethics, Council of Europe
Norio Fujiki, Vice President, International Bioethics Committee, United Nations Educational,
Scientific and Cultural Organization
Bartha M. Knoppers, Chair, Ethics Committee of The Human Genome Organization
Donald Chalmers, Chair, Health Ethics Committee, Australia
Abbyann Lynch, Chair, Consent Panel Task Force, National Council on Bioethics in
Human Research, Canada
Manuel Velasco-Suarez, President, Comision Nacional de Bioetica, Mexico
Joze V. Trontelj, Chair, National Committee for Medical Ethics, Slovenia
Robert Levine, Council for International Organizations of Medical Sciences
Nenad Hlaca, Law Commission for the Family Code and Transsexualism, Croatia
Amy Gutman, Princeton University**
Daniel Winkler, President, International Association of Bioethics
Stephano Rodota, Ethics Advisor, European Commission on Ethical Implications of Biotechnology

December 13, 1996

Robert Gellman, National Committee of Vital Health Statistics
Karen Rothenberg, University of Maryland Law School
Rebecca Eisenberg, University of Michigan Law School

**Participants at the Summit of National Bioethics Advisory Bodies, San Francisco, California*

** *Luncheon Address*

January 10, 1997

David Korn, American Association of Medical Colleges
Debra Saslow, National Action Plan on Breast Cancer
Mark Guyer, National Center for Human Genome Research
Rebecca Dresser, Case Western Reserve University
Robert J. Levine, Yale University

February 24, 1997

Jack Schwartz, Chief Counsel, Office of the Attorney General, State of Maryland
Celia B. Fisher, Fordham University
Jeffrey Kahn, University of Minnesota
Anna C. Mastroianni, University of Washington
Jeremy Sugarman, Duke University

March 5, 1997

Dorothy Wertz, Shriver Center for Mental Retardation
Chuck Denk, Mathematica Policy Research
Ronald Cole-Turner, Pittsburgh Theological Seminary

March 13-14, 1997

Lisa Cahill, Boston College, Department of Theology
Rabbi Elliot Dorff, University of Judaism, Los Angeles
Nancy Duff, Princeton Theological Seminary
Leon R. Kass, University of Chicago
Ruth Macklin, Albert Einstein College of Medicine
Gilbert C. Meilaender, Jr., Valparaiso University
Father Albert S. Moraczewski, Pope John Center
James L. Nelson, University of Tennessee
Professor John Robertson, University of Texas Law School
Abdulaziz Sachedina, University of Virginia
Rabbi Moshe Tendler, Yeshiva University
Shirley Tilghman, Princeton University

April 12-13, 1997

Ruth Faden, Chair, Advisory Committee on Human Radiation Experiments
Helen McGough, Applied Research Ethics National Association (ARENA)
Stuart Orkin, Dana Farber Cancer Institute
Janet Roussant, Samuel Lunenfeld Research Institute

May 2, 1997

Elisa Eiseman, Critical Technologies Institute, RAND Corporation

July 14-15, 1997

Rebecca Dresser, Case Western University

Rex Cowdry, National Institute of Mental Health

Nina Schooler, University of Pittsburgh Medical Center

Adil Shamoo, Citizens for Responsible Care in Psychiatry and Research

Paul Applebaum, University of Massachusetts Medical School

September 18-19, 1997

Robert Temple, Center for Drug Evaluation and Research, Food and Drug Administration

James Wells, Center for Health Policy Studies

Bartha M. Knoppers, University of Montreal

Courtney Campbell, Oregon State University

October 19, 1997

James Wells, Center for Health Policy Studies

Robert Weir, University of Iowa

November 23, 1997

Carol Tamminga, Psychiatric Research Institute

Trey Sunderland, National Institute of Mental Health

Charles R. McCarthy, Georgetown University

John C. Fletcher, University of Virginia

Elisa Eiseman, Critical Technologies Institute, RAND Corporation

James Wells, Center for Health Policy Studies

Robert Weir, University of Iowa

Mark Sobel, National Cancer Institute

Frances Pitlick, American Society for Investigative Pathology

December 9, 1997

John Y. Killen, National Institute of Allergy and Infectious Diseases

Debra Saslow, National Action Plan for Breast Cancer

Public Testimony Before the National Bioethics Advisory Commission

October 4, 1996

Gwendon Plair
Jeffery Cossman
Charles MacKay
Suzanne Tomlinson
Acie Byrd
Robert McMurrugh

November 21, 1996

Norman Daniels
John Cavanaugh O'Keefe
Laura Bishop

December 13, 1996

George Gasparis
Susan Pollin

December 16, 1996

Joan Rachlin
Susan Rose

January 9-10 1997

Chris Kline
Adil Shamoo
Carol Isaacson-Barash
Nancy Reame

February 24, 1997

Jim Shelton

March 5, 1997

Mark Sobel

March 13, 1997

Nancy Reame
Judith Lamb-Lion
Robert W. Weise
Michelle Theiman

March 14, 1997

Daniel B. McGee
Gladys White
Claire Nader
John Cavanaugh O'Keefe
Dan Crow
J. D. Hanson

April 13, 1997

John Cavanaugh O'Keefe

May 2, 1997

Mary Lyman Jackson
Paulette Roseboro
Sheena Talbot
Lisa Tennant
Audria Williams

May 17, 1997

Gail Youness
John Cavanaugh O'Keefe

June 7, 1997

Randolfe Wicker
Alan Grayson

July 15, 1997

Sidney Wolfe
John Cavanaugh O'Keefe

September 18, 1997

Robert Aller
Janice Becker
Joseph Friend
Arlis Neason
Shalmah Lee Prince
Stephen Post
Beverly Post
Maggie Scheie-Lurie
Vera Hassner Sharav
Arun K. Guha

September 19, 1997

John Cavanaugh O'Keefe

October 19, 1997

W. Truxton Boyce
Ron Thompson
Harlan Girard
Adil Shamoo

November 23, 1997

Allen Barker

December 9, 1997

Mark Sobel

