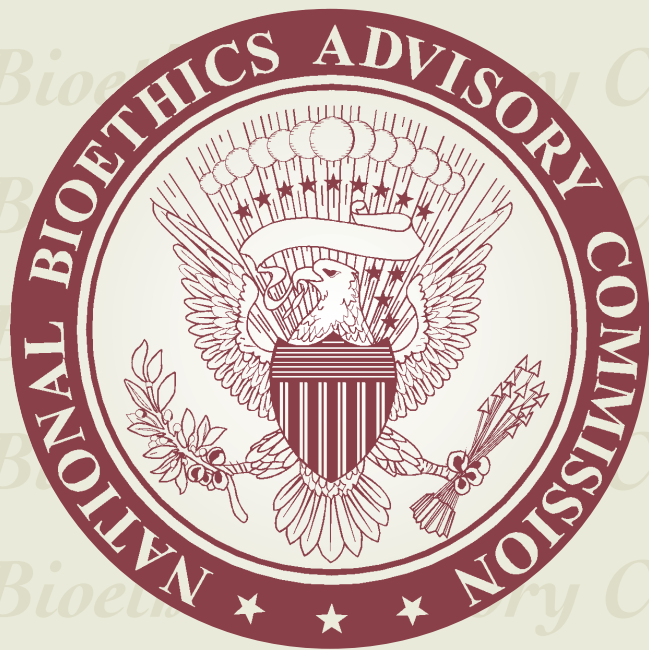




*National Bioethics Advisory Commission*  
*1998–1999 Biennial Report*

National Bioethics Advisory Commission  
6705 Rockledge Drive, Suite 700, Bethesda, Maryland 20892-7979  
Telephone: 301-402-4242 • Fax: 301-480-6900 • Website: [www.bioethics.gov](http://www.bioethics.gov)



*National Bioethics Advisory Commission*  
*1998–1999 Biennial Report*

# Preface

The past two years have been productive for the Commission. We have completed three reports and initiated two new projects related to the protection of human subjects in research. As the new millennium approached, we met for the 36th time in December 1999, in Baltimore, Maryland, continuing a trend of convening our regular meetings in different locations around the country.

This second biennial report provides a summary of our accomplishments and describes our ongoing agenda, which has always been centered on issues surrounding the protection of human subjects in research and ethical issues in the use of genetic and other medical information. In 1998–1999, two of the three reports we completed were in these areas: one on the ethical conduct of research involving persons whose decisionmaking capacity is limited by mental illness, and a second report on the ethical and policy issues concerning the research use of human biological materials. In addition, as in the past, the Commission was asked by President Clinton to temporarily put its agenda on hold to deliberate and issue recommendations on an emerging area of research—in this case, human embryonic stem cell research. That report, undertaken in the midst of the Commission’s ongoing work, was completed in September 1999.

Over this period, the Commission staff have established important and fruitful relationships with many groups that have a vital stake in our work, including international organizations, patient groups, scientific groups, academic institutions, health care providers, federal agencies, and offices of Congress. Input from these groups and consistent outreach from the Commission to them has enriched our work and has made it more valuable. In addition to official outreach from Commission staff members, commissioners have served as emissaries, speaking to groups in their own communities and communicating in personal ways their experiences and views on some of the nation’s most complex and important bioethical issues.

We increasingly have seen our work widely read and disseminated, which is especially gratifying, as we believe that an ongoing national conversation about these issues is a critically important component of policy development. As in any complex policy area, the views expressed by commissioners are diverse and frequently reflect the range of perspectives to be found in our society.

In the next year we look forward to completing our discussions concerning ethics in international research and our comprehensive review of the current system of human subjects protections in the United States. As always, we could not complete our assignments without the hard work and dedication of our staff and consultants and the many scholars and experts who provide testimony and written materials in support of our work.

Harold T. Shapiro  
*Chair*

# National Bioethics Advisory Commission

## 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  
Assistant Director  
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 Morgan 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., M.A.C.P.

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

## R. Alta Charo, J.D.

Professor of Law and Medical Ethics  
Schools of Law and Medicine  
The University of Wisconsin  
Madison, Wisconsin

## James F. Childress, Ph.D.

Kyle Professor of Religious Studies  
Professor of Medical Education  
Co-Director, Virginia Health Policy Center  
Department of Religious Studies  
The University of Virginia  
Charlottesville, Virginia

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

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

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

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

## Laurie M. Flynn

Executive Director  
National Alliance for the Mentally Ill  
Arlington, Virginia

## Carol W. Greider, Ph.D.

Professor of Molecular Biology and Genetics  
Department of Molecular Biology and Genetics  
The 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  
The University of California, San Francisco  
San Francisco, California

## Lawrence H. Miike, M.D., J.D.

Kaneohe, Hawaii

## Thomas H. Murray, Ph.D.

President  
The Hastings Center  
Garrison, New York

## William C. Oldaker, LL.B.

Senior Partner  
Oldaker and Harris, L.L.P.  
Washington, D.C.  
Co-Founder and General Counsel  
NeuralStem Biopharmaceuticals Ltd.  
College Park, Maryland

## Diane Scott-Jones, Ph.D.

Professor  
Department of Psychology  
Temple University  
Philadelphia, Pennsylvania

# 1998–1999 Biennial Report

## Introduction

Since its last biennial report in 1997, the National Bioethics Advisory Commission (NBAC) has met 19 times in various locations across the country. The Commission also has completed three significant reports and has initiated two new major projects that focus on the protection of human research subjects here and abroad. NBAC was established in October 1995 to advise the White House National Science and Technology Council and other federal agencies on bioethical issues arising from research on human biology and behavior. The Commission's third and fourth years were prolific as it deliberated and reported on some of the most complex ethical, legal, and scientific issues currently facing the nation.

The three major reports submitted to the President in 1998 and 1999 offer 52 recommendations designed to improve the protection of human subjects in research. (All NBAC reports are available at [www.bioethics.gov](http://www.bioethics.gov).) (See Exhibits A, B, and C.)

*In Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity* (December 1998), NBAC recommended that additional regulations are needed to govern this type of research in order to protect research subjects from abuse and to ensure that important research is allowed to proceed.

*In Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (August 1999), NBAC recommended ways to clarify current federal regulations to ensure that the nearly 300 million human biological specimens now stored in various universities, laboratories, hospitals, and other repositories throughout the country can be used in an ethically appropriate manner. The report also makes recommendations about improving the processes by which consent should be obtained when such materials are collected in the future.

*In Ethical Issues in Human Stem Cell Research* (September 1999), NBAC responded to a request from President Clinton for recommendations outlining the conditions under which such research could be eligible for federal funding.

In addition to issuing these reports, the Commission engaged in numerous other activities critical to informing federal agencies, Congress, international groups, the research community, and the public about the various dimensions of complex bioethical issues and their importance in public policy development.

- ❖ NBAC commissioners and staff (see Appendix A for a listing of staff and consultants) testified five times before Congress, appearing before subcommittees of the House and Senate to discuss completed projects or ongoing work.

*continued on page 8*

# Exhibit A:

## *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity: Volume I (December 1998)*

Research examining mental disorders has yielded many important and clinically relevant scientific findings. But at the same time, some of these investigations have generated public controversy and led to government sanctions—and occasionally lawsuits.

Since the 1970s, a number of unsuccessful attempts have been made to extend more regulatory protections to people with mental disorders who serve as research subjects and whose decisionmaking ability may be limited. In 1997, NBAC undertook an effort to explore the various dimensions of research conducted with this population to determine how ethically acceptable research could be conducted, whether additional protections are needed, and if so, what those protections should be and how they should be applied.

After 18 months of study, NBAC produced an 88-page report entitled *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity*. The Commission concluded that research involving subjects with mental disorders that may affect their decisionmaking capacity should be governed by specific further regulations to ensure that they are appropriately protected from harm. Current U.S. regulations promote ensuring ethical treatment of human research subjects with mental disorders; however, the Commission noted that these provide no specific guidance for Institutional Review Boards and investigators regarding vulnerable subjects, a gap that the Commission would like to see filled, especially concerning informed consent and who may decide whether an individual with a mental disorder can or should participate in research.

NBAC based its 21 recommendations in this report on testimony heard at more than a dozen meetings convened around the country representing a range of views, including those from legal scholars; philosophers; mental health advocates; scientists; former research subjects and their families; and the general public. In addition, a number of papers were commissioned from leading experts in law, medicine, psychiatry, and ethics and were published in a separate volume of the report (see below); a sampling of research protocols drawn from the field was analyzed; and 120 public comments that were received on a draft of the final report were reviewed.

NBAC's recommendations are directed at the development of new federal regulations for the protection of human subjects, while others are aimed at investigators and Institutional Review Boards, state legislatures, the National Institutes of Health, health professionals, federal agencies subject to the 1991 Federal Policy for the Protection of Human Subjects in Research (the Common Rule, or 45 CFR 46 Subpart A), and others responsible for human subjects protection. The report provides a set of requirements that NBAC believes must be met in all research protocols involving persons with mental disorders, as well as several additional or optional protections that would be appropriate in certain circumstances.

NBAC believes that the enhanced protections recommended in its report will augment existing regulations and promote broader support for further research by engendering greater

public trust and confidence that subjects' rights and interests are fully respected. Given that it will likely take time for the needed protections to be codified in federal regulations, NBAC has encouraged institutions, researchers, Institutional Review Boards, and other investigators to adopt the spirit and substance of its recommendations in the interim.

## Volume II: Commissioned Papers (May 1999)

*Decisionally Impaired Research Subjects:  
Disorders and Research Promises*

Paul S. Appelbaum  
University of Massachusetts Medical Center

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

Rebecca Dresser  
Washington University, St. Louis

*Relational Ethics and Research with Vulnerable Populations*

Celia B. Fisher  
Fordham University

*Critical Issues Concerning Research Involving Decisionally  
Impaired Persons*

Jonathan D. Moreno  
University of Virginia

*Competency to Decide on Treatment and Research:  
The MacArthur Capacity Instruments*

Elyn R. Saks  
University of Southern California Law School

*“If the public is convinced that all research will be done under appropriate ethical restraints, this will encourage greater support for this kind of research.”*

NBAC Chair Harold Shapiro,  
quoted in the *Washington Post*,  
November 8, 1998



# Exhibit B:

## *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance: Volume I (August 1999)*

The medical and scientific practice of storing human biological materials is more than a century old. NBAC estimates that there are nearly 300 million human biological materials—including cells, tissues, and biopsy specimens obtained for diagnostic purposes—stored in the nation’s laboratories, tissue repositories, and health care institutions. Recent advances in the biological sciences have provided tools that can be used to mine these biological materials in research efforts directed toward improving health. But the very power of these new research tools raises a number of important ethical questions:

- ❖ How well does existing federal policy for the protection of human subjects meet the objective of protecting human subjects from harm in research using their biological materials?
- ❖ Does current federal policy provide clear direction to research sponsors, investigators, Institutional Review Boards, and others regarding the conduct of research using these materials?

In addition, the growing availability to third parties of genetic and other medical information about individuals has raised concerns about medical privacy and discrimination. NBAC is sensitive to the possibility that use of information obtained from human biological samples can be harmful as well as beneficial.

After nearly two years of study, the Commission produced a 113-page report entitled *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*. NBAC found that while the federal regulations are generally satisfactory, the Common Rule does not address a number of issues and provides, in some cases, vague guidelines on how to conduct research with human biological materials. NBAC also found that certain parts of current regulations fall short of ensuring the ethical use of such material in research and require some modification.

Despite these shortfalls, NBAC believes it is critical that human biological materials continue to be available to qualified researchers, with specific protections in place to protect the privacy and confidentiality of those individuals whose materials are used. NBAC’s 23 recommendations offer clarifications and interpretations of the current federal regulations; outline measures to be taken to ensure that research involving human biological materials will continue to benefit from appropriate oversight and Institutional Review Board review; provide investigators and Institutional Review Boards with clear guidance regarding the use of human biological materials in research; and present a coherent public policy for research in this area that will endure and be responsive to new scientific developments.

## Volume II: Commissioned Papers (January 2000)

*Privacy and the Analysis of Stored Tissues*

Sheri Alpert  
Alexandria, Virginia

*An Ethical Framework for Biological Samples Policy*

Allen Buchanan  
University of Arizona

*Research on Human Tissue: Religious Perspectives*

Courtney S. Campbell  
Oregon State University

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

Elisa Eiseman  
RAND Critical Technologies Institute

*Control of DNA Samples and Information*

Bartha Maria Knoppers, Marie Hirtle, Sébastien Lormeau, Claude M. Laberge,  
and Michelle Laflamme  
CRDP (Public Law Research Centre), Faculty of Law, Université de Montréal, Québec

*Contribution of the Human Tissue Archive to the Advancement of Medical Knowledge  
and the Public Health*

David Korn  
Stanford University School of Medicine

*The Ongoing Debate About Stored Tissue Samples*

Robert F. Weir  
University of Iowa

*Mini-Hearings on Tissue Samples and Informed Consent*

James A. Wells and Dana Karr  
Center for Health Policy Studies

# Exhibit C:

## *Ethical Issues in Human Stem Cell Research: Volume I* (September 1999)

On November 14, 1998, President Clinton asked NBAC to conduct a thorough review of issues surrounding human stem cell research. This was the second time that the President had called on NBAC to consider a highly charged bioethical issue (the first was his request that NBAC review the ethics of cloning human beings<sup>1</sup>). The President's request followed a series of reports that researchers had isolated and cultured human embryonic stem (ES) cells and embryonic germ (EG) cells. These reports have generated considerable scientific and clinical interest because of the prospect these efforts pose for treating injuries or debilitating conditions such as Alzheimer's disease, Parkinson's disease, or heart disease. But this research also raises serious ethical concerns, mainly because the major current sources of stem cells are cadaveric fetal tissue obtained following elective abortions and embryonic tissue derived from embryos remaining after infertility treatments.

After nine months of study, the commission produced its 109-page report entitled *Ethical Issues in Human Stem Cell Research*. This report makes 13 recommendations meant to offer a policy framework to provide the public with assurance that important, potentially life-saving research can be conducted with federal support within a publicly accountable and rigorous system of oversight and review.

The Commission recommended that federal sponsorship of research involving the derivation and use of human ES cells and human EG cells should be limited in two ways. First, research should be limited to using only two sources of such cells, namely cadaveric fetal material and embryos remaining after infertility treatments. Second, such sponsorship should be contingent on an appropriate and open system of national oversight and review. The report also addresses requirements related to the means of ensuring appropriate consent of women or couples who donate cadaveric fetal tissue or embryos remaining after infertility treatments; the need for restrictions on the sale of these materials and the designation of those who may benefit from their use; the need for ethical oversight and review of such research at the national and institutional levels; and the appropriateness of voluntary compliance by the private sector.

NBAC noted that recent developments in human stem cell research have raised hopes that new therapies will become available that will serve to relieve human suffering. These developments also have served to remind society of the deep moral concerns that are related to research involving human embryos and cadaveric fetal tissue. Serious ethical discussion will and should continue on these issues. But it is clear that the scientific and clinical benefits of stem cell research should not be overlooked. The Commission strongly believes that carrying out human stem cell research under federal sponsorship is important, but only if it is conducted in an ethically responsible manner.

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<sup>1</sup> The report *Cloning Human Beings* was published by NBAC in June 1997 and is available at [www.bioethics.gov](http://www.bioethics.gov).

## Volume II: Commissioned Papers (January 2000)

*State Regulation of Embryo Stem Cell Research*

Lori B. Andrews  
Chicago-Kent College of Law

*The Food and Drug Administration's Statutory and  
Regulatory Authority to Regulate Human Pluripotent Stem Cells*

Robert P. Brady, Molly S. Newberry, and  
Vicki W. Girard  
Hogan & Hartson L.L.P.

*Quick Response: Use of Human Fetal Tissue in Federally  
Funded Research*

Elisa Eiseman  
RAND Science and Technology Policy Institute

*Analysis of Federal Laws Pertaining to Funding of Human  
Pluripotent Stem Cell Research*

Ellen J. Flannery and Gail H. Javitt  
Covington & Burling

*Deliberating Incrementally on Human Pluripotential  
Stem Cell Research*

John C. Fletcher  
University of Virginia

*Bioethical Regulation of Human Fetal Tissue and Embryonic  
Germ Cellular Material: Legal Survey and Analysis*

J. Kyle Kinner, Presidential Management Intern  
National Bioethics Advisory Commission

*Regulating Embryonic Stem Cell Research:  
Biomedical Investigation of Human Embryos*

J. Kyle Kinner, Presidential Management Intern  
National Bioethics Advisory Commission

*International Perspectives on Human Embryo and  
Fetal Tissue Research*

Lori P. Knowles  
The Hastings Center

*What Has the President Asked of NBAC? On the Ethics and  
Politics of Embryonic Stem Cell Research*

Erik Parens  
The Hastings Center

*Locating Convergence: Ethics, Public Policy, and Human  
Stem Cell Research*

Andrew W. Siegel  
The Johns Hopkins University

*“Although the ethical issues have not diminished, it now appears that this research may have real potential for treating such devastating illnesses as cancer, heart disease, diabetes, and Parkinson’s disease. With this in mind, I am also requesting that the Commission undertake a thorough review of the issues associated with such human stem cell research, balancing all ethical and medical considerations.”*

President Clinton,  
November 14, 1998

*continued from page 1*

- ❖ NBAC commissioners and staff were involved in numerous public education activities domestically and abroad to discuss the Commission's recommendations or work in progress. Activities included participation in public lectures, seminars, and conferences; consultations with the World Health Organization, the United Nations Educational, Scientific, and Cultural Organization (UNESCO), and the Council on International Organizations of Medical Sciences; and co-sponsorship of the Second International Summit of National Bioethics Commissions in Tokyo. (See Appendix C.)
- ❖ In January 1998, NBAC launched its website, [www.bioethics.gov](http://www.bioethics.gov), as a comprehensive source of information, posting reports, meeting agendas, transcripts, and related materials. Since its debut, the website has received more than 300,000 "hits." Many national and international groups have established links to NBAC's website and rely on it for up-to-date information about bioethics developments in the United States. Commission staff have been working to upgrade the site and improve site navigation. Later in 2000, a new, improved website will be up and running.

*“We really appreciate the Commission’s timely and very important contributions to the national debate on what are clearly some of the most controversial issues in science policy we face today. Certainly your work reflects well on the wisdom of establishing this Commission.”*

Dr. Neal F. Lane, Assistant to the President for Science and Technology, Executive Office of the President, addressing the Commission on October 22, 1999



*Neal F. Lane, Assistant to the President for Science and Technology, and Harold T. Shapiro, NBAC Chair*

NBAC's contribution to national discussions on bioethics, science, and law has drawn praise from many sources for its clarity, depth, scholarship, sensitivity to public views, and long-term policy impact. NBAC's recommendations and perspectives have been featured in many leading national publications, including the *Los Angeles Times*, the *New York Times*, the *Wall Street Journal*, and the *Washington Post*, as well as prominent medical and scientific journals such as the *Journal of the American Medical Association*, the *New England Journal of Medicine*, *Nature*, and *Science*.

## Follow-up and Impact of NBAC's Reports

All NBAC reports are submitted to the President through the National Science and Technology Council. In February 1998, NBAC was informed that its report *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity* had been circulated to federal departments and agencies for comment and that comments were to be received in May 1998. To date, no action has been taken by federal agencies on any of the report's 21 recommendations. However, the National Institutes of Health issued a guidance document and a set of "points to consider" that addresses similar issues. Consistent with its Charter authority, NBAC wrote to several federal departments in October 1999 to request a response within 180 days to the recommendations that were made to them.

NBAC's report on research involving human biological materials has served as a useful guide to research institutions aiming to establish ethical policies and practices regarding research access to stored blood and tissue samples. The federal Office for Human Research Protections cites NBAC's recommendations regarding identifiability of samples when responding to requests for clarification from investigators and research institutions.

NBAC reports have been widely circulated both domestically and internationally. All reports can be obtained in hard copy format by contacting the Commission offices, or they can be downloaded directly from NBAC's website. NBAC's report on human biological materials has been translated into Japanese, and Germany's Institut für Wissenschaft und Ethik is publishing two NBAC report summaries in its 2000 edition of the "Yearbook for Science and Ethics."

While it is difficult to assess the direct impact of NBAC's recommendations, there is ample indirect evidence that the Commission's work has stimulated discussion and informed the public policy debate in this country and elsewhere. For example, Japan recently enacted legislation permitting federal funding for the derivation and use of embryonic stem cells from embryos remaining after infertility treatments. Japan's policy on stem cell research parallels NBAC's recommendations. Similarly, in a recent working paper on human stem cell research, the Nuffield Council on Bioethics in the United Kingdom endorsed a number of NBAC's recommendations. NBAC staff continue to monitor the literature and print media and will be comprehensively assessing the impact of the Commission's work.

*The National Bioethics Advisory Commission “has demonstrated its legitimate claim to respect for its efforts as a national body to promote public input into social policy related to advances in biomedical research.”*

American Association for the Advancement of Science  
“Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research,” November 1999

## Public Involvement

Historically, U.S. bioethics commissions have used a variety of strategies to involve the public in their debates. As a federal advisory committee, NBAC must comply with the Federal Advisory Committee Act (FACA), which requires that Commission meetings be held in public, that its recommendations be agreed to in public, and that the public must be able to access Commission materials. From the outset, NBAC has embraced both the spirit and substance of FACA, upholding its obligation to both engage and be accountable to the public. The public is notified of the dates and sites for meetings through the NBAC website, direct mail, and announcements in the *Federal Register*. Drafts of recommendations and background papers that are commissioned from outside experts or prepared by staff also are available to the public. In addition, NBAC makes available copies of all materials at its regularly scheduled meetings, and regular updates of the Commission’s work appear in the lay press and scientific journals.

At every NBAC meeting, 30 minutes are reserved in 5-minute increments to permit public testimony. Individuals need only inform NBAC staff that they wish to testify, and they can do so even on the day of the meeting. At several Commission meetings, patients and former research subjects have been given the opportunity to share their experiences in research. Over the past two years, 36 individuals have taken advantage of this opportunity to offer their views on a range of subjects. To engage broader public participation, many of NBAC’s 19 meetings in 1998–1999 have been held in cities other than Washington D.C., including Miami, Florida; Northbrook, Illinois; Cleveland, Ohio; and Portland Oregon. (See Appendix B.)

When time allows, NBAC employs a formal public comment period to obtain critical and constructive public input on draft reports and recommendations. For the report *Research Involving Persons with Mental*



*Disorders That May Affect Decisionmaking Capacity*, more than 120 comments from individuals and organizations were received and analyzed by NBAC staff. Many of these comments helped commissioners identify issues that ultimately led to revisions in the report's final recommendations. Similarly, for the report *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*, the Commission received 63 comments, many from professional and scientific organizations.

## National and International Outreach Activities

Over the course of the past two years, commissioners have been actively involved in public discussions about NBAC's work. (See Exhibit D.) These activities include public and professional

# Exhibit D:

## *Commissioner Activities*

In 1998 and 1999, members of the Commission published more than 90 articles, chapters, and books on issues specifically related to bioethics and health policy. In addition, commissioners spoke in a variety of venues on nearly 100 separate occasions about NBAC's work. Following are some examples:

- ❖ Commissioner R. Alta Charo addressed the Public Responsibility in Medicine and Research 1998 Annual Meeting, speaking on "A National Agenda for Human Subjects Protection."
- ❖ Commissioner Bernard Lo presented the Ethics Grand Rounds, "Ethical Issues in Caring for Patients from Different Cultures," at the National Institutes of Health in February 1999.
- ❖ Commissioner Alexander Capron presented "Counting Sheep: Ethical, Legal and Social Implications of Human Cloning," at the California Institute of Technology in January 1998.
- ❖ Commissioner Rhetaugh Dumas provided "An Update on the Work of NBAC and My Role and Experiences as the Only Nurse Member" to the National Advisory Committee for the National Institute of Nursing Research, National Institutes of Health.
- ❖ Commissioner Thomas Murray presented "Genetics, Race and Bioethics" at the Center for Bioethics Fall Conference at Tuskegee University in September 1998.
- ❖ Commissioner Patricia Backlar discussed "Research Advance Directives" at the National Alliance for the Mentally Ill Annual Convention in July 1999.
- ❖ On a visit to West Africa in December 1999 as part of her work for the National Science Foundation, Commissioner Diane Scott Jones discussed with West African investigators and university officials NBAC's ongoing work in the protection of subjects in international research.
- ❖ Commissioner Bette Kramer, one of NBAC's public members, has been a key contributor to Bioethics 2000, a collaborative project with the University of Richmond, United Network for Organ Sharing, Virginia Commonwealth University, Southern California Organ Procurement Center, Virginia Transplant Council, and Mills Godwin High School.





*Left to Right:  
Harold T. Shapiro,  
NBAC Chair; Hiroo  
Imura, Chair of the  
Japanese Bioethics  
Commission;  
Jean-Pierre Changeux,  
Chair of the French  
national bioethics  
committee (CCNE), at  
the Second International  
Summit of National  
Bioethics Commissions  
in Tokyo, November 1998.*

lectures, media interviews, and publications and editorials in the scholarly literature and the popular press.

In addition, as NBAC has become a more visible deliberative body, it has been asked to organize, consult, attend, or provide input to a variety of national and international meetings and projects. In the past two years, the Commission has been involved in the activities described below.

### *Second International Summit of National Bioethics Commissions, November 1998*

As discussed in its 1996–1997 Report, NBAC was instrumental in convening the First International Summit of National Bioethics Commissions, held in San Francisco in 1996. The positive reaction to this Summit encouraged NBAC to collaborate in the organization of the Second International Summit of National Bioethics Commissions, which was held in Tokyo, Japan, November 4–5, 1998, in conjunction with the Fourth World Congress of the International Association of Bioethics. As in San Francisco, NBAC Chair Harold T. Shapiro, Ph.D., was one of the co-chairs. Dr. Shapiro, along with Dr. Hiroo Imura, Chair of the Japanese Bioethics Commission, and Dr. Jean-Pierre Changeux, Chair of France’s national bioethics committee, Comité Consultatif National d’Ethique (CCNE), convened a two-day meeting that brought together Delegates and Observers from more than 30 countries and 5 international organizations. Commissioners Alexander Capron, R. Alta Charo, and Thomas Murray attended the Summit, as did NBAC Executive Director Eric Meslin. An important outcome of the Summit was the “Tokyo Communiqué” (see Appendix C), which identified a number of common issues of interest and resulted in an agreement that national bioethics commissions will continue to explore ways to work together. The Summit will reconvene in 2000 in London, England.

### *Belmont Report 20th Anniversary Conference*

NBAC co-sponsored a meeting in April 1999 at the University of Virginia in Charlottesville to celebrate the 20th anniversary of the publication of the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. This anniversary was an opportune time for scholars and academics involved in the work to revisit one of the most influential documents in bioethics. The *Belmont Report* was prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and has provided the ethical foundation for the current federal system of human subjects protections in the United States. The conference was co-chaired by NBAC Chair Harold T. Shapiro and Commissioner James Childress. Commissioners Alexander Capron, Eric Cassell, R. Alta Charo, and Thomas Murray and NBAC Executive Director Eric Meslin presented papers, which will be published in a book being edited by Harold Shapiro, James Childress, and Eric Meslin.

### *Journées Annuelle (Annual Ethics Days): CCNE, France*

In December 1999, NBAC was represented by Commissioners Alexander Capron and R. Alta Charo and Executive Director Eric Meslin at the annual meeting of France's CCNE. In contrast with NBAC, the CCNE is not bound by the requirement to hold all meetings in public. Thus, its annual ethics forum is an opportunity for the public to observe and participate in the country's biomedical ethics debates. Each year, the CCNE invites experts from around the world to review its work and discuss a variety of French bioethics laws and issues. A constructive and helpful relationship has developed between the two national commissions.

### *World Health Organization Consultation*

In December 1999, the World Health Organization convened a meeting of 40 experts and groups to seek advice on the direction it should take in addressing ethical issues in genetics and related advances in medicine and biology. Commissioners Alexander Capron and R. Alta Charo and Executive Director Eric Meslin participated in this consultation.

## **Commission Functions and Operations**

The Commission continues to function according to the original Executive Order. However, there have been several administrative changes that have occurred since the last biennial report. (See Appendix D.)

*Extension of Executive Order and New Charter.* As an indication of the value that NBAC offers to the policymaking arena, President Clinton, on September 16, 1999, extended the Commission's term for two additional years, via Executive Order 13137. This Executive Order expires on October 3, 2001. On October 20, 1999, a new Charter was signed by Department of Health and Human Services Secretary Donna Shalala.

*New Member.* William C. Oldaker, LL.B., of Potomac, Maryland, was appointed to the Commission in September 1999. Mr. Oldaker is the co-founder of and general counsel to NeuralStem Biopharmaceuticals Ltd., which conducts research into genetic therapies. He replaced Ezekiel Emanuel, M.D., Ph.D., associate professor of medical ethics at Harvard Medical School, who left NBAC in February 1998 to head the Department of Clinical Bioethics at the National Institutes of Health.

*“NBAC finds that the current federal regulations have served to prevent most recurrences of the gross abuses associated with biomedical research in the earlier part of this century. Nonetheless, some abuses still occur, and the system is in need of significant revision.”*

NBAC Summary of Preliminary Findings: Adequacy of Federal Protections for Human Subjects in Research, May 1999

*Budget.* NBAC's operating budget for FY 1998 was \$1.9 million. Its operating budget for FY 1999 was \$2 million. In contrast with previous years, NBAC currently receives its budget from a single federal agency, the Department of Health and Human Services.

*Subcommittees Disbanded.* On September 15, 1999, NBAC informed the White House and the Department of Health and Human Services that it was disbanding the Human Genetics Subcommittee and the Human Subjects Subcommittee.

## Work in Progress

With the Commission now extended until October 2001, additional reports are under way and nearing completion.

### *Ethical and Policy Issues of International Research*

The adequate protection of the rights and welfare of all individuals who participate in clinical trials, regardless of nationality or the site of the research in all countries involved, is emerging as a critical issue in international research ethics. Over the past 10 years, there has been a significant increase in the amount of clinical research that the United States conducts or sponsors in other countries, particularly in countries that are resource poor. By late fall 2000, NBAC expects to produce a set of recommendations that will address the ethical, legal, and policy issues that arise when research subject to U.S. research regulations is sponsored or conducted in other countries.

NBAC's goal is to identify these issues and determine whether they are unique to international settings and deserve attention from policymakers. NBAC will be looking at recruitment of subjects, informed consent, and the risks and potential benefits of conducting research. The report also will analyze many national and international guidelines and statements to make recommendations about possible ways to enhance international collaborative research. It also will focus on the obligations of private and public

sponsors of investigations to research participants, communities, and countries throughout the research process.

### *Ethical and Policy Issues in the Oversight of Human Subjects Research in the United States*

In September 1999, President Clinton asked NBAC to undertake a thorough examination of the federal system of human research subject protections. The President's request stems from concerns that the current decentralized system of oversight places too much responsibility on individual investigators and their sponsoring institutions. In May 1999, NBAC wrote to the President indicating several areas of concern, noting that federal protections for people serving as subjects in research do not yet extend to all Americans and that many federal agencies find the interpretation and implementation of the Common Rule confusing or unnecessarily burdensome. The Commission's effort in this area comes against a backdrop of intensifying public concern about the state of human research oversight in the United States.

NBAC's charge is to assess the adequacy of the current federal system of protections; review relevant statutes and regulations with particular attention to the effectiveness of the Common Rule and its applicability to the full range of government-sponsored research activities involving human subjects; and examine the strengths and weaknesses of the infrastructure responsible for ensuring the entire system's integrity. The goal of the report, expected to be completed by early 2001, will be to offer recommendations that ensure that all federal research involving humans is conducted ethically.

### **Archiving NBAC's Work**

Plans are now under way to ensure that all reports, materials, and related documents from NBAC's work are accessible to scholars and the public in both hard copy and electronic formats. By the end of 2000, it is expected that an agreement will be reached with a university to archive these materials.

*“It took 10 long years to promulgate the Common Rule in 1991, and yet even at that time it was agreed that additional work needed to be done to provide adequate coverage for every research subject, including special populations. One of the driving forces behind NBAC’s establishment was the desire to accelerate progress towards the goal of ensuring such coverage.”*

Dr. Neal Lane, Assistant to the President for Science and Technology, Executive Office of the President, addressing the Commission on October 22, 1999

# Appendix A

## National Bioethics Advisory Commission Staff, Consultants, and Volunteers, 1998–1999

### *Executive Director*

Eric M. Meslin, Ph.D.

### *Research Staff*

Elisa Eiseman, Ph.D., Senior Research Analyst  
Emily C. Feinstein, Program Analyst (until May 1999)  
Ellen L. Gadbois, Ph.D., Senior Policy Analyst  
Melissa Goldstein, J.D., Research Analyst (until May 1999)  
Kathi E. Hanna, M.S., Ph.D., Research Director (until October 1999)  
Everson R. Hull, Program Analyst (until May 1999)  
Stuart Kim, J.D., M.S., Research Analyst  
Kyle Kinner, J.D., Presidential Management Intern (until July 1999)  
Kerry Jo Lee, Research Assistant  
Debra McCurry, M.S., Information Specialist  
Alice Page, J.D., M.P.H., Senior Policy Analyst, Project Manager (International)  
Daniel J. Powell, Intern (Summer 1999)  
Andrew Siegel, Ph.D., J.D., Staff Philosopher (until August 1999)  
Sean A. Simon, Program Analyst (until May 1999)  
Robert S. Tanner, J.D., Program Analyst (until February 2000)

### *Administrative Staff*

Jody L. Crank, Assistant to the Executive Director  
LaShell L. Gaskins, Administrative Technician (until July 1999)  
Evadne M. Hammett, Administrative Officer  
Henrietta Hyatt-Knorr, M.A., Acting Deputy Executive Director (until November 1998)  
Patricia Norris, Public Affairs Officer (until October 1999)  
Lisa N. Price, Secretary (until October 1999)  
Margaret C. Quinlan, Office Manager  
Sherrie D. Senior, Secretary

### *Consultants and Volunteers*

Burness Communications, Communications Consultant  
Sara Davidson, M.A., Editor  
William F. Freeman, M.D., M.P.H., Volunteer (until September 1998)  
Kathi E. Hanna, M.S., Ph.D., Editorial Consultant (from November 1999)  
Jeffrey P. Kahn, Ph.D., M.P.H., Bioethics Consultant (until September 1999)  
Tamara Lee, Graphic Designer  
Ruth Macklin, Ph.D., Senior Consultant  
Joel M. Mangel, J.D., Volunteer (until December 1998)  
Jonathan D. Moreno, Ph.D., Senior Consultant (until October 1999)  
LeRoy B. Walters, Ph.D., Bioethics Consultant (until October 1999)

# Appendix B

## Meeting Dates, Locations, and Testimony Provided

January 6–8, 1998

Arlington, Virginia

**Public Testimony:**

John Cavanaugh O’Keefe, American Bioethics Advisory Commission

Norman Carl Rabin, Long Island, New York

David Shore, National Institute of Mental Health

Mark Sobel, National Cancer Institute

**Expert Testimony:**

Patricia Barr, National Action Plan on Breast Cancer

Gary B. Ellis, Office for Protection from Research Risks

John C. Fletcher, University of Virginia

C.K. Gunsalus, University of Illinois

Rachel Levinson, Office of Science and Technology Policy

Susan E. Old, National Heart, Lung, and Blood Institute

Joan Porter, Office of Science and Technology Policy

Jack Schwartz, Office of the Attorney General, State of Maryland

February 5–6, 1998

Los Angeles, California

**Public Testimony:**

Art Ablin, University of California, San Francisco

Robert Aller, Patient Rights Network

Con Hopper, University of California System

Kathy Kasten, Los Angeles, California

Betsy Manning

Felicia McCarty, Mira Loma, California

David Shore, National Institute of Mental Health

Joan Siegemund

**Expert Testimony:**

Rachel Levinson, Office of Science and Technology Policy

Elyn Saks, University of Southern California

March 3–4, 1998

Tysons Corner, Virginia

**Public Testimony:**

Judith Brunden, Union City, New Jersey

John Cavanaugh O’Keefe, American Bioethics Advisory Commission

Karen Rothenberg, University of Maryland

Adil Shamoo, Citizens for Responsible Care in Psychiatry and Research

**Expert Testimony:**

Lisa Brooks, National Human Genome Research Institute

Bernard M. Dickens, University of Toronto

Mark Guyer, National Human Genome Research Institute

J. Thomas Puglisi, Office for Protection from Research Risks



May 19–20, 1998  
Cleveland, Ohio

**Public Testimony:**

Tillman Bauknight, Cleveland, Ohio  
Vicki Casagrande, West Bloomfield, Michigan

**Expert Testimony:**

C. Christopher Hook, The Mayo Clinic  
Ruth Macklin, Albert Einstein College of Medicine  
Stuart L. Nightingale, Food and Drug Administration  
Donald L. Rosenstein, National Institute of  
Mental Health  
David Shore, National Institute of Mental Health  
Marjorie A. Speers, Centers for Disease Control  
and Prevention

July 14–15, 1998  
Portland, Oregon

**Public Testimony:**

Ted Falk, Portland, Oregon  
Sid Glasser, San Francisco, California  
Karen Hansen, Public Responsibility in Medicine  
and Research

**Expert Testimony:**

Allen Buchanan, University of Arizona  
Frank C. Dukepoo, Northern Arizona University  
Albert R. Jonsen, University of Washington  
Mary-Claire King, University of Washington

September 16–17, 1998  
Alexandria, Virginia

**Public Testimony:**

Irene Lynch, Colts Neck, New Jersey  
Marcia Pines, Baltimore, Maryland  
David Shore, National Institute of Mental Health

October 20, 1998  
Arlington, Virginia

**Public Testimony:**

Wesley Alcorn, National Alliance for the Mentally Ill  
Catherine Clapp, Fragile X Research Foundation  
Kathy Mannion, Port Washington, New York  
James McNulty, National Alliance for the  
Mentally Ill  
Harold Pincus, American Psychiatric Association  
Jaqueline Shannon, National Alliance for the  
Mentally Ill

November 17–18, 1998  
Miami, Florida

**Public Testimony:**

Michael Guarino, Autism Society of America  
David Shore, National Institute of Mental Health  
Michael West, Advanced Cell Technology

**Expert Testimony:**

Ralph Brinster, University of Pennsylvania

January 19–20, 1999  
Washington, D.C.

**Public Testimony:**

Kneale Ewing, Collegians Activated to Liberate Life  
Olga Fairfax, Wheaton, Maryland  
Will Goodman, Civil Rights and Antidefamation  
League of Embryonic Life  
John Price  
Mark Sobel, American Society of Investigative Pathology  
E.J. Suh, Collegians Activated to Liberate Life

**Expert Testimony:**

Françoise Baylis, Dalhousie University  
John Gearhart, The Johns Hopkins University  
Patricia King, Georgetown University School of Law  
Karen Lebacqz, Pacific School of Religion  
Erik Parens, The Hastings Center  
Daniel Perry, Alliance for Aging Research  
Ted Peters, Center for Theology and the Natural  
Sciences  
John Robertson, University of Texas School of Law  
Austin Smith, University of Edinburgh  
James Thomson, University of Wisconsin  
Harold Varmus, National Institutes of Health

February 2–3, 1999  
Princeton, New Jersey

**Expert Testimony:**

David Blumenthal, Massachusetts General Hospital  
Robert Brady, Hogan & Hartson L.L.P.  
Brigid Hogan, Vanderbilt University  
Barbara Mishkin, Hogan & Hartson L.L.P.

March 2–3, 1999  
Vienna, Virginia

**Public Testimony:**

Phil Noguchi, Food and Drug Administration

**Expert Testimony:**

John Fanning, Department of Health and Human  
Services  
John Fletcher, University of Virginia  
Nancy Kass, Johns Hopkins University  
Lori Knowles, The Hastings Center  
Jeremy Sugarman, Duke University  
LeRoy Walters, Georgetown University

April 15–16, 1999  
Charlottesville, Virginia

**Public Testimony:**

Ida Chow, American Society of Developmental Biology  
Richard Doerflinger, National Conference of Catholic  
Bishops  
Ethics and Religious Liberty Commission of the Southern  
Baptist Convention (submitted written testimony)  
Edward Furton, National Catholic Bioethics Center  
Sidney Gunst, Jr., Richmond, Virginia  
Karen Poehailos

**Expert Testimony:**

Patricia Marshall, Loyola University

May 7, 1999  
Washington, D.C.

**Public Testimony:**

Dena Davis, Cleveland-Marshall College of Law  
Richard Doerflinger, National Conference of Catholic Bishops

**Expert Testimony:**

Ronald Cole-Turner, Pittsburgh Theological Seminary  
Demetrios Demopoulos, Holy Trinity Greek Orthodox Church  
Elliot Dorff, University of Judaism  
Nancy Duff, Princeton University Theological Seminary  
Margaret Farley, Yale University  
Gilbert Meilaender, Jr., Valparaiso University  
Edmund Pellegrino, Georgetown University  
Abdulaziz Sachedina, University of Virginia  
Moshe Tendler, Yeshiva University  
Kevin Wildes, Georgetown University  
Laurie Zoloth, San Francisco State University

May 11–12, 1999  
Northbrook, Illinois

**Public Testimony:**

Peggy Connelly, Wheaton, Illinois  
Daniel McConchie, Center of Bioethics and Human Dignity

**Expert Testimony:**

Lori Andrews, Chicago-Kent College of Law  
Sander Shapiro, University of Wisconsin-Madison

June 28–29, 1999  
Washington, D.C.

**Public Testimony:**

Phil Noguchi, Food and Drug Administration

**Expert Testimony:**

Roger Cortesi, Environmental Protection Agency  
Nancy Dubler, Albert Einstein College of Medicine  
Paul Gatons, Department of Housing and Urban Development  
Timothy Gerrity, Department of Veterans Affairs  
Renee M. Landers, Ropes & Gray  
Edward M. Lane, Department of Defense  
Barbara C. Levin, National Institute on Standards and Technology  
Beth McCormick, National Aeronautics and Space Administration  
Stuart Plattner, National Science Foundation  
Blanca Rosa Rodriguez, U.S. Department of Education  
James D. Shelton, U.S. Agency for International Development  
Lana Skirboll, National Institutes of Health  
Majorie Speers, Centers for Disease Control and Prevention

July 13–14, 1999  
Cambridge, Massachusetts

September 16–17, 1999  
Arlington, Virginia

**Public Testimony:**

Peter Lurie, Public Citizen's Health Research Group

**Expert Testimony:**

Donald S. Burke, Johns Hopkins School of Hygiene & Public Health  
Jack Killen, National Institute of Allergy and Infectious Diseases  
Alfred Sommer, Johns Hopkins School of Hygiene & Public Health

October 21–22, 1999  
Washington, D.C.

**Public Testimony:**

Adnan Hyder, Johns Hopkins School of Hygiene & Public Health  
Susan Poland, National Reference Center for Bioethics Literature

**Expert Testimony:**

Lori B. Andrews, Chicago-Kent College of Law  
Sam Avrett, AIDS Vaccine Advocacy Coalition  
Neal F. Lane, Office of Science and Technology Policy  
Sana Loue, Case Western Reserve University  
Mark Sagoff, University of Maryland

December 2–3, 1999  
Baltimore, Maryland

**Public Testimony:**

Steven Gordon, The Johns Hopkins University  
Kohar Jones, Yale University  
Peter Lurie, Public Citizen's Health Research Group  
Terry Rhinehart

**Expert Testimony:**

Gary Chase, Henry Ford Health Sciences Center  
Kay Dickersin, Brown University  
Dennis Dixon, National Institute of Allergy and Infectious Diseases  
Stephen Lagakos, Harvard School of Public Health  
David Lepay, Food and Drug Administration  
Christopher C. Whalen, Case Western Reserve University  
Sidney M. Wolfe, Public Citizen's Health Research Group



# Appendix C

## Second International Summit of National Bioethics Commissions: Tokyo Communiqué

*The Delegates to the Second International Summit of National Bioethics Commissions,*

*Representing* more than 30 countries and every inhabited continent, who have gathered for two days of open dialogue and exchange of ideas and experiences,

*Recalling* the history of international efforts in this century both to promote progress in biology and medicine as a means of improving the human condition, and to safeguard the well-being and to respect the worth of all persons, particularly those made vulnerable by disease,

*Recognizing* that developments in the life sciences and in the provision of health care and public health services generate ever more complex issues for advisory bodies in all nations concerning, for example:

- ❖ access to healthcare resources in the face of scarcity
- ❖ permissible means to reduce suffering in the process of dying
- ❖ the prospect of creating human beings through cloning
- ❖ selecting the sex of children
- ❖ transgenic animals and genetically engineered foods
- ❖ molecular therapy for enhancement of human capacities rather than treatment of disease

*Bearing in mind* that many issues have international ramifications concerning, for example:

- ❖ the need for research leading to inexpensive pharmaceutical and nutritional interventions of great potential value in the poorest nations
- ❖ the need for sustainable development in light of the rapid increase in human population and use of natural resources
- ❖ the standards for clinical trials of drugs and vaccines in developing nations
- ❖ intentional manipulation of the human genome
- ❖ payment for human organs for transplantation
- ❖ ownership of DNA information derived from mapping and sequencing the human genome

*Aspiring* to advance the field of bioethics, which attempts to analyze and understand such issues, and to provide healthcare professionals, research scientists, citizens, patients and families, and governmental policymaking bodies in healthcare, biotechnology, environment, population and related fields with ideas and recommendations that may improve the way they carry out their responsibilities,

*Taking* into account the importance of working together to promote education and enlightenment on bioethics around the world, of increasing the know-how of national commissions in dealing with difficult issues, and of developing the necessary information-gathering and policy-making capabilities, particularly in nations that now lack relevant academic and governmental resources,

*Realizing* the need to learn from, and work closely with, experts in the social and natural sciences and the humanities in order to address bioethical issues in an informed and productive fashion,

*Wishing to* cooperate in ways that will effectively address and take action not only on the issues of today but that will anticipate issues that will emerge tomorrow, and

*Desiring to* carry on the process begun at the First International Summit of National Bioethics Advisory Bodies in San Francisco in November 1996 and continued at the present Second International Summit in Tokyo, not only through such meetings but also on an on-going basis in order to permit all our countries to learn from each other's experiences and to explore topics that may benefit from coordinated responses,

*Do hereby establish* the Global Summit of National Bioethics Commissions in order to foster progress on subjects of mutual interest in this field,

*Delegate* to an Interim Working Committee, with members from all continents, the responsibility

(1) to make appropriate arrangements with the World Health Organization and other national and international organizations which are willing to provide the secretariat and documentation functions needed for our continued cooperation and coordination, with the expectation that such arrangements will be concluded within three months,

(2) to assemble the reports of national bioethics commissions and organize their findings by topic, with the assistance of the Comité Consultatif National d'Ethique pour les Sciences de la Vie et de la Santé, and report the results back to the commissions, as a means of moving forward with the process of exploring common interests,

(3) based upon this analysis and upon the discussion of topics at the Tokyo Summit (particularly such issues as the ethics of multicenter, international clinical trials, and the ethical aspects of various types of healthcare reform), to circulate a list of possible topics where coordinated examination by national advisory bodies working simultaneously might produce results that would not be as easily obtained through such bodies working alone, and then to select one or two such topics on which the process of international collaboration can begin,

(4) to make appropriate arrangements for the next meeting of the Global Summit,

(5) to consult with international organizations working on bioethics and establish appropriate collaborative ties with them, and

(6) through a process of consultation with the national commissions, to formulate a set of basic by-laws for the Global Summit.

## *Signed, this 4th day of November 1998 in Tokyo, Japan*

SIGNATORIES\* TO THE GLOBAL SUMMIT OF NATIONAL BIOETHICS COMMISSIONS:  
TOKYO COMMUNIQUÉ, NOVEMBER 4, 1998

### Summit Co-Chairs

Hiroo Imura, Japan  
Jean-Pierre Changeux, France  
Harold T. Shapiro, USA

### Delegates

Argentina	Juan Carlos Tealdi,
Australia	Donald Chalmers, Australian Health Ethics Committee
Bangladesh	Hasna Begum
Belgium	Etienne Vermeersch
Brazil	Leo Passini, National Commission of Ethics in Research Involving Human Beings
Canada	Neil MacDonald, Medical Research Council
Croatia	Ivan Segota
Denmark	Soren Holm, Danish Council on Ethics
Egypt	Ibrahim Badran
Finland	Tuija Takala Matti Hayry
Hungary	Bela Blassauer
India	Vasantha Muthuswamy, Indian Council of Medical Research
Ivory Coast	Lazare Marcelin-Poame
Korea	Song Sang-Yong
Mexico	Horacio Garcia-Romero Manuel Velasco-Suarez
The Netherlands	Egbert Schrotten, Standing Committee on Medical Ethics and Health Law, Health Council of the Netherlands
New Zealand	Ken R. Daniels
Poland	Zbigniew Szawarski
Portugal	Daniel Serrao, Portuguese National Ethics Committee for Life Sciences
Russia	Boris Yudin
Scotland	Donald Bruce, Genetic Engineering Working Group, Church of Scotland
South Africa	Solomon Benatar
Sweden	Stellan Welin
United Kingdom	Colin Campbell, Human Genetics Advisory Commission Sandra M. Thomas, Nuffield Council on Bioethics
USA	Alexander M. Capron, National Bioethics Advisory Commission

### International Organizations

Council on International Organizations of Medical Sciences  
John Bryant

European Group of Ethics, European Commission  
Octavi Quintana-Trias

International Association of Bioethics  
Alastair V. Campbell.

International Union of Biological Sciences  
Darryl Macer

World Health Organization  
Daniel Wikler

UNESCO, International Bioethics Committee  
Michael Kirby

*\*Unless indicated, signatories are signing on behalf of themselves  
revised as of 7/27/1999*

# Appendix D

## Executive Order 12975 of October 3, 1995

*Federal Register: October 5, 1995 (Volume 60, Number 195) Page 52063-52065*

### Presidential Documents

#### 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. 5701-5707).

(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 Amendment to Executive Order 12975, Extension of The 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 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.

## Executive Order 13137

### Further Amendment to Executive Order 12975, as Amended, 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 more accurately describe the expertise requirements for members selected for the National Bioethics Advisory Commission, it is hereby ordered that Executive Order 12975, as amended ("Order"), is further amended as follows:

**Section 1.** Section 3 of the order shall read as follows: "Sec. 3. Establishment of National Bioethics Advisory Commission. There is established in the Department of Health and Human Services a National Bioethics Advisory Commission (NBAC). The NBAC shall be subject to the Federal Advisory Committee Act, as amended (5 U.S.C. App)."

**Sec. 2.** A new section 4 shall be added to the order to read: "Sec. 4. Structure.

(a) The National Bioethics Advisory Commission shall be composed of not more than 18 non-government members appointed by the President. At least one member shall be selected from each of the following

categories of primary expertise: (1) philosophy/theology; (2) social/behavioral science; (3) law; (4) medicine/allied health professions; and (5) biological research. At least three members shall be selected from the general public, bringing to the Commission expertise other than that listed. The membership shall be approximately evenly balanced between scientists and non-scientists. Close attention will be given to equitable geographic distribution and to ethnic and gender representation.

(b) Members of the Commission will serve for terms of 2 years and may continue to serve after the expiration of their term until a successor is appointed. A member appointed to fill an unexpired term will be appointed to the remainder of such term.

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

Sec. 3. (a) “[S]ection 5” in the third sentence of section 1(b) of the order shall be deleted and “section 6” shall be inserted in lieu thereof.

(b) Current sections 4 through 7 of Executive Order 12975 shall be renumbered sections 5 through 8.

(c) New section 8(b) is amended by deleting “October 3, 1999” and inserting “October 3, 2001” in lieu thereof.

WILLIAM J. CLINTON  
*The White House,*  
September 15, 1999.

## National Bioethics Advisory Commission Charter

### Purpose

The National Bioethics Advisory Commission will provide advice and make recommendations to the National Science and Technology Council, chaired by the President; other appropriate entities and the public, on bioethical issues arising from research on human biology and behavior, and the applications, including the clinical applications, of that research.

### Authority

Executive Order 12975, as amended. This Commission is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U. S.C. Appendix 2), which sets forth standards for the formation of advisory committees, and implementing regulations (41C.F.R. 101.6.10).

### Functions

The National Bioethics Advisory Commission shall advise, consult with, and make recommendations to the National Science and Technology Council, chaired by the President; Federal agencies; and other appropriate entities, and also make available to the public the Commission’s advice and recommendations. The Commission’s purview includes 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 applications, including the clinical applications, of that research. The Commission shall identify broad, overarching principles to govern the ethical conduct of research, citing individual projects only as illustrations for such principles. The Commission shall not be responsible for the review and approval of individual projects.

As a first priority, the Commission will direct its attention to consideration of

- A. Protection of the rights and welfare of human research subjects; and
- B. Issues in the management and use of genetics information including but not limited to human gene patenting.



In addition to responding to requests for advice and recommendations from the National Science and Technology Council, the Commission also may accept suggestions for issues for consideration from both the Congress and the public. The Commission 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. The Commission shall consider four criteria -in establishing priority for its activities:

- A. The public health or public policy urgency of the bioethical issue.
- B. The relation of the bioethical issue to the goals for Federal investment in science and technology.
- C. The absence of another body able to deliberate fruitfully on the bioethical issue.
- D. The extent of interest in the issue across the government. (The Commission ordinarily will not deliberate on a bioethical issue of interest to just one department or agency.)

## Structure

The National Bioethics Advisory Commission shall consist of not more than 18 members including the Chairperson. Appointments shall be made by the President, who shall select from knowledgeable non-Government experts and community representatives with special qualifications and competence to deal effectively with bioethical issues. At least one member shall be selected from each of the following categories of primary expertise: (1) philosophy/theology; (ii) social/behavioral science; (iii) law; (iv) medicine/allied health professions; and (v) biological research. At least three members shall be selected from the general public, bringing to the Commission expertise other than that listed. The membership shall be approximately evenly balanced between scientists and non-scientists. Close attention will be given to equitable geographic distribution and to ethnic and gender representation.

Members of the Commission will serve for terms of 2 years and may continue to serve after the expiration of their term until a successor is appointed. A member appointed to fill an unexpired term will be appointed to the remainder of such terms. The Chairperson shall be appointed by the President. The term of office for the Chairperson shall be two years, renewable by appropriate action of the President.

If a vacancy occurs on the Commission, the President shall make an appointment to fulfill the term. Any member appointed to fill a vacancy occurring prior to expiration of the term for which his or her predecessor was appointed shall serve for the remainder of such term. Members may serve after the expiration of their terms until their successors have taken office.

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

The Commission may conduct inquiries, hold hearings and establish subcommittees, as necessary.

The Commission is authorized to solicit information from relevant human research subject groups.

The Commission is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on the Commission, the Secretary of Health and Human Services is also authorized to contract for the services of non-governmental consultants who may conduct analyses, prepare reports and background papers or prepare other materials for consideration by the Commission, as appropriate.

In order to avoid duplication of effort, the Commission is encouraged to review the deliberations of other entities. The Commission may incorporate or otherwise use the results of the deliberations of other entities, as it deems appropriate.

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 of the subcommittee, and estimated frequency of meetings.

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



## Meetings

Meetings of the Commission shall be held up to 12 times a year at the call of the Chairperson. Meetings of the subcommittee(s) shall be convened as necessary. A Federal Government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Assistant to the President for Science and Technology and the Secretary of Health and Human Services. Advance notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of proceedings kept, as required by applicable laws and Federal regulations.

## Compensation

Members may be compensated at a rate not to exceed the maximum pay authorized by 5 U. S.C. 3109, plus per them and travel expenses as in accordance with standard government travel regulations,

## Annual Cost Estimate

The estimated annual cost for operating the National Bioethics Advisory Commission is \$3,000,000.

## Reports

Reports by the National Bioethics Advisory Commission on specific issues shall be submitted to the National Science and Technology Council, chaired by the President, and then to the appropriate committees of Congress, and other appropriate entities. The Commission may specifically identify the Federal department, agency or other entity to which particular recommendations are directed and request a response from the Federal department, agency or other entity within 180 days of publication of such recommendation.

Executive summaries of each report of the Commission shall be published in the Federal Register or on the World Wide Web. Such summaries shall specifically list the department, agency, or other entity to which any recommendations are directed and the date by which such responses are expected.

An annual report shall be submitted to the National Science and Technology Council and the appropriate committees of Congress. It shall contain, at a minimum, (1) the Commission's function; (ii) a list of members and their business addresses; (iii) the dates and places of meetings; (iv) a summary of the Commission's activities during the year; (v) a summary of the Commission's recommendations made during the year; and (vi) a summary of responses made by departments, agencies, or other entities to the Commission's recommendations during the year.

## General Provisions

Notwithstanding the provisions of any other Executive Order, the functions of the President under the Federal Advisory Committee Act that are applicable to the Commission, 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.

## Termination Date

Unless renewed by Executive Order prior to its expiration, this National Bioethics Advisory Commission will terminate on October 3, 2001.

## Approved:

Donna E. Shalala, Secretary  
October 20, 1999

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