

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. note	re: non-selection (1 page)	07/03/1996	b(6)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

FOLDER TITLE:

IAWG [Interagency Working Group] - NBAC [National Bioethics Advisory
Commission]

2014-0046-S

rc1441

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

NIH to Kill DNA Advisory Committee

Director Says Replacement Panel Would Defer to FDA on Gene Proposals

By Rick Weiss
Washington Post Staff Writer

Despite vocal opposition from scientists, ethicists and at least four members of Congress, National Institutes of Health Director Harold Varmus announced in Monday's Federal Register that he intends to abolish the Recombinant DNA Advisory Committee, the NIH panel that oversees human gene therapy experiments.

The plan was detailed publicly for the first time yesterday by NIH and Food and Drug Administration officials at a gene therapy conference in Bethesda. Under the plan, said Lana R. Skirboll, NIH associate director for science policy, "RAC is eliminated."

That does not mean the government will have one less abbreviation to kick around. Countering criticism that the change would stymie public oversight of human genetic experiments, Varmus is proposing a new panel, the Office of Recombinant DNA Activities Advisory Committee, or OAC.

Like the RAC, OAC would consist of scientists, ethicists and lay representatives (although the size would be reduced from 25 members to about six). Like RAC members, OAC members would consider social and ethical aspects of the rapidly growing field of gene therapy. And like the RAC, the OAC would meet quarterly.

"We named it OAC for a reason," Skirboll said. "It is very similar to the RAC."

Where OAC will differ from RAC is in the power to approve or toss out individual gene therapy proposals. That would go to the FDA, which already has sole authority to approve routine gene therapy experiments but defers to the RAC for novel protocols that break new scientific or ethical ground.

Some say that's a major problem, because the FDA does not consider ethical issues in its approval process as the RAC does. Research centers where the experiments would be done all have institutional review boards that would now be charged with weighing ethical considerations, but some suspect these boards are not up to the task.

A June 26 letter from Sens. David Pryor (D-Ark.), Ron Wyden (D-Ore.) and Mark O. Hatfield (R-Ore.) and Rep. Henry A. Waxman (D-Calif.) to Varmus cites a March General Account Office report that found IRBs overworked and ill equipped. "It is our concern that abolishing the RAC could abruptly add new and unfamiliar responsibilities to the workloads of IRBs across the country," the congressmen wrote.

Varmus received another opposition letter from Charles R. McCarthy, who for 14 years was director of NIH's Office of Protection of Research Subjects. "I am convinced that discontinuing protocol review by the RAC could endanger research subjects," McCarthy wrote last month. "Furthermore, FDA is highly unlikely to give in-

creased attention to the rights of human subjects at a time when it is facing harsh political pressure to accelerate its decision making."

Skirboll countered that OAC could look at protocols submitted to FDA and consider issues arising from those requests. Moreover, OAC would sponsor quarterly gene therapy policy conferences to discuss controversial issues, such as the propriety of performing gene therapy on fetuses or for cosmetic purposes.

But W. French Anderson, the University of Southern California scientist who performed the nation's first gene therapy test in 1990, doubted the OAC's viability. "Nobody who's any good would spend time on a committee that has no power," he said. "Why should these people bother to show up just for some window dressing?"

The proposal has some support. The Biotechnology Industry Organization, which represents more than 650 biotech companies and other institutions, "believes that the RAC has outlived its usefulness," said Dominique Cahn, BIO's director of federal government activities. And Inder Verma, the Salk Institute professor who led a recent committee assessing the federal gene therapy program, called the plan "bold and imaginative."

Still unknown is how the majority of scientists and citizens feels. Skirboll implored people to write with comments during the 30-day public comment period, which ends Aug. 7.

wp 7/12/96

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NBAC

Dr. Harold T. Shapiro, President of Princeton University and Professor of Economics and Public Affairs, has been selected to chair the Commission. Dr. Shapiro is a member of numerous honorary professional societies including the Institute of Medicine and has been awarded many honorary degrees. Dr. Shapiro serves on advisory boards to several public organizations and corporations and is a past member of the President's Council of Advisors on Science and Technology (1990-1993).

Dr. Patricia Backlar, M.D. of Oregon, is a Senior Scholar at the Center for Ethics in Health Care at Oregon Health Sciences University. Dr. Backlar specializes in issues concerning individuals with severe and persistent mental disorders.

Dr. Arturo Brito, M.D. of Florida, is an Assistant Professor of Clinical Pediatrics at the University of Miami School of Medicine. Dr. Brito is also the Medical Director of the Pediatric Mobile Clinic of Miami.

Mr. Alexander M. Capron, LL.B., of California is co-director of the Pacific Center for Health Policy and Ethics at the University of Southern California. Professor Capron specializes in legal-medical issues and biomedical ethics. He is a member of the Institute of Medicine, a founding Fellow of the Hastings Center and a past member of the Human Gene Therapy Subcommittee.

Dr. Eric J. Cassell, M.D. of New York, is Physician to In-Patients at The New York Hospital-Cornell Medical Center. For five years, Dr. Cassell directed the Cornell University Medical College Program for the Study of Ethics and Values in Medicine.

Ms. R. Alta Charo, J.D., of Wisconsin, holds joint assistant professorships in the University of Wisconsin Medical and Law Schools. A Fellow at the Hastings Center, Ms. Charo has also held government appointments in the Office of Technology Assessment and the U.S. Agency for International Development.

Mr. James F. Childress, Ph.D., of Virginia, is the Edwin B. Kyle Professor of Religious Studies and Professor of Medical Education at the University of Virginia. Dr. Childress is the author of numerous articles and several books on biomedical ethics and is former vice-chairman of the National Task Force on Organ Transplantation.

Dr. David R. Cox, M.D., Ph.D., of California, is Professor of Genetics and Pediatrics at the Stanford University School of Medicine. Dr. Cox is a world-renowned expert on genetic diseases associated with defects in chromosome 21, including Down Syndrome and ataxia-telangiectasia. He is a member of the American Society of Human Genetics, the American Academy of Pediatrics, the American Federation for Clinical Research and the Human Genome Organization.

Dr. Ezekiel J. Emanuel, M.D., Ph.D., of Massachusetts, is an Assistant Professor of

Medicine, Social Medicine and Clinical Epidemiology at the Dana-Farber Cancer Institute, Harvard Medical School. A member of the Ethics Group under the President's Health Care Task Force, Dr. Emanuel is the author of many articles on medical ethics, focusing particularly on decision-making in terminal care.

Ms. Laurie M. Flynn of Virginia, is the Executive Director of the National Alliance for the Mentally Ill. A consultant to child welfare organizations, federal, state, and county governments, Ms. Flynn is also the author of numerous publications on family mental health services.

Mr. Steven H. Holtzman of Massachusetts, is Chief Business Officer of Millennium Pharmaceuticals, Inc, a company using genetics, genomics and bioinformatics to identify genes responsible for common major diseases and in their work on human biology directed toward drug development. Mr. Holtzman also chairs the Ethics Panel of the Biotechnology Industry Organization.

Ms. Diane Scott-Jones, Ph.D., of Pennsylvania, is Associate Professor in the Department of Psychology at Temple University. Dr. Scott-Jones is a Fellow of the American Psychological Association, and co-author of the Association's ethics guidelines. She is also a member and past chair of the Ethics Committee of the Society for Research in Child Development. Her research involves the role of family in supporting children's scholastic achievement.

Dr. Bernard Lo, M.D., of California, is a Professor of Medicine and Director of the Program in Medical Ethics at the University of California, San Francisco, where he teaches a required course on medical ethics, law and economics. Dr. Lo has served as a member of a number of public advisory committees including an Office of Technology Assessment (OTA) project on Life Sustaining Technologies in the Elderly.

Dr. Lawrence H. Miike, M.D., J.D., of Hawaii is the Director of the Department of Health for the state of Hawaii, which includes the Nation's 3rd largest public hospital system. Previously, Dr. Miike worked for the U.S. Congress. His studies led to the National Childhood Vaccine Injury Compensation Act, AIDS policies, and action of on health care for American Indians and Alaskan Natives.

Mr. Thomas H. Murray, Ph.D., of Ohio, is Professor of Biomedical Ethics and Director of the Center for Biomedical Ethics at the Case Western Reserve University School of Medicine. Dr. Murray's research focuses on ethics in medicine and science, including ethical aspects of health policy, the care of newborns and children, occupational health, and genetic engineering.

From the Desk of

JONATHAN FOSTER

July 20, 1996

To: Elizabeth Drye
Diane Regas

Elizabeth, Diane -

Attached you will find copies of (1) the NBAC press release that finally went out at 7:30 last night (Friday night), (2) the NBAC charter, (3) the Q&As we are using internally (a shorter set went to the NBAC appointees), and (4) the article on NBAC that ran in this morning's Washington Post.

Jon

Attachments

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

July 19, 1996

**PRESIDENT CLINTON NAMES MEMBERS TO THE
NATIONAL BIOETHICS ADVISORY COMMISSION**

President Clinton today announced his intention to appoint the Chairman and members of the National Bioethics Advisory Commission. Established by Presidential Executive Order on October 3, 1995, the National Bioethics Advisory Commission (NBAC) will provide guidance to federal agencies on the ethical conduct of current and future human biological and behavioral research. The Commission members' expertise includes the fields of philosophy and theology, law and medicine, biology, and other social and behavioral sciences. The President also included community representatives to ensure a well-rounded Commission.

The President is announcing the appointment of the following individuals:

Dr. Harold T. Shapiro of Princeton, New Jersey, is President of Princeton University and a Professor of Economics and Public Affairs. Dr. Shapiro has been selected to chair the Commission. He is a past member of the President's Council of Advisors on Science and Technology.

Patricia Backlar of Portland, Oregon, is a Senior Scholar at the Center for Ethics in Health Care at Oregon Health Sciences University where she specializes in issues concerning individuals with severe and persistent mental disorders. She is also a senior research associate in the Department of Philosophy at Portland State University. Ms. Backlar is also the Editor of the Ethics Section for the Community Mental Health Journal.

Arturo Brito, M.D., of North Miami, Florida, is Assistant Professor of Clinical Pediatrics at the University of Miami School of Medicine. Dr. Brito is also the Medical Director of the Pediatric Mobile Clinic of the University of Miami.

Alexander M. Capron of Santa Monica, California, is University Professor of Law and Medicine at the University of Southern California, where he is also co-director of the Pacific Center for Health Policy and Ethics. Dr. Capron specializes in legal-medical issues and biomedical ethics.

-more-

Eric J. Cassell, M.D., of New York is Clinical Professor of Public Health at Cornell Medical College and Attending Physician at the New York Hospital. Dr. Cassell is a Fellow and Member of the Board of Directors for the Hastings Center and has written extensively about ethical issues for more than 20 years.

R. Alta Charo of Madison, Wisconsin, holds joint associate professorships in the University of Wisconsin Medical and Law Schools. Ms. Charo has held government appointments in the Office of Technology Assessment and the U.S. Agency for International Development.

James Childress of Charlottesville, Virginia, is the Edwin B. Kyle Professor of Religious Studies and Professor of Medical Education at the University of Virginia where he is also the Co-Director of the Virginia Health Policy Research Center. Dr. Childress has previously served as Vice-Chairman of the National Task Force on Organ Transplantation.

David Cox, M.D., of Belmont, California, is a Professor of Genetics and Pediatrics at the Stanford University School of Medicine. Dr. Cox is a world-renowned expert on genetic defects associated with Chromosome 21, including Down Syndrome.

Ezekiel J. Emanuel, M.D., Ph.D., of Brookline, Massachusetts, is Associate Professor of Medicine and Social Medicine at the Dana-Farber Cancer Institute of Harvard Medical School. A member of the Ethics Group in the 1994 President's Health Care Task Force, Dr. Emanuel is the author of many articles on medical ethics, focusing particularly on decision-making in terminal care, the physician-patient relationship and managed care.

Laurie M. Flynn of Alexandria, Virginia, is the Executive Director of the National Alliance for the Mentally Ill. Ms. Flynn is the author of numerous publications on family mental health services and has been a consultant to child welfare and family support organizations at the federal, state and county government levels.

Steven H. Holtzman of Sudbury, Massachusetts, is Chief Business Officer of Millennium Pharmaceuticals, Inc., a company which uses genetics in identifying genes responsible for common major diseases. Mr. Holtzman is the co-chair of the Biotechnology Industry Organization's (BIO) Bioethics Committee.

Bernard Lo, M.D., of Berkeley, California, is Professor of Medicine and Director of the Program in Medical Ethics at the University of California, San Francisco. His research focuses on decisions regarding life-sustaining interventions, ethical issues regarding HIV infection, and the doctor-patient relationship in managed care.

Lawrence H. Miike, M.D., of Kaneohe, Hawaii, is the Director of the Department of Health, in the State of Hawaii. A former Senior Associate with the Congressional Office of Technology Assessment, Dr. Miike's studies led to the National Childhood Vaccine Injury Compensation Act, helped shape federal policy on AIDS, and on health care for American Indians and Alaska Natives.

Thomas H. Murray, Ph.D., of Shaker Heights, Ohio, is Professor of Biomedical Ethics and Director of the Center for Biomedical Ethics at the Case Western Reserve University School of Medicine. Dr. Murray's research focuses on ethics in medicine and science, including ethical aspects of health policy, the care of newborns and children, occupational health, and genetics.

Diane Scott-Jones, Ph.D., of Gwynedd Valley, Pennsylvania, is Professor of Psychology at Temple University. Dr. Scott-Jones is a member and past Chair of the Ethics Committee of the Society for Research in Child Development. She is also a member of the American Psychological Association/American Psychological Society Joint Task Force to Revise the Ethical Principles for Psychological Research. Her research involves the family's influence on children's development.

The Commission is expected to hold its first meeting in late summer or early fall. As a first priority, the Commission will focus on protection of the rights and welfare of human research subjects and issues in the management and use of genetic information. In setting the remainder of NBAC's agenda, the Commission will be guided by the following criteria: the public health or public policy urgency of the issue, the relation of the issue to the goals of Federal investment in science and technology, the relative capacity of the Commission as compared to other entities to deliberate on an issue, and the extent of interest in the issue across the government. The Commission may also address issues suggested by Congress and members of the public.

NATIONAL BIOETHICS ADVISORY COMMISSION CHARTER

Purpose

The National Bioethics Advisory Commission will provide advice and make recommendations to the National Science and Technology Council, 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. 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 (41 C.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, 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 genetic 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: (i) 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 shall be appointed for overlapping four-year terms. Initially, members will be appointed for two-, three- or four-year terms. Terms of more than two years are contingent upon renewal of the National Bioethics Advisory Commission by appropriate action prior to its termination. 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, and 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 10 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 diem 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 \$500,000.

Reports

Reports by the National Bioethics Advisory Commission on specific issues shall be submitted to the National Science and Technology Council, 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 promulgated in the Federal Register. 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, (i) 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 appropriate action prior to its expiration, this National Bioethics Advisory Commission will terminate two years from the date of the first meeting.

Approved:


John H. Gibbons
Assistant to the President for
Science and Technology

July 18, 1996
Date

National Bioethics Advisory Commission

This document has been prepared by the Office of Science and Technology Policy for internal use only.

Q. What issues will NBAC examine?

A. As stated in Executive Order 12975, NBAC shall direct its attention to consideration of the protection of the rights and welfare of human research subjects and issues related to the use and management of genetic information including but not limited to human gene patenting. Within the four criteria listed below, members of NBAC will use their discretion in deciding what additional issues might be on their agenda.

NBAC will 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 body able to deliberate fruitfully on the bioethical issue.
4. The extent of interest in the issue within the Federal Government.

Q. Will NBAC look at [any given specific issue]?

A. Within the parameters of its overall charge from the President, NBAC will determine which specific issues it addresses.

Q. Will NBAC address issues related to human radiation experiments?

A. NBAC will provide advice and recommendations to Executive Branch agencies regarding the ethical conduct of ongoing or future research. It is intended to be a forward-thinking effort that will enable us to deal effectively with issues presented by the advent of and access to new knowledge and technology. It will consider past experimental activities, including the human radiation experiments, as valuable experience from which to learn in developing their guidance.

Q. What is the Administration's response to the Advisory Committee on Human Radiation Experiments's (ACHRE) recommendations?

A. The Administration has taken a number of actions to respond to ACHRE. This Fall, the Administration plans to issue a consolidated outline of completed and future actions.

Q. How was NBAC's membership selected?

A. The Commission's members were drawn from the following disciplines: philosophy/theology, social and behavioral sciences, law, medicine and the allied health professions, and biological research. Several members will be drawn from the general public. The membership shall be approximately evenly balanced between scientists and non-scientists.

Q. Is there a mechanism for public participation in NBAC?

A. In addition to several public members of the Commission, individual citizens can bring issues, views or information to the attention of the Commission—directly or through representatives or advocates; by letter or by testimony.

Q. Why is the Administration creating NBAC?

A. The President is filling a void that has existed since the last such Commission went out of business in 1983. That is, a national body to deliberate in public on the most sensitive, ethical dimensions of biomedical, behavioral and clinical research. We are determined to see that our ethics are as good as our science.

Science and technology are advancing at an unprecedented rate and presenting new challenges that were unimaginable even a few years ago. NBAC provides a forum for ongoing public debate on complex ethical issues to ensure that fundamental societal values continue to be integrated into Federal research and development.

Q. Who is running NBAC?

A. Dr. Harold Shapiro, president of Princeton University, has been appointed to chair the Commission. Management and support functions will be provided by the Department of Health and Human Services. NBAC will report to the President.

Q. Will NBAC members be paid?

A. No. However, they will have their expenses (travel and per diem) reimbursed.

Q. Will NBAC have a paid staff?

A. HHS will assemble a small staff, including an Executive Director, that will provide full-time support to NBAC.

Q. What will NBAC cost?

A. The Department of Health and Human Services will provide NBAC with \$500,000 to carry out its functions.

Q. How is NBAC funded?

A. As the agency that conducts and supports the lion's share of human subject research within the Federal government, the Department of Health and Human Services will provide core support for the Commission.

Q. Where will HHS get the money for NBAC? Will it discontinue other programs in order to fund NBAC?

A. NBAC funding represents a very small portion of HHS's overall budget and will be drawn from HHS funds. No programs will need to be discontinued.

Q. If NBAC's budget is controlled by HHS, what ensures that it will have sufficient autonomy to provide an unbiased assessment of issues?

A. HHS has committed funds to NBAC, regardless of the issues the Commission chooses to address or the outcome of their deliberations.

Q. Why did it take the President so long to appoint Commissioners?

A. In response to our Federal Register notice of August 12, 1994, over 170 nominations were received from the public, members of Congress, professional societies and Federal agencies. Painstaking work went into the identification and recruitment of respected individuals who had the time available to make a serious commitment through 2 to 4 years.

Q. What will determine NBAC's tenure?

A. As is routine with Federal Advisory Committees, NBAC's charter has been written for two years from the date of the first meeting, with the option for renewal.

Q. Will NBAC dictate ethics to the Nation?

A. No. NBAC will gather and examine the multitude of viewpoints held across society and offer guidance to Executive Branch agencies on how to proceed in accord with, and with respect for, the prevailing ethical viewpoints.

Q. Will NBAC affect the way the FDA regulates private sector human subject research?

A. While NBAC recommendations are non-binding on the agencies, they certainly may be utilized by individual agencies in the process of reviewing and reforming their own programs and administration. Of course, the President may choose to issue guidance to the agencies based on NBAC recommendations.

Q. Will NBAC regulate research on a project-by-project basis?

A. No. NBAC has been tasked to develop broad, overarching principles to ensure that government-sponsored research on human biology and behavior is conducted according to the highest ethical standards. It will review individual projects only as examples of particular issues.

Q. What will be NBAC's final product?

A. NBAC will set its own agenda and, in doing so, will decide the manner in which their findings are most effectively presented.

Q. If NBAC's recommendations are non-binding, what ensures that this effort won't produce simply another report to be shelved away, and represent yet another waste of taxpayer money?

A. The complex ethical issues raised by the application of science and technology do not lend themselves to easy answers; nor do they demand or warrant command and control solutions. All of the Federal agencies involved in human subject research have strongly supported NBAC's creation and welcome its input as they continue to grapple with difficult questions. We expect that NBAC's recommendations ultimately will be reflected in agency program guidelines, research protocols, and corresponding legislation.

Clinton Names 15 to Advisory Panel on Ethics in Human Experimentation

By Rick Weiss

Washington Post Staff Writer

President Clinton yesterday appointed the first members of a newly formed National Bioethics Advisory Commission, whose mission will be to consider ethical issues arising from experiments on human biology and behavior.

The 15-member commission, which includes specialists in the biological and social sciences, medicine, law, theology and philosophy, as well as community representatives, will be chaired by Princeton University President Harold T. Shapiro.

Shapiro is a professor of economics and public policy and a past member of the President's Council of Advisers on Science and Technology.

The commission's immediate charge will be to consider how best to protect the rights and welfare of human research subjects, with spe-

cial emphasis on the proper use and management of people's genetic information. As part of that work, the commission is to consider the scientific, legal and ethical implications of patenting human genes.

More generally, the commission's charter calls for the group to advise the National Science and Technology Council, part of the White House, on matters of its choosing related to biomedical ethics.

In recent years, scientists and others have called for a national discussion of such topics as research on human embryos and assisted suicide.

"We are committed to supporting world-class research," said Jack Gibbons, director of the White House Office of Science and Technology Policy. "But we want to make sure that our ethics are as good as our science."

The commission, which Clinton created by executive order, is the latest incarnation of sev-

eral such panels appointed over the past 22 years, which have varied considerably in their effectiveness.

The most recent, a 14-member Biomedical Ethics Advisory Committee, was created by Congress in 1985.

It expired four years later without accomplishing even its first piece of business because of endless bickering over the issue of abortion rights.

By contrast, the first national bioethics panel was successful. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created by Congress in 1974 to draw up rules to protect patients who participated in clinical trials.

Within 10 months it issued its first report—a collection of recommendations governing the use of human fetuses in research. Two months later those suggestions were codified as federal regulations.

In the remaining three years before that commission's charter expired, its members created widely respected regulations relating to the protection of prisoners and children in medical research.

In 1978, Congress created the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

That group's definition of brain death became the national standard. It also laid much of the ethical and legal groundwork relating to the acceptability of forgoing life-sustaining treatment.

Like previous such panels, the new National Bioethics Advisory Commission is not empowered to review or approve specific research projects, but is meant to focus on broad principles that affect the ethical conduct of research. It will be able to conduct inquiries, hold hear-

ings and establish subcommittees.

Besides Shapiro, the members are:

Patricia Backlar, senior scholar at the Center for Ethics in Health Care at Oregon Health Sciences University in Portland;
 Arturo Brito, assistant professor of clinical pediatrics at the University of Miami School of Medicine;
 Alexander M. Capron, a professor of law and medicine and co-director of the Pacific Center for Health Policy and Ethics at the University of Southern California;
 Eric J. Cassell, a professor of public health at Cornell Medical College and board member of the Hastings Center, a bioethics think tank;
 R. Alto Charo, who holds joint professorships in law and medicine at the University of Wisconsin, Madison;
 James Childress, professor of religious studies and medical education at the University of Virginia and co-director of the Virginia Health Policy Research Center;
 David Cox, professor of genetics and pediatrics at Stanford University School of Medicine;
 Ezekiel J. Emanuel, associate professor of medicine and social medicine at the Harvard Medical School's Dana-Farber Cancer Institute;
 Laurie M. Flynn, executive director of the National Alliance for the Mentally Ill in Alexandria;
 Steven H. Holtzman, chief business officer at Millenium Pharmaceuticals Inc., a gene research company in Cambridge, Mass., and co-chair of the Biotechnology Industry Organization's bioethics committee;
 Bernard Lo, director of the program in medical ethics at the University of California, San Francisco;
 Lawrence H. Muike, director of Hawaii's state department of health;
 Thomas H. Murray, director of the Center for Biomedical Ethics at the Case Western Reserve University School of Medicine;
 Diane Scott-Jones, professor of psychology at Temple University.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, DC 20500

June 11, 1996

MEMORANDUM FOR DISTRIBUTION

FROM: SAM SEIDEL *SS*

SUBJECT: NBAC

Please find attached information on NBAC provided by Rachel Levinson of OSTP. Please contact her with any questions you may have.

Distribution:

Phil Caplan

✓ Elizabeth Drye

Jonathan Foster

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

May 22, 1996

NOTE TO LIZ MONTOKA

FROM: RACHEL E. LEVINSON *REL*

SUBJECT: NATIONAL BIOETHICS ADVISORY COMMISSION - Radiation
Community Representation

Based on your conversation earlier today, Ernie Moniz asked me to provide you with additional information regarding the National Bioethics Advisory Commission (NBAC); specifically, a request for representation of "radiation survivors and victims of government-sponsored radiation experiments."

The attached letter from the Task Force on Radiation and Human Rights describes their desire to be represented on NBAC, and their belief that the Federal Advisory Committee Act requires such inclusion. The Task Force is unhappy with the outcome of the deliberations of the Advisory Committee on Human Radiation Experiments (ACHRE) and believes that the results would have been more satisfactory if their membership had been represented on the Advisory Committee. They cite FACA language requiring that members be chosen from "a cross-section of those most directly affected" by NBAC. In fact, NBAC has a much broader mandate than radiation experiments. The agencies that proposed establishment of NBAC view it as a forward-thinking body deliberating on the ethical conduct of current and future research on human biology and behavior. OSTP is concerned about an overemphasis on past experiments. The Interagency Working Group on Human Radiation Experiments expects that resolution of compensation issues (which may not be completed before NBAC is appointed) will deflect much of the interest in NBAC. However, the Working Group has recommended that NBAC take up broader consideration of compensation for research subjects, which would create a financial conflict of interest for members of NBAC who had been or are subjects of government-sponsored research.

After a February meeting of radiation stakeholders, the possibility of nominating an individual from this community was discussed with Jack Gibbons. As with ACHRE, it was decided that no stakeholders or representatives of a single group or viewpoint would be considered for nomination.

Please let me know if I may provide further information on this or other matters related to NBAC.

Attachment

cc: Jack Gibbons
Ernie Moniz



Task Force on Radiation and Human Rights

Washington D.C. Office:
National Committee for Radiation Survivors
6935 Laurel Avenue, Takoma Park, MD 20912
Tel: (202) 775-8786 Fax: (301) 891-3992

May 20, 1996

-- Via Facsimile and First Class Post --

Dr. John Gibbons, Director
Office of Science and Technology Policy
Old Executive Office Building, #424
Washington, D.C. 20500

RE: the National Bioethics Advisory Commission

Dear Dr. Gibbons,

We are writing on behalf of thirty groups representing radiation survivors and the victims of government-sponsored radiation experiments. Many of these organizations' members were first identified as potential experiment subjects in 1994, when the Advisory Committee on Human Radiation Experiments ("ACHRE"), appointed by President Clinton, began its investigation. Upon announcement of those selected by the President to serve on ACHRE, the Task Force on Radiation and Human Rights ("Task Force") strongly raised the concern, with both the White House and the Department of Energy, that the membership makeup of the Advisory Committee violated the letter and the spirit of the Federal Advisory Committee Act ("FACA") -- because those most directly affected were not selected to serve on ACHRE. True, there was one lay person "citizen's representative" selected, Lois Norris, qualified on the grounds that she had served on an Internal Review Board at a university hospital. However, Ms. Norris refused to identify herself as a representative of those most affected by ACHRE's work, even after DOE identified her to us as such.

Notwithstanding one continuing vacancy on the President's Advisory Committee, no one representing the interests and concerns of the experiment victims was added to fill that vacancy. When pressed as to why not, the Task Force was told or otherwise led to believe by members and staff of ACHRE, by representatives of DOE, and by other government officials, that the radiation survivors' time would come because the experiment victims and/or their family members would be considered for membership on the National Bioethics Advisory Committee ("NBAC") to be formed upon completion of the Advisory Committee's investigation.

• Alliance of Atomic Veterans • American Environmental Health Studies Project • Atomic Reclamation & Conversion Project • Center for Atomic Radiation Studies • Cincinnati Families of Radiation Victims Organization • Citizens Call • Citizen Soldier • Colorado Atomic-Agent Orange Veterans Coalition • Committee of Atomic Bomb Survivors in the USA • Concerned Relatives of Cancer Study Patients • Fernald School "Science Club" • Hanford Downwinder Health Concerns • Hiroshima/Nagasaki Peace Committee • Indigent Transients & Survivors of Oak Ridge • Laguna-Acoma Coalition for a Safe Environment • National Association of Atomic Veterans • National Association of Radiation Survivors • National Committee for Radiation Victims • Native Alaskans of Point Hope • Navajo Uranium Radiation Victims Committee • Oak Ridge Health Liaison • Oregon State Prison Experiment Victims • Portsmouth-Piketon Residents for Environmental Safety & Security • Rochester Radiation Victims/Survivors Association • Survivors of Medical Radiation Experiments • Trinity Post 7-45 • Vanderbilt Irradiated Victims Organization •

Dr. John Gibbons

RE: National Bioethics Advisory Commission

On October 3rd of last year, President Clinton, in receiving the report of the Advisory Committee, announced the formation of NBAC. He noted that, among other things NBAC would be tasked with overseeing the government's implementation of the Advisory Committee's recommendations. Thus, with a continued stake in the process, we looked forward to the opportunity of submitting representatives of our groups for NBAC consideration. We also felt that those most directly affected by historic government-sponsored human experiments would be an ideal "moral compass" for NBAC when it began to discuss how to prevent ethical wrongs identified by ACHRE from ever happening again.

Unfortunately, upon contacting your office shortly after the President's announcement, we learned that membership on NBAC had already been under consideration for some time. Indeed, it was not long thereafter that the nomination process for NBAC membership was closed. We subsequently learned that three community representatives had been nominated to the fifteen-member panel, but that none of those under consideration were from the radiation survivors/radiation experiment victims community.

That we had been excluded from NBAC was protested to the Interagency Working Group on Human Radiation Experiments throughout the fall and winter. In February of this year, we raised our exclusion before an IAWG workshop. At that time, we were encouraged by both DOE, DOD, and the White House representative to request a meeting with the White House to discuss, among other matters relating to follow-up, Task Force nominations to NBAC -- that it wasn't too late. We immediately requested a meeting with the White House where at our concerns could be raised. However, because the meeting with the White House has not yet been granted, and because we now understand that plans are moving forward to finalize NBAC membership without Task Force representation, we are taking the initiative at this time in seeking to correct what otherwise will become an on-going problem of fair representation on NBAC.

We believe it is imperative under the mandate of FACA, 5 U.S.C. Appendix 2, that NBAC be diverse in all points of view it purports to represent. An advisory committee, including one that advises the President, must be created pursuant to a plan to "attain fairly balanced membership. The plan will insure that, in the selection of members for the committee, the agency will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the committee." 41 CFR 101-6.1007 (iii), GSA implementing regulations for P.L. 92-463; 86 Stat. 770, Sec. 5 (b) (2), effective 10/72. In order to fulfill this requirement, NBAC needs representation from the group of experiment victims whose tragic situations justified its formation and their chosen advocates. Certainly there can be no doubt but that the government-sponsored human radiation

Dr. John Gibbons

RE: National Bioethics Advisory Commission

experiments of the Cold War years and their attendant and dramatic national and international publicity gave credibility to the formation of NBAC.

As you are well aware, while there is no mandate that certain individuals be selected, there is a legal requirement that the members be chosen from a "cross-section of those most directly affected" by NBAC -- unless a purely technical committee is envisioned (which is clearly not the case with NBAC). Thus, the Task Force submits the following names to be drawn from, for inclusion (one or more) as additional appointees to NBAC:

Ms. Sandra Reid, a public health nurse from Oak Ridge, TN;
Gwendon Plair, Ph.D., a family member of a Cincinnati, OH, radiation experiment;
Dennis Nelson, Ph.D., a Utah downwinder;
Leonard Schroeter, Esq., a renowned Seattle public interest and human rights attorney;
Tod Ensign, Esq., long-time advocate for the rights of veterans and military personnel;
Lincoln Grahls, Ph.D., an atomic veteran from St. Louis;
Mr. Manuel Pino, a member of the Laguna-Acoma Pueblo Indians;
Ms. Darcy Solarz-Thrall, a Hanford downwinder.

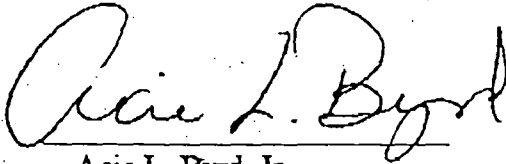
These nominees were selected by acclamation from our thirty member groups.
Resumes will be provided at your request.

Please understand that we have deep and sincere appreciation for the process that has been undertaken by the White House and Interagency Working Group to rectify and remedy the tragedy created by Cold War human radiation experiments, which obviously includes formation of NBAC. However, that process needs to be more than appreciated, it needs to be credible - to all parties concerned and particularly to those the process is designed to benefit. The radiation survivors and experiment victims have, in the past, voiced serious reservations about the credibility of the process that led to the formation of the Advisory Committee on Human Radiation Experiments and, subsequently, to the Advisory Committee investigation and final report. Much of this criticism could, quite frankly, have been avoided had they not been excluded from meaningful involvement. NBAC is far too important to suffer a similar fate. It deserves the credibility that can and will result by inclusion, even at this later hour, of members representing certainly one of the most egregious chapters in the history of human research.

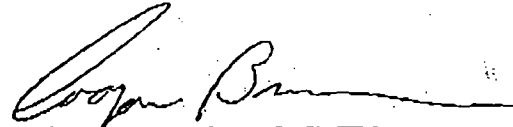
Dr. John Gibbons
RE: National Bioethics Advisory Commission

On behalf of the Task Force Executive Committee, we are

Sincerely yours,



Acie L. Byrd, Jr.



E. Cooper Brown

cc. The Honorable Hazel O'Leary, Secretary of Energy
The Honorable Donna Shalala, Secretary of Health & Human Services
Mr. Phil Kaplan, Office of the President
Deputy Ass't Attorney General Eva Plaza
Senator Ted Stevens
Senator John Glenn

Talking Points Regarding Appointment of Stakeholders to NBAC

On August 12, 1994, OSTP published a draft charter and request for candidates to be considered for appointment to NBAC.

NBAC was established by the President to provide guidance to all Federal agencies on the ethical conduct of human biological, behavioral and clinical research, and the applications of that research.

One initial charge to NBAC is to develop advice on how to ensure that current and future government-sponsored research adequately protects the rights and welfare of human subject participants.

Although NBAC was established to address the broad scope of all human subject research, it has become associated with human radiation experimentation through Executive Order 12975, which established NBAC and directed Federal agencies funding and conducting human subject research to undertake a review of their human subject protections and report the results to NBAC.

As part of this process, the research agencies have asked that NBAC take up certain issues identified by the Advisory Committee on Human Radiation Experiments. Included among these issues is the question of compensation of subjects injured in the course of government-sponsored research.

As a consequence of this responsibility, deliberations of NBAC may result in recommendations bearing on compensation for injured research subjects, including radiation experiment subjects. Therefore, individuals who have a vested financial interest in seeing that this issue is addressed and resolved in their favor and no stakeholders; people who are known to have a conflict of interest concerning issues likely to be taken up by NBAC, have been selected as candidates for membership.

However, gathering input from a wide variety of sources, including those who have past and current experience concerning the ethical dimensions of human biological, behavioral and clinical research will be a central focus in all phases of NBAC's deliberations.

More importantly, as dictated by its charter, NBAC membership will be approximately (in fact, exactly, as currently proposed) evenly balanced between scientists and non-scientists. Three of its members will be lay people as community representatives.

Every effort will be made to make the public aware of and be included in NBAC meetings. Suggestions on how to make this an effective, inclusive process are welcome.

Separate note to Phil: An argument may be made the FACA requires affected parties to be represented on an advisory committee. I don't know if such a case would stand up but I would make two comments in this regard:

1) The affected group is really our whole population because we are all potential research subjects. NBAC is intended to be forward-thinking; to guide the way for design of future research protocols. Therefore, it appropriate and necessary to include as members people who truly convey the public attitude, cultural and moral values. Ethics is not static but more a dynamic, moving entity. NBAC will need to build into its recommendations allowance for changes in public values over time. Past research subjects have a small role to play in the formulation of such advice, but not a unique role.

2) Fairness - If a decision was made to include a past subject, and a radiation subject was selected, I believe that other groups, including all those patients who were helped and not injured, would have a compelling argument that they deserve representation also. It would be unjust to raise one group's interest over another.

Presidential Documents

Title 3—

Executive Order 12975 of October 3, 1995

The President

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 Clinton

THE WHITE HOUSE,
October 3, 1995.

[FR Doc. 95-24921

Filed 10-3-95; 2:11 pm]

Billing code 3195-01-P

5-29-96

DRAFT

NATIONAL BIOETHICS ADVISORY COMMISSION REVISED CHARTER

Purpose

The National Bioethics Advisory Commission will provide advice and make recommendations to the National Science and Technology Council, 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

42 U.S.C. 6617(a)(2). 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 (41 C.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, Federal agencies, and other appropriate entities, and also make their advice and recommendations available to the public. 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 genetic 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 fruitfully deliberate 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 15 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 of concern to the participating departments and agencies. At least one member shall be selected from each of the following categories of primary expertise: (i) 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 shall be appointed for overlapping four-year terms. Initially, members will be appointed for two-, three- or four-year terms. Terms of more than two years are contingent upon renewal of the National Bioethics Advisory Commission by appropriate action prior to its termination. 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 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, and 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 10 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 diem 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 \$500,000.

Reports

Reports by the National Bioethics Advisory Commission on specific issues shall be submitted to the National Science and Technology Council, 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 promulgated in the Federal Register. 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.

National Bioethics Advisory Commission

Potential questions upon release of membership

Q. Will NBAC look at issues X, Y and Z?

A. One way to answer is to restate the two priorities (i.e., human subject protections and management of genetic information) and say that, "Of course, the Commissioners will use their discretion in deciding what additional issues might be on their agenda."

Q. re: human radiation experiments:

A. "The Commissioners will want to carefully review the findings and recommendations of the White House Advisory Committee on Human Radiation Experiments with an eye towards the most actionable items."

Q. Composition of the membership:

A. "As stated in Executive Order 12975, the Commissioners have been chosen so that there is excellent balance between scientists and nonscientists. Most important is that any individual citizen can bring an issue, views or information the attention of the Commissioners---directly or through representatives or advocates; by letter or by testimony. This is as public a body as one can possibly devise.

Q. Why NBAC? Why now?

A. "The President is filling a void that has existed since the last such Commission went out of business in 1983. That is, a national body to deliberate in public on the most sensitive, ethical dimensions of biomedical and behavioral research. We are determined to see that our ethics are as good as our science."

Q. Who is running NBAC?

A. "The President has assigned management and support functions to the Secretary of Health and Human Services. The NBAC Chair and Commissioners report directly to the President in his role as Chairman of the National Science and Technology Council."

Q. Who is paying for support of NBAC?

A. "As the agency that conducts and supports the lion's share of human subject research within the Federal government, the Department of Health and Human Services will provide core support for the Commission, but other agencies may call upon NBAC for guidance on issues that cut across agency boundaries."

Q. Why did it take the President so long to appoint Commissioners?

A. "In response to our Federal Register notice of August 12, 1994, over 170 nominations were received from the public, members of Congress, professional societies and Federal agencies. Painstaking work went into the identification and recruitment of thought-leaders who had the time available to make a serious commitment through 2 to 4 years."

Q. Will NBAC to dictate ethics to the Nation?

A. No. The Commissioners will be charged to gather and examine the multitude of viewpoints held across our pluralistic society and offer guidance to researchers on how to proceed in accord with, and with respect for, the prevailing viewpoints. And, to point out where it may be most appropriate to defer research until some later time."

Q. Will NBAC regulate research on a project-by-project basis?

A. "No. NBAC has been tasked to develop broad, overarching principles to ensure that government-sponsored research on human biology and behavior is conducted according to the highest ethical standards. It will review individual projects only as examples of particular issues."

Talking Points Regarding Appointment of Stakeholders to NBAC

On August 12, 1994, OSTP published a draft charter and request for candidates to be considered for appointment to NBAC.

NBAC was established by the President to provide guidance to all Federal agencies on the ethical conduct of human biological, behavioral and clinical research, and the applications of that research.

One initial charge to NBAC is to develop advice on how to ensure that current and future government-sponsored research adequately protects the rights and welfare of human subject participants.

Although NBAC was established to address the broad scope of all human subject research, it has become associated with human radiation experimentation through Executive Order 12975, which established NBAC and directed Federal agencies funding and conducting human subject research to undertake a review of their human subject protections and report the results to NBAC.

As part of this process, the research agencies have asked that NBAC take up certain issues identified by the Advisory Committee on Human Radiation Experiments. Included among these issues is the question of compensation of subjects injured in the course of government-sponsored research.

As a consequence of this responsibility, deliberations of NBAC may result in recommendations bearing on compensation for injured research subjects, including radiation experiment subjects. Therefore, individuals who have a vested financial interest in seeing that this issue is addressed and resolved in their favor and no stakeholders; people who are known to have a conflict of interest concerning issues likely to be taken up by NBAC, have been selected as candidates for membership.

However, gathering input from a wide variety of sources, including those who have past and current experience concerning the ethical dimensions of human biological, behavioral and clinical research will be a central focus in all phases of NBAC's deliberations.

More importantly, as dictated by its charter, NBAC membership will be approximately (in fact, exactly, as currently proposed) evenly balanced between scientists and non-scientists. Three of its members will be lay people as community representatives.

Every effort will be made to make the public aware of and be included in NBAC meetings. Suggestions on how to make this an effective, inclusive process are welcome.

Separate note to Phil: An argument may be made the FACA requires affected parties to be represented on an advisory committee. I don't know if such a case would stand up but I would make two comments in this regard:

1) The affected group is really our whole population because we are all potential research subjects. NBAC is intended to be forward-thinking; to guide the way for design of future research protocols. Therefore, it appropriate and necessary to include as members people who truly convey the public attitude, cultural and moral values. Ethics is not static but more a dynamic, moving entity. NBAC will need to build into its recommendations allowance for changes in public values over time. Past research subjects have a small role to play in the formulation of such advice, but not a unique role.

2) Fairness - If a decision was made to include a past subject, and a radiation subject was selected, I believe that other groups, including all those patients who were helped and not injured, would have a compelling argument that they deserve representation also. It would be unjust to raise one group's interest over another.

Genetic data will be closely guarded, but Kaiser hopes to make the registry a resource for future genetic research studies and will compete for NIH grants.

BIOETHICS COMMISSIONS MUST HAVE INDEPENDENT STAFFS, BUDGETS AND AGENDAS, BU'S ANNAS SAYS

Successful bioethics commissions have independent staffs, budgets, and a strong mandate, George Annas, Boston University School of Medicine and Public Health said at a May 9-10 Public Responsibility in Medicine and Research conference in Boston.

In a luncheon address, Annas said that only a few "bioethics groups have been successful over the last 25 years," including the 1979 National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research and the President's Advisory Commission on Human Radiation Experiments in 1995.

"All of those had in common a separate budget, a very specific mandate and the ability to hire their own staff and set their own agenda," Annas said.

He predicted the success of the proposed National Bioethics Advisory Commission (NBAC) would hinge on these factors:

"You will know the day that President Clinton announces [the commission] whether it will be successful or not based on whether it has its own budget, has its own staff, and whether it is independent of existing federal agencies," Annas said.

Annas added: "If it is stuck in NIH or the White House Office of Science and Technology [Policy], and if it is staffed by people who are already on existing staffs, you can expect nothing from the group."

The president has proposed the \$2 mil. commission be located within the NIH Office of Protection from Research Risks, with OPRR to provide most of the management and support.

NBAC is first charged with examining federal human subject protection guidelines and the management and use of genetic information ("The Blue Sheet" Oct. 4, 1995, p. 2). How much independence the commission will have remains to be seen. The roster of commission members is expected to be named shortly.

Annas charged that a lack of autonomy led to the current turmoil in the Ethical, Legal and Social Implications (ELSI) Working Group. The group is jointly sponsored by the National Center for Human Genome Research and the Department of Energy. Lori Andrews, Chicago-Kent School of Law, resigned recently as the group's chair, citing concerns about autonomy.

Andrews is "the first chairman of a government ethics committee in the last 25 years ever to resign," the Boston University official said. "That is a watershed event."

"Either there is something strange about her, which I doubt, or ELSI was not an exception, ELSI was the rule — that government committees get captured and government committees can't be independent," Annas maintained. "They have to do whatever their [sponsors] want them to do."

Restructuring Working Group "A Waste Of Time"

An 11-member committee of academics is beginning a review of the structure and function of the working group ("The Blue Sheet" May 8, p. 3). Troy Duster, University of California at Berkeley, is serving as the working group's acting chair. The selection of a new chair will likely wait until completion of the ELSI review.

Annas declared, however: "It is a waste of time to try to make the ELSI Working Group independent."

"Ethics cannot be independent, because people will not put up with an independent ethics group...because it undermines them," he said.

"You have to toe the party line or you become irrelevant in terms of ethics," Annas said. "Ethics is taken seriously by scientists and physicians only when it fosters their agenda."

Expecting the ELSI Working Group or other ethics groups to be simultaneously independent and authoritative springs from a misconception of the role of ethics in America, Annas said.

"Economics will trump ethics and maybe even law every time," Annas said. "Ethicists and geneticists have consistently underestimated the power of the American market."

He said that Joseph Schulman, who is offering genetic testing at Genetics and IVF Institute, Fairfax, Va., "represents American entrepreneurship in medicine."

Schulman "is the norm. The norm is not NIH-funded research. The norm is entrepreneurship in medicine, and applied to genetics — he's it," Annas said.

Karen Rothenberg, NIH Office of Research on Women's Health, asked the Boston University ethicist: "If you had an independent commission and you in your ideal world could choose who would be sitting on it in a multicultural society...who would you put on it and how would you determine who gets nominated and the approval process?"

NATIONAL BIOETHICS ADVISORY COMMISSION FACT SHEET

The Office of Science and Technology Policy (OSTP), in consultation with members of the National Science and Technology Council and interested members of Congress, has developed a proposal to create a standing body of experts to consider bioethical issues arising from research on human biology and behavior, including clinical research, and the applications of such research. The goal is to establish a panel of non-government experts in the relevant scientific disciplines, law, and ethics, as well as community representatives, to provide advice and recommendations to the Federal government. To engage broader public participation in the discussion of such a group's role and composition, a draft charter for a National Bioethics Advisory Commission was published in the *Federal Register* for comment. Comments received in response to this Notice have been incorporated into the final document. The Commission will report to the President's National Science and Technology Council and will operate under the provisions of the Federal Advisory Committee Act. The President established the Commission on October 3, 1995 (E.O. 12975).

BACKGROUND: OSTP began developing this proposal at the request of the Departments of Energy and Health and Human Services, in October 1993. These agencies had been considering establishment of a joint advisory panel to examine issues related to maintaining the confidentiality of genetic information resulting from the Human Genome Project. It became clear that there were a number of other bioethical issues that would benefit from consideration by an expert, standing advisory body. Thus, the informal interagency working group was expanded to include representatives of DOD, NASA, VA, NSF and Justice. The products of these discussions are the draft charter and preamble that were published in the *Federal Register* (August 12, 1994).

The key points of the charter are:

- The immediate charge to the Commission will be to consider issues in the protection of the rights and welfare of human research subjects and management and use of genetic information.
- The general charge to the Commission will be to consider current and prospective issues pertinent to the conduct of research on human biology and behavior and to identify broad, overarching principles to govern the ethical conduct of such research. The Commission will have the authority to establish its own priorities and agenda, in accordance with four criteria described in the charter, and subject to the approval of the National Science and Technology Council.
- The Commission will be composed of experts in the fields of philosophy and theology, social and behavioral science, law, medicine and biological research, in addition to representatives of the general public. Its members will be appointed by the President.

For further information contact: Rachel E. Levinson (202) 456-6137.

CANDIDATES FOR CONSIDERATION AS MEMBERS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION

The names attached were selected as the result of a process that began on August 12, 1994, with publication of a notice in the *Federal Register* requesting nominations for individuals to be considered as members of the National Bioethics Advisory Commission (59 FR 41584). The Office of Science and Technology Policy received 75 nominations in response to the notice. Additional names were submitted through an interagency task force that included the Department of Health and Human Services, Department of Energy, Department of Defense, Department of Justice, Veterans Administration, National Aeronautics and Space Administration, and the National Science Foundation. Members of Congress submitted 10 names and sent letters of support for several individuals. All of these names were reviewed at an August 22 meeting of the interagency task force, resulting in the accumulated 170 candidates being reduced to 28 for consideration as members. The attached list of candidates represents the conclusions of this group, with some modifications based on OSTP discussions with other WH staff. For example, it was decided that industry representation on the Commission would be beneficial. To that end, the biotechnology trade association, BIO, was asked to nominate an appropriate individual. Similarly, the American Psychological Association was asked for suggestions for the category of social and behavioral sciences and other professional societies submitted nominations.

A separate process was established internally to identify candidates for chair of the Commission. Consultation with WH Personnel and the Office of the Vice President resulted in the selection of a highly respected individual who would be desirable to serve as chair. Harold Shapiro, President of Princeton University, has agreed to be considered for such a position, subject to WH clearance.

Executive Order 12975 (October 3, 1995) requests that Executive Branch agencies that conduct, support or regulate human subject research review their policies for the protection of the rights and welfare of research subjects. Agencies are further required to report the results of their findings and any proposals to enhance human subject protections to the National Bioethics Advisory Commission, within 120 days of the date of the E.O.. Therefore, it is advisable that the Commission be operational within this timeframe. Achieving this goal will require rapid processing of personnel and security clearances (OBE).

5-29-96

DRAFT

NATIONAL BIOETHICS ADVISORY COMMISSION REVISED CHARTER

Purpose

The National Bioethics Advisory Commission will provide advice and make recommendations to the National Science and Technology Council, 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

42 U.S.C. 6617(a)(2). 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 (41 C.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, Federal agencies, and other appropriate entities, and also make their advice and recommendations available to the public. 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 genetic 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 fruitfully deliberate 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 15 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 of concern to the participating departments and agencies. At least one member shall be selected from each of the following categories of primary expertise: (i) 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 shall be appointed for overlapping four-year terms. Initially, members will be appointed for two-, three- or four-year terms. Terms of more than two years are contingent upon renewal of the National Bioethics Advisory Commission by appropriate action prior to its termination. 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 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, and 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 10 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 diem 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 \$500,000.

Reports

Reports by the National Bioethics Advisory Commission on specific issues shall be submitted to the National Science and Technology Council, 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 promulgated in the Federal Register. 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, (i) 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 appropriate action prior to its expiration, this National Bioethics Advisory Commission will terminate two years from the date of the first meeting/this charter is approved.

[FR Doc. 94-19568 Filed 8-11-94; 8:45 am]
BILLING CODE 4710-20-M

OFFICE OF SCIENCE AND TECHNOLOGY

National Bioethics Advisory Commission Proposed Charter

AGENCY: Office of Science and Technology Policy (OSTP).

ACTION: Request for Comments.

SUMMARY: This notice describes a proposal to establish a National Bioethics Advisory Commission within the Executive Branch. The Commission would be charged to consider issues of bioethics arising from research on human biology and behavior, and the applications of that research.

DATES: Comments must be received on or before October 11, 1994.

ADDRESSES: Submit written comments by mail to: Bioethics Docket, Office of Science and Technology Policy, Room 436, OEOB, Washington, D.C. 20500, or by FAX to: 202-456-6027.

FOR FURTHER INFORMATION CONTACT: By mail: Rachel E. Levinson, Assistant Director for Life Sciences, Office of Science and Technology Policy, Room 436, OEOB, Washington, D.C. 20500. Office telephone number: 202-456-6137.

SUPPLEMENTARY INFORMATION: OSTP proposes that a standing advisory body be established within the Executive Branch to consider issues of bioethics arising from research on human biology and behavior, and the applications of that research. This action would fulfill a need recognized by all branches of the Federal government. For example, a report by the House of Representatives Committee on Government Operations recommended establishment of an advisory committee to examine the ethical, legal and social implications of the Human Genome Project. The proposed advisory body would expand the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; the Department of Health, Education and Welfare's Ethics Advisory Board; and the President's Commission for the Study of Ethics Problems in Medicine and Biomedical and Behavioral Research.

OSTP seeks comments on a draft charter for a proposed National Bioethics Advisory Commission (NBAC). The NBAC would report to the President's National Science and Technology Council (NSTC). This arrangement will facilitate access to the

deliberations and recommendations of the NBAC for the Executive Branch agencies most heavily invested in biological and behavioral research.

The Commission would be asked to identify and develop broad overarching principles to govern the ethical conduct of biological and behavioral research, and the applications of that research. The proposed NBAC would not have responsibility for the review and approval of individual projects.

The draft charter seeks to strike a balance between defining the NBAC's agenda so as to fulfill governmental needs, and allowing the Commission sufficient flexibility to advise the government on issues this group of experts and stakeholders believe should be addressed.

The charter specifies two prospective areas of inquiry, issues in the management and use of genetic information and protection of the rights and welfare of research subjects. Discrete issues that fall under these two broad topics include: issues of genetic privacy, screening for genetic disorders, intellectual property rights, access to research data or materials developed with public funding, current views on informed consent, adequacy and implementation of Federal human subject research guidelines, and the concept of "minimal risk."

In addition, several other potential issues for consideration by the Commission have been raised in discussions to date including: adequacy and implementation of Federal human subject research guidelines, recommendations on requirements to maintain research data, and the ethical aspects of access to costly health care technology. The question is, how best might the scope of the Commission's charge be defined so as to meet public needs for deliberation of pressing issues in bioethics, without being so broad as to limit its effectiveness? An alternative option for addressing the last issue, for example, might be referral to a body more directly involved with decisions related to the provisions of health care and relevant cost/benefit analysis.

The Commission would be established in accordance with the Federal Advisory Committee Act (FACA). As such, its meetings would be open to the public and announced in advance to facilitate public participation. In addition, reports produced by the NBAC would be made available to public either *in toto*, or in summary. The purpose of these efforts would be to involve the public in the deliberations of the NBAC to the greatest extent possible.

As a FACA committee, the NBAC will be required to have a balanced membership. Naturally, selection of Commission members is going to be a delicate process that should take into account the social and cultural mores of the times in order to establish a body that is sensitive to the potential impacts of its deliberations and recommendations. The draft charter proposes that members be appointed by the President. Suggestions for potential members or membership posts are sought through this Notice.

Draft Charter

Proposed National Bioethics Advisory Commission

Purpose

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

Authority

42 U.S.C. 6617(a)(2). 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 (41 CFR 101-6.10).

Functions

The National Bioethics Advisory Commission shall advise, consult with, and make recommendations to the National Science and Technology Council and other appropriate entities, and also make their advice and recommendations available to the public. 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 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. Issues in the management and use of genetic information; and

B. Protection of the rights and welfare of research subjects.

In receiving and responding to requests for advice and recommendations from 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 fruitfully deliberate 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.)

The Commission also shall have the authority to identify bioethical issues, on its own behalf, for deliberation. The Commission will accept suggestions of issues for consideration from Federal agencies, Congress and the public. The Commission's decision to deliberate on a specific topic shall be made in consultation with the National Science and Technology Council. In all such instances, the four stated criteria for establishing priority shall pertain.

Structure

The National Bioethics Advisory Commission shall consist of not more than 15 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 of concern to the participating departments and agencies. At least one member shall be selected from each of the following categories of primary expertise: (i) bioethics/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.

Members shall be appointed for overlapping four-year terms. Initially, members will be appointed for two-, three- or four-year terms. Terms of more than two years are contingent upon renewal of the National Bioethics Advisory Commission by appropriate action prior to its termination. 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 Commission may conduct inquiries, hold hearings and establish subcommittees, as necessary.

The Commission is authorized to conduct analyses and develop reports or other materials. In order to augment the expertise present on the Commission, the Commission 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 may, in lieu of, or as part of any of its authorized activities, incorporate the results of the deliberations of another entity as long as the Commission sets forth its reasons for doing so.

The Assistant to the President for Science and Technology 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.

Management and support services shall be provided by the Office for Protection from Research Risks, Department of Health and Human Services. Additional resources including, but not limited to personnel, office support and printing will be provided by other NSTC member agencies.

Meetings

Meetings of the Commission shall be held up to 10 times a year at the call of the Chairperson with the advance approval of a Federal Government official who shall also approve the agenda. 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. 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 diem 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, including compensation and travel expenses for members and contracting and publication services costs, but excluding that for staff support, \$1,500,000. The estimated annual person years of staff support is six, at an estimated annual cost of \$500,000.

Reports

Reports by the National Bioethics Advisory Commission on specific issues shall be submitted to the National Science and Technology Council, 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 recommendations.

Executive summaries of each report of the Commission shall be promulgated in the Federal Register. 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, (i) 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.

Termination Date

Unless renewed by appropriate action prior to its expiration, this National Bioethics Advisory Commission will

terminate two years from the date this charter is approved.

Barbara Ann Ferguson,

Administrative Officer, Office of Science and Technology Policy.

[FR Doc. 94-19688 Filed 8-11-94]

BILLING CODE 3170-01 OSTP-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Criteria and Application Process for the Secretarial Award for Excellence in Transportation Technology Research and Development

AGENCY: Department of Transportation, Office of the Secretary.

ACTION: Notice of Request for Nominations.

SUMMARY: The Department of Transportation (DOT) announces procedures for nominating individuals and organizations for the Secretarial Award for Excellence in Transportation Technology Research and Development. Awards are made annually by the Secretary of Transportation to recognize research and development contributions advancing the ability of the U.S. transportation industry to compete globally.

DATES: Nominations must be postmarked no later than October 30, 1994.

ADDRESSES: An original and three copies of the nomination should be sent to: Noah Rifkin, Director of Technology Deployment, Office of the Secretary, U.S. Department of Transportation, 400 7th Street, SW, Washington, DC 20590, Room 10200.

FOR FURTHER INFORMATION CONTACT: John E. Hohl, Technology Sharing Officer, Research and Special Programs Administration, U.S. DOT 400 7th Street, SW, Washington D.C. 20590 Telephone: (202) 366-4978.

SUPPLEMENTARY INFORMATION:

Background

This notice solicits nominations for the Secretarial Award for Excellence in Transportation Technology Research and Development and provides relevant information on the nomination and selection process. The award is honorary recognition in the form of a certificate from the Secretary of Transportation. Awards will be presented annually.

Purpose

DOT is committed to providing the nation with a safe, efficient, environmentally sound and

technologically advanced transportation system that promotes economic growth, enhances international economic competitiveness, and contributes to a secure and healthy environment. In fulfilling this mission, the Department intends to accelerate technological advances that promote the development and export of transportation technology and manufactured products. To further these goals, the Secretary of Transportation has established the Secretarial Award for Excellence in Transportation Technology Research and Development to recognize significant contributions to expanding the technology knowledge base and the ability of the transportation industry to compete internationally.

Organization Defined

- For purposes of this award, organizations include but are not limited to:
 - Domestic or U.S. Corporations, including nonprofit corporations;
 - Partnerships;
 - Professional associations;
 - Institutions of higher education;
 - Federal, State, or local government; and
 - Professional teams assembled for the specific projects.

Evaluation Criteria

Nominations will be evaluated based on the following criteria:

- Quality and innovative nature of the technology developed;
- How the technology has enhanced industry competitiveness, both domestically and internationally.
- Significance of individual or organization nominated to the success of the development effort:
 - Entrepreneurial nature of research effort (nature of collaboration);
 - Potential for positive economic benefits to the U.S. or specific region; and
 - Applicability to more than one mode of transportation.

The qualifying work may be a singular accomplishment or a series of accomplishments that have had a substantial effect over time. Generally, technologies applicable to more than one transportation mode will be more favorably considered.

Examples of achievements that may be recognized include but are not limited to:

- **Safety Improvements**—Technology that reduces the likelihood of vehicle accidents or the likelihood of serious injury when a vehicle accident does occur or otherwise improves the chances of post-accident survival/recovery of accident victims. This could

include research and development of instrumentation equipment, human factors, or biomechanics.

- **Energy Savings**—Technology that saves energy in the production, operation, or disposition of vehicles through research in materials development, alternative fuels, engine and propulsion modifications, aerodynamic modeling and drag reduction, and combustion research.

- **Environmental Quality**—Technology applicable to transportation that reduces emissions; hazardous, solid or toxic waste; noise. This could include research and development of products, processes, or measurement instrumentation.

- **International Industrial Competitiveness**—Technology that allows the U.S. transportation industry to achieve sustainable world-class capabilities to compete in the global marketplace through the sale of transportation vehicles and equipment in overseas markets or the provision of freight and passenger transportation services to support international trade and travel.

- **Job Creation**—Transportation technology that creates jobs and makes a positive contribution to the U.S. economy.

Evaluation Process

The DOT Research and Technology Coordinating Council, chaired by the Director of Technology will appoint an Evaluation Committee to evaluate nominations under the prescribed criteria and to recommend awardees.

Recommendations of the Evaluation Committee will be reviewed by a Selection Committee made up of members of the Research and Technology Steering Committee. Final selections will be made by the Secretary of Transportation.

Nominating Procedures

Any person may nominate individuals or organizations from industry, academia, or government. Nomination should be in the form of a letter and must demonstrate that the nominee has provided significant contributions, through technology research and development, to advancing the ability of the U.S. transportation industry to compete globally in an area of transportation systems development, vehicle or facility design, construction, operation, or maintenance. Nominations must include the following:

- Name and address of the individual or organization being nominated;
- Name, address, and telephone number of the nominator. If the

NBAC

**INTERAGENCY WORKING GROUP STAFF
PRELIMINARY DRAFT RESPONSE TO THE
RECOMMENDATIONS OF THE
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS**

BACKGROUND

The Advisory Committee on Human Radiation Experiments (ACHRE), chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January 1994. Acting in cooperation with Federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the Committee was charged to provide expert advice to the Cabinet-level Interagency Working Group (IAWG) on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The Committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

FINAL REPORT OF THE ADVISORY COMMITTEE

The Committee's report began by identifying the ethical standards that applied to the government and to the medical and research professions in the post-war period. Several "case studies" were then reviewed in detail, including the injections of plutonium into 18 hospital patients during World War II, research with prisoners, and research funded by the military on patients who had previously been exposed to total body irradiation in clinical settings. Intentional environment releases of radioactivity were also reviewed.

The Committee also considered issues related to some radiation exposures associated with government activities that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

Finally, the Committee reviewed 125 current or recent Federally-funded studies (not limited to radiation research) and interviewed patients at selected hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects

and evaluating research risks and to sample attitudes toward human subject research.

The Advisory Committee's recommendations fall into three major areas: biomedical experiments and population exposures (1944-1974); current human subject protection; and secrecy and openness.

BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES

Recommendation 1: Apology and compensation for three specific experiments where secrecy was involved, and thus, individuals were denied the opportunity to pursue alleged grievances. These experiments involved Department of Energy (DOE) predecessor agencies and contractors only.

Recommendation 2: Apology and compensation where harm can be established, and where there was no prospect of direct medical benefit to the subject of the experiment. Several experiments and categories of experiments were proposed as candidates by the Committee.

Summary Response: The agencies involved, in coordination with the Department of Justice, are engaged in ongoing discussions with numerous claimant representatives concerning compensation issues.

Recommendation 3: Apology (without compensation) for experiments in which subjects were wronged but not harmed, i.e. where no consent or inadequate consent was obtained or the selection of the subjects constituted an injustice. One experiment was proposed as a candidate with the indication that there may be many others.

Summary Response: At the ceremony in which Dr. Faden presented him the report, President Clinton formally apologized on behalf of the government to the victims of human radiation experiments.

Recommendation 4: Subject notification and medical follow-up unnecessary; criteria for subsequent notification if new experiments come to light. These criteria included both the level of risk from radiation exposure and the potential benefit from medical follow-up in exposed individuals.

Summary Response: (revised) The IAWG staff has generally agreed with the Advisory Committee that no further response is warranted at this time and that the criteria set forth by the Committee are appropriate for evaluating future cases. This recommendation has generated a great deal of controversy among stakeholders, which was expressed at the Stakeholders Workshop of February 26, and 27, 1996, held by the IAWG. Although it is difficult to generalize about the diversity of views presented at the Workshop, the stakeholders generally seemed to want some form of notification along with medical care provided by physicians of their own choice, rather than medical follow-up by the government. They viewed the latter as a continuation of suspect government activities.

In addition, at hearings on human radiation experiments held by the Senate Committee on Governmental Affairs on March 12, 1996, Senator Glenn suggested that subjects may want to be notified whether or not they were harmed.

In response, the IAWG staff has further discussed and reviewed its response to this recommendation. Many staff members have pointed out that the entire human radiation experiments effort as carried out by the Federal agencies has involved a public notification process, though generally not at the level of individual participants. Lists of experiments have been made public as has a large volume of documents. The whole process has received extensive publicity.

In one example, the National Aeronautics and Space Administration (NASA) sent a detailed letter notifying all current and former NASA employees, contractors and grantees about the human research radiation review. Headquarters, the nine NASA Field Installations, and the Jet Propulsion Laboratory participated in this notification. These avenues of notification included those universities and institutions at which human radiation research was performed through NASA grants. Additional notification was accomplished through various NASA alumnae associations and professional organizations. At the same time, except for astronaut

medical records, NASA did not and does not retain any administrative or individual medical records of human radiation research subjects.

In addition, through the Interagency Helpline, individuals who think they may have been involved in experiments have had their cases reviewed by the appropriate agency. In response to these inquiries, for example, DOE has notified a number of individuals that they appear to have been participants in a human radiation experiment in which DOE had some involvement.

The VA reported that it focused its attention on early radiation research projects for which at least some of the names of research subject were known. These studies were chosen because of the possibility of contacting veterans or family members to encourage medical surveillance or submission of a compensation claim, if warranted. An expert committee including specialists in nuclear medicine, radiation oncology, health physics, and radiation dosimetry reviewed information about these projects and not veterans were identified who were felt to warrant special follow-up actions specifically because of their radiation exposure.

Several agencies have been evaluating the issue of notification for specific categories of experiments:

Treatment with Nasopharyngeal (NP) Radium during Military Service

The Departments of Defense (DOD) and Veterans Affairs (VA) have been considering a relatively large group which has attracted public attention: the servicemen who received NP irradiation during and immediately following World War II. Nasopharyngeal irradiation was considered accepted medical treatment at the time, and records identifying individuals receiving this treatment are difficult to locate. DOD has been able to locate names of a few servicemen who received nasopharyngeal irradiation and sent them a letter informing of this fact and providing a fact sheet about the therapy.

The VA, along with the Centers for Disease Control (CDC) and Yale University, co-sponsored a workshop on the public health response to NP irradiation which was held in New Haven, Connecticut in September 1995. Consensus did not support

medical screening of asymptomatic individuals but recommended that individuals treated with NP radium inform their health care providers for consideration when they are examined or evaluated. VA officials have published information on NP radium treatments in medical journals and sent information to veterans' service organizations for their newsletters.

The VA and CDC are planning a satellite teleconference in September 1996 to provide health professionals information about this issue. Currently, veterans treated with NP radiation do not have special eligibility for VA care. A current bill (HR #2080), if enacted, would provide priority eligibility to veterans treated with NP radium in service. A VA legislative proposal also currently under consideration would make veterans treated with NP radium eligible for the VA's Ionizing Radiation Program.

Alaskan Natives

A number of Alaskan Natives were involved in the U.S. Air Force Arctic Aeromedical Laboratory Iodine-131 thyroid test, which took place in 1956 and 1957. Although both the Advisory Committee and the Institute of Medicine (IOM) determined that there was no evidence of lifetime risk to the participants in these tests, notification and follow-up of the juvenile participants was recommended by the latter as prudent. The Air Force is currently determining appropriate follow-on concerning the minors involved in the Iodine-131 study. In general, the Air Force and the Radiation Experiments Command Center (RECC) are following up on the recommendations of the IOM in its recent report concerning the Iodine-131 experiments involving Native Alaskans. Efforts are ongoing to locate documents about experiments involving Native Alaskans and to identify the six Native Alaskans and six soldiers whose names were omitted from the study report.

DOE Efforts

In addition to the subjects of the plutonium injection experiments, whose next-of-kin, where located, were notified, DOE is trying to identify whether there are any other subjects for whom it has information that would make notification possible. Although the agency does not currently believe that this information is available, a

letter has been sent to all DOE facilities at which human radiation experiments were identified. The letter requests the facilities to provide detailed information about the availability of data, if any, relating to individual subjects, the feasibility of notification, and whether any kind of notification process has already taken place. DOE has carefully considered the issues raised by notification and the agency's continuing concerns about the value and feasibility of this process were included in the testimony of Dr. Tara O'Toole before the Senate Committee on Governmental Affairs on March 12, 1996.

Recommendation 5: Working with Congress to amend the Radiation Exposure Compensation Act of 1990 (RECA) to cover other exposed populations, including citizens exposed around the Hanford site.

Summary Response: (revised) The IAWG staff agrees with the Advisory Committee's concern for treating exposed populations fairly. Studies that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats, and Oak Ridge are underway. If these studies reveal an increase in cancer resulting from the operation of DOE facilities, the government will work with Congress to amend existing laws to cover those affected. The GAO has been provided with a list of all studies currently in process.

Recommendation 6: (revised) Updating the epidemiologic tables that govern relief for veterans and improving the administration of the current laws governing compensation.

Summary Response: The VA has established a Working Group led by the Undersecretary for Benefits to follow-up on the recommendation. Representatives from the Departments of Defense (DOD) and Health and Human Services (HHS) are included. The Task Force is also evaluating the efficacy of the current law and regulations relating to compensation of veterans whose illnesses or deaths may be attributable to radiation exposure while in military service. The report is expected to be completed in the late spring or early summer of 1996. Specifically, the report will recommend the most feasible way to accomplish updating the epidemiologic

tables; describe the administration of laws governing compensation of Atomic Veterans; and, if appropriate, recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

Recommendation 7: Working with Congress to possibly amend the Radiation Exposure Compensation Act of 1990 (RECA) relating to uranium miners. The changes would involve a widening of eligibility for compensation and a loosening of documentation requirements.

Summary Response: A committee of government scientists and attorneys with appropriate experience and expertise was established to review the provisions in RECA that relate to compensation for uranium miners. The committee also reviewed the Department of Justice's (DOJ) implementing regulations under RECA to ensure that they are not unduly restrictive. The committee consists of four scientists from the National Institute of Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI), and three attorneys from DOJ. The committee report is in the process of completion.

The committee has agreed on a series of recommendations that propose significant and substantial modification to the statutory compensation criteria for lung cancer and nonmalignant respiratory diseases, and to the regulations that govern proof of these diseases. In a few instances, it has recommended that statutory criteria be modified but has not proposed specific alternative criteria. In these cases, the committee was unable to locate sufficient reliable data to review and analyze in the time allotted or because the appropriate solution ultimately depends on a purely policy judgment.

Recommendation 8: Continuing the current medical monitoring and treatment program for citizens of the Marshall Islands as long as any member of the exposed population remains alive. In addition, consideration should be given to adding the populations of other exposed atolls to the south and east; to involving the Marshall Islanders in the design of any further medical research conducted on them; and

establishing an independent panel to review the adequacy of the current monitoring and treatment program.

Summary Response: (revised) Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other northern Marshall Island atolls were a factor of 30-90 times less than at Rongelap and about 10-25 percent of those at Utirik based upon external dose measurements and on estimates of thyroid doses. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by DOE and managed by CDC. If new data is developed to indicate that residents of atolls south and east of Bikini, other than Rongelap and Utirik, are at increased health risk, Congress would need to consider expanding the current medical surveillance program.

The planned Joint Commission for Accreditation of Healthcare Organizations (JCAHO) review of the DOE Marshall Islands Program, administered by the Brookhaven National Laboratory, has recently been suspended. At the request of the Government of the Republic of the Marshall Islands (RMI), the mechanism for such a review is being reevaluated based on further input from RMI. Discussions with the RMI Ambassador to the United States have taken place and RMI has requested a broader review that might be done by the National Research Council/National Academy of Sciences. The Department is considering the use of a Blue Ribbon Panel as another possible mechanism for this review.

Representatives of RMI participated in the February Stakeholders Workshop and DOE is generally working with RMI representatives to determine how to enhance the program to better meet their current needs. DOE is also in the process of locating additional documentation requested by RMI and facilitating their access to material already located.

CURRENT HUMAN SUBJECT PROTECTION (revised)

Overview: Responses to these recommendations involve a wide range of approaches, some of which are activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that are being implemented in the near term while others will require preliminary groundwork prior to full implementation. A third group of responses involve referring certain recommendations to the National Bioethics Advisory Commission (NBAC), an independent body established by the President through Executive Order 12975 on October 3, 1995. (Presidential appointments to NBAC are pending.)

In general, agency activities in response to these recommendations fall into the following categories:

- Remanding specific Advisory Committee recommendations to NBAC which will provide expert advice on issues of bioethics;
- Developing educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in non-Federally funded research with the ethical considerations in conducting research involving human subjects;
- Implementing training programs within Federal agencies to educate senior level officials on regulations and policies governing human subjects research;
- Reminding institutions conducting Federally funded research of their ongoing responsibilities with respect to Institutional Review Board (IRB) review;
- Pooling resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the government's

system for the protection of human subjects, and to establish processes for oversight or review of compliance;

- Considering the proposal of legislation to remedy some of the gaps in the current system for protecting human subjects.
- Implementing educational workshops and an active dialogue with international partners with whom Federal agencies cooperate in human research to develop common ethical principles and to ensure the rights of human subjects are protected, e.g. specific activities proposed by NASA.

Individual Recommendations and Summary Responses:

Recommendation 9: Efforts to ensure centrality of ethics in the conduct of human subjects research.

Summary Response: NBAC will provide advice and make recommendations to the National Science and Technology Council and other appropriate government entities in the areas of bioethical issues arising from research on human biology and behavior and the clinical applications of that research. NBAC will also identify broad principles to govern the ethical conduct of research. The IAWG staff has identified activities carried out in recent years to address this issue as well as major new efforts to upgrade or expand these activities that will be carried out by HHS, DOE, DOD, and NASA. Some of these are discussed below.

In addition, the National Institutes of Health (NIH) is leading an interagency initiative to fund the development of new knowledge related to the informed consent process. Despite the vigor with which all parties embrace the informed consent process, little is actually known or understood about it. Much of the Advisory Committee's commentary on current human subjects research was centered on informed consent, and NIH, NASA, DOE, and DOD are committed to supporting research that will more fully illuminate the process. A Request for Applications (RFA) is in preparation, and Fiscal Year 1997 monies are intended to support this RFA.

Recommendation 10: Changes IRBs in five critical areas: better focus on studies that pose more than minimal risk; better mechanisms for providing information to potential subjects that distinguishes research from treatment; realistically explain benefits, and clearly describe the potential for discomfort and pain; better mechanisms for providing information to potential subjects on sponsors and purposes of the research; better mechanisms for providing information to potential subjects on financial implications; and recognition that the IRBs must determine if the quality of the science justifies the risk.

Summary Response: The IAWG staff has agreed that agencies will instruct IRBs to be responsive to these recommendations and will provide oversight and review to ensure compliance. The IAWG staff will work with NBAC and the National Science and Technology Council in carrying out these recommendations.

The Office of Protection from Research Risks (OPRR), National Institutes of Health, leads a national educational effort to showcase the Advisory Committee's message. OPRR collaborates closely with Public Responsibility in Medicine & Research (PRIM&R), a Boston-based private, nonprofit organization, to stage an annual public meeting for individuals interested in the governance of human subjects research. More than 600 people attended the October 1995 PRIM&R meeting, at which the Advisory Committee recommendations were presented for the first time to the IRB community. OPRR has scheduled presentations and discussions of the recommendations at national workshops in Atlanta, Oklahoma City, Honolulu, Peoria, and Houston. The November 1996 PRIM&R annual conference in San Diego is expected to address IRB implementation of the recommendations. The recent placement of the Advisory Committee report on the World Wide Web makes it possible for IRBs to examine its full text.

In October 1995, the Food and Drug Administration (FDA) issued a major, 154-page revision of its "Information Sheets for Institutional Review Boards and Clinical Investigators," to take into account the latest thinking and to provide guidance to IRBs.

OPRR and FDA make extensive use of public meetings, forums, hearings, FAX call, and electronic media to address evolving issues on human subjects protection.

OPRR and FDA actively identify and mail to IRBs and other interested parties copies of Federal Register notices and "Dear Colleague" letters regarding human subjects protection.

Recommendation 11: A mechanism for the continuing interpretation of ethical rules in a public forum.

Summary Response: It is expected that NBAC will develop and maintain a forum for implementing this continuing review and interpretation of ethical rules.

Recommendation 12: Improving the rights and interests of military personnel with respect to human subject research by reviewing policies and procedures, educating officers and investigators, maximizing voluntariness, and maintaining a registry of volunteers.

Summary Response: DOD has agreed to a number of specific steps including revision of directives or Military Department regulations to meet these proposals and incorporation of appropriate training into courses for commanders and senior leadership as well as those involved in human subjects research. In the summer of 1996, DOD will publish a revised human subjects protection regulation that will include policy changes recommended by the Advisory Committee. For example, the new policy will preclude officers and non-commissioned officers from playing a role in selecting volunteers for military tests to avoid undue command influence.

Recommendation 13: Improving the current Federal system for protecting the rights and interests of human subjects in the areas of oversight, sanctions, and scope.

Summary Response: In addition to Federal agencies undertaking specific activities in response to this recommendation, some of which are described below, it is expected that NBAC will fully address this recommendation in carrying out its responsibilities.

Recommendation 14: Resolving the longstanding issue of whether and how all persons injured in the future from Federally-funded research should be compensated.

Summary Response: The IAWG staff recommends to NBAC that it begin an early assessment of compensation for research injury. Despite being addressed twice before by the HEW Secretary's Task Force (1977) and the President's Commission (1982), a definitive resolution of the long-standing social policy issue remains elusive.

NBAC Update: The principal response of the Executive Branch to the Advisory Committee findings and recommendations was the creation of NBAC. As a first priority, NBAC shall direct its attention to protection of the rights and welfare of human research subjects. Human radiation experiments, per se, are not referenced in NBAC's charter.

Although its chartering was catalyzed by the Advisory Committee report, NBAC in fact represents the reinstitution by the President of an entity that has been absent since 1983. That entity is a national, deliberative body of private citizens that provides advice and recommendations to the government on bioethical issues arising from research on human biology and behavior, and the applications of that research. As such, NBAC can be expected to pursue various issues identified in these Committee recommendations based on their merits, as judged by NBAC.

The President is expected to appoint the NBAC membership soon, with meetings to begin in mid-1996. Reports provided to NBAC by agencies that carry out current human research will permit NBAC to begin a critical assessment of the implementation of the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule"). Such independent analysis is critically needed, five years after the promulgation of the regulations.

At the March 12th hearing, both the Chairman and the Ranking Minority Member of the Senate Committee on Governmental Affairs expressed concerns about human subjects protection in non-Federally-funded research -- a specific Advisory Committee concern as well. The Advisory Committee had called for the IAWG to

take steps to ensure that all human subjects are adequately protected, and the IAWG staff will work closely with the Senate Committee as it pursues this issue. NBAC can also be expected to address this issue.

Current Agency Activities: As part of the Executive Order, all agencies that are involved in current human subject research (not only those agencies represented on the IAWG) were required to review this research in the light of the Advisory Committee recommendations and report to NBAC. DOE, DOD, DHHS, NASA, VA, CIA, and DOJ (along with many other agencies) are providing NBAC with reports that are fully responsive to the President's October 3, 1995 Executive Order. The following are some specific activities that have been undertaken by IAWG agencies in relation to, or as a result of, this review.

The Department of Energy:

- Developed a newly revised handbook on protecting human subjects which is in pre-publication review. The handbook specifically addresses issues raised by the Advisory Committee on informed consent and classified research.
- Has begun a program of regular site visits to its facilities performing human subjects research, for education and review. Each site will be visited approximately once every three years.
- Requested all DOE laboratories to provide a sample of current informed consent documents. These are being reviewed by a team charged with improving and monitoring the quality of these documents.
- Has begun drafting a model informed consent document that will be sent to all sites to adapt and use.
- Requested all laboratories to provide plans that detail local activities to improve the human subjects research review system.

- Issued a brochure to educate the DOE community on human subjects protection, updated its human subjects research database, held its annual human subjects workshop, and made a database of current human subjects research sponsored by the Department available on the Internet.

The Department of Defense:

- Reviewed in detail DOD's existing policies and procedures for the protection of human research subjects and has undertaken extensive revision of DOD Directive 3216.2, "Protection of Human Subjects in DOD Supported Research."
- Proposed changes to current policies that would:
 - Adopt investigator assurances of familiarity with the Nuremberg code, the Belmont Report, the Common Rule, and related requirements;
 - Incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals;
 - Include specific language in the revised directive that would emphasize the expedited review process for certain categories of minimal risk research that are detailed in the Common Rule (32 CFR 219);
 - Require education in human subjects regulations at the executive level of training for commanders and senior civilians who may be involved in human subjects research and for individual investigators, IRB members, research administrators, and support personnel; and
 - Ensure that officers and senior NCOs in the chain of command not be present during research recruitment briefings of personnel under their command, and that an ombudsman be present at group recruitment briefings.

The National Aeronautics and Space Administration:

- Established an external Bioethics Policy Task Force to review all NASA human use research policies and procedures, chaired by Baruch Brody, Ph.D., Leon Jaworski Professor of Biomedical Ethics and Director of the Center for Ethics, Medicine and Public Issues at Baylor College of Medicine. The final report of the Task Force was provided on February 14, 1996. In collaboration with the Task Force, NASA enhanced the conduct of human subjects research so that it satisfies the requirements both of the Federal Common Rule and of the highest principles of research ethics.
- Updated the NASA Management Instruction (NMI) on the conduct of Human Research, issued on August 8, 1995, to reflect the Federal Common Rule and incorporate the relevant recommendations reflected in the Advisory Committee's final report. NASA Headquarters has also established a process for oversight and assurance. An Agency Authorizing Official has been named for the authorization of human research and the protection of human subjects. Documentation of assurance of human subjects protection is required every five years, from all nine NASA Field Installations and the Jet Propulsion Laboratory, if the Center is conducting human subjects research. Centers not conducting such research must recertify by letter every year.
- Conducted internal reviews at Headquarters, Johnson Space Center, and Ames Research Center to ensure that elements of the Common Rule and Advisory Committee recommendations were incorporated into agency and center instructions.
- Because much of its future space research will be conducted with its partners on the International Space Station, has conducted the first in a series of forums to inform NASA's international biomedical community on issues related to the ethics of human subjects research. These workshops will effect a transnational understanding of the sensitivity to ethical issues in human research and ensure that all international partners support common ethical principles regarding the protection of human subjects. A common consent

form for use on the international space station was agreed upon and will undergo periodic review.

- Initiated ethics forums on the Common Rule and protection of human subjects for its domestic biomedical research community.

The Central Intelligence Agency:

- Obtained the services of a prominent ethicist from the academic community to become a permanent voting member of the Agency's Human Subject Research Panel (HSRP).
- Revised agency regulations to indicate that all research carried out or sponsored by the Agency that utilizes human subjects shall be brought to the HSRP for approval. The Chairman must certify as exempt or approve a research proposal before it can proceed; final approval rests with the Agency Director.
- Disseminated an agency bulletin to all employees specifying the rationale and function of the panel and necessity of referring human subject research to it for approval.
- Revised the Agency's Contracting Manual to guarantee that HSRP approval is obtained prior to approval of any contract involving human subject research.

The Department of Health and Human Services:

- Designated the Office for Protection from Research Risks, National Institutes of Health, to coordinate the preparation of the NBAC report with information drawn from the Public Health Service agencies and other operating divisions.
- Began activities to improve the procedures for protecting human subjects. For example, CDC is developing an on-line education system in research integrity and ethics that will be mandatory for investigators.

- Ensured that FDA will respond to NBAC, not only as part of the Department, but also in its capacity as a regulator of research done by private industry.

Other Agencies:

- VA has planned IRB site visits to review procedures and their Office of Research and Development is reviewing its policy manual to identify any needed revisions.
- The Department of Education anticipates reporting to NBAC on ongoing training activities, and efforts to disseminate information through guidance documents and establish networks within that Department.
- The Environmental Protection Agency (EPA) is planning to issue an internal order implementing the Common Rule.
- The Consumer Product Safety Commission is updating and changing its internal documents and policies.

SECRECY AND OPENNESS

Recommendation 15: a) No waiver of informed consent for classified research and informing the potential subjects of the identity of the sponsoring agency and that classified research is involved and b) For classified research, establishing an independent panel, whose records are permanent, to review scientific merit, risk/benefit, consent, and whether subjects need a security clearance.

Summary Response: (revised) The IAWG proposes that 15 (a) be referred to NBAC to determine if there are indeed no occasions where this consent should be waived for classified research or when withholding the sponsoring agency would be appropriate.

The IAWG staff is reluctant to propose creating a new oversight body for 15(b). Instead it proposes to use the current IRB system which already must include at

least one member not affiliated with the institution. The IRBs could be directed to guarantee participation of non-government persons in reviewing classified research by establishing a dedicated panel for classified research review or by ensuring that all IRB members possess the necessary clearances.

Recommendation 16: a) Review by an independent panel of any planned environmental release where any aspect involves secrecy and b) Environmental oversight of classified programs (now done by EPA) should include keeping review records permanently and reporting to Congress.

Summary Response: (revised) (16a) EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. All Federal agencies are obligated by Executive Order 12088 to comply with environmental laws and fully cooperate with EPA, and state, interstate, and local agencies to prevent, control, and abate environmental pollution, regardless of whether the activities of regulated Federal agencies are classified. There is concern that creating a new regulatory entity, such as an independent review panel, would add to the bureaucratic complexities of ensuring environmental safety.

(16b) While EPA currently does oversee all Federal government operations, whether classified or not, through its enforcement program, which assures compliance with environmental laws by Federal agencies, EPA does not have as yet a systematic information gathering, coordination, or reporting process specifically related to issues of national security and/or activities subject to the Federal government's information secrecy program under Executive Order 12958.

In the past, EPA and state inspectors have obtained, on a case by case basis, appropriate clearances for access to national security information and facilities. To operate an effective enforcement capability over classified projects, EPA is considering systematically identifying cleared personnel and to seek from the operating federal agencies through a series of Memoranda of Understanding the appropriate "need to know" access. This new process would assure that EPA

could handle most environmental compliance matters through administrative processes in classified settings. The EPA recommends however that each Federal agency be responsible for its own handling of classified material.

With respect to the National Environmental Policy Act (NEPA), EPA staff that are assigned as liaisons to the Department of Defense and the Department of Energy hold the appropriate security clearances and, in the event it becomes necessary to review a classified NEPA document, the individual typically goes to the offices of the lead agency and reviews the classified material there. EPA has seen no need to establish a system to document this procedure, and does not have any evidence that federal actions are not being appropriately reviewed in the NEPA review process.

Recommendation 17: Ensuring historical records are organized and accessible by 1) hastening movement of records to Archives; 2) making indexes and finding aids readily available; 3) improving public access to records in the custody of agencies; 4) maintaining records of document destruction; and 5) reviewing policies governing access to records of grantees and contractors.

Summary Response: (revised) For 1, 2, 3, and 5, the IAWG staff agrees with moving aggressively down the path to openness exemplified by this project and will work to make government records more accessible including using new technology to enhance access. For 4, the IAWG staff is investigating the feasibility of making the records of classified human subjects research permanent, not just the records of destruction. It is also considering the possibility of making all records of human subjects research permanent.

Current Agency Activities: IAWG members have initiatives underway to ensure that information retrieved for the human radiation experiments project is readily available to the public, and to respond to specific Advisory Committee recommendations on openness.

The Department of Energy:

- The Department has produced three publications which include background information, record series descriptions, topical essays, a list of over 400 experiments, and oral histories. Most of this information, along with over 250,000 scanned historical documents, is located on the Internet, with paper copies of all documents at the Coordination and information Center (CIC) in Nevada.
- In response to Advisory Committee recommendations, DOE is
 - Negotiating the transfer of over 3,000 cubic feet of records to the National Archives; and
 - Actively making finding aids to records still in agency custody more readily available to the public, and has prepared records access guidance. To date, finding aids from Headquarters records and a number of filed sites have been placed in public reading rooms across the DOE complex.
- The Department continues to update its World Wide Web site on the Internet with additional documents of interest and recently added three new experiments to its experiment list.

The Department of Defense:

- The Department is preparing a guide similar to the DOE *Roadmap* that will describe DOD documents found during the human radiation records search, and will identify and list human ionizing radiation experiments conducted or sponsored by the DOD. It will also include information on DOD events that were not human radiation experiments but were specifically included by the DOD in its search efforts, such as atmospheric releases. Scheduled availability is summer 1996.

- The documents will be available on the Internet and hard copies will be deposited at the CIC. DOD has also declassified many documents identified in the search for human radiation experiments and is also planning to transfer them to OpenNet, an Internet source for recently declassified documents.
- DOD has taken the lead in an interagency effort to create a home page on the Internet, modeled after DOE's, providing access to documents located by all agencies as part of this project.
- DOD is expediting its response to Freedom of Information Act requests concerning human radiation experiment subjects.

The National Aeronautics and Space Administration:

- NASA will maintain a permanent collection of human radiation experiment records and a database at Johnson Space Center. A process for submission of an response to requests for information has been developed.
- The agency is also working to make radiation research documents available on the Internet. The agency is creating a NASA Radiation Review Homepage which summarizes the agency's search and findings.

The Central Intelligence Agency:

- The CIA is transferring approximately 1,000 pages of declassified documents and a CIA Inspector General report on human subject research procedures to the National Archives. The documents will also be available on the Internet.
- The agency is reviewing for declassification a few documents relevant to the MKULTRA program that had not been previously declassified and released. An independent review of the CIA's record system has been undertaken by the National Archives and will be completed in approximately six months.

Health and Human Services and Veterans Affairs:

- These agencies are preparing documents for availability on the Internet sometime in the spring or summer of 1996. Paper copies have been transferred to the National Archives.

Recommendation 18 : a) Review of CIA recordkeeping by CIA Inspector General or other groups with special attention to facilitating public access and b) Priority given to declassification of CIA historical records such as MKULTRA.

Summary Response: The National Archives has begun a scheduled review of CIA's records management program, including records access issues and the CIA has agreed to give top priority to declassification of human subjects research records.