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Draft of January 27, 1994

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DRAFT C H A R T E R

National Bioethics Advisory Commission

Purpose

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

Authority

42 U.S.C. 6617(a)(2). This Commission is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation of advisory committees.

Functions

The National Bioethics Advisory Commission, through the Bioethics Policy Committee, shall advise, consult with, and make recommendations to the National Science and Technology Council, other appropriate entities, and 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 applications of that research.

In receiving and responding to requests for advice and recommendations from the Bioethics Policy Committee, National Science and Technology Council,* the Commission shall consider four criteria in establishing priority for its activities:

- The number of departments or agencies to which the request is of interest. (The Commission ordinarily will not deliberate on a bioethical issue of interest to just one department or agency.)
- The public health or public policy urgency of the bioethical issue.
- The absence of another body able to fruitfully deliberate on the bioethical issue.
- The relation of the bioethical issue to the goals for Federal investment in science and technology.

The Commission also shall have the authority to^{*} identify bioethical issues, on its own behalf, for deliberation. In 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 experts and community representatives with special qualifications and competence to deal effectively with bioethical issues of concern to the participating departments and agencies. Members 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 nonscientists.

Members shall be appointed for overlapping 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 elected by the members. The term of office for the Chairperson shall be two years, renewable by appropriate action of Commission members.

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. If a vacancy occurs on the Commission, the President* shall make an appointment to fulfill the term.

The Commission may conduct inquiries, hold hearings, consult and contract with experts, and establish subcommittees.

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

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, 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 may be provided by other 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 Director, Office for Protection from Research Risks, in consultation with 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 shall be paid at the rate of ***\$000 per day, 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 services costs but excluding that for staff support, is \$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 through the Bioethics Policy Committee to the National Science and Technology Council and

1 other appropriate entities.* The Commission ~~shall~~/may specifically identify the department,
2 agency, or other entity to which each recommendation is directed.*

3
4 An annual report shall be submitted through the Bioethics Policy Committee to the National
5 Science and Technology Council. It shall contain, at a minimum, (i) the Commission's
6 function; (ii) a list of members and their business addresses; (iii) the dates and places of
7 meetings; (iv) a summary of the Commission's activities during the year; (v) a summary of
8 the Commission's recommendations made during the year; and (vi) a summary of any
9 responses made by departments, agencies, or other entities to the Commission's
10 recommendations during the year.

12 Executive summaries of each report of the Commission shall be promulgated in the Federal
13 Register. Such summaries shall specifically list the department, agency, or other entity to
14 which any recommendations are directed.

15
16 Termination Date

17 Unless renewed by appropriate action prior to its expiration, this National Bioethics Advisory
18 Commission will terminate two years from the date this charter is approved.

19 Approved:

20 _____
21 Date

William Jefferson Clinton

Current issues of potential interest to
proposed Bioethics Policy Committee
and
proposed National Bioethics Advisory Commission

- ☐ Concept of "vulnerable" individuals and populations in 1990s
- ☐ Additional protections for populations judged to be vulnerable
- ☐ Compensation for research-related injury
- ☐ Financing of costs of research
- ☐ Seeking voluntary consent among employees
- ☐ Concept of "minimal risk"
- ☐ Research where the experimental subject is more than one individual
- ☐ Conduct of AIDS vaccine trials
- ☐ Recruitment and retention of minorities and women in clinical research

January 27, 1994 draft

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DRAFT CHARTER

BIOETHICS POLICY COMMITTEE

NATIONAL SCIENCE AND TECHNOLOGY COUNCIL

The Bioethics Policy Committee is hereby established by action of the National Science and Technology Council (NSTC).

Purpose

The purpose of the Bioethics Policy Committee is to advise and assist the NSTC in assuring that all Federal programs that involve human biology research are conducted in an ethical manner that adequately protects the rights and welfare of the individuals involved. The Committee will address significant national policy matters which cut across agency boundaries and shall provide a formal mechanism for interagency policy development and coordination regarding bioethical issues arising from research on human biology research and the applications of that research.

Functions

Reporting to and under the direction of the NSTC, the Bioethics Policy Committee will:

- o Review existing rules, policies, guidelines and regulations related to standards of behavior governing human biology research;
- o Assess the adequacy of such policies and programs and measures to assure compliance;
- o Recommend revisions, updates or other modifications, as necessary, to ensure the highest level of adherence to identified standards of ethical behavior in the conduct of human biology research and the applications of such research;
- o Recommend options for implementing policies or programs that ensure uniform adherence to identified standards;
- o Review progress toward meeting stated goals; and

- o Consider ethical implications of new programs or advances in technology or scientific knowledge that may require new approaches or revisions to existing rules, policies, guidelines or regulations.

Relationship to the National Bioethics Advisory Commission

The National Bioethics Advisory Commission (NBAC) will be established in order to provide advice and make recommendations through the Bioethics Policy Committee to the NSTC.

In order to carry out the functions described above, the Committee may task the National Bioethics Advisory Commission to conduct analyses, prepare reports, and develop briefing and other background materials for consideration by the Committee. The National Bioethics Advisory Commission is expected to provide recommendations to the Committee concerning bioethical issues arising from research on human biology and applications of that research.

Structure

The Committee Chairs and White House Co-Chair are appointed by the Assistant to the President for Science and Technology. The Executive Secretary is designated by the Committee Chairs. Additional staff and funding assistance, consistent with the terms of this charter, are the responsibility of the Committee Chairs.

The Committee Chairs will hold no fewer than four meetings of the Committee a year and will approve agendas. Minutes of meetings will be prepared by the Committee Executive Secretary and distributed to all members of the Committee and to the Executive Director of the NSTC.

The Committee Chairs will meet bimonthly with the White House Co-Chairs and the chairs of other NSTC committees to evaluate progress, discuss policy coordination, receive instructions from the Assistant to the President for Science and Technology, and report on ongoing activities.

The Committee Chairs will recommend action on major activities to the Assistant to the President for Science and Technology for approval.

The following departments and agencies are represented on the Committee at the Assistant Secretary level or above:

Agency for International Development
Central Intelligence Agency
Consumer Product Safety Commission
Department of Agriculture
Department of Commerce

Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of the Interior?
Department of Justice
Department of State
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
National Aeronautics and Space Administration
National Science Foundation
Council of Economic Advisers
Domestic Policy Council
Office of Management and Budget
Office of Science and Technology Policy

The Committee may establish such subcommittees and Working Groups as are necessary to carry out its functions. The Committee Chairs will appoint the chairs of all Subcommittees and Working Groups after consultation with the Committee and approval by the Assistant to the President for Science and Technology. Chairs of BPC Subcommittees and Working Groups will arrange assistance from their own agencies or from other agencies represented on the Subcommittees or Working Groups.

Membership on Subcommittees and Working Groups is not restricted to Committee members, but all members must be full-time Federal employees.

Charters and Statements of Roles and Objectives (SROs) will be recommended for approval to the Assistant to the President for Science and Technology for all Subcommittees and Working Groups, respectively. The Charters and SROs will identify the issues to be addressed and specify the desired products and delivery times to the Committee. Charters will be distinguished from SROs by scope and by duration, with Charters developed around broad issues, renewable from year to year, and SROs focused on more short-term issues and subject to dissolution at any time.

Private Sector and Public Interface

The Committee will recommend to the Special Assistant to the President for Science and Technology the nature of private sector and public advice needed to accomplish its mission. The Assistant to the President for Science and Technology will take necessary steps to ensure appropriate interactions between the National Bioethics Advisory Commission, President's Committee of Advisors on Science and Technology (PCAST) and the NSTC Committee.

The Committee may also interact with and receive ad hoc advice from various private sector groups as consistent with the Federal Advisory Committee Act.

Compensation

All members are full-time Federal employees who are allowed reimbursement for travel expenses by their agencies plus per diem or subsistence while serving away from their duty stations and in accordance with standard government travel regulations.

Documentation

Agendas and records of actions of Committee meetings are prepared and disseminated to members by the Executive Secretary. Records of actions are submitted to members for approval. Complete records of all Committee activities, including those of Subcommittees and Working Groups, are maintained in the office of the Chair.

The Committee prepares a report for the Chairman of the NSTC not later than 60 days after the end of each fiscal year. The report contains, as a minimum, the Committee's functions; a list of members; a list of Subcommittees and Working Groups; a review of all Subcommittees and Working Groups that have discharged their responsibilities and are recommended by the Committee to be brought to closure; and brief highlights of the previous year.

Termination Date

Unless renewed by the Chairman of NSTC prior to its expiration, the Bioethics Policy Committee shall terminate no later than [one year from date of establishment].

Determination

I hereby determine that the formation of the Bioethics Policy Committee is in the public interest in connection with the performance of duties imposed on the Executive Branch by law and that such duties can best be performed through the advice and counsel of such a group.

Approved:

Assistant to the President for Science
and Technology

Date

Table 1-1—Broad-Based Federal Policy Bodies in Biomedical Ethics^a

Year	Initiative	Locus
1974-78 ^b	National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	Department of Health, Education, and Welfare
1978-80 ^c	Ethics Advisory Board	Department of Health, Education, and Welfare ^d
1978-83 ^e	President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research	Independent executive branch commission
1985-89 ^f	Biomedical Ethics Advisory Committee	Congress

^a Currently, as part of the Human Genome Project, the National Institutes of Health and the U.S. Department of Energy each fund grants through an Ethical, Legal, and Social Issues (ELSI) program. A joint ELSI Working Group advises both programs, but it is not a policy body.

^b Public Law 93-348 (§ 202, 88 Stat. 342, 1974) created the National Commission in July 1974.

^c Although disbanded in 1980, current DHHS regulations provide for the existence of an EAB (45 CFR 46.204). In fact, efforts to reestablish and recharter an EAB stalled in 1988 (53 FR 35232).

^d With reorganization of the Department in 1980, EAB became part of the U.S. Department of Health and Human Services.

^e Public Law 95-622 (42 U.S.C. Ch.6A) authorized creation of the President's Commission in November 1978 and set its termination for December 1982. Public Law 97-377 extended this date through March 1983. Due to delays in appointments and funding, the President's Commission was actually operational for just over 3 years.

^f In reality, BEAC functioned for approximately 1 year. Public Law 99-158 established BEAC in May 1985. It was overseen by the Biomedical Ethics Board (BEB), which was comprised of Members of Congress. Almost a year elapsed before BEB was appointed and then nearly 2 1/2 more years before BEAC was constituted.

SOURCE: Office of Technology Assessment, 1993.

MARK O. HATFIELD
OREGON

United States Senate

WASHINGTON, DC 20510-3701

January 12, 1994

Mr. Jack Gibbons
Director
Office of Science and Technology Policy
Old Executive Office Building
17th & Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Jack:

Attached is a letter to President Clinton in which I urge him to establish a national bioethics commission. I want to be sure you are aware of this correspondence because of your obvious relationship to it in your current position and because of your connection to it when you served as Director of the Office of Technology Assessment.

As you may know, I am convinced of the need for the establishment of a national bioethics commission and have introduced legislation in the Senate to establish such a commission to be located within the Department of Health and Human Services. I am not wedded to the details of this legislation and would be pleased to see the goal of a standing bioethics commission realized, regardless of the particular form it may take.

Jack, please feel free to contact me on this issue. I look forward to working with you to accomplish this and other objectives.

Best personal regards.

Sincerely,



Mark O. Hatfield
United States Senator

MOH/dpk
Enclosure

MARK O. HATFIELD
OREGON

United States Senate

WASHINGTON, DC 20510-3701

January 12, 1994

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

I write to respectfully urge you to establish a standing commission, broad in its scope, charged with reviewing and making recommendations to federal officials on ethically difficult questions that arise in biomedicine. This nation has been too long without the dialogue and guidance such a commission would help provide. Without the assistance of such a body, the United States has lurched from one ethics crisis to the next, at great cost to the nation.

Society will reap great benefits from advances made by modern science. Cures for hereditary diseases, a revolution in agriculture, miracle drugs and an end to human infertility are all being predicted for our future. History has taught us, however, that new technologies often bring with them costs as well as benefits. New capabilities often pose dilemmas for society because they exceed the ethical and legal parameters we have in place to deal with them.

I have watched these advancements with great inspiration and continue to be one of the leading proponents of federal biomedical research funding in the Congress. At the same time however, I have watched as the federal government has allowed many of the most difficult biomedical ethical questions of our time to linger with little federal guidance or dialogue. While society struggles to cope, public officials have too often preferred to allow such issues to be decided by default in a vacuum of leadership.

The examples are numerous. For example, in 1991, the National Institutes of Health sought to patent over 2,000 gene sequences from human brain DNA. Many were astounded to learn that the Patent Office, aided only by centuries old patent law, could offer such protection. Last year in Virginia, a child was born without most of her brain. The child, dubbed "Baby K," could not think, see, hear or feel yet was kept alive at the insistence of her mother and against the advice of Fairfax Hospital officials. Just last October, researchers at George Washington University raised one of the most serious bioethical questions to date when they announced their efforts to clone human embryos. Questions about the limits of in vitro fertilization have continued to

emerge since this announcement.

Finally, federal disclosures of radiation testing on humans during the Cold War and the ongoing health care reform debate have raised profound ethical questions for federal policymakers. I commend you for your leadership in both these areas of great importance and complexity. However, I believe the presence of a standing bioethics commission could provide a welcome addition to the debate in these areas by serving as a source of independent ethical input. I have introduced legislation in the Senate to establish such a commission.

I urge you not await legislative action, but to immediately establish a national bioethics commission. While absolute solutions to the many difficult biomedical ethics dilemmas posed by advancements in modern science will be difficult, if not impossible to find, the need is tremendous and the subject matter is of great importance.

I look forward to working with you on this issue and would be happy to provide any assistance you or your staff require in accomplishing this objective.

Sincerely,



Mark O. Hatfield
United States Senator

MOH/dpk

BIOETHICS POLICY PLANNING MEETING
2:00 p.m., Thursday, February 3, 1994
Eisenhower Conference Room

AGENDA

- | | |
|---|---|
| I. Historical Background | Gary B. Ellis, DHHS |
| II. Current Congressional Interest | DOE/DHHS |
| III. Current Administration Activities | M.R.C. Greenwood, OSTP |
| IV. Review and Discussion of draft Charters | Rachel E. Levinson, OSTP
Gary B. Ellis, DHHS |