

'96 APR 16 P1:18

April 9, 1996

Mr. Alan J. Weisbard
314 Acadia Drive
Madison, Wisconsin 53717-1105

Dear Alan:

Thanks so much for your e-mail message concerning the National Bioethics Advisory Commission.

As you are aware, I created the NBAC by Executive Order 12975 on October 3, 1995. The Commission will fulfill an important role by ensuring that publicly-funded human subject research is conducted in an ethically sound manner. We look forward to receiving the advice of the philosophers, theologians, scientists, legal and medical experts, and other members of the Commission regarding the ethical aspects of human biological, behavioral, and clinical research.

I am in the process of selecting members from among the more than 140 nominations received over the past year from a variety of sources. I hope to announce the appointments shortly and enable the Commission to begin its deliberations as soon as possible.

I appreciate your interest in this important issue.

Sincerely,

BILL CLINTON

BC/DOC/JZS/bws (Corres. #2809263)
(4.weisbard.aj)

cc: Rachel Levinson
cc: Phil Caplan

FW

OFFICE OF SCIENCE AND TECHNOLOGY POLICY



FAX TRANSMITTAL SHEET

Date: 12/21/94

To: Phil Caplan
fax 66704

From: Holly Gwin
202-456-2735, FAX 202-456-6049

Subject: National Bioethics Advisory Commission

Pages: Cover + 6

Comments: A revised charter is attached. We're meeting with the interagency group next week to discuss; please join us if you can. Call if you have questions.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

December 21 1994

MEMORANDUM TO DISTRIBUTION

From: ANGELA PHILLIPS DIAZ 
NSTC EXECUTIVE SECRETARY

Subject: Review of revised charter for the National Bioethics Advisory Commission

Ref: December 29, 1994 10:30 am OEOB Room 472

OSTP, in consultation with members of the NSTC, developed a proposal to create a standing body of experts to consider bioethical issues arising from research on human biology and behavior, and the applications of such research. A draft charter for the National Bioethics Advisory Commission (NBAC) was published on August 12 in the Federal Register; 78 letters, providing comments and/or nominations for NBAC, were received.

A sampling of the major comments are referenced below:

- the scope of NBAC's deliberations should be more clearly defined with respect to health care issues such as access, quality, and financing of health care;
- the scope of NBAC's deliberations should be more clearly defined with respect to issues in clinical ethics, such as assisted suicide, futile care, and end of life issues;
- NBAC should have greater independence from NSTC;
- the staffing and funding levels proposed may not be adequate;
- the relationship between NBAC and other entities should be clarified.

In addition, we received many specific suggestions about specific types of expertise that should be represented on the panel and many suggested topics for NBAC deliberation.

In response to public comment, several changes have been made in the charter. A revised draft is attached for your review.

We will be meeting December 29, at 10:30 am in Room 472 of the Old Executive Office Building to discuss the revised charter and the next steps in establishing NBAC. The charter will be transmitted to NSTC principals for review prior to transmission of the final proposal to the President (who has recently indicated his intention to move forward with NBAC). Therefore, please initiate the necessary steps within your agency/department to inform the appropriate parties of the process we are following and be prepared to represent your agency/department's views on additional revisions to the proposed charter.

Please contact Holly Gwin, (202) 456-2735, if you have questions prior to the meeting. Please call Laurel Kayse at (202) 456-6100 by December 28th to confirm your attendance.

Attachment

Distribution

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Mary Clutter, NSF

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 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 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 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 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 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, is \$1,500,000. The estimated annual person years of staff support from the Office for the Protection from Research Risk 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 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.

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.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

February 24, 1995

MEMORANDUM FOR PHIL CAPLAN

FROM:

HOLLY GWIN 

SUBJECT:

NATIONAL BIOETHICS ADVISORY COMMISSION:
REVIEW OF EXECUTIVE ORDER AND CHARTER

A working group of the National Science and Technology Council drafted the attached materials: an executive order and charter for a proposed National Bioethics Advisory Commission (NBAC). Previous versions of the proposal were shared with your office; these materials have now been submitted to the National Science and Technology Council for concurrence.

Briefly, NBAC would consist of up to 15 members appointed by the President. NBAC would provide advice and make recommendations to the NSTC and other appropriate entities on the bioethical issues arising from research on human biology and behavior, and applications of that research. The executive order and charter identify two high priority categories for NBAC deliberations:

- Management and use of genetic information, including but not limited to human gene patenting; and
- Protection of the rights and welfare of research subjects.

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

As you know, this proposal has been in the works since Fall of 1993, and its timing has been adjusted to accommodate the work of the Advisory Committee on Human Radiation Experiments. Your comments on the proposal would be appreciated, and I hope we can discuss any continuing issues of timing at your earliest convenience.

THE WHITE HOUSE

WASHINGTON

February 23, 1995

MEMORANDUM FOR NATIONAL SCIENCE AND TECHNOLOGY COUNCIL (NSTC)

FROM: JOHN H. GIBBONS 
ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY

SUBJECT: National Bioethics Advisory Commission

Two items are enclosed for your review: 1) an executive order establishing a National Bioethics Advisory Commission (NBAC); and 2) a charter for NBAC. An ad hoc working group of the NSTC, comprising representatives from the Departments of Health and Human Services, Energy, Veterans' Affairs, and Defense, the National Science Foundation, and the National Aeronautics and Space Administration, drafted the documents in consultation with members of the Human Subjects Research Subcommittee of the NSTC Committee on Health, Safety, and Food and various White House offices.

Please provide your written concurrence/comments by Monday, March 13, to this office, attention: Angela Phillips Diaz, Executive Secretary, NSTC, at (202) 456-6026 (FAX).

NBAC will consist of up to 15 members appointed by the President. NBAC will provide advice and make recommendations to the NSTC and other appropriate entities on the bioethical issues arising from research on human biology and behavior, and applications of that research. The executive order and charter identify two high priority categories for NBAC deliberations:

- Management and use of genetic information, including but not limited to human gene patenting; and
- Protection of the rights and welfare of research subjects.

Management and support services for NBAC shall be provided by the Office for Protection from Research Risks (OPRR), 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.

A draft charter for NBAC was published in the Federal Register in August 1994. Public comments on the proposal were generally favorable, and many nominations for members were received in response to the notice. Interested members of Congress were also consulted on the initial and revised drafts.

Thank you for your interest in and support of the National Science and Technology Council and its activities.

Enclosure

CONCURRENCE:

Signature

Date

Department/Agency

2/23/95
DRAFT
EXECUTIVE ORDER

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. Establishment. (a) There shall be 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 comply with the Federal Advisory Committee Act, as amended, 5 U.S. C. App. 2.

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

Section 2. Functions. NBAC will provide advice and make recommendations to the National Science and Technology Council and other appropriate entities. NBAC'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. NBAC shall identify broad, overarching principles to govern the ethical conduct of research, citing individual projects only as illustrations for such principles. NBAC shall not be responsible for the review and approval of individual projects.

As a first priority, NBAC will direct its attention to consideration of:

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

In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC shall have the authority to identify bioethical issues, on its own behalf, for deliberation. NBAC will also accept suggestions of issues for consideration from Congress and the public. NBAC 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. (NBAC ordinarily will not deliberate on a bioethical issue of interest to just one department or agency.)

Section 3. 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) The Commission may conduct inquiries, hold hearings and establish subcommittees, as necessary. 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.

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.

(c) 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).

(d) Management and support services for NBAC shall be provided by the Office for Protection from Research Risks (OPRR), 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.

Section 4. 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 Congress, shall be performed by OPRR, 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.

2-23-95

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.

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

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

In addition to responding to requests for advice and recommendations from the National Science and Technology Council, the Commission shall have the authority to identify bioethical issues, on its own behalf, for deliberation. The Commission will also accept suggestions of issues for consideration from Congress and the public. The Commission shall consider four criteria in establishing priority for its activities:

- A. The public health or public policy urgency of the bioethical issue.
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- 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 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 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 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. 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, is \$1,500,000. The estimated annual person years of staff support from the Office for the Protection from Research Risk 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 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.

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.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

95 SEP 12 AM 1:15

September 11, 1995

MEMORANDUM FOR DESIGNATED AGENCY HEADS
(SEE ATTACHED DISTRIBUTION LIST)

FROM: Robert G. Damus *RGD*
General Counsel

SUBJECT: Proposed Executive Order Entitled "National
Bioethics Advisory Commission"

Attached is a proposed Executive order entitled "National
Bioethics Advisory Commission."

It was prepared by Office of Science and Technology Policy,
in accordance with the provisions of Executive Order No. 11030,
as amended.

On behalf of the Director of the Office of Management and
Budget, I would appreciate receiving any comments you may have
concerning this proposal. If you have any comments or
objections, they should be received no later than close of
business Thursday, September 14, 1995. Please be advised that
agencies that do not respond by the September 14, 1995 deadline
will be recorded as not objecting to the proposal.

Comments or inquiries may be submitted by telephone to Mr.
Mac Reed of this office (Phone: 395-3563; Fax: 395-7294).

Thank you.

Attachments - Distribution List
Proposed Executive Order

cc: Jack Lew
John Koskinen
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Honorable Todd Stern
Assistant to the President
and Staff Secretary

Honorable Jack Quinn
Chief of Staff to the Vice President

8/21/95
DRAFT
EXECUTIVE ORDER

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. Establishment. (a) There shall be 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 comply with the Federal Advisory Committee Act, as amended, 5 U.S. C. App. 2.

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

Section 2. Functions. NBAC will provide advice and make recommendations to the National Science and Technology Council and other appropriate entities. NBAC'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. NBAC shall identify broad, overarching principles to govern the ethical conduct of research, citing individual projects only as illustrations for such principles. NBAC shall not be responsible for the review and approval of individual projects.

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

In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC shall have the authority to identify bioethical issues, on its own behalf, for deliberation. NBAC will also accept suggestions of issues for consideration from Congress and the public. NBAC shall consider four criteria in establishing priority for its activities:

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- 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. (NBAC ordinarily will not deliberate on a bioethical issue of interest to just one department or agency.)

Section 3. 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) The Commission may conduct inquiries, hold hearings and establish subcommittees, as necessary. 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.

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.

(c) 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).

(d) 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. The Office for Protection from Research Risks, DHHS, will provide management and support services to NBAC.

Section 4. 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 Congress, shall be performed by OPRR, 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.

OSTP

Executive Office of the President
Office of Science and Technology Policy
Washington, D.C. 20500

SCIENCE DIVISION

FAX TRANSMITTAL SHEETDATE: *10/3*

TO:

Phil Carter

ORGANIZATION:

PHONE:

FAX:

FROM:

Rachel E. Lennon

PHONE:

FAX:

NUMBER OF PAGES INCLUDING COVER PAGE: *1*SPECIAL INSTRUCTIONS: *original will follow*

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 on August 12, 1994, 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.

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*.

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.

President Clinton Pledges Openness in Government Tuesday, October 3, 1995



"America's greatness is measured not only in how we so frequently do right, but also in how we act when we do wrong: we confront our mistakes and take action."

President Clinton, October 3, 1995

Openness in Government. Shortly after President Clinton entered office, we discovered that during the Cold War, the U.S. government carried out experiments involving radiation on our citizens. The President moved quickly to get the full truth about the experiments out in the open:

- o Created a Commission to find the truth about human radiation:
 - o Whether the experiments met ethical and scientific standards.
 - o Whether today's research lives up to our highest values.
- o Declassified thousands of pages of documents to help find the truth.

Making Government Accountable. The Commission reported that thousands of government radiation experiments took place -- some of which did not meet today's ethical standards or the standards of all time. They failed the test of our national values. The President is determined to make our government more open and accountable -- a government that reflects our values.

Executive Action. Today, the President will take executive action to make sure that nothing like this ever happens again:

- o Direct the Cabinet to build on the recommendations made in the Commission's report and to devise promptly a system of relief -- including compensation where appropriate -- that meets the standards of both justice and conscience.
- o Sign an executive order instructing every arm and agency of government that conducts, supports, or regulates research involving human beings to review immediately their procedures and to report back by Christmas.
- o Create a Bio-Ethics Advisory Commission to supervise this process, to watch over all such research, and to see to it that we never again stray from the basic value of protecting our people.

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

96 JUN 11 P6:06

June 11, 1996

MEMORANDUM FOR DISTRIBUTION

FROM: SAM SEIDEL *GS*

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 MONTTOYA

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 renown 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.

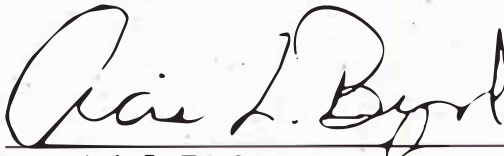
These nominees were selected by acclamation from our thirty member groups.
Resumes will be provided at your request.

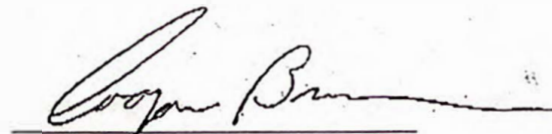
Please understand that we have deep and sincere appreciation for the process that has been undertaken by the White House and Interagency Working Group to rectify and remedy the tragedy created by Cold War human radiation experiments, which obviously includes formation of NBAC. However, that process needs 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.

Agenda
Interagency Working Group on Human Radiation Experiments
June 20, 1996, 2:30-4:00

- I. National Bioethics Advisory Committee- Rachel Levinson,
Jon Foster
- . Status and content of announcement
 - . ACHRE recommendations identified as possible referrals to NBAC:
 - Recommendation 9:** NBAC's role in establishing strategies to ensure the centrality of ethics in human subject research.
 - **Recommendation 10:** NBAC's role in changing IRB's.
 - Recommendation 11:** Ongoing public forum needed to discuss ethical issues raised by human experimentation.
 - Recommendation 13:** NBAC's role in improving oversight, sanctions, and scope of human subjects protections.
 - Recommendation 14:** NBAC's role in future compensation for research injury.
 - Recommendation 15:** NBAC's role in deciding whether federal rules should be changed to codify "no waivers" of consent.
- II. Uranium Miners (Recommendation 7) - Paul Yanowitch
- III. Public Involvement in follow-up to ACHRE
- IV. Next Steps
- . . Next meeting schedule and agenda (proposed: atomic veterans; Marshall islanders; nasopharyngeal radiation)

96 JUN 26 P5:58

FAX Transmittal Sheet**DATE:** June 26, 1996**TO:** Phil Caplan**ORGANIZATION:** _____**TELEPHONE:** 62704**FAX:** 62215**FROM:** RACHEL E. LEVINSON**TELEPHONE:** 202-456-6137**FAX:** 202/456-6027**NUMBER OF PAGES, INCLUDING COVER PAGE:** 6**SPECIAL INSTRUCTIONS:** See marked section on page 3

6-19-96

DRAFT

NATIONAL BIOETHICS ADVISORY COMMISSION REVISED CHARTER**Purpose**

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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 ~~advice and recommendations~~ 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.

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- 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 ~~engineering~~ ~~engineering~~.

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 relative capacity of the Commission as compared to other entities to 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 ~~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 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.

/William J. Clinton/

The Commission may publish a statement of specific concerns and seek input from those agencies whose activities relate to those concerns.



OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Science Division

Executive Office of the President
436 Old Executive Office Building
Washington, DC 20502

202-456-6130

202-456-6027 (FAX)

FAX TRANSMITTAL SHEET

DATE: 7 . 8 . 96

TO: Phil Caplan

PHONE NUMBER: 456 2702

FAX NUMBER: 456 2215

FROM: Cassie Gilson (OSTP)

NUMBER OF PAGES (INCLUDING COVER SHEET): 9

ADDITIONAL MESSAGE:

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

July 8, 1996

MEMORANDUM FOR DISTRIBUTION

FROM: Cassie Gilson (OSTP) *CK*.
SUBJECT: NBAC Q & A's

It has come to my attention that the package of NBAC material you received last Wednesday did not include a copy of the Q&A's designed for use inside the Administration. I am forwarding that document, as well a revised draft of the external Q&A's that will be sent to NBAC members upon their appointment.

I hope this has not caused you any inconvenience. If you have any questions or comments, please contact me at (202) 456-6078.

Thank you.

Distribution:

OSTP

Ernest Moniz
Rachel Levinson

White House

Phillip Caplan
Elizabeth Drye
Diane Regas

HHS

Harold Varmus
Betsy D'Jamoos

DOE

Tara O'Toole

DRAFT 2
7/ 2/ 96

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 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 relative capacity of the Commission as compared to other entities to deliberate 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 is eager to respond quickly to the ACHRE recommendations and has formulated an interagency group to do so. This group, led by the Domestic Policy Council, is developing a number of proposals, which will include a range of initiatives to address and reach resolution on issues raised by ACHRE.

Q. Will the IAWG issue a public report? When?

A. Answer to be provided by DPC.

Q. How is 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, ethically and otherwise, 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 supplied 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. Other services may be provided by other agencies.

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. Furthermore, NBAC will only be addressing Federally-funded research. However, the Commission's findings and subsequent recommendations &/or guidelines will be made available to the private sector.

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 testing have strongly supported NBAC's creation and welcome its input as they continue to grapple with difficult questions. We expect that NBAC's recommendations will ultimately be reflected in agency program guidelines, research protocols, and corresponding legislation.

DRAFT 3
7 / 8 / 96

National Bioethics Advisory Commission

The following background materials have been prepared in anticipation of NBAC's public announcement. You may find the information useful in responding to any press inquiries you may receive.

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. NBAC members 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 relative capacity of the Commission as compared to other entities to deliberate 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. The Commission was established to help enable us to deal effectively with current issues presented by the advent of and access to new knowledge and technology. It will consider past research activities, including the human radiation experiments, as valuable experience from which to learn in developing their guidance.

Q. Who will serve on NBAC ?

A. The Commission's members are drawn from the following disciplines: philosophy/theology, social and behavioral sciences, law, medicine and the allied health professions, and biological research. Several NBAC members are drawn from the general public and the Commission is balanced between scientists and non-scientists.

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

A. In addition to the 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. Commission meetings will also be announced in the Federal Register as required by law.

Q. Why is NBAC necessary?

A. 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. Will NBAC members be paid?

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

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. Furthermore, NBAC will only be addressing Federally-funded research. However, the Commission's findings and subsequent recommendations &/or guidelines will be made available to the private sector.

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

issucs.

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. However, all of the Federal agencies involved in human subject research have strongly supported NBAC's creation and welcome its input as they grapple with difficult questions. Furthermore, NBAC's recommendations will be delivered to the President for his consideration. We expect that NBAC's recommendations will ultimately be reflected in agency program guidelines, research protocols, and corresponding legislation.

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

96 JUL 5 4 8: 57

July 3, 1996

MEMORANDUM FOR DISTRIBUTION

FROM: JONATHAN FOSTER *JF*
Deputy Director for Management and General Counsel

SUBJECT: Upcoming Announcement of NBAC Appointments

We expect to announce NBAC appointments shortly. In preparation for the announcement, OSTP has prepared two sets of questions and answers, a longer set for internal use, and a shorter set to send to the NBAC appointees. We have also prepared a short press release. I have enclosed all three of these documents for your review. If you have any comments or edits, please let Rachel Levinson or me know by noon on Monday, July 8. Rachel can be reached at 456-6137; I can be reached at 456-2735.

Thank you.

Attachments

cc: OSTP
Ernest Moniz, Associate Director, Science Division
Rachel Levinson, Assistant Director, Life Sciences, Science Division

Distribution:

White House

Phillip Caplan, Special Assistant to the President and Deputy Staff Secretary
Elizabeth Drye, Chief of Staff, DPC
Diane Regas, Senior Policy Analyst, DPC

HHS

Harold Varmus, Director, NIH
Betsy D'Jamoos, White House Liaison

DOE

Tara O'Toole, Assistant Secretary, Environment, Safety & Health

DRAFT

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release
July 11, 1996

Contact: Rick Borchelt, (202) 456-6020

**PRESIDENT CLINTON NAMES NATIONAL
BIOETHICS ADVISORY COMMISSION**

President Clinton today announced appointments to the National Bioethics Advisory Commission. Established by Presidential Executive Order 12975 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, appointed by the President, are experts in the fields of philosophy and theology, biology, social and behavioral science, law and medicine. Community representatives fill out the Commission's expertise. 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.

[2-3 Sentences about each of the members will be inserted here.]

The Commission is expected to hold its first meeting this Fall. In setting 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 the 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 by members of the public.

##

National Bioethics Advisory Commission

The following background materials have been prepared in anticipation of NBAC's public announcement. You may find the information useful in responding to any press inquiries you may receive.

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 of genetic information, including, but not limited to, human gene patenting. NBAC members 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 relative capacity of the Commission as compared to other entities to deliberate 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. The Commission was established to help enable us to deal effectively with current 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. Who will serve on NBAC ?

A. The Commission's members are drawn from the following disciplines: philosophy/theology, social and behavioral sciences, law, medicine and the allied health professions, and biological research. Several NBAC members are drawn from the general public and the Commission is balanced between scientists and non-scientists.

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

A. In addition to the 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 NBAC necessary?

A. Science and technology are advancing at an unprecedented rate and presenting new challenges, ethically and otherwise, 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. Will NBAC members be paid?

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

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. Furthermore, NBAC will only be addressing Federally-funded research. However, the Commission's findings and subsequent recommendations &/or guidelines will be made available to the private sector.

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. While NBAC will set its own agenda and, in doing so, will decide the manner in which their findings are most effectively presented, all of the Federal agencies involved in human subject testing have strongly supported NBAC's creation and welcome its input as they grapple with these difficult questions. Furthermore, NBAC's recommendations will be delivered to the President for his consideration. We expect that NBAC's recommendations will ultimately be reflected in agency program guidelines, research protocols, and corresponding legislation.

DRAFT
7 / 3 / 96

National Bioethics Advisory Commission

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