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Boards and Commissions - National Bioethics Advisory Comm [Commission]

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**2**

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**9**

**Position:**

**2**

From the Desk of

**JONATHAN FOSTER**

Kathi -

The attached is fyi on the  
Ezekiel Emmanuel issue.

Jon

P.S. - Rachel Lurman is the person who  
handles NBAC issue for us. "Eric"  
is Eric Moriz, vvo Associate Director  
for Science. Harold Shapiro is the  
chairman of NBAC.

Author: Rachel E. Levinson at ostp  
Date: 9/27/96 11:03 AM  
Priority: Urgent  
TO: Jonathan Foster  
TO: Lisa Duffey (Ernie Moniz)  
Subject: Ezekial Emanuel

----- Message Contents -----

Jon- Thanks for letting me know about your communication with Kathi Whalen. I have some additional information that may be useful to pass along to her.

Instead of an IPA, NIH has proposed that a Professional services contract be let to Dr. Emanuel to make it clear that he is not a Federal employee and that he will not be hired in a policymaking or supervisory capacity. I think this might allow him to serve on the Commission without violating our term "non-Government" in the charter.

However, there is another issue of conflict that must be taken into consideration. The President's first charge to the Commission is to review the adequacy of Federal procedures for the protection of the rights and welfare of human research subjects. While he has had no responsibility for such procedures to date, Dr. Emanuel is to be appointed Chief of the NIH Division of Clinical Ethics in October 1997. This appointment is public information.

I was inclined to let him come on NBAC while his consulting for NIH was estimated to be one day per week, assuming that he would not be considered a Federal employee. I think you agreed with this. Ernie had asked that there be documentation that once this commitment increased, he would have to resign from NBAC. Now that we know that he is clearly in line to become a Federal employee, I'm less comfortable.

Harold Shapiro has suggested that at its first meeting, NBAC members go around the table and discuss their individual potential conflicts. This might be a good one for them to chew on, provided we could go either way.

In any case, this must be resolved quickly in light of the upcoming meeting, NEXT Friday.

-- Rachel

THE WHITE HOUSE  
WASHINGTON

September 9, 1996

MEMORANDUM FOR KATHY WHALEN

From: Patsy Thomasson, *Patsy Thomasson*  
Deputy Assistant to the President and  
Deputy Director for Presidential Personnel

RE: EZEKIAL J. EMANUEL, MEMBER  
NATIONAL BIOETHICS ADVISORY COMMISSION

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Attached is a memorandum from Jonathan Foster from the Office of Science and Technology requesting guidance from the General Counsel's office on an issue that has risen with Dr. Ezekial Emanuel. He has been awarded an Intergovernmental Personnel Action with the National Institutes for Health in which he will be spending 20 percent of his time as a Special Consultant on Clinical Bioethics.

OSTP is concerned about the charter provision that states the NBAC members will not be a governmental expert. I've attached the charter and the memo from OSTP for your review. Please advise us if this relationship poses a problem. Thank you for your assistance.

Rahm's  
brother

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PT doesn't want to  
kill him if can  
be helped.

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

August 23, 1996

MEMORANDUM FOR LIZ MONTROYA

FROM: JONATHAN FOSTER   
SUBJECT: EZEKIAL J. EMANUEL -- NBAC APPOINTEE

A question has arisen concerning an appointed member of the National Bioethics Advisory Commission (NBAC). The President appointed Ezekial J. Emanuel, M.D., Ph.D., to NBAC last month. However, at that time, OSTP was not aware that Dr. Emanuel was in the final stages of negotiating an Intergovernmental Personnel Action (IPA) with NIH to become a Special Consultant on Clinical Bioethics. The question is whether Dr. Emanuel's affiliation with NIH necessitates his resignation from NBAC.

NBAC's purpose is to advise and make recommendations to the National Science and Technology Council (NSTC), other appropriate entities and the public, on bioethical issues arising from research on human biology and behavior, and the applications of that research. As stated in the NBAC charter, 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" (emphasis added) (see attached NBAC Charter).

As the IPA is currently structured, Dr. Emanuel will retain his academic position at Harvard but spend 20% of his time at NIH in 1996-1997 increasing to 60% of his time in 1997-1998, with the ultimate goal of becoming the Director of a new Department of Clinical Bioethics at the NIH. NIH will pay a pro rata proportion of his salary to Harvard. NIH has indicated that it would explore the possibility of Harvard paying Dr. Emanuel's full salary if NIH's payment of a portion of the salary requires Dr. Emanuel's resignation from NBAC.

Under the terms of the charter, Dr. Emanuel will serve on NBAC for a term of at least two years, and, therefore, for at least one year will spend 60% of his time at NIH. Apparently, other candidates for NBAC were not considered because of similar affiliations with the government. The question is, therefore, whether the IPA prevents Dr. Emanuel from being a non-Government expert, and, therefore, preclude him from serving on NBAC.

Per our conversation, we will rely upon your office, working with the White House Counsel's Office, to provide guidance on this matter. If you need any additional information, please call me at 6-2735. Thank you.

Attachment

cc: E. Moniz  
R. Levinson

## NATIONAL BIOETHICS ADVISORY COMMISSION CHARTER

### Purpose

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

### Authority

Executive Order 12975. This Commission is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation of advisory committees, and implementing regulations (41 C.F.R. § 101-6.10).

### Functions

The National Bioethics Advisory Commission shall advise, consult with, and make recommendations to the National Science and Technology Council, Federal agencies, and other appropriate entities, and also make available to the public the Commission's advice and recommendations. The Commission's purview includes the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to bioethical issues arising from research on human biology and behavior, and applications, including the clinical applications, of that research. The Commission shall identify broad, overarching principles to govern the ethical conduct of research, citing individual projects only as illustrations for such principles. The Commission shall not be responsible for the review and approval of individual projects.

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

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

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

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

### Structure

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

Members shall be appointed for overlapping four-year terms. Initially, members will be appointed for two-, three- or four-year terms. Terms of more than two years are contingent upon renewal of the National Bioethics Advisory Commission by appropriate action prior to its termination. The Chairperson shall be appointed by the President. The term of office for the Chairperson shall be two years, renewable by appropriate action of the President.

If a vacancy occurs on the Commission, the President shall make an appointment to fulfill the term. Any member appointed to fill a vacancy occurring prior to expiration of the term for which his or her predecessor was appointed shall serve for the remainder of such term.

Members may serve after the expiration of their terms until their successors have taken office.

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

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

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

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

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

The Assistant to the President for Science and Technology and the Secretary of Health and Human Services shall be notified upon establishment of each subcommittee, and shall be provided information on the name, membership (including chair), function, estimated duration of the subcommittee, and estimated frequency of meetings.

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

#### Meetings

Meetings of the Commission shall be held up to 10 times a year at the call of the Chairperson. Meetings of the subcommittee(s) shall be convened as necessary. A Federal Government official shall be present at all meetings.

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

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

#### Compensation

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

#### Annual Cost Estimate

The estimated annual cost for operating the National Bioethics Advisory Commission is \$500,000.

#### Reports

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

NATIONAL BIOETHICS ADVISORY COMMISSION

Independent

AUTHORITY: Executive Order 12975, October 3, 1995 (establishes)

METHOD: Appointed by the President

MEMBERS: Not more than FIFTEEN

CHAIRPERSON: Designated by the President from among the members

TERM: Pleasure of the President

SALARY: Members shall be compensated in accordance with Federal law and 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).

PURPOSE: Commission shall (a) 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) Shall identify broad principles to govern the ethical conduct of research, citing specific projects only as illustrations for such principles.

(CONTINUED - PAGE TWO)

NATIONAL BIOETHICS ADVISORY COMMISSION

Independent

- (c) 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, the Commission also may accept suggestions of 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.

ADMINISTRATIVE  
SUPPORT:

The Secretary of Health and Human Services shall provide management and support services to the Commission.

TERMINATION:

Shall terminate October 2, 1997, unless extended prior to that date.

## EXECUTIVE ORDERS

No. 12975

Executive Order 12975 of October 3, 1995

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

60 F.R. 52063

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:

## EXECUTIVE ORDERS

No. 12975

(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).

## EXECUTIVE ORDERS

No. 12975

(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.

Executive Order 12976 of October 5, 1995

### Compensation Practices of Government Corporations

60 F.R. 52829

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, and sections 1105, 1108, and 1111 of title 31, United States Code, it is hereby ordered as follows:

#### **Section 1. Statement of Presidential Principles.**

Government corporations subject to this order should not pay bonuses in excess of those authorized by sections 4501 through 4507 of title 5, United States Code, except as otherwise specifically provided by law.

**Sec. 2. Administration Review.** (a) Before taking action to approve any bonus in excess of those authorized in section 4502 of title 5, United States Code, each corporation subject to this section (as provided in section 6 of this order) shall submit information to the Director of the Office of Management and Budget (OMB) relating to such bonuses as provided in subsection (b). Such corporation shall refrain from approving any such bonus until the Director of OMB has had an opportunity to review the information provided by the corporation.