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Request for ballot
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NOV - 1 1993

INSTITUTE OF MEDICINE

NATIONAL ACADEMY OF SCIENCES

2101 CONSTITUTION AVENUE WASHINGTON, D. C. 20418

KENNETH I. SHINE, M. D.
PRESIDENT

October 27, 1993

Re: Nominations of Candidates for Election in 1994

Dear Members of the Institute:

The capacity of the Institute of Medicine for genuine achievement depends upon its membership, and it is now time to turn our attention to the important matter of proposing new candidates for election to the IOM next year. Complete proposals for election in 1994 will be accepted until February 28, 1994. Candidates must be proposed by two regular or senior or foreign associate members of the Institute.

On behalf of the Council and the Membership Committee, I want to encourage you again this year to identify and nominate qualified individuals in a number of areas whose representation we would like to increase: distinguished **minority** (including, of course, Asian and Hispanic individuals) and **women candidates**; and distinguished individuals in the following disciplines (identified by the Membership Committee for emphasis this year): **nutrition; emergency medicine; toxicology; environmental/occupational medicine; genetic counseling; long term care; and critical care**. I am certain that most of you are aware of outstanding individuals in one or more of these areas who meet our criteria for membership, and I urge you to nominate them.

In addition, all members are asked to assist in identifying qualified candidates for two of our sections: **Section 1** (Physical, Mathematical, Computer, Information & Engineering Sciences), because its small size and heterogeneity have hindered its ability to identify candidates from many of the disciplines represented in the section; and **Section 8** (Family Medicine, Emergency Medicine, Physical Medicine & Rehabilitation, and Osteopathy), because it is the smallest section and predominantly represents family medicine.

I want to remind you that candidates nominated in the 1993 election who did not appear on the final ballot will not be automatically considered for the next election. If you wish a candidate to be reconsidered, you may renominate that individual or request that the candidate's proposal be reactivated. This latter request must be made in writing by both the sponsor and co-sponsor of the candidate and should be sent to the IOM Membership Office at the above address by February 28.

The primary criterion for membership is professional excellence in a field relevant to the mission of the Institute of Medicine. Although the diversity of our membership is essential to our mission, representation of specific organizations, interest groups, or professional disciplines is not a criterion for membership.

I cannot stress strongly enough the importance of the need to propose the very best people in the various relevant areas of endeavor. Although you each may have a natural tendency to want to enlarge the number of members from your own school or institution, proposals will be considered strengthened if the nominee is from outside the sponsor's institution.

Guidelines for Nominations

In order to maintain a membership of the highest quality and distinction, it is crucial that we have a focus and rigor in the nominating process. Therefore, we have developed the following guidelines for the nomination of candidates:

1. The proposal shall clearly identify the single currently active and ongoing achievement of the candidate.
2. The proposal shall document that the individual is a leader in the field of nomination. For example, if you are nominating a person because of the quality of her/his science, you should document the first-rate quality of the science, that it has real moment, and that the thrust of the work continues. If the person is an outstanding practitioner, evidence must be provided.

In the administrative area, candidates should be nominated for their contributions to administration, not because of the administrative position they hold. The following criteria--recommended by an ad hoc group that reviewed the administrative category (Section 12) and endorsed by the Council and Membership Committee--should be applied: original contributions to the field of administration and/or outstanding performance as a practitioner in a management role (for example, a history of improvement in an organization during the tenure of the individual; a discernible track record over time reflected by the introduction of new, and/or the transference of, ideas; ability to solve the apparently insoluble). Of particular interest in the administrative arena are outstanding individuals in the fields of financing and insurance, health services delivery, and management of technology transfer.

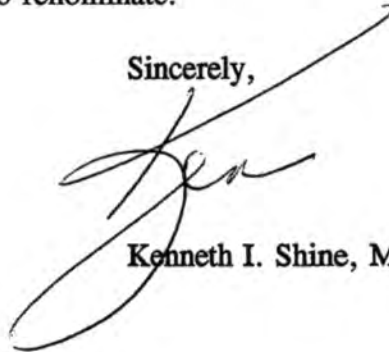
3. You should consider your selection of the section for membership carefully. The choice should be consistent with the primary field or area of the candidate's most important current achievement/contribution.

In many cases, a candidate will have additional qualities and dimensions that would add greatly to the expertise and distinction of our membership. These qualities enhance the nomination, but of primary importance is the identification and validation of a candidate's current excellence in a single, specific field.

Both the Council and the Membership Committee want to ensure that no candidate is placed at a disadvantage because of an inadequate proposal. We therefore have asked that the section leaders review each proposal for their section as soon as it is received, and if necessary, request that the sponsor(s) modify the proposal. In order to provide a uniform basis for the evaluation of all candidates proposed, only information presented on the official proposal form, within the space allotted, will be reviewed; no additional co-sponsoring statements or other letters of support will be accepted. (Although the nomination and election of foreign associates follow the same procedures as the election of all other members, a separate nomination form is required. These forms also can be obtained from the IOM Membership Office.) A member can submit a nomination for consideration to any section. The section classification for each nomination should be indicated by the candidate's primary sponsor on the front of the proposal form.

Once again, **complete proposals for the 1994 election will be accepted until February 28, 1994.** Nomination forms, as well as nomination forms for foreign associate membership, may be requested on the attached request form, which should be sent to Mrs. Jana Surdi at the above address or faxed to her attention at 202-334-1694. Mrs. Surdi also can assist with any questions you may have about unsuccessful candidates nominated in previous elections whom you may wish to renominate.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ken', with a long, sweeping horizontal line extending to the right.

Kenneth I. Shine, M.D.

Enclosures: Request for 1994 IOM Nomination Form
(for regular, senior, or foreign associate membership)
Election Schedule - 1994

FAX TRANSMISSION COVER SHEET**ROUNDTABLE FOR THE DEVELOPMENT OF DRUGS
AND VACCINES AGAINST AIDS**

Institute of Medicine
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

202-334-2453
202-334-2939 (FAX)

Date: October 6, 1993

Number of Pages Including Cover: 9

TO: Retina Holmes/Kristine Gebbie

FROM: Leslie Hardy, Director, AIDS Roundtable

COMMENTS: Please see attached.

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE WASHINGTON, D.C. 20418

DIVISION OF HEALTH PROMOTION
AND DISEASE PREVENTION

FAX: 202/334-2939

MEMORANDUM

TO: Kristine Gebbie

FROM: Leslie Hardy *Leslie*

DATE: September 16, 1993

SUBJECT: IOM Roundtable for the Development of Drugs and Vaccines
Against AIDS

I'm delighted that you're willing to serve on the AIDS Roundtable, and look forward to your participation in our future sessions. As we discussed, I'm faxing you materials on the Roundtable, some of which you may have already received. The first items are a current roster of the Roundtable membership and a background document describing its mission and activities. Also attached is a summary of a recent meeting of the Roundtable, during which a subgroup of members explored the future of the Roundtable (e.g., its continuation as a forum for dialogue, its format of operation, composition, and important topics on which the Roundtable should focus over the next few years).

As you know, the Roundtable's final meeting this year will be held on **Friday, December 10** in the Lecture Room of the National Academy of Sciences building, 2101 Constitution Avenue, NW. It will focus on correlates of protective immunity to HIV. The one-day workshop will be preceded by a dinner/executive session of the Roundtable on **Thursday evening, December 9**. We'll convene in the Members Room of the NAS building around 6:00 pm for a reception/executive session; dinner will begin around 7:30 pm. An agenda for the workshop and further details regarding the dinner session will be sent in several weeks. As I mentioned, if you need to choose between the workshop and dinner session, I think your participation in the dinner/executive session would be most helpful.

We will be sending out calendars for next year to begin scheduling 1994 meetings in the spring and fall. We will do our best to accommodate your schedule as we plan these events.

The AIDS Roundtable: A Neutral Forum

Communication among policy makers, biomedical researchers, care providers, and patient advocates is an important element in the development of new, more effective therapies and vaccines to treat or prevent HIV infection and its associated medical conditions. Recognizing the need for such ongoing dialogue, in 1988 the IOM established the Roundtable for the Development of Drugs and Vaccines Against AIDS as a convening mechanism to explore impediments to the rapid availability of safe, effective drugs and vaccines for HIV infection and AIDS.

The committee (co-chaired by **Barton F. Haynes**, Duke University Arthritis Center, and **Paul A. Volberding**, San Francisco General Hospital) comprises 21 leaders from government, the pharmaceutical industry, academia, and patient advocacy groups, representing a unique blend of expertise and viewpoints on scientific and public policy questions related to AIDS drug and vaccine development. The Roundtable is sponsored by the American Foundation for AIDS Research, the departments of the Army and of Veterans Affairs, the Pharmaceutical Manufacturers Association, and the Public Health Service.

The Roundtable meets quarterly and holds workshops on topics selected for their urgency and potential to expedite drug and vaccine development. Past workshops have examined:

- o the use of surrogate endpoints in evaluating AIDS drugs for effectiveness and approving them for marketing;
- o expanding patient access to investigational therapies for HIV infection and AIDS;
- o the development of effective therapies for AIDS-related infections;
- o understanding HIV pathogenesis and its implications for drug and vaccine development;
- o HIV drug resistance and the use of combination antiretroviral therapies to treat HIV infection and AIDS; and
- o the development and evaluation of preventive HIV vaccines.

The Roundtable's 1993 activities include a May workshop on gene therapy approaches for treating HIV infection and AIDS, a September workshop on the changing demographics of the HIV/AIDS epidemic and their impact on clinical research, and a final workshop in December on correlates of immunity to HIV. Summaries of the Roundtable's workshops are issued periodically.

The success of the Roundtable rests on the IOM's singular ability to assemble individuals from the public and private sectors in a national forum on neutral ground to examine scientific and policy dilemmas of mutual interest and to discuss potentially contentious issues surrounding the development of AIDS drugs and vaccines.

For further information about the Roundtable's activities or publications, contact Leslie M. Hardy, Project Director, at (202) 334-2453.

INSTITUTE OF MEDICINE

Roundtable for the Development of Drugs and Vaccines Against AIDS

ROSTER

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AIDS Activities - Institute of Medicine

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INSTITUTE OF MEDICINE

Roundtable for the Development of Drugs and Vaccines Against AIDS

Meeting Summary
July 22, 1993

As the Roundtable for the Development of Drugs and Vaccines Against AIDS nears completion of its second term in mid-1994, it seems appropriate to reflect on its value and continuation as a neutral forum for dialogue on scientific and public policy questions pertaining to HIV drug and vaccine development. To this end, a subgroup of Roundtable members (see attached participants list and agenda) convened on July 22, 1993, to discuss the future course of the Roundtable—its continuation, format of operation, composition, and the important topics or areas on which the Roundtable should focus its attention over the next few years.

Expanding the Roundtable's Influence

As a prelude to exploring the Roundtable's future directions, Paul Volberding (Roundtable co-chair) introduced a discussion of ways to extend the impact of the Roundtable's activities (including broader dissemination of the workshops' results) beyond those individuals who participate in our meetings. Queta Bond (IOM Executive Officer) offered several options for distributing syntheses of the Roundtable's workshop discussions to a wider audience. They are listed below. (NOTE: Any one or combination of these options could be used for dissemination purposes. We could also publish, as we have in the past, a brief free-standing IOM report [e.g., 15-20 pages] that distills the information presented at the meeting.)

- Highlight the salient issues or questions raised at a particular workshop in a 1,000-word, *From the Institute of Medicine*, column published in *JAMA*. This column appears roughly every six weeks and covers various aspects of the IOM's work (e.g., recommendations from IOM study committees, highlights from workshops or meetings, etc.) It could provide a quick, efficient mechanism for widely disseminating brief synopses of Roundtable workshops.
- Develop a comprehensive article (e.g., 2,500 words or more) that synthesizes the workshop presentations and discussions and provides additional information as needed. Such a paper could be written by a Roundtable member or group of members and staff for submission to a peer-reviewed journal, such as *NEJM* or *Science*. The full Roundtable membership would review the manuscript before submission to the journal.

- Prepare a signed, op-ed piece about a specific issue or workshop for distribution through the Academy's op-ed service. Although these pieces are generally picked up by smaller newspapers, they still reach a wide audience who may not have ready access to the kinds of information frequently discussed at the Roundtable's workshops.

Roundtable members revisited the issue of opening our workshops to the press. They recognized the value of closing the meetings on occasion but acknowledged that some workshop topics may warrant broader coverage by the press. The group decided that before each workshop we should discuss whether the meeting will be open to the media and what the written product(s) will be.

The Roundtable concluded that the upcoming September workshop, *The Changing Demographics of the HIV Epidemic: Implications for Clinical Research*, should be open to the press, and we should develop a full journal article based on the workshop presentations and discussions. It was suggested that a subcommittee of Roundtable members who are participating in the September workshop could be designated as the writing group. (Lawrence Brown, Gerald Friedland, Helen Rodriguez-Trias, and Catherine Wilfert have agreed to serve as the drafting committee for this manuscript.)

Future of the Roundtable

Roundtable's Value and Unique Qualities

Paul Volberding launched the discussion of the Roundtable's future by posing several questions to the group: Should the Roundtable continue to operate? Should we change the structure, composition, and direction of the Roundtable? Members unanimously endorsed its continuation. They observed that the Roundtable brings together a diverse group of leaders from government, academia, the pharmaceutical and biotechnology industries, and patient advocacy communities, and thereby forms a unique blend of expertise and viewpoints on scientific and policy questions pertaining to HIV drug and vaccine development. Further, it provides a neutral forum (or "safe harbor") in which to explore and debate a variety of thorny issues (or "sticky wickets") surrounding the development of effective AIDS drugs and vaccines. Finally, the Roundtable offers an opportunity to examine areas in which science and public policy intersect and to consider the policy implications of scientific inquiry and discovery in the area of HIV drug and vaccine development.

Roundtable's Format of Operation

Meeting participants also discussed the format of the Roundtable's operations (e.g., number, size, and content of meetings or workshops). Several members suggested that the Roundtable resist convening strictly scientific or technical sessions on HIV drug and vaccine development, as there are multiple forums in which scientific data are presented and discussed. Rather, the Roundtable should identify problem areas or difficult, controversial issues that can be uniquely addressed by the Roundtable's diverse perspectives and expertise. Although the selection of topics for discussion will necessarily guide the structure of the Roundtable's meetings, one member suggested that we convene smaller, focused sessions (either separately or following a larger, public workshop) during which a few key scientists, policy makers, and the Roundtable members can grapple with specific scientific and policy dilemmas that complicate AIDS drug and vaccine development. Several members pointed out that the value of the Roundtable's meetings and workshops is the length of time devoted to discussion, and this unique opportunity for extensive dialogue should be fostered and preserved.

Roundtable's Mission

As the National Commission on AIDS concludes its tenure, it is appropriate to consider whether the Roundtable, as the longest standing IOM AIDS committee, should broaden its scope and mission to include such issues as prevention and behavioral research. Although several members favored expanding the Roundtable's scope of activities beyond HIV drug and vaccine research and development, many cautioned that this expansion might ultimately dilute the effectiveness of the Roundtable and diminish its depth of expertise. Furthermore, one member strongly argued that a shift in the Roundtable's focus to include issues of prevention would be perceived by the patient community as abandoning those individuals who are already infected with HIV. In the wake of the 1993 International AIDS Conference and the feelings of depression and confusion about the results of current HIV treatment research, another member urged that the Roundtable retain its current mission and "reinvigorate" its focus on impediments to the rapid development of effective HIV drugs and vaccines, as well as the process and coordination of treatment research efforts.

Following considerable debate, the group agreed upon an alternative to broadening the scope of the Roundtable's activities. Participants acknowledged that HIV prevention and behavioral research efforts are sufficiently important to warrant specific attention and recommended that the IOM assemble a separate roundtable to address these issues. In developing the scope and focus of such an "HIV prevention roundtable," it is critical to maintain a strong link with the current IOM drug and vaccine roundtable. One suggestion was that the current AIDS drug and vaccine roundtable could participate in launching a "prevention roundtable" by holding a workshop to examine the "successes and failures" of behavioral and social research efforts in the area of HIV prevention.

Possible Topics for Future Roundtable Meetings/Workshops

- Correlates of protective immunity (including rationale for developing immunotherapy for HIV; critical experiments that need to be conducted to determine the feasibility of HIV immunotherapy; and if immunotherapy is shown to be a viable therapeutic alternative, what are the necessary studies that need to be completed in order to quickly develop and produce an effective immune-based therapy for HIV?)
- Targeted or directed HIV research program vs. investigator-initiated basic biomedical and HIV research (relative balance and resources distributed between these types of research).
- Impact of GMP (good manufacturing practice) requirements on development of biological therapies for HIV and AIDS.
- Methodologies for evaluating results of HIV/AIDS clinical trials (e.g., intention-to-treat analysis vs. other types of treatment analysis); revisit surrogate markers and endpoints for clinical trials; and issues of trial design and selection of study populations.
- Public perception of AIDS research (e.g., process of disseminating scientific information to the public). Suggestion: Roundtable could co-sponsor a meeting for journalists to explore this issue further.
- Health care reform and implications for HIV drug and vaccine development (e.g., cost of drugs and vaccines; coverage for experimental therapies and care associated with clinical research).

**FAX TRANSMISSION COVER SHEET****ROUNDTABLE FOR THE DEVELOPMENT OF DRUGS
AND VACCINES AGAINST AIDS**

NOV 17 1993

Institute of Medicine
2101 Constitution Avenue, N.W.
Washington, D.C. 20418

202-334-2453
202-334-2939 (FAX)

Date: November 16, 1993Number of Pages Including Cover: 2

TO: Kristine Gebbie

FROM: Leslie Hardy

COMMENTS: Attached is a revised agenda for the November 29 meeting to discuss the IOM AIDS program. Please call me at the above number if you have any questions. We look forward to seeing you on the 29th.

INSTITUTE OF MEDICINE
Meeting on IOM AIDS Program

November 29, 1993

Room 104, Green Building
2001 Wisconsin Avenue, N.W.
Washington, DC

REVISED AGENDA

- 12:30 Working Lunch
- 1:00 Welcoming Remarks and Goals of the Meeting
• Harvey Fineberg, *Dean, Harvard School of Public Health*
- 1:15 Introduction of Participants
• Each participant to introduce him or herself, briefly describe present position and professional background, and offer some reflections (if relevant) on past or current involvement in IOM/NAS AIDS-related activities (e.g., study, roundtable, conference)
- 1:45 Review of Current and Planned IOM AIDS Activities
• Kenneth Shine, *IOM President*
- 2:00 National AIDS Policy Activities
• Kristine Gebbie, *National AIDS Policy Coordinator*
- 2:15 Future Directions in AIDS Research
• Harold Varmus, *NIH Director-designate*
- 2:30 Discussion
- 3:00 Break
- 3:15 Discussion of Future IOM AIDS Activities
(e.g., Important Issues or Topics for Studies, Workshops, or Conferences)
- 5:30 Adjourn

SEP 27 1993

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE WASHINGTON, D. C. 20418

KENNETH I. SHINE, M. D.
PRESIDENT

September 16, 1993

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator
750 17th St., NW, Ste. 1060
Washington, DC 20006

Dear Kristine:

I am writing to invite your participation in a planning meeting to discuss the current and future AIDS program of the Institute of Medicine. As you know, we are at a significant juncture in the formulation of sound national AIDS policy. The National Commission on AIDS issued its final report in June 1993, calling for strong leadership and a "clear, well-articulated national plan for confronting AIDS." In July 1993, the IOM held a meeting to review the future course and direction of its longest standing AIDS committee, the Roundtable for the Development of Drugs and Vaccines Against AIDS. This group was assembled in December 1988 as a neutral forum for dialogue on scientific and public policy questions pertaining to HIV drug and vaccine development. In the absence of the AIDS Commission, in light of the changes in national leadership, particularly that influencing health care and AIDS policy making, and completion of the second term of our roundtable in mid-1994, we feel it is important to reflect upon the IOM's AIDS program to date and explore how we can be most helpful in the HIV/AIDS policy arena in the future.

To assist us in our planning, I do hope you can join us on **Monday, November 29, 1993** from 12:30 pm to 5:30 pm in Room 104 of the Green Building, 2001 Wisconsin Avenue, N.W., Washington, DC. The goal of this meeting will be to discuss the current AIDS activities of the IOM and to explore possible AIDS-related projects that we should pursue in the future. We have invited Harold Varmus to address the group regarding future directions in AIDS research, and we look forward to hearing your comments regarding national AIDS policy activities. A tentative agenda and list of meeting invitees are enclosed for your information.

*Return - I think
this on the
calendar already
AA/Buck/Ben/Gerep/
Carlos
fyi & ideas/comments*

Kristine M. Gebbie, R.N., M.N.
September 16, 1993
Page 2

Please feel free to contact Leslie Hardy, IOM AIDS Coordinator, or her assistant, Jennifer Holliday, at (202) 334-2453 if you have any questions. To facilitate preparation for the meeting, we would appreciate you calling the project staff by **October 22, 1993** to confirm your attendance.

With best wishes,

Sincerely,

A handwritten signature in cursive script, appearing to read "Ken", written in dark ink.

Kenneth I. Shine, M.D.

Enclosures

INSTITUTE OF MEDICINE
Meeting on IOM AIDS Program

November 29, 1993

Room 104, Green Building
2001 Wisconsin Avenue, N.W.
Washington, DC

TENTATIVE AGENDA

12:30 pm	Working Lunch
1:00 pm	Welcoming Remarks and Goals of the Meeting • Harvey Fineberg, <i>Dean, Harvard School of Public Health</i>
1:15 pm	Introduction of Participants • Each participant to identify his or her critical concerns in the HIV/AIDS policy arena
1:45 pm	Review of Current and Planned IOM AIDS Activities • Kenneth Shine, <i>IOM President</i>
2:15 pm	Discussion
2:30 pm	National AIDS Policy Activities • Kristine Gebbie, <i>National AIDS Policy Coordinator</i>
2:45 pm	Discussion
3:00 pm	Future Directions in AIDS Research • Harold Varmus, <i>NIH Director-designate</i> (invited)
3:15 pm	Discussion
3:30 pm	Break
3:45 pm	Discussion of Future IOM AIDS Activities (e.g., Important Issues or Topics for Studies, Workshops, or Conferences)
5:30 pm	Adjourn

Invitees

Meeting on IOM AIDS Activities November 29, 1993

Moises Agosto, *Treatment and Research Advocate, National Minority AIDS Council*

David Barr, *Assistant Director of Policy, Gay Men's Health Crisis*

David Barry, *Vice President, Research, Development and Medical Affairs, The Wellcome Research Laboratories, Burroughs Wellcome Co.*

Thomas Coates, *Professor of Medicine and Director, Center for AIDS Prevention Studies, University of California, San Francisco*

Deborah Cotton, *Assistant Professor, Department of Health Policy and Management, Harvard School of Public Health*

James Curran, *Associate Director for HIV/AIDS, Centers for Disease Control and Prevention*

Donald DesJarlais, *Director of Research, Chemical Dependency Institute, Beth Israel Medical Center*

Gordon Douglas, Jr., *Vice President Merck & Co., Inc. and President, Merck Vaccine Division*

Joycelyn Elders, *Surgeon General, U.S. Public Health Service*

Anthony Fauci, *Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health*

Harvey Fineberg, *Dean, Harvard School of Public Health*

Kristine Gebbie, *National AIDS Policy Coordinator, The White House*

Margaret Hamburg, *Health Commissioner, New York City Department of Health*

Barton Haynes, *F.M. Hanes Professor of Medicine and Director, Duke University Arthritis Center*

Karen Hein, *Professor of Epidemiology, Pediatrics, and Social Medicine, Albert Einstein College of Medicine*

D.A. Henderson, *Deputy Assistant Secretary for Health, Department of Health and Human Services*

Michael Iskowitz, *Legal Counsel, Senate Committee on Labor and Human Resources*

David Kessler, *Commissioner, Food and Drug Administration*

Mathilde Krim, *Founding Co-Chair, American Foundation for AIDS Research*

Philip Lee, *Assistant Secretary for Health, Department of Health and Human Services*

Jeffrey Levi, *Director of Governmental Affairs, AIDS Action Council*

Steve Morin, *Associate Staff, House Committee on Appropriations*

June Osborn, *Former Dean, School of Public Health, The University of Michigan and
Former Chair, National Commission on AIDS*

Ralph Payne, *Legislative Assistant, The Honorable Diane Feinstein, U.S. Senate*

Helen Rodriguez-Trias, *President, American Public Health Association*

David Rogers, *The Walsh McDermott University, Professor of Medicine, The New York
Hospital-Cornell Medical Center*

Harold Varmus, *Director-designate, National Institutes of Health*

Paul Volberding, *Chief, AIDS Program and Clinical Oncology, San Francisco
General Hospital*

Timothy Westmoreland, *Counsel, House Subcommittee on Health and Environment*

Roy Widdus, *Former Executive Director, National Commission on AIDS*

INSTITUTE OF MEDICINE

Roundtable for the Development of Drugs and Vaccines Against AIDS

ROSTER

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INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE WASHINGTON, D. C. 20418

June 25, 1993

Kristine M. Gebbie, R.N., M.N.
Former Secretary
State of Washington Dept. of Health
101 G Street, SW, Apt. A707
Washington, DC 20024

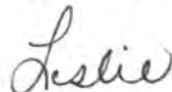
Dear Kristine:

We are pleased to invite you to attend an invitational workshop, *The Changing Demographics of the HIV Epidemic: Implications for Clinical Research*. The workshop will be held on Wednesday, September 8, 1993 from 8:15 am until 5:00 pm in the Lecture Room of the National Academy of Sciences building, 2101 Constitution Avenue, N.W., Washington, D.C. A tentative agenda is enclosed. During the workshop, we hope to explore the biological bases (e.g., similarities and differences in drug metabolism across population groups, variations in the natural history of HIV infection in adults and children) for enhancing heterogeneity in HIV-related clinical studies, as well as the social, ethical, and public health considerations in fostering such diversity. We also plan to discuss some of the obstacles to achieving greater diversity in clinical research and mechanisms to overcome them, and to explore the roles of government and industry in fostering heterogeneity in drug development and clinical research.

The workshop has been planned by the Institute of Medicine's Roundtable for the Development of Drugs and Vaccines Against AIDS, whose mission is to identify and help resolve impediments to the rapid availability of effective drugs and vaccines for HIV infection and AIDS. The Roundtable's membership comprises leaders from the public and private sectors, including representatives from government, the pharmaceutical industry, academia, and patient advocacy groups. A membership roster is enclosed.

We hope that you are able to participate in what should be a lively and interesting workshop. As there is limited space available, please register by August 6. (Registration will be limited to the first 100 people responding.) You may fax (202-334-2939) or mail the completed registration form to Jennifer Holliday, Project Assistant. If you register for the workshop but ultimately are unable to attend, please notify Ms. Holliday at (202) 334-2453 as soon as possible to cancel your reservation. Enclosed is information about parking availability and the nearest metro (subway) station to the Academy.

Sincerely,



Leslie M. Hardy, M.H.S.
Project Director

Probably
yes —
at least part of
the day —

Institute of Medicine
Roundtable for the Development of Drugs
and Vaccines Against AIDS

The Changing Demographics of the HIV Epidemic: Implications for Clinical Research

September 8, 1993

Lecture Room
National Academy of Sciences
2101 Constitution Avenue, N.W.
Washington, D.C.

TENTATIVE AGENDA

- 7:45 Registration and Continental Breakfast
- 8:15 **Welcome and Introduction**
- Helen Rodriguez-Trias, President, American Public Health Association and Member, Roundtable
 - Lawrence S. Brown, Assistant Clinical Professor of Medicine, College of Physicians and Surgeons, Columbia University and Member, Roundtable
- 8:25 **OVERVIEW OF THE CHANGING EPIDEMIOLOGY OF HIV INFECTION AND AIDS IN THE UNITED STATES**
- Discussion Leader:* James Curran, Associate Director for HIV/AIDS, Centers for Disease Control and Prevention
- 8:30 Epidemiological Trends in HIV Infection and AIDS Among Adults and Children
- Harold Jaffe, Acting Director, Division of HIV/AIDS, Centers for Disease Control and Prevention
- 8:50 Discussion
- 9:10 **BIOLOGICAL CONSIDERATIONS FOR ENHANCING HETEROGENEITY IN DRUG DEVELOPMENT AND CLINICAL RESEARCH**
- Discussion Leader:* Carl Peck, Director, Center for Drug Evaluation and Research, Food and Drug Administration
- 9:15 Similarities and Differences in Drug Disposition Across Population Groups
- Leslie Benet, Professor and Chairman, Department of Pharmacy, University of California, San Francisco
- 9:30 Variation in Clinical Manifestations and Progression of HIV Infection in Adults
- Gerald Friedland, Director, AIDS Program, Yale University School of Medicine

- 9:45 Variation in Natural History of HIV Infection and Therapeutic Responses in U.S. Military Populations
- John Brundage, Director, Division of Preventive Medicine, Walter Reed Army Institute of Research
- 10:00 Drug Development for Pediatric HIV Infection and AIDS: A Clinical Pharmacology Perspective
- Paul Lietman, Wellcome Professor of Clinical Pharmacology, Johns Hopkins University School of Medicine
- 10:15 Discussion
- 10:45 Break
- 11:00 **SOCIAL AND ETHICAL CONSIDERATIONS FOR ENHANCING HETEROGENEITY IN DRUG DEVELOPMENT AND CLINICAL RESEARCH**
- Discussion Leader:* Mark Smith, Executive Vice President, The Henry J. Kaiser Family Foundation
- 11:05 Understanding the Historical Context of Clinical Research in Diverse Populations
- Allan Brandt, Kass Professor of Medical History, Department of Social Medicine, Harvard Medical School
- 11:20 Social and Public Health Policy Rationale for Broadening Participation in Clinical Research
- Reed Tuckson, President, Charles R. Drew University of Medicine & Science (to be confirmed)
- 11:35 Ethical Considerations for Expanding Participation in Clinical Research
- To be announced
- 11:50 A Community Response to Enhancing Diversity in Clinical Research
- Stephen Thomas, Associate Professor, Division of Behavioral Sciences and Health Education, Emory University School of Public Health
- 12:05 Discussion
- 12:45 Lunch
- 1:45 **CHALLENGES AND OPPORTUNITIES FOR ACHIEVING HETEROGENEITY IN CLINICAL RESEARCH**
- Discussion Leader:* Diane Wara, Professor of Pediatrics and Division Head, Pediatric Immunology/Rheumatology, University of California, San Francisco
- 1:50
- Arlene Bardeguet, Assistant Professor of Obstetrics and Gynecology, New Jersey Medical School (to be confirmed)
 - Peter Selwyn, Associate Professor of Internal Medicine, Epidemiology, and Public Health, Yale University School of Medicine
 - Catherine Wilfert, Professor of Pediatrics and Microbiology, Duke University Medical Center
- 2:20 Discussion
- 3:00 Break

3:15 GOVERNMENT AND INDUSTRY ROLES IN ENHANCING HETEROGENEITY IN CLINICAL RESEARCH

Discussion Leader: David Martin, Executive Vice President, Research and Development,
The DuPont Merck Pharmaceutical Company

3:20 Demographics of NIH-Sponsored AIDS Clinical Trials and Mechanisms to Increase Diversity

- George Counts, Chief, Clinical Research Management Branch, Division of AIDS, National Institute of Allergy and Infectious Diseases

3:35 A View from the Pharmaceutical Industry on Enhancing Heterogeneity in Drug Development

- David Barry, Vice President, Research, Development, and Medical Affairs, The Wellcome Research Laboratories, Burroughs Wellcome Co.

3:50 An FDA Perspective on Regulation and Its Role in Enhancing Heterogeneity in Drug Development

- David Feigal, Director, Division of Antiviral Drug Products, Center for Drug Evaluation and Research, Food and Drug Administration

4:05 A Clinical Investigator's View on Fostering Diversity in Clinical Research

- Lawrence S. Brown, Assistant Clinical Professor of Medicine, College of Physicians and Surgeons, Columbia University

4:20 Discussion

5:00 Adjourn

INSTITUTE OF MEDICINE

Roundtable for the Development of Drugs and Vaccines Against AIDS

ROSTER

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**Institute of Medicine
Roundtable for the Development of Drugs and
Vaccines Against AIDS**

**The Changing Demographics of the HIV Epidemic:
Implications for Clinical Research**

September 8, 1993

Lecture Room
National Academy of Sciences
2101 Constitution Avenue, NW, Washington, DC

BREAKFAST AND LUNCH

Continental breakfast and lunch will be served in the anteroom of the Lecture Room. (Please note that breakfast begins at 7:45 am.)

HOTEL

Participants are responsible for their own travel and lodging arrangements. You may wish to consider staying at one of the following hotels, which are convenient to the Academy.

The St. James
950 24th St., NW
800-852-8512

The Wyndham Bristol
2430 Pennsylvania Ave., NW
800-822-4200

One Washington Circle Hotel
One Washington Circle, NW
800-424-9671

PARKING

Parking is not available at the Academy. The nearest parking facilities are Colonial Parking at 20th Street and Virginia Avenue, NW (between E and F Streets) and Columbia Plaza at 23rd Street and Virginia Avenue, NW. Additional public parking is available at George Washington University's Marvin Center on H Street between 21st and 22nd Streets. The nearest Metro (subway) station is Foggy Bottom/George Washington University at 23rd and I Streets.

MESSAGE CENTER/TELEPHONES

It will not be possible to page participants during the conference. Urgent calls should be directed to 202-334-2453. Messages will be taken and held at the registration table outside the Lecture Room. Telephones are available in the C Street lobby and the second floor mezzanine.

INSTITUTE OF MEDICINE
Office of Membership Services
tel: (202) 334-2174

CALL FOR NOMINATIONS

Regular, Senior, and Foreign Associate Members:

The deadline for submission of completed nominations will be February 28, 1994. The preferential balloting will occur in the spring of 1994, the final ballot will be issued in late summer, and the newly-elected members will be announced just prior to the 1994 Annual Meeting in October.

In an effort to reduce substantially our printing and mailing costs of the nomination forms, we will not automatically send a 1994 nomination form to each member as we have done in the past. **ONLY MEMBERS REQUESTING THE FORMS WILL RECEIVE THEM.** If you would like to receive a nomination form, please complete the information below. Please return this form to me at the following address or fax your response to the number listed below.

TO: Mrs. Jana Surdi
Institute of Medicine
NAS-327
2101 Constitution Avenue, N.W.
Washington, DC 20418

FAX: (202) 334-1694

Please send me: 3 copies of Regular/Senior Proposal Form, 1994.
_____ copies of Foreign Associate Proposal Form, 1994.

KRISTINE GEBBIE

(Name of IOM member -- PLEASE PRINT)

Institute of Medicine

ELECTION OF 1994

Election Cycle

- October 18-19, 1993 **ANNUAL MEETING**
 - (1) Membership Committee meets day preceding annual meeting for consensus on membership needs
 - (2) Section meetings - focus on discovery; meet at lunch on 1st day
 - (3) Membership Committee meets for review of priorities in context of section input
- October 22, 1993 **Call for Nominations**
- February 28, 1994 **Deadline for Nominations**
- mid-April to mid-May 1994 **Preferential balloting**
- June 1994 **Membership Committee meets to prepare final ballot; prepare for next election**
- July 1994 **Final ballot to Council for approval**
- September 1994 **Final balloting**
- 1994 Annual Meeting **New Members announced - terms effective immediately**

IOM
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INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
2101 CONSTITUTION AVENUE WASHINGTON, D. C. 20418

DEC 21 1993

KENNETH I. SHINE, M. D.
PRESIDENT

December 17, 1993

Dear IOM Members, Friends, and Staff:

Nineteen hundred and ninety-three was a good year for the Institute of Medicine. The policy environment included the initiation of a serious debate about reform of the health care system and the introduction of several important pieces of legislation, including the Health Security Act and several other alternatives. The Institute contributed several important reports, which helped to inform policymakers (*Assessing Health Care Reform; Access to Health Care in America; Employment and Health Benefits; and, Including Children and Pregnant Women in Health Care Reform*). We organized a series of colloquia workshops on global budgets, basic benefits, and quality of care, which will be continued into 1994, to address such issues as underserved populations, state implementation, and other topics to be selected by a committee chaired by Dr. Jerome Grossman. A new roundtable, chaired by Dr. Joseph Martin, was established to address the impact of health care reform on research and education in academic health centers. Many of our members and staff participated actively in the development of approaches to health care reform, and will continue to do so as the debate continues. The First Lady gave a truly impressive performance at our Annual Meeting and encouraged us to continue to inform the debate in an objective and nonpartisan manner.

We demonstrated our capacity to identify and consider issues that were not popular by using our own funds and by obtaining foundation support and subsequently, in some cases, government support, e.g., fetal research, contraceptive research, unintended pregnancy, cDNA patenting, and antiprogestins (RU 486). We also have used our own resources to initiate a major project on intellectual property, technology transfer and conflict of interest in molecular biology, which will address some very important contemporary issues in science policy. Our reputation for independent, objective work with bold new approaches was enhanced by several reports (*The Children's Vaccine Initiative; Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam; and, Veterans at Risk*). We also demonstrated our capacity to provide solid, deliberative advice in a very timely manner (*An Assessment of the Women's Health Initiative; Clinical Applications of Mifepristone (RU 486) and Other Antiprogestins; and, Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command*). Timeliness was also a feature of the landmark report *Emerging Infections: Microbial Threats to Health in the United States*, which not only affected public awareness and the organization of federal surveillance, but also has led to the creation of a new roundtable on emerging microbial threats.

December 17, 1993

Page 2

With the help of the membership, we met the requirements of the NAS/IOM Kellogg Matching Endowment Campaign. Under the leadership of Bill Kelley and the membership committee, we have undertaken a new discovery process to ensure that we will elect the very best members from a diverse population. And, we successfully concluded our own internal planning, which has restated our mission and goals with an accompanying action plan (see enclosure for the highlights of that plan).

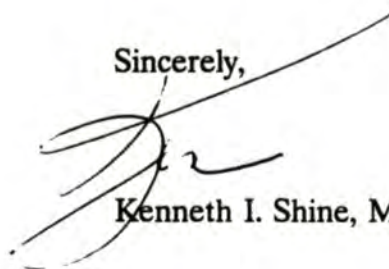
A steering committee has been established to plan for the Silver Anniversary of the Institute in 1995. Our capacity to initiate new projects and proceed in a timely way has been enhanced remarkably by endowment and flexible funds. Although we presently are working on setting goals and developing plans for a capital campaign related to our 25th Anniversary, gifts in the meantime from members and friends of the Institute would still be greatly appreciated.

We have been blessed with an outstanding staff, led by our truly extraordinary executive officer, Dr. Enriqueta Bond. The staff has responded to our efforts to increase our timeliness and relevance with enthusiasm, energy, and dedication.

As the year comes to an end, I extend my heartfelt thanks to all of you and to our outstanding staff for achieving these successes. Even more challenges present themselves for 1994, but we are well-positioned to respond. To each of you, I wish happy holidays and a successful, fulfilling, and healthy New Year.

All my best wishes,

Sincerely,

A handwritten signature in black ink, appearing to read 'Ken Shine', with a long, sweeping horizontal line extending from the end of the signature towards the top right of the page.

Kenneth I. Shine, M.D.

Enclosure

INSTITUTE OF MEDICINE
ACTION PLAN**
1993

MISSION STATEMENT

The mission of the Institute of Medicine is to advance scientific knowledge and the health and well-being of all people of this nation and the world consistent with the role conferred by its congressional authority. It accomplishes this mission by providing objective, timely, and authoritative information to government, the professions and the public through its elected membership and access to the best expertise.

GOALS

GOAL I:

To identify and frame important issues of science and policy and to respond when appropriate to requests from public and private agencies for studies and advice on matters related to health by

- setting priorities for the work to be accomplished;
- initiating and conducting studies in a non-partisan, objective, and timely manner. Convening knowledgeable individuals from appropriate disciplines and perspectives;
- preparing authoritative statements, disseminating information and promoting understanding of the issues and recommendations;
- evaluating the overall program of the Institute, as well as individual studies.

GOAL II:

To elect a diverse and active membership:

- of distinction and achievement;
- devoted to the advancement of the health sciences;
- broadly based in health, the medical and biological sciences, the physical and mathematical sciences, behavioral and social sciences, law, engineering, and health policy;
- committed to contributing actively their efforts to the mission and goals of the Institute.

GOAL III:

To recruit, retain and motivate a high quality staff that supports the institute's program in an efficient, creative, and cost-effective manner.

** Approved by the IOM Council on November 15, 1993. A complete copy of the plan will appear in the next IOM Newsletter.

Best Wishes for a Joyous Holiday Season!

With special thanks for your help and support,



Oliver Fein



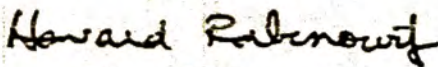
Jeffrey Geller



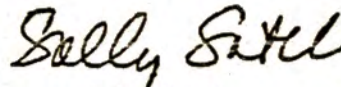
Karen Hein



David Michaels



Howard Rabinowitz



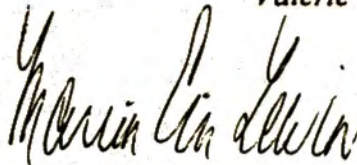
Sally Satel



Karen Orlando



Valerie Tate



Marion Ein Lewin

*1993-1994 Robert Wood Johnson Health Policy Fellows
and
IOM Office of Health Policy Programs and Fellowships*

INSTITUTE OF MEDICINE
NATIONAL ACADEMY OF SCIENCES
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OFFICE OF HEALTH POLICY
FELLOWSHIP PROGRAMS

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October 29, 1993



NOV 22 1993

Kristine Gebbie, M.N.
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Dear Kristine:

As the orientation for the 1993-1994 Robert Wood Johnson Health Policy Fellows moves to a close, I want to thank you for your special contribution to this important component of the Fellowships program. The Fellows enjoyed meeting with you and benefited enormously from your informative and thoughtful remarks.

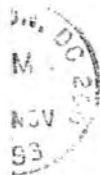
The orientation sessions always receive rave reviews. The Fellows continually comment on how privileged they feel in having the opportunity to be briefed and educated by such an outstanding roster of Washington-based decision makers. Perhaps even more important, they always are touched by the warm and welcome reception they receive.

As soon as the Fellows have decided on their placements, we will send you information on the offices for which they will be working, either in Congress or the Executive Branch.

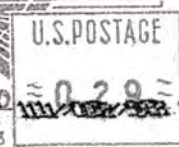
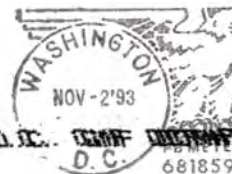
Again, deep appreciation for you special efforts.

Sincerely,

Marion Ein Lewin
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file

MEMORANDUM

TO: Members, Roundtable for the Development of Drugs and Vaccines
Against AIDS

FROM: Jennifer Holliday, Project Assistant 

DATE: November 24, 1993

SUBJECT: Background Items For Your Information

For your information, we have enclosed two documents that may be of interest. The first, *Brief Description of Organization and IOM/NAS AIDS Program Activities*, provides an overview of the origin and mission of the National Academy of Sciences and Institute of Medicine. It also lists the AIDS-related reports that have been published by the Academy since 1986, and describes current IOM/NAS AIDS projects and those under development. The second document, *The Human Immunodeficiency Virus Vaccine Challenge: Issues in Development and International Trials*, is the final report of the FCCSET Working Group on HIV Vaccine Development and International Field Trials. Some of you may already have a copy of this report, but, if not, we wanted to be sure that you did.

**Institute of Medicine
National Academy of Sciences**

**Brief Description of Organization and IOM/NAS
AIDS Program Activities**

November 1993

ORGANIZATION OF THE NATIONAL ACADEMY OF SCIENCES

The National Academy of Sciences (NAS) complex consists of the National Academy of Sciences, the National Academy of Engineering, the National Research Council, and the Institute of Medicine.

The National Academy of Sciences is a private, self-perpetuating society of distinguished scholars in scientific and engineering research, dedicated to the furtherance of science and its use for the general welfare. Its charter, an Act of Incorporation passed by the U.S. Congress and signed by President Abraham Lincoln on 3 March 1863, named the first 50 members of the Academy; empowered it to create its own organization and bylaws; and called upon it to serve as an official advisor, upon request and without fee, to the U.S. government on any question of science or technology.

The National Academy of Engineering (NAE) was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of distinguished engineers, autonomous in its administration and in its selection of members, and sharing with the National Academy of Sciences its responsibility for advising the federal government.

Most of the activities undertaken by the two Academies are carried out through the Commissions, Offices, and Boards of the *National Research Council* (NRC), which draw upon a wide cross-section of the nation's leading scientists and engineers for advisory services to government agencies and the Congress.

The Institute of Medicine (IOM) was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the medical and other professions in the study of issues and problems that affect the public's health. Its purpose is the advancement of the health sciences and education and the improvement of health care.

ORGANIZATION AND GENERAL ACTIVITIES OF THE INSTITUTE OF MEDICINE

The IOM's principal resource for carrying out its mission is its membership, which currently numbers 479 regular, 510 senior members, and 33 foreign associates. The charter stipulates that at least one-quarter of the IOM membership be elected from professions other than health and medicine. More than one-quarter of the present members are from law, economics, engineering, and the physical sciences, a diversity that ensures a breadth of perspective and multidisciplinary approach to Institute studies. The health professions in the membership include basic biological and behavioral scientists, clinical scientists, and health care practitioners. Election to membership is accompanied by a member's commitment to active participation, without compensation, in the Institute's work.

IOM program activities (studies, forums, and other projects) are organized in eight program units-six divisions and two program initiatives. These include the divisions of Biobehavioral Sciences and Mental Disorders, Food and Nutrition Board, Health Care Services, Health Promotion and Disease Prevention, Health Sciences Policy, and International Health. The two program areas--the Health Policy Fellowship activities and the Medical Follow-Up Agency--complement and extend the scope of IOM's activities. The AIDS program, previously a separate initiative, was consolidated into the Division of Health Promotion and Disease Prevention in mid-1991.

Institute of Medicine/National Academy of Sciences
AIDS Activities

COMPLETED REPORTS

Mobilizing Against AIDS: The Unfinished Story of a Virus, 1986; revised 1989. (IOM)

Confronting AIDS: Directions for Public Health, Health Care, and Research, 1986. (IOM)

Confronting AIDS: Update 1988, 1988. (IOM)

AIDS: Sexual Behavior and Intravenous Drug Use, 1989. (NRC)

Evaluating AIDS Prevention Programs, 1989; expanded edition, 1991. (NRC)

AIDS: The Second Decade, 1990. (NRC)

The AIDS Research Program of the National Institutes of Health, 1991. (IOM)

HIV Screening of Pregnant Women and Newborns, 1991. (IOM)

The Social Impact of AIDS in the United States, 1993. (NRC)

Conference/Workshop reports

- *An Agenda for AIDS Drug Development*, 1988. (IOM)
- *Prospects for Vaccines Against HIV Infection*, 1988. (IOM)
- *Approaches to Modeling Disease Spread and Impact*, 1988. (IOM)

Roundtable for the Development of Drugs and Vaccines Against AIDS reports

- *The Potential Value of Research Consortia in the Development of Drugs and Vaccines Against HIV Infection and AIDS*, 1989. (IOM)
- *Surrogate Endpoints in Evaluating the Effectiveness of Drugs Against HIV Infection and AIDS*, 1990. (IOM)
- *Expanding Access to Investigational Therapies for HIV Infection and AIDS*, 1991. (IOM)
- *Developing Effective Therapies for AIDS-Related Infections*, 1992. (IOM)
- *Understanding HIV Pathogenesis: Implications for Drug and Vaccine Development*, 1992. (IOM)

CURRENT PROJECTS

Roundtable for the Development of Drugs and Vaccines Against AIDS

Communication among policy makers, biomedical researchers, care providers, and patient advocates is an important element in the development of new, more effective therapies and vaccines to treat or prevent HIV infection and its associated medical conditions. Recognizing the need for such ongoing dialogue, in 1988 the IOM established the Roundtable for the Development of Drugs and Vaccines Against AIDS as a convening mechanism to explore impediments to the rapid availability of safe, effective drugs and vaccines for HIV infection and AIDS. The committee (see Appendix A) comprises 21 leaders from government, the pharmaceutical industry, academia, and patient advocacy groups, representing a unique blend of expertise and viewpoints on scientific and public policy questions related to AIDS drug and vaccine development. The Roundtable reviews the state of scientific knowledge relevant to the design of therapeutic and preventive agents; examines some of the impediments to drug and vaccine development, approval, and availability; and discusses strategies to promote the development of drugs and vaccines against HIV infection. The roundtable also holds workshops and conferences on topics selected for their urgency and for their potential to expedite drug and vaccine development and availability.

Past Roundtable workshops have examined: (a) the use of surrogate endpoints in evaluating the effectiveness of AIDS drugs; (b) the development and evaluation of preventive HIV vaccines; (c) HIV drug resistance and research related to combination antiretroviral therapies; (d) the development of effective therapies for AIDS-related infections; (e) progress in developing drugs for pediatric HIV infection; (f) gene therapy approaches for treating HIV disease; (g) the changing demographics of the HIV epidemic and implications for clinical research; and other timely subjects. The upcoming December 1993 workshop will explore the current scientific knowledge and understanding of possible correlates of protective immunity to HIV. Summaries of the Roundtable's meetings and workshops are issued periodically.

The Roundtable's current term expires in mid-1994, but as a result of the July 1993 meeting of the Roundtable (see Attachment 1), plans are being developed to renew this group for another two to three year period.

Study of Substance Abuse and Mental Health Issues in AIDS Research

The IOM established an expert committee in April 1993 to examine substance abuse and mental health issues in AIDS research. This congressionally mandated study will assess the AIDS research portfolios of the National Institute on Drug Abuse (NIDA), the National Institute on Alcohol Abuse and Alcoholism (NIAA), and the National Institute of Mental Health (NIMH). In particular, it will address: (1) the scope and content of the institutes' AIDS research program activities; (2) the relationship between their research and the services-oriented programs at SAMHSA, CDC, and HRSA; (3) the balance between biomedical and behavioral research; (4) the role of behavioral prevention interventions in the institutes' research programs; (5) the role of the public and field opinion in influencing the direction of AIDS research; (6) the adequacy of the administrative structure to support the institutes' AIDS programs; and (7) the adequacy of interagency coordination of AIDS activities.

The 15-member committee (see Appendix B) combines expertise in a variety of basic, clinical, behavioral and social science disciplines, as well as public health and patient advocacy. The committee will meet four to five times during the course of the 18-month study. One meeting has already included a site visit to the Center for AIDS Prevention Studies at the University of California, San Francisco. There was also a recent public hearing during which AIDS researchers, service providers, and constituency group representatives presented to the committee their concerns about and experiences with substance abuse and mental health issues in AIDS research and services. The committee's review of the AIDS research program of NIAA, NIDA, and NIMH and the resulting recommendations on future directions for research and coordination will be summarized in a final report to be published in fall 1994.

Study of Needle Exchange and Bleach Distribution Programs

In response to a Congressional request, the NRC Commission on Behavioral and Social Sciences and Education (CBASSE) assembled the Panel on Needle Exchange and Bleach Distribution Programs (see Appendix C) in June 1993 to study the impact of needle (syringe) exchange and bleach programs on drug use behavior and the spread of HIV infection and other blood-borne diseases. The Panel will gather and analyze the relevant research regarding the effect of such programs on rates of drug use, the behavior of drug users, and the spread of HIV and other diseases, such as hepatitis, among injection drug users and their partners. In addition, the Panel will examine closely related issues of importance to the research and services communities, such as the characteristics associated with effective exchange programs, and will provide recommendations for future research directions and methods applicable to the evaluation of syringe exchange and bleach programs.

This study, sponsored by the National Institute on Drug Abuse, is a joint project of the National Research Council and the Institute of Medicine. In order to fulfill its mandate, the Panel has planned to issue two publications. The first publication in early 1994 will summarize research findings on needle exchange and bleach distribution programs presented at a panel workshop in September 1993. The Panel's final report, which will present an assessment of the impact of such programs and offer recommendations, is scheduled to be released in early 1995.

Study of Post-Separation HIV-Positive Military Personnel Lost to Follow-up

At the request of the Walter Reed Army Institute of Research (WRAIR), the IOM's Medical Follow-up Agency in 1991 initiated a study of post-separation HIV-positive military personnel lost to follow-up. The study seeks to locate approximately 900 HIV-infected health care beneficiaries (HCBs) who are "lost to follow-up" to the Army health care system. All individuals contacted will be health care beneficiaries of the Department of Defense health care system. Once located, these individuals will be asked to provide information regarding their current health status and sources of health care, as well as to undergo a standard disease-staging clinical evaluation. The primary goal of this research is to determine whether HIV-infected HCBs who have been lost to follow-up differ in terms of the natural history and progression of their disease from HCBs who continue to be followed within the Army health care system. The data collected in this study will be analyzed collaboratively by the Medical Follow-up Agency and the Department of Epidemiology, Division of Preventive Medicine, WRAIR. Results of this investigation will be communicated to the requesting agency in a written report and published in a scientific journal.

Study to Review HIV Transmission to Hemophiliacs Through Blood Products

At the request of Secretary of Health and Human Services Donna Shalala, the IOM has launched a study to review and evaluate the transmission of HIV to people with hemophilia through blood and blood products during the period of 1982 to 1986. This 18-month study will describe and evaluate the consideration of policy options and how policy decisions were made prior to FDA approval of HIV screening kits and the routine antiviral heat treatment of blood products. A thorough review will be conducted of the amount of information and technology available to decision makers during this period and the scientific basis of the decisions made vis-a-vis HIV transmission through the blood supply. The study will include a compilation of the policy options considered and the outcomes or impacts that could reasonably have been expected from adoption of each such option. The objective of this study is to identify methods to improve public health decision making and public health policy to better protect the blood supply in the future. Based on the conclusions drawn from the findings of the historical review, the study committee will recommend a framework for addressing future unknown challenges to the blood supply in a manner that will minimize

risks to the public health. The IOM will not conduct any original medical or epidemiological studies, and will not consider or make recommendations regarding specific individual cases. The resulting report will not seek to determine liability or affix blame for any individual or collective cases of HIV transmission through the blood supply during this time period.

PROJECTS UNDER DEVELOPMENT

Prenatal and Newborn Screening for HIV Infection

In 1991, an IOM study committee concluded that voluntary HIV screening should be offered to all pregnant women in high-prevalence areas, but recommended against screening newborns for HIV infection at that time. The committee acknowledged, however, that changes in HIV diagnostic capability and therapeutic interventions for pediatric HIV infection might warrant reexamination and possible modification of its screening recommendations. Since the committee's report, *HIV Screening of Pregnant Women and Newborns*, was issued, new information about HIV diagnostic technology and medical therapy for children with HIV has emerged.

In light of these developments, the IOM is planning a study to explore and analyze the technological, medical, scientific, and epidemiological changes that have occurred since the 1991 screening report was issued, as well as to reevaluate the justifications for and appropriateness of screening newborns for HIV at this time. In addition to reviewing the technological and medical developments in the area of pediatric HIV infection and assessing their impact on newborn screening proposals, the study committee would revisit some of the legal, ethical, and social issues involved in screening and how they may have been affected as a result of the above developments. The study also would examine prenatal HIV screening programs to assess the scope and relative effectiveness of these efforts in identifying HIV-infected women and ensuring appropriate referrals for clinical evaluation and follow-up care. Current prenatal HIV screening policies or recommendations would also be reevaluated in light of the changing epidemiology of HIV infection and AIDS in the United States. The resulting study report would present the committee's findings and conclusions about the status of prenatal HIV screening programs and whether current approaches to screening pregnant women for HIV should be modified. The report would also provide the committee's judgement about whether the conditions that would justify newborn HIV screening have been satisfied at the present time, as well as offer guidance in developing and implementing neonatal screening programs, if judged appropriate.

Arresting AIDS in Sub-Saharan Africa: Data and Research Priorities

The U. S. Agency for International Development (USAID) has asked the National Research Council's Committee on Population to assist in providing a broad overview of the HIV/AIDS epidemic in Africa in order to identify data and trends that will enable the Agency to better focus its prevention programs. In response, the Committee on Population is planning an 18-month panel study of the data and research needs for slowing the spread of HIV infection and AIDS in sub-Saharan Africa, focusing primarily on social and behavioral issues. The study is designed to provide information critical for designing and implementing effective HIV prevention and control programs and to assist USAID and other agencies in the evaluation of existing programs. The panel will be asked to review the relevant scientific and research literature with the objective of identifying prevention or coping strategies that have been successful in one region of Africa and are likely to be transferable to other African settings. From this vantage point, the panel will identify remaining research gaps that, if filled, could have immediate policy implications for enhancing the effectiveness of existing prevention or coping strategies, or could assist in the development of new strategies.

ATTACHMENT I

INSTITUTE OF MEDICINE

Roundtable for the Development of Drugs and Vaccines Against AIDS

Abridged Meeting Summary
July 22, 1993

As the Roundtable for the Development of Drugs and Vaccines Against AIDS nears completion of its second term in mid-1994, it seems appropriate to reflect on its value and continuation as a neutral forum for dialogue on scientific and public policy questions pertaining to HIV drug and vaccine development. To this end, a subgroup of Roundtable members convened on July 22, 1993, to discuss the future course of the Roundtable—its continuation, format of operation, composition, and the important topics or areas on which the Roundtable should focus its attention over the next few years.

Future of the Roundtable

Roundtable's Value and Unique Qualities

Paul Volberding launched the discussion of the Roundtable's future by posing several questions to the group: Should the Roundtable continue to operate? Should we change the structure, composition, and direction of the Roundtable? Members unanimously endorsed its continuation. They observed that the Roundtable brings together a diverse group of leaders from government, academia, the pharmaceutical and biotechnology industries, and patient advocacy communities, and thereby forms a unique blend of expertise and viewpoints on scientific and policy questions pertaining to HIV drug and vaccine development. Further, it provides a neutral forum (or "safe harbor") in which to explore and debate a variety of thorny issues (or "sticky wickets") surrounding the development of effective AIDS drugs and vaccines. Finally, the Roundtable offers an opportunity to examine areas in which science and public policy intersect and to consider the policy implications of scientific inquiry and discovery in the area of HIV drug and vaccine development.

Roundtable's Format of Operation

Meeting participants also discussed the format of the Roundtable's operations (e.g., number, size, and content of meetings or workshops). Several members suggested that the Roundtable resist convening strictly scientific or technical sessions on HIV drug and vaccine development, as there are multiple forums in which scientific data are presented and discussed. Rather, the Roundtable should identify problem areas or difficult, controversial

issues that can be uniquely addressed by the Roundtable's diverse perspectives and expertise. Although the selection of topics for discussion will necessarily guide the structure of the Roundtable's meetings, one member suggested that we convene smaller, focused sessions (either separately or following a larger, public workshop) during which a few key scientists, policy makers, and the Roundtable members can grapple with specific scientific and policy dilemmas that complicate AIDS drug and vaccine development. Several members pointed out that the value of the Roundtable's meetings and workshops is the length of time devoted to discussion, and this unique opportunity for extensive dialogue should be fostered and preserved.

Roundtable's Mission

As the National Commission on AIDS concludes its tenure, it is appropriate to consider whether the Roundtable, as the longest standing IOM AIDS committee, should broaden its scope and mission to include such issues as prevention and behavioral research. Although several members favored expanding the Roundtable's scope of activities beyond HIV drug and vaccine research and development, many cautioned that this expansion might ultimately dilute the effectiveness of the Roundtable and diminish its depth of expertise. Furthermore, one member strongly argued that a shift in the Roundtable's focus to include issues of prevention would be perceived by the patient community as abandoning those individuals who are already infected with HIV. In the wake of the 1993 International AIDS Conference and the feelings of depression and confusion about the results of current HIV treatment research, another member urged that the Roundtable retain its current mission and "reinvigorate" its focus on impediments to the rapid development of effective HIV drugs and vaccines, as well as the process and coordination of treatment research efforts.

Following considerable debate, the group agreed upon an alternative to broadening the scope of the Roundtable's activities. Participants acknowledged that HIV prevention and behavioral research efforts are sufficiently important to warrant specific attention and recommended that the IOM assemble a separate roundtable to address these issues. In developing the scope and focus of such an "HIV prevention roundtable," it is critical to maintain a strong link with the current IOM drug and vaccine roundtable. One suggestion was that the current AIDS drug and vaccine roundtable could participate in launching a "prevention roundtable" by holding a workshop to examine the "successes and failures" of behavioral and social research efforts in the area of HIV prevention.

APPENDIX A

INSTITUTE OF MEDICINE

Roundtable for the Development of Drugs and Vaccines Against AIDS

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INSTITUTE OF MEDICINE

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Panel on Needle Exchange and Bleach Distribution Programs

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***The Human Immunodeficiency
Virus Vaccine Challenge:
Issues in Development and
International Trials***



Committee on Life Sciences and Health

**Federal Coordinating Council on Science, Engineering,
and Technology**

July 1993

KRISTINE M. GEBBIE, R.N., M.N., F.A.A.N.
NATIONAL AIDS POLICY COORDINATOR
DEPARTMENT OF HEALTH & HUMAN SERVICES
Room 729H Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

DAY Tuesday DATE October 19, 1993

TIME 10:30 am LOCATION 2101 Constitution Ave., NW

SUBJECT IOM Annual Meeting

PARTICIPANTS:

TUESDAY, OCTOBER 19, 1993
(For IOM Members & Robert Wood Johnson Health Policy Fellows Only)

TOWN MEETING ON HEALTH CARE REFORM **

Program

7:30 a.m. **REGISTRATION** C Street Entrance
Continental Breakfast

8:30 a.m. **Welcome and Plan for the Day**
Kenneth I. Shine, M.D.
President
Institute of Medicine

8:45 a.m. **A Plan for Health Care Reform**

9:45 a.m. **What Are and How Will State and Private
Sector Reforms Relate to this Plan?**
Lawrence S. Lewin, M.B.A. (Moderator)
Chairman and CEO
Lewin-VHI, Inc.

 Gail L. Warden
President and Chief Executive Officer
Henry Ford Health System

10:45 a.m. **BREAK**

11:15 a.m. **What Role Should Academic Centers Play in a Reformed
System? How Will We Finance Education and Research?**
Walter J. McNerney (Moderator)
Herman Smith Professor of Health Policy
J.I. Kellogg Graduate School of Management
Northwestern University

 William N. Kelley, M.D.
Chief Executive Officer
University of Pennsylvania Medical Center
and Health System

 James J. Mongan, M.D.
University of Missouri
Kansas City School of Medicine

 Mary O. Munding, R.N., Dr. P.H.
Dean and Professor, School of Nursing
Columbia University College of Physicians & Surgeons

12:15 p.m. LUNCH - Refectory

1:15 p.m. **Health Care Reform and Reinventing Public Health**
Philip R. Lee, M.D.
Assistant Secretary for Health
U.S. Department of Health and Human Services

2:15 p.m. **What are Work Force Needs in a Reformed Health Care System?**
John M. Eisenberg, M.D. (Moderator)
Chairman and Physician-in-Chief
Department of Medicine
Georgetown University Medical Center

Linda H. Aiken, Ph.D.
Trustee Professor of Nursing and Sociology
Director, Center for Health Services & Policy Research
University of Pennsylvania

John Luddens, M.D.
Corporate Medical Director
Harvard Community Health Plan

3:15 p.m. **Summation of the Day**
Kenneth I. Shine, M.D.

3:30 p.m. ADJOURNMENT

NATIONAL AIDS POLICY OFFICE
OFFICE OF THE COORDINATOR

ROUTING SLIP

DATE: 11/9

TO: regrets conveyed by
phone 11/18.

FROM: W. STEVE LEE

☒ For your information

☐ For your action

☐ Review and comment by (date)

☐ Prepare reply for Coordinator's signature

☐ Reply directly and blind copy Coordinator

☐ Circulate/forward to:

☐ File

COMMENTS: Called - in Atlanta
but could make it happen if
important. Would like to
spend some time with
this group - please see
what might be possible
without making other
commitments -

INSTITUTE OF MEDICINE

NATIONAL ACADEMY OF SCIENCES

2101 CONSTITUTION AVENUE WASHINGTON, D.C. 20418

RCVD
NOV - 6 1993



OFFICE OF HEALTH POLICY
PROGRAMS AND FELLOWSHIPS

PHONE: 202/334-1506
FAX: 202/334-1694

October 29, 1993

Kristine Gebbie, M.N.
National AIDS Policy Coordinator
The White House
Washington, DC 20500

Dear Kristine:

I am pleased to invite you to attend a special dinner in honor of the New Pew Health Policy Fellows on **Thursday, November 18** at 6:30pm in the Decks room at Sequoia Restaurant (3000 K Street at the Washington Harbour). We will begin with appetizers and a cash bar and plan to start dinner around 7:30pm. In order to get an accurate head count, please contact my assistant Valerie Tate at the above number by **Friday, November 12.**

This year's New Pew Fellows meeting will be held from November 17-19 at the main National Academy of Sciences building (2101 Constitution Avenue, N.W.). Fellows from Brandeis University and the University of California at San Francisco will begin the program this year.

I have enclosed a tentative agenda for the meeting. As always, we welcome and encourage your attendance at any of our programmatic sessions. Please let us know if you plan to attend any of these sessions. If you have any questions concerning the meeting please do not hesitate to contact the office. I look forward to seeing you next month.

Sincerely,

Marion Ein Lewin
Program Director
Pew Health Policy Program

Enclosure

Hope you can make it!

**PEW HEALTH POLICY PROGRAM
WASHINGTON MEETING FOR NEW PEW FELLOWS**

Institute of Medicine
National Academy of Sciences
2101 Constitution Avenue, N.W.
Washington, D.C.

**Health Care Reform:
Translating Vision into Programs and Policies**
Tentative Agenda
November 17-19, 1993

Wednesday, November 17

National Academy of Sciences Building
Executive Dining Room

6:00 p.m. - 6:30 p.m. Reception

6:30 p.m. - 8:30 p.m. Dinner

Welcoming Remarks

*Marion Ein Lewin, Director
Health Policy Programs and Fellowships
Institute of Medicine*

*Carolyn H. Asbury, Sc.M.P.H., Ph.D.
Director
Health and Human Services
The Pew Charitable Trusts*

**Wearing a New Hat: Perspectives on
Washington in an Era of Health Care Reform**

Speaker:

*Philip R. Lee, M.D.
Assistant Secretary for Health
Department of Health and Human Services*

Thursday, November 18
NAS Building, Room 150

- 9:00 a.m. - 10:00 a.m. **Introductions of the New Fellows**
Continental Breakfast Provided
- 10:00 a.m. - 10:15 a.m. **Background on the Pew Health Policy Program**
- 10:15 a.m. - 10:30 a.m. Break
- 10:30 a.m. - 12:00 noon **How Congress Really Works**
Judith Schneider
Specialist in American National Government
Congressional Research Service
Library of Congress
- 12:15 p.m. - 1:45 p.m. **An Insiders Look at the Administration's Health Care Reform Plan**
Lunch Speaker: *Walter Zelman*
Senior Advisor to Ira Magaziner
The White House
- 2:00 p.m. - 3:30 p.m. **Addressing the Needs of Children and Special Populations Under Health Care Reform**
Sarah Rosenbaum
Senior Research Staff Scientist
Center for Health Policy Research
George Washington University
- 3:30 p.m. - 3:45 p.m. Break
- 3:45 p.m. - 5:00 p.m. **The IOM's Agenda on International Health**
Polly Harrison, Ph.D.
Director, Division of International Health
Institute of Medicine
- 6:30 p.m. - 9:00 p.m. **Cocktails and Dinner at Sequoia**
with 1993-94 Robert Wood Johnson Health Policy
Fellows
and Other Invited Guests
3000 K Street, N.W. at the Washington Harbour

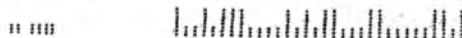
Friday, November 19
NAS Building, Room 150

- 8:30 a.m. - 9:00 a.m. Continental Breakfast
- 9:00 a.m. - 11:00 a.m. **Shaping Health Care Reform in the Congress:
Some Perspectives**
Michael Hash (invited)
Minority Staff
Subcommittee on Health and the Environment
House Committee on Energy and Commerce
- Susan Bartlett Foote, J.D.*
Senior Legislative Aide for Health
Office of Senator Dave Durenberger (R-MN)
- Faye Drummond (invited)*
Senior Health Counsel
Senate Finance Committee
- Rikki Baum (invited)*
Chief of Staff
Office of Congressman Sander Levin (D-MI)
- 11:00 a.m. - 11:15 a.m. Break
- 11:15 a.m. - 12:30 p.m. **Perinatal Substance Abuse:
Federal, State, and Local Policy**
Susanna Ginsburg, M.S.W.
Vice President
Lewin-VHI, Inc.
- Barbara Bazron, Ph.D.*
Vice President
Lewin-VHI, Inc.
- 12:30 p.m. - 2:00 p.m. **A Status Report on Women's Health**
Lunch Speaker: *Vivian W. Pinn, M.D.*
Director
Office of Research on Women
National Institutes of Health
- 2:00 p.m. - 2:15 p.m. Break
- 2:15 p.m. - 3:00 p.m. **Summary and Wrap Up**

INSTITUTE OF MEDICINE
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2101 CONSTITUTION AVENUE
WASHINGTON, D. C. 20418



Kristine Gebbie, M.N.
National AIDS Policy Coordinator
The White House
Washington, DC 20500



REGISTRATION FORM

Response Due by August 13, 1993*

Institute of Medicine

Roundtable for the Development of Drugs
and Vaccines Against AIDS

**The Changing Demographics of the HIV Epidemic: Implications for Clinical Research
September 8, 1993**

Name Kristine M. Gebbie, RN, MN, FAAN

Title National AIDS Policy Coordinator

Department White House

Organization Domestic Policy Office

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Is this a substitution? Yes _____ No X

If Yes, for whom? _____

FAX COMPLETED FORM TO JENNIFER HOLLIDAY AT (202) 334-2939

*Registration is limited to the first 100 people responding. If you are unable to attend the workshop after sending in your registration, please notify our office to cancel your reservation.

July 8, 1993

Claudia Carl
Institute of Medicine
Room F03061

Dear Claudia:

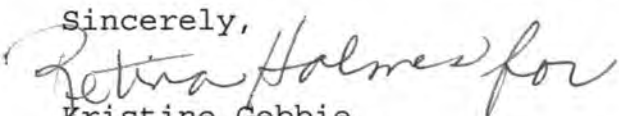
I have had a chance to review the Committee comments in response to the review of the Agent Orange Report, and to re-read Chapter 8 in its revised format.

The committee has been quite responsive to the comments raised by reviewers. The response includes rewriting and clarifying numerous passages to deal with ambiguities or errors in the original draft. The use of additional tables and cross-references makes it much easier for a reader to follow the development of reasoning, both for conclusions about individual cancers, and for the overall recommendations.

I believe that the most important of the reviewer concerns have been dealt with. There are two issues which might be considered not fully resolved, both arising most strongly from the same reviewer. These are the decision about categorization of conclusions and the recommendation to conduct a further effort at exposure assessment. I do not see the study committee ready to make these more radical changes, but I do see the positive effect of a major effort to clarify the committee's reasoning and conclusions.

Given the above, I am satisfied that the study committee was responsive to the review, and that the report now meets the IOM criteria. If I can clarify any points, or there is anything more I can do, please let me know.

Sincerely,


Kristine Gebbie