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Institute of Medicine

AIDS Activities Planning Meeting

November 29, 1993

Kristine Gebbie

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NOV 24 1993

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: Participants, Meeting on IOM AIDS Activities

FROM: Leslie Hardy, IOM AIDS Coordinator *LH*

DATE: November 8, 1993

SUBJECT: Background Material for November 29 Meeting

Thank you all for agreeing to participate in the **November 29, 1993** planning meeting to review the current and future AIDS program of the Institute of Medicine. As Ken Shine noted in his September 16 invitation letter, we think it is important to reflect upon the IOM's AIDS-related activities to date and explore how the Institute can best contribute to HIV/AIDS policy-making efforts in the future, particularly in light of this year's changes in national leadership and the conclusion of the AIDS Commission's four-year tenure.

As you know, we will convene at 12:30 pm in **Room 104 of the Green Building, 2001 Wisconsin Avenue, N.W.** and expect to conclude our meeting at 5:30 pm. An agenda is enclosed for your information. The goal of this meeting will be to discuss the current AIDS activities of the IOM and to explore AIDS-related projects that we should pursue in the future. To begin our discussion, Ken Shine will briefly describe some of the current and planned IOM AIDS projects. Kristine Gebbie and Harold Varmus will then offer their perspectives on national AIDS policy activities and future directions in HIV/AIDS research, respectively. The balance of the meeting will focus on developing ideas for possible future AIDS activities. In preparation for this discussion, I have enclosed a listing of all AIDS-related reports published by the IOM and National Research Council, as well as brief descriptions of ongoing IOM/NAS AIDS-related projects and those under development. We hope this document helps you to understand the scope of the IOM's current AIDS program and to identify areas or issues that may require further exploration in future activities.

We look forward to a fruitful discussion on the 29th. Please feel free to call me at (202) 334-2453 or my assistant, Jennifer Holliday, if you have further questions.

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
- Research - target/breadth*
Treatment - health care
Prevention - localized } *sub, disease*
Nat'l Framework
where science is emerging / if unclear
evaluate the science is emerging / unclear

Institute of Medicine
AIDS Activities Planning Meeting

PARTICIPANTS

November 29, 1993

Cynthia H. Abel
Program Associate
Div. of Health Promotion and
Disease Prevention
Institute of Medicine
National Academy of Sciences
2101 Constitution Ave., NW, FO-3027
Washington, DC 20418
(202) 334-2383

Moises Agosto, M.A.
Treatment and Research Advocate
Department of Public Policy
National Minority AIDS Council
300 Eye St., NE, Suite 400
Washington, DC 20002
(202) 544-1076

David Barr, J.D.
Assistant Director of Policy
Gay Men's Health Crisis
129 West 20th Street
New York, NY 10011
(212) 337-1229

David W. Barry, M.D.
Vice President, Research, Development
and Medical Affairs
The Wellcome Research Laboratories
Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park, NC 27709
(919) 315-4534

Queta C. Bond, Ph.D.
Executive Officer
Institute of Medicine
National Academy of Sciences
2101 Constitution Ave., NW, NAS-325
Washington, DC 20418
(202) 334-2177

Thomas J. Coates, Ph.D.
Prof. of Medicine and Director
Center for AIDS Prevention Studies
Univ. of California, San Francisco
74 New Montgomery St., Suite 600
San Francisco, CA 94105
(415) 597-9157 or (415) 476-6933

Robert M. Cook-Deegan, M.D.
Dir., Div. of Biobehavioral Sciences
and Mental Disorders
Institute of Medicine
National Academy of Sciences
2101 Constitution Ave., NW, FO-3020
Washington, DC 20418
(202) 334-2328

Deborah J. Cotton, M.D., M.P.H.
Asst. Prof. of Medicine
Harvard Medical School
Infectious Disease Unit/Gray 5
Massachusetts General Hospital
Fruit Street
Boston, MA 02114
(617) 726-3812

James W. Curran, M.D., M.P.H.
Assoc. Dir. for HIV/AIDS
Centers for Disease Control and
Prevention
1600 Clifton Rd., NE, MS D-21
Atlanta, GA 30333
(404) 639-0900

Donald C. Des Jarlais, Ph.D.
Director of Research
Chemical Dependency Institute
Beth Israel Medical Center
First Avenue at 16th Street
New York, NY 10013
(212) 966-8700 ext. 523

June E. Osborn, M.D.
Prof. of Epidemiology
School of Public Health
University of Michigan
1401 Culver Road
Ann Arbor, MI 48103
(313) 662-5732

Ralph Payne
Legislative Assistant
The Honorable Diane Feinstein
331 Hart Senate Office Bldg.
Washington, DC 20510
(202) 224-9641

Helen Rodriguez-Trias, M.D.
Pediatric Consultant in
Health Programming
P.O. Box 418
11565 Alta Via Road
Brookdale, CA 95007
(408) 338-2369

David E. Rogers, M.D.
The Walsh McDermott University
Professor of Medicine
New York Hospital-Cornell
Medical Center
1300 York Ave., Rm. A-127
New York, NY 10021
(212) 746-5431

Valerie P. Setlow, Ph.D.
Dir., Div. of Health Sciences Policy
Institute of Medicine
National Academy of Sciences
2101 Constitution Ave., NW, FO-3016
Washington, DC 20418
(202) 334-2351

Kenneth I. Shine, M.D.
President
Institute of Medicine
National Academy of Sciences
2101 Constitution Ave., NW, NAS-323
Washington, DC 20418
(202) 334-3300

Susanne A. Stoiber, M.S.
Dir. Div. on Social and
Economic Studies
National Research Council
National Academy of Sciences
2101 Constitution Ave., NW, HA-172
Washington, DC 20418
(202) 334-1395

Michael A. Stoto, Ph.D.
Dir., Div. of Health Promotion and
Disease Prevention
Institute of Medicine
National Academy of Sciences
2101 Constitution Ave., NW, FO-3026
Washington, DC 20418
(202) 334-2383

Harold E. Varmus, M.D.
Director Designate
National Institutes of Health
Building 1, Room 126
9000 Rockville Pike
Bethesda, MD 20892
(301) 402-3376

Paul A. Volberding, M.D.
Chief, AIDS Program and
Clinical Oncology
San Francisco General Hospital
995 Potrero Ave., Ward 84
San Francisco, CA 94110
(415) 476-4082 ext. 84232

Timothy Westmoreland, J.D.
Counsel
House Subcommittee on Health
and Environment
2415 Rayburn House Office Bldg.
Washington, DC 20006
(202) 225-4952

Roy Widdus, Ph.D.
Consultant
National Vaccine Program Office
Hubert H. Humphrey Bldg.
200 Independence Ave., Rm. 730E
Washington, DC 20016
(202) 401-8141

Randolf F. Wykoff, M.D.
Dir., Office of AIDS Coordination
Food and Drug Administration
Parklawn Building, Rm. 12A-40
5600 Fishers Lane
Rockville, MD 20857
(301) 443-0104

R. Gordon Douglas, Jr., M.D.
Vice President, Merck & Co., Inc.
President, Merck Vaccine Division
Merck & Co., Inc.
1 Merck Drive, P.O. Box 100
Whitehouse Station, NJ 08889-0100
(908) 423-3235

Harvey V. Fineberg, M.D., Ph.D.
Dean
Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115
(617) 432-1025

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator
Executive Office of the President
750 17th St., NW, Ste. 1060
Washington, DC 20006
(202) 632-1090

Margaret A. Hamburg, M.D.
Health Commissioner
New York City Dept. of Health
125 Worth Street
New York, NY 10013
(212) 788-5261

Leslie M. Hardy, M.H.S.
AIDS Coordinator
Institute of Medicine
National Academy of Sciences
2101 Constitution Ave., NW, FO-3032
Washington, DC 20418
(202) 334-2453

Barton F. Haynes, M.D.
F.M. Hanes Prof. of Medicine and
Dir., Duke Univ. Arthritis Center
Dept. of Medicine, Box 3258
Duke Univ. School of Medicine
Durham, NC 27710
(919) 684-5093

Karen Hein, M.D.
Prof. of Epidemiology, Pediatrics,
and Social Medicine
Albert Einstein College of Medicine
RWJ Health Policy Fellow (1993-1994)
3905 Huntington St., NW
Washington, DC 20005
(202) 363-4132

Jennifer K. Holliday
Project Assistant, AIDS Activities
Institute of Medicine
National Academy of Sciences
2101 Constitution Ave., NW, FO-3030B
Washington, DC 20418
(202) 334-2453

Michael Iskowitz, J.D.
Legal Counsel
Senate Committee on Labor and
Human Resources
428 Dirksen Senate Office Bldg.
Washington, DC 20510
(202) 224-6572

Jack Killen, M.D.
Acting Director
Division of AIDS
NIAID/NIH
6003 Executive Blvd., Rm. 2A16
Bethesda, MD 20892
(301) 496-0545

Mathilde Krim, Ph.D.
Founding Co-Chair
American Foundation for
AIDS Research
733 Third Ave., 12th Fl.
New York, NY 10017-3204
(212) 682-7440

Philip R. Lee, M.D.
Asst. Secretary for Health
Dept. of Health and Human Services
Hubert H. Humphrey Bldg, Rm. 716-G
200 Independence Ave., SW
Washington, DC 20201
(202) 690-7694

Jeffrey Levi
Dir. of Governmental Affairs
AIDS Action Council
1875 Connecticut Ave., NW, Ste. 700
Washington, DC 20009
(202) 986-1300 ext. 17

Steve Morin, Ph.D.
Associate Staff
House Committee on Appropriations
240 Cannon House Office Bldg.
Washington, DC 20515
(202) 225-4965

INSTITUTE OF MEDICINE
Meeting on IOM AIDS Program

November 29, 1993

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

AGENDA

- | | |
|----------|---|
| 12:30 pm | Working Lunch |
| 1:00 pm | Welcoming Remarks and Goals of the Meeting <ul style="list-style-type: none">• Harvey Fineberg, <i>Dean, Harvard School of Public Health</i> |
| 1:15 pm | Introduction of Participants <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Kenneth Shine, <i>IOM President</i> |
| 2:15 pm | Discussion |
| 2:30 pm | National AIDS Policy Activities <ul style="list-style-type: none">• Kristine Gebbie, <i>National AIDS Policy Coordinator</i> |
| 2:45 pm | Discussion |
| 3:00 pm | Future Directions in AIDS Research <ul style="list-style-type: none">• Harold Varmus, <i>NIH Director-designate</i> |
| 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 |

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

This study was initiated in response to the request of Senators Edward Kennedy (D-MA) and Bob Graham (D-FL) and Representative Porter Goss (R-FL) to Secretary of Health and Human Services Donna Shalala. Secretary Shalala asked the IOM to conduct a study to review and evaluate the transmission of HIV to people with hemophilia through blood and blood products during the period of 1982 through 1986.

This 18-month study will describe and evaluate policy options and policy making prior to FDA approval of HIV screening kits and the routine 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

ROSTER

Barton F. Haynes, M.D. (*co-chair*)
F.M. Hanes Professor of Medicine and
Director, Duke University Arthritis Center
Department of Medicine, Box 3258
Duke University School of Medicine
Durham, NC 27710
(919) 684-5093
(919) 684-5230 (FAX)

Paul A. Volberding, M.D. (*co-chair*)
Chief, AIDS Program and Clinical Oncology
San Francisco General Hospital
995 Potrero Avenue, Ward 84
San Francisco, CA 94110
(415) 476-4082 ext. 84232
(415) 476-9233 (FAX)

James Allen, M.D., M.P.H.
Vice President, Group on Science
Technology and Public Health
American Medical Association
515 N. State Street
Chicago, IL 60610
(312) 464-5334
(312) 464-5841 (FAX)

Arthur J. Ammann, M.D.
Director, The Ariel Project for the
Prevention of HIV Transmission
From Mother to Infant
81 Digital Drive
Novato, CA 94949
(415) 883-1796
(415) 883-1845 (FAX)

David Barr, J.D.
Assistant Director of Policy
Gay Men's Health Crisis
129 West 20th Street
New York, NY 10011
(212) 337-1229
(212) 337-3656 (FAX)

David W. Barry, M.D.
Vice President, Research, Development
and Medical Affairs
The Wellcome Research Laboratories
Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park, NC 27709
(919) 315-4534
(919) 315-8349 (FAX)

Lawrence S. Brown, Jr., M.D., M.P.H.
Assistant Clinical Professor of Medicine
College of Physicians and Surgeons
Columbia University and
Senior Vice President
Addiction Research and Treatment Corporation
22 Chapel Street
Brooklyn, NY 11201
(718) 260-2917
(718) 522-3186 (FAX)

Donald S. Burke, M.D.
Colonel, Medical Corps, US Army
Director, Division of Retrovirology
Walter Reed Army Institute of Research
13 Taft Court, Suite 201
Rockville, MD 20850
(301) 295-6414
(301) 295-6422 (FAX)

Bruce A. Chabner, M.D.
Director
Division of Cancer Treatment
National Cancer Institute
National Institutes of Health
Bldg. 31, Rm. 3A44
Bethesda, MD 20892
(301) 496-4291
(301) 496-0826 (FAX)

Max D. Cooper, M.D.
Investigator
Howard Hughes Medical Institute
Professor of Medicine, Pediatrics, and
Microbiology
University of Alabama at Birmingham
263 Wallace Tumor Institute
UAB Station
Birmingham, AL 35294
(205) 934-3370
(205) 934-1875 (FAX)

Martin Delaney
Co-Executive Director and President
Project Inform
1965 Market Street, Suite 220
San Francisco, CA 94103-1012
(415) 332-0184
(415) 331-2114 (FAX)

R. Gordon Douglas, Jr., M.D.
Vice President Merck & Co., Inc.
President, Merck Vaccine Division
Merck & Co., Inc.
1 Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889-0100
(908) 423-3235
(908) 735-1232 (FAX)

Anthony S. Fauci, M.D.
Associate Director
Office of AIDS Research
Director, National Institute of
Allergy and Infectious Diseases
National Institutes of Health
Building 31, Rm. 7A03
Bethesda, MD 20892
(301) 496-2263
(301) 496-4409 (FAX)

David Feigal, Jr., M.D., M.P.H.
Director
Division of Antiviral Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, HFD-530
Rockville, MD 20857
(301) 443-9550
(301) 443-9292 (FAX)

Gerald Friedland, M.D.
Director, AIDS Program
Yale University School of Medicine
Yale-New Haven Hospital
135 College St., 3rd Fl.
New Haven, CT 06510-2483
(203) 737-2450
(203) 737-4051 (FAX)

L. Patrick Gage, Ph.D.
Executive Vice President
Genetics Institute, Inc.
87 CambridgePark Drive
Cambridge, MA 02140
(617) 876-1170
(617) 876-1504 (FAX)

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator
Executive Office of the President
750 17th St., NW, Suite 1060
Washington, DC 20503
(202) 632-1090
(202) 632-1096 (FAX)

Peter Barton Hutt, LL.M.
Partner
Covington & Burling
1201 Pennsylvania Avenue, N.W.
P.O. Box 7566
Washington, DC 20044
(202) 662-5522
(202) 662-6291 (FAX)

Stephen W. Lagakos, Ph.D.
Professor of Biostatistics
Department of Biostatistics
Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115
(617) 432-2815
(617) 432-2832 (FAX)

Helen Rodriguez-Trias, M.D.
Pediatric Consultant in Health Programming
P.O. Box 418
11565 Alta Via Road
Brookdale, CA 95007
(408) 338-2369
(408) 338-7902 (FAX)

Catherine M. Wilfert, M.D.
Professor of Pediatrics and Microbiology
Department of Pediatrics
Division of Infectious Diseases
Duke University Medical Center
1079 Duke South
P.O. Box 2951
Durham, NC 27710
(919) 684-8772
(919) 684-8514 (FAX)

AIDS Activities - Institute of Medicine

Leslie Hardy, M.H.S., Project Director
Joanne Albanes, Research Assistant
Jennifer Holliday, Project Assistant
2101 Constitution Avenue, N.W.
Washington, DC 20418
(202) 334-2453
(202) 334-2939 (FAX)

APPENDIX B

INSTITUTE OF MEDICINE

Committee on Substance Abuse and Mental Health Issues in AIDS Research

ROSTER

H. Keith H. Brodie, M.D. (*Chair*)
President Emeritus, and
James B. Duke Professor of
Psychiatry and Law
Duke University
East Duke Building, Rm. 205
Durham, NC 27708-0763
(919) 684-5121
(919) 684-6465 (FAX)

Hortensia de los Angeles Amaro, Ph.D.
Professor
Dept. of Social and Behavioral Sciences
Boston Univ. School of Public Health
85 East Newton St., Rm. M-840
Boston, MA 02118
(617) 638-5160
(617) 638-4483 (FAX)

Ira B. Black, M.D.
Dept. of Neurosciences and Cell Biology
The Robert Wood Johnson Medical School
Univ. of Medicine and
Dentistry of New Jersey
675 Hoes Lane
CABM Building, Room 342
Piscataway, NJ 08854-5635
(908) 235-5388
(908) 235-4990 (FAX)

Colleen Conway-Welch, Ph.D., C.N.M., F.A.A.N.
Professor and Dean
Vanderbilt Univ. School of Nursing
111 Godchaux Hall
21st Avenue South
Nashville, TN 37240
(615) 343-8876
(615) 343-7711 (FAX)

Curtis L. Decker, J.D.
Executive Director
National Association of Protection
& Advocacy Systems, Inc.
900 2nd St., NE, Suite 211
Washington, DC 20002
(202) 408-9514
(202) 408-9520 (FAX)

Baruch Fischhoff, Ph.D.
Prof. of Social and Decision Sciences and
of Engineering and Public Policy
Dept. of Social & Decision Sciences
Carnegie Mellon University
5000 Forbes Ave., Porter Hall Rm. 208
Pittsburgh, PA 15213
(412) 268-3246
(412) 268-6938 (FAX)

Mindy Thompson Fullilove, M.D.
Assoc. Prof. of Clinical
Psychiatry and Public Health
Columbia University
Research Psychiatrist
New York State Psychiatric Institute
Community Research Group
722 West 168th Street, Unit 29
New York, NY 10032
(212) 740-7297
(212) 795-4222 (FAX)

Margaret A. Hamburg, M.D.
Health Commissioner
New York City Department of Health
125 Worth Street
New York, NY 10013
(212) 788-5261
(212) 964-0472 (FAX)

James G. Haughton, M.D., M.P.H.
Senior Health Services Policy Advisor
Los Angeles County Department of
Health Services
241 North Figueroa Street
Los Angeles, California 90012
(213) 240-7710; 7732
(213) 240-8499 (FAX)

James Inciardi, Ph.D.
Professor and Director
Center for Drug and Alcohol Studies
University of Delaware
77 East Main Street
Newark, DE 19716
(302) 831-6286
(302) 831-1275 (FAX)

Edward H. Kaplan, Ph.D.
Professor of Management Sciences,
Yale School of Organization and Management *and*
Professor of Medicine,
Yale School of Medicine
Yale University, Box 1A
New Haven, CT 06520
(203) 432-6031
(203) 432-9995;6316 (FAX)

Richard W. Price, M.D.
Professor and Head
Department of Neurology
University of Minnesota
Minneapolis, MN 55455
(612) 625-8983
(612) 625-7950 (FAX)

Alfred Saah, M.D., M.P.H.
Assoc. Prof. of Epidemiology
School of Hygiene and Public Health, *and*
Assoc. Prof. of Medicine
School of Medicine
Johns Hopkins University
624 North Broadway
Baltimore, MD 21205
(410) 955-1228
(410) 955-1836 (FAX)

Peter Selwyn, M.D., M.P.H.
Assoc. Dir., AIDS Program
Assoc. Prof. of Internal Medicine
Epidemiology, and Public Health
Yale University School of Medicine
135 College Street, Suite 323
New Haven, CT 06510-2483
(203) 737-2685
(203) 737-4051 (FAX)

Institute of Medicine Staff

Judy Auerbach, Ph.D., Study Director
Christina Wypijewski, M.P.H., Staff Officer
Holly Dawkins, Research Assistant
Karen Autrey, Project Assistant
Institute of Medicine
2101 Constitution Avenue, NW
Washington, DC 20418
(202) 334-3654
(202) 334-1385 (FAX)

NATIONAL RESEARCH COUNCIL
Commission on Behavioral and Social Sciences and Education
Panel on Needle Exchange and Bleach Distribution Programs

ROSTER

Lincoln E. Moses, Ph.D. (*Chair*)
 Professor of Statistics
 Department of Statistics
 Stanford University, Sequoia Hall
 Stanford, CA 94305
 (415) 723-6910
 (415) 725-6951 (FAX)

Ronald S. Brookmeyer, Ph.D.
 Dept. of Biostatistics
 School of Hygiene & Public Health
 The Johns Hopkins University
 615 N. Wolfe Street
 Baltimore, MD 21205-3179
 (410) 955-3519
 (410) 955-0958 (FAX)

Lawrence S. Brown, Jr., M.D., M.P.H.
 Assist. Clin. Prof. of Medicine
 Dept. of Medicine, Harlem Hospital
 College of Physicians and Surgeons
 Columbia University
 New York, NY 10035
 (718) 260-2917
 (718) 522-3186 (FAX)

Richard F. Catalano, Jr., Ph.D.
 Associate Director
 Social Development Research Group
 University of Washington
 146 N. Canal St., Suite 211
 Seattle, WA 98103
 (206) 543-6382
 (206) 543-4507 (FAX)

David S. Cordray, Ph.D.
 Chair, Dept. of Human Resources
 Peabody College, Rm. 110 Jesup Bldg.
 Vanderbilt University, 18th Ave. S.
 Nashville, TN 37203
 (615) 343-4714
 (615) 343-9494 (FAX)

Donald C. DesJarlais, Ph.D.
 Director of Research
 Chemical Dependency Institute
 National Development & Research
 Institutes, Inc.
 Beth Israel Med. Ctr., 11 Beach St.
 New York, NY 10013
 (212) 966-8700 (NDRI); 447-9801 (BIMC)
 (212) 334-8417 (NDRI); 447-9803 (BIMC)

Caswell A. Evans, Jr., D.D.S., M.P.H.
 Dir., Public Health Programs & Services
 Assistant Director of Health Services
 County of Los Angeles Dept. of Health Services
 313 North Figueroa Street, Suite 909
 Los Angeles, CA 90012
 (213) 240-8156
 (213) 481-2739 (FAX)

Mark B. Feinberg, M.D., Ph.D.
 Assistant Investigator
 Gladstone Institute of Virology
 and Immunology
 P.O. Box 419100
 San Francisco, CA 94141-9100
 (415) 695-3813
 (415) 826-1514 (FAX)

Herbert D. Kleber, M.D.
 Executive Vice President &
 Medical Director
 Center on Addiction and
 Substance Abuse
 Columbia University
 722 West 168th Street
 New York, NY 10032
 (212) 841-5220; 960-5770
 (212) 956-8020 (FAX)

Patrick M. O'Malley, Ph.D.
 Research Scientist
 Institute for Social Research
 University of Michigan
 Box 1248, 426 Thompson St.
 Ann Arbor, MI 48106-1248
 (313) 763-5043
 (313) 936-0043 (FAX)

Nancy S. Padian, Ph.D., M.P.H.
Assistant Adjunct Professor
Dept. of Obstetrics, Gynecology,
and Reproductive Sciences, Ward 6D
San Francisco General Hospital
San Francisco, CA 94110
(415) 206-5322
(415) 206-3112 (FAX)

Marian Gray Secundy, Ph.D.
Professor of Medicine
Dept. of Community Health
and Family Practice
Howard University
520 W Street, Rm. 2400
Washington, DC 20060
(202) 806-6300
(202) 806-4898 (FAX)

David Vlahov, Ph.D.
Assoc. Professor of Epidemiology
School of Hygiene and Public Health
The Johns Hopkins University
Hampton House, Room 894
624 North Broadway
Baltimore, MD 21205
(410) 955-1848
(410) 955-1836 (FAX)

W. Wayne Wiebel, Ph.D.
Principal Investigator
AIDS Outreach Intervention Project
Professor, School of Public Health
Epidemiology & Biostatistics (M/C 925)
Univ. of Illinois at Chicago
2121 West Taylor Street
Chicago, IL 60612-7260
(312) 996-5523
(312) 996-0064 (FAX)

David R. Williams, Ph.D.
Assoc. Research Scientist and
Assoc. Professor of Sociology
Institute for Social Research
University of Michigan
426 Thompson Street
Ann Arbor, MI 48106
(313) 936-0649
(313) 747-4575 (FAX)

National Research Council Staff

*Commission on Behavioral and Social Sciences and
Education*

Susanne A. Stoiber, Director
Div. on Social and Economic Studies
Jacques L. Normand, Project Director
Sahr J. Kpundeh, Staff Officer
Elaine McGarraugh, Research Associate
Susan R. McCutchen, Senior Project
Assistant
2101 Constitution Ave., NW, Rm. HA-156
Washington, DC 20418
(202) 334-3018
(202) 334-3829 (FAX)

Institute of Medicine Staff

Health Promotion and Disease Prevention

Michael Stoto, Director
Leslie Hardy, Program Officer
2101 Constitution Ave., NW, Rm. FO-3030
Washington, DC 20418
(202) 334-2453
(202) 334-2939 (FAX)

**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 policy options and policy making prior to FDA approval of HIV screening kits and the routine 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

ROSTER

Barton F. Haynes, M.D. (*co-chair*)
F.M. Hanes Professor of Medicine and
Director, Duke University Arthritis Center
Department of Medicine, Box 3258
Duke University School of Medicine
Durham, NC 27710
(919) 684-5093
(919) 684-5230 (FAX)

Paul A. Volberding, M.D. (*co-chair*)
Chief, AIDS Program and Clinical Oncology
San Francisco General Hospital
995 Potrero Avenue, Ward 84
San Francisco, CA 94110
(415) 476-4082 ext. 84232
(415) 476-9233 (FAX)

James Allen, M.D., M.P.H.
Vice President, Group on Science
Technology and Public Health
American Medical Association
515 N. State Street
Chicago, IL 60610
(312) 464-5334
(312) 464-5841 (FAX)

Arthur J. Ammann, M.D.
Director, The Ariel Project for the
Prevention of HIV Transmission
From Mother to Infant
81 Digital Drive
Novato, CA 94949
(415) 883-1796
(415) 883-1845 (FAX)

David Barr, J.D.
Assistant Director of Policy
Gay Men's Health Crisis
129 West 20th Street
New York, NY 10011
(212) 337-1229
(212) 337-3656 (FAX)

David W. Barry, M.D.
Vice President, Research, Development
and Medical Affairs
The Wellcome Research Laboratories
Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park, NC 27709
(919) 315-4534
(919) 315-8349 (FAX)

Lawrence S. Brown, Jr., M.D., M.P.H.
Assistant Clinical Professor of Medicine
College of Physicians and Surgeons
Columbia University and
Senior Vice President
Addiction Research and Treatment Corporation
22 Chapel Street
Brooklyn, NY 11201
(718) 260-2917
(718) 522-3186 (FAX)

Donald S. Burke, M.D.
Colonel, Medical Corps, US Army
Director, Division of Retrovirology
Walter Reed Army Institute of Research
13 Taft Court, Suite 201
Rockville, MD 20850
(301) 295-6414
(301) 295-6422 (FAX)

Bruce A. Chabner, M.D.
Director
Division of Cancer Treatment
National Cancer Institute
National Institutes of Health
Bldg. 31, Rm. 3A44
Bethesda, MD 20892
(301) 496-4291
(301) 496-0826 (FAX)

Max D. Cooper, M.D.
Investigator
Howard Hughes Medical Institute
Professor of Medicine, Pediatrics, and
Microbiology
University of Alabama at Birmingham
263 Wallace Tumor Institute
UAB Station
Birmingham, AL 35294
(205) 934-3370
(205) 934-1875 (FAX)

Martin Delaney
Co-Executive Director and President
Project Inform
1965 Market Street, Suite 220
San Francisco, CA 94103-1012
(415) 332-0184
(415) 331-2114 (FAX)

R. Gordon Douglas, Jr., M.D.
Vice President Merck & Co., Inc.
President, Merck Vaccine Division
Merck & Co., Inc.
1 Merck Drive
P.O. Box 100
Whitehouse Station, NJ 08889-0100
(908) 423-3235
(908) 735-1232 (FAX)

Anthony S. Fauci, M.D.
Associate Director
Office of AIDS Research
Director, National Institute of
Allergy and Infectious Diseases
National Institutes of Health
Building 31, Rm. 7A03
Bethesda, MD 20892
(301) 496-2263
(301) 496-4409 (FAX)

David Feigal, Jr., M.D., M.P.H.
Director
Division of Antiviral Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, HFD-530
Rockville, MD 20857
(301) 443-9550
(301) 443-9292 (FAX)

Gerald Friedland, M.D.
Director, AIDS Program
Yale University School of Medicine
Yale-New Haven Hospital
135 College St., 3rd Fl.
New Haven, CT 06510-2483
(203) 737-2450
(203) 737-4051 (FAX)

L. Patrick Gage, Ph.D.
Executive Vice President
Genetics Institute, Inc.
87 CambridgePark Drive
Cambridge, MA 02140
(617) 876-1170
(617) 876-1504 (FAX)

Kristine M. Gebbie, R.N., M.N.
National AIDS Policy Coordinator
Executive Office of the President
750 17th St., NW, Suite 1060
Washington, DC 20503
(202) 632-1090
(202) 632-1096 (FAX)

Peter Barton Hutt, LL.M.
Partner
Covington & Burling
1201 Pennsylvania Avenue, N.W.
P.O. Box 7566
Washington, DC 20044
(202) 662-5522
(202) 662-6291 (FAX)

Stephen W. Lagakos, Ph.D.
Professor of Biostatistics
Department of Biostatistics
Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115
(617) 432-2815
(617) 432-2832 (FAX)

Helen Rodriguez-Trias, M.D.
Pediatric Consultant in Health Programming
P.O. Box 418
11565 Alta Via Road
Brookdale, CA 95007
(408) 338-2369
(408) 338-7902 (FAX)

Catherine M. Wilfert, M.D.
Professor of Pediatrics and Microbiology
Department of Pediatrics
Division of Infectious Diseases
Duke University Medical Center
1079 Duke South
P.O. Box 2951
Durham, NC 27710
(919) 684-8772
(919) 684-8514 (FAX)

AIDS Activities - Institute of Medicine
Leslie Hardy, M.H.S., Project Director
Joanne Albanes, Research Assistant
Jennifer Holliday, Project Assistant
2101 Constitution Avenue, N.W.
Washington, DC 20418
(202) 334-2453
(202) 334-2939 (FAX)

APPENDIX B

INSTITUTE OF MEDICINE

Committee on Substance Abuse and Mental Health Issues in AIDS Research

ROSTER

H. Keith H. Brodie, M.D. (*Chair*)
President Emeritus, *and*
James B. Duke Professor of
Psychiatry and Law
Duke University
East Duke Building, Rm. 205
Durham, NC 27708-0763
(919) 684-5121
(919) 684-6465 (FAX)

Hortensia de los Angeles Amaro, Ph.D.
Professor
Dept. of Social and Behavioral Sciences
Boston Univ. School of Public Health
85 East Newton St., Rm. M-840
Boston, MA 02118
(617) 638-5160
(617) 638-4483 (FAX)

Ira B. Black, M.D.
Dept. of Neurosciences and Cell Biology
The Robert Wood Johnson Medical School
Univ. of Medicine and
Dentistry of New Jersey
675 Hoes Lane
CABM Building, Room 342
Piscataway, NJ 08854-5635
(908) 235-5388
(908) 235-4990 (FAX)

Colleen Conway-Welch, Ph.D., C.N.M., F.A.A.N.
Professor and Dean
Vanderbilt Univ. School of Nursing
111 Godchaux Hall
21st Avenue South
Nashville, TN 37240
(615) 343-8876
(615) 343-7711 (FAX)

Curtis L. Decker, J.D.
Executive Director
National Association of Protection
& Advocacy Systems, Inc.
900 2nd St., NE, Suite 211
Washington, DC 20002
(202) 408-9514
(202) 408-9520 (FAX)

Baruch Fischhoff, Ph.D.
Prof. of Social and Decision Sciences *and*
of Engineering and Public Policy
Dept. of Social & Decision Sciences
Carnegie Mellon University
5000 Forbes Ave., Porter Hall Rm. 208
Pittsburgh, PA 15213
(412) 268-3246
(412) 268-6938 (FAX)

Mindy Thompson Fullilove, M.D.
Assoc. Prof. of Clinical
Psychiatry and Public Health
Columbia University
Research Psychiatrist
New York State Psychiatric Institute
Community Research Group
722 West 168th Street, Unit 29
New York, NY 10032
(212) 740-7297
(212) 795-4222 (FAX)

Margaret A. Hamburg, M.D.
Health Commissioner
New York City Department of Health
125 Worth Street
New York, NY 10013
(212) 788-5261
(212) 964-0472 (FAX)

James G. Haughton, M.D., M.P.H.
Senior Health Services Policy Advisor
Los Angeles County Department of
Health Services
241 North Figueroa Street
Los Angeles, California 90012
(213) 240-7710; 7732
(213) 240-8499 (FAX)

James Inciardi, Ph.D.
Professor and Director
Center for Drug and Alcohol Studies
University of Delaware
77 East Main Street
Newark, DE 19716
(302) 831-6286
(302) 831-1275 (FAX)

Edward H. Kaplan, Ph.D.
Professor of Management Sciences,
Yale School of Organization and Management *and*
Professor of Medicine,
Yale School of Medicine
Yale University, Box 1A
New Haven, CT 06520
(203) 432-6031
(203) 432-9995;6316 (FAX)

Richard W. Price, M.D.
Professor and Head
Department of Neurology
University of Minnesota
Minneapolis, MN 55455
(612) 625-8983
(612) 625-7950 (FAX)

Alfred Saah, M.D., M.P.H.
Assoc. Prof. of Epidemiology
School of Hygiene and Public Health, *and*
Assoc. Prof. of Medicine
School of Medicine
Johns Hopkins University
624 North Broadway
Baltimore, MD 21205
(410) 955-1228
(410) 955-1836 (FAX)

Peter Selwyn, M.D., M.P.H.
Assoc. Dir., AIDS Program
Assoc. Prof. of Internal Medicine
Epidemiology, and Public Health
Yale University School of Medicine
135 College Street, Suite 323
New Haven, CT 06510-2483
(203) 737-2685
(203) 737-4051 (FAX)

Institute of Medicine Staff

Judy Auerbach, Ph.D., Study Director
Christina Wypijewski, M.P.H., Staff Officer
Holly Dawkins, Research Assistant
Karen Autrey, Project Assistant
Institute of Medicine
2101 Constitution Avenue, NW
Washington, DC 20418
(202) 334-3654
(202) 334-1385 (FAX)

NATIONAL RESEARCH COUNCIL
Commission on Behavioral and Social Sciences and Education

Panel on Needle Exchange and Bleach Distribution Programs

ROSTER

Lincoln E. Moses, Ph.D. (*Chair*)
 Professor of Statistics
 Department of Statistics
 Stanford University, Sequoia Hall
 Stanford, CA 94305
 (415) 723-6910
 (415) 725-6951 (FAX)

Ronald S. Brookmeyer, Ph.D.
 Dept. of Biostatistics
 School of Hygiene & Public Health
 The Johns Hopkins University
 615 N. Wolfe Street
 Baltimore, MD 21205-3179
 (410) 955-3519
 (410) 955-0958 (FAX)

Lawrence S. Brown, Jr., M.D., M.P.H.
 Assist. Clin. Prof. of Medicine
 Dept. of Medicine, Harlem Hospital
 College of Physicians and Surgeons
 Columbia University
 New York, NY 10035
 (718) 260-2917
 (718) 522-3186 (FAX)

Richard F. Catalano, Jr., Ph.D.
 Associate Director
 Social Development Research Group
 University of Washington
 146 N. Canal St., Suite 211
 Seattle, WA 98103
 (206) 543-6382
 (206) 543-4507 (FAX)

David S. Cordray, Ph.D.
 Chair, Dept. of Human Resources
 Peabody College, Rm. 110 Jesup Bldg.
 Vanderbilt University, 18th Ave. S.
 Nashville, TN 37203
 (615) 343-4714
 (615) 343-9494 (FAX)

Donald C. DesJarlais, Ph.D.
 Director of Research
 Chemical Dependency Institute
 National Development & Research
 Institutes, Inc.
 Beth Israel Med. Ctr., 11 Beach St.
 New York, NY 10013
 (212) 966-8700 (NDRI); 447-9801 (BIMC)
 (212) 334-8417 (NDRI); 447-9803 (BIMC)

Caswell A. Evans, Jr., D.D.S., M.P.H.
 Dir., Public Health Programs & Services
 Assistant Director of Health Services
 County of Los Angeles Dept. of Health Services
 313 North Figueroa Street, Suite 909
 Los Angeles, CA 90012
 (213) 240-8156
 (213) 481-2739 (FAX)

Mark B. Feinberg, M.D., Ph.D.
 Assistant Investigator
 Gladstone Institute of Virology
 and Immunology
 P.O. Box 419100
 San Francisco, CA 94141-9100
 (415) 695-3813
 (415) 826-1514 (FAX)

Herbert D. Kleber, M.D.
 Executive Vice President &
 Medical Director
 Center on Addiction and
 Substance Abuse
 Columbia University
 722 West 168th Street
 New York, NY 10032
 (212) 841-5220; 960-5770
 (212) 956-8020 (FAX)

Patrick M. O'Malley, Ph.D.
 Research Scientist
 Institute for Social Research
 University of Michigan
 Box 1248, 426 Thompson St.
 Ann Arbor, MI 48106-1248
 (313) 763-5043
 (313) 936-0043 (FAX)

Nancy S. Padian, Ph.D., M.P.H.
Assistant Adjunct Professor
Dept. of Obstetrics, Gynecology,
and Reproductive Sciences, Ward 6D
San Francisco General Hospital
San Francisco, CA 94110
(415) 206-5322
(415) 206-3112 (FAX)

Marian Gray Secundy, Ph.D.
Professor of Medicine
Dept. of Community Health
and Family Practice
Howard University
520 W Street, Rm. 2400
Washington, DC 20060
(202) 806-6300
(202) 806-4898 (FAX)

David Vlahov, Ph.D.
Assoc. Professor of Epidemiology
School of Hygiene and Public Health
The Johns Hopkins University
Hampton House, Room 894
624 North Broadway
Baltimore, MD 21205
(410) 955-1848
(410) 955-1836 (FAX)

W. Wayne Wiebel, Ph.D.
Principal Investigator
AIDS Outreach Intervention Project
Professor, School of Public Health
Epidemiology & Biostatistics (M/C 925)
Univ. of Illinois at Chicago
2121 West Taylor Street
Chicago, IL 60612-7260
(312) 996-5523
(312) 996-0064 (FAX)

David R. Williams, Ph.D.
Assoc. Research Scientist and
Assoc. Professor of Sociology
Institute for Social Research
University of Michigan
426 Thompson Street
Ann Arbor, MI 48106
(313) 936-0649
(313) 747-4575 (FAX)

National Research Council Staff

*Commission on Behavioral and Social Sciences and
Education*

Susanne A. Stoiber, Director
Div. on Social and Economic Studies
Jacques L. Normand, Project Director
Sahr J. Kpundeh, Staff Officer
Elaine McGarraugh, Research Associate
Susan R. McCutchen, Senior Project
Assistant
2101 Constitution Ave., NW, Rm. HA-156
Washington, DC 20418
(202) 334-3018
(202) 334-3829 (FAX)

Institute of Medicine Staff

Health Promotion and Disease Prevention

Michael Stoto, Director
Leslie Hardy, Program Officer
2101 Constitution Ave., NW, Rm. FO-3030
Washington, DC 20418
(202) 334-2453
(202) 334-2939 (FAX)

**CONFRONTING AIDS: DIRECTIONS FOR PUBLIC HEALTH, HEALTH CARE,
AND RESEARCH, 1986. (IOM)**

Steering Committee

DAVID BALTIMORE (*Co-chair*), The Rockefeller University, New York
SHELDON M. WOLFF (*Co-chair*), Tufts University School of Medicine and New England
Medical Center Hospital, Boston
JOHN J. BURNS, Roche Institute of Molecular Biology, Nutley, New Jersey
LEON EISENBERG, Harvard Medical School, Boston
BERNARD N. FIELDS, Harvard Medical School, Boston
HARVEY V. FINEBERG, Harvard School of Public Health, Boston
FRANK LILLY, Albert Einstein College of Medicine, Bronx
JUNE E. OSBORN, School of Public Health, University of Michigan, Ann Arbor
MARGERY W. SHAW, University of Texas Health Science Center, Houston
PAUL VOLBERDING, San Francisco General Hospital
IRVING WEISSMAN, Stanford University School of Medicine

Health Care and Public Health Panel

SHELDON M. WOLFF (*Chair*), Tufts University School of Medicine and New England
Medical Center Hospital, Boston
JAMES CHIN, California State Department of Health Services, Berkeley
WILLIAM J. CURRAN, Harvard School of Public Health, Boston
DAVID W. FRASER, Swarthmore College, Swarthmore, Pennsylvania
JEFFREY E. HARRIS, Centers for Disease Control and Prevention
ARTHUR LIFSON, Equitable Life Assurance Society of the United States, New York
DOROTHY NELKIN, Department of Sociology and School of Law, New York University
JUNE E. OSBORN, School of Public Health, University of Michigan, Ann Arbor
SAMUEL W. PERRY, Cornell University Medical Center, New York
PAUL VOLBERDING, San Francisco General Hospital
LeROY WALTERS, Kennedy Institute of Ethics, Georgetown University, Washington, DC

Research Panel

DAVID BALTIMORE (*Chair*), The Rockefeller University, New York
LEON EISENBERG, Harvard Medical School, Boston
BERNARD N. FIELDS, Harvard Medical School, Boston
JEROME E. GROOPMAN, New England Deaconess Hospital
MAURICE R. HILLEMANN, Merck Institute for Therapeutic Research,
Merck, Sharp & Dohme Research Labs, West Point, Pennsylvania

Research Panel (Continued)

RICHARD T. JOHNSON, Johns Hopkins University School of Medicine,
Baltimore, Maryland
ROBERT F. MURRAY, Jr., Howard University College of Medicine, Washington, DC
ROLAND K. ROBINS, Molecular Research Institute and ICN Pharmaceuticals,
Costa Mesa, California
P. FREDERICK SPARLING, University of North Carolina School of Medicine, Chapel Hill
CLADD E. STEVENS, New York Blood Center
HOWARD M. TEMIN, University of Wisconsin School of Medicine, Madison
IRVING WEISSMAN, Stanford University School of Medicine

Epidemiology Working Group Chairman

J. THOMAS GRAYSTON, University of Washington, Seattle

CONFRONTING AIDS: UPDATE 1988, 1988. (IOM)

Committee for the Oversight of AIDS Activities

THEODORE COOPER (*Chair*), The Upjohn Company, Kalamazoo, Michigan
STUART ALTMAN, Brandeis University, Waltham, Massachusetts
DAVID BALTIMORE, The Rockefeller University, New York
KRISTINE GEBBIE, National AIDS Policy Coordinator, Office of the President
DONALD R. HOPKINS, Global 2000, Inc., Chicago
KENNETH PREWITT, The Rockefeller Foundation, New York
HOWARD M. TEMIN, University of Wisconsin School of Medicine, Madison
PAUL VOLBERDING, San Francisco General Hospital

AIDS: SEXUAL BEHAVIOR AND INTRAVENOUS DRUG USE, 1989. (NRC)

Committee on AIDS Research and the Behavioral, Social, and Statistical Sciences

MARSHALL H. BECKER, School of Public Health, University of Michigan, Ann Arbor
ROBERT BORUCH, Graduate School of Education and Department of Statistics,
University of Pennsylvania
LESTER BRESLOW, Division of Cancer Control, School of Public Health,
University of California at Los Angeles

**Committee on AIDS Research and the Behavioral, Social,
and Statistical Sciences (Continued)**

J. BROOKS-GUNN, Education Policy and Research Division, Educational Testing Service,
Princeton, New Jersey
THOMAS J. COATES, Division of General Internal Medicine, Center for AIDS
Prevention Studies, University of California at San Francisco
ROBYN M. DAWES, Department of Social and Decision Sciences,
Carnegie Mellon University
DONALD C. DES JARLAIS, Chemical Dependency Institute,
Beth Israel Medical Center, New York
JOHN H. GAGNON, Department of Sociology, State University of
New York at Stony Brook
ALBERT R. JONSEN, Department of Medical History and Ethics,
University of Washington at Seattle
SHIRLEY LINDENBAUM, Department of Anthropology, Graduate Center,
City University of New York
GARDNER LINDZEY, Center for Advanced Study in the Behavioral Sciences,
Stanford, California
ROBERT M. MAY, Department of Zoology, University of Oxford
JANE MENKEN, Department of Sociology, and Population Studies Center,
University of Pennsylvania
LINCOLN E. MOSES (*Chair*), Department of Statistics, Stanford University
BAILUS WALKER, School of Public Health, University of Oklahoma
LAURIE SCHWAB ZABIN, Department of Population Dynamics, Johns Hopkins
University School of Hygiene and Public Health

Panel on Statistical Issues in AIDS Research

JOAN L. ARON, Department of Population Dynamics, Johns Hopkins University
School of Hygiene and Public Health
LYNNE BILLARD, Department of Statistics, University of Georgia
RON S. BROOKMEYER, Department of Biostatistics, Johns Hopkins University
School of Hygiene and Public Health
JANE MENKEN (*Chair*), Department of Sociology, University of Pennsylvania
LINCOLN E. MOSES, Department of Statistics, Stanford University
BRUCE D. SPENCER, Department of Statistics, Northwestern University
MICHAEL A. STOTO, Division of Health Promotion and Disease Prevention,
Institute of Medicine

Panel on AIDS and IV Drug Use

LAWRENCE S. BROWN, JR. Addiction Research and Treatment Corporation, and
Columbia University, New York
DONALD C. DES JARLAIS (*Chair*), Chemical Dependency Institute,
Beth Israel Medical Center, New York
SAMUEL R. FRIEDMAN, Narcotics and Drug Research, Inc., New York
ROBERT L. HUBBARD, Center for Social Research and Policy Analysis,
Research Triangle Institute
SHIRLEY LINDENBAUM, Department of Anthropology, Graduate Center,
City University of New York
JOHN A. NEWMAYER, Haight-Ashbury Free Medical Clinic, San Francisco

EVALUATING AIDS PREVENTION PROGRAMS, 1989; expanded edition, 1991. (NRC)

Panel on the Evaluation of AIDS Interventions

ROBERT F. BORUCH (*Chair*), Graduate School of Education and Department of
Statistics, University of Pennsylvania
THOMAS J. COATES (*Liaison to Committee*), Division of General Internal Medicine and
Center for AIDS Prevention Studies, University of California at San Francisco
JEFFREY P. DAVIS, Bureau of Community Health and Prevention,
Wisconsin Division of Health
BRIAN R. FLAY, Prevention Research Center, University of Illinois at Chicago
ROBERT L. HUBBARD, Center for Social Research and Policy Analysis,
Research Triangle Institute
RONALD C. KESSLER, Institute for Social Research, University of Michigan, Ann Arbor
NAN M. LAIRD, Department of Biostatistics, Harvard School of Public Health
JOHN L. MARTIN, School of Public Health, Columbia University
LINCOLN E. MOSES, Department of Statistics, Stanford University
JESSICA M. UTTS, Division of Statistics, University of California at Davis
JOHN B. WALLER, Jr., Department of Community Medicine, Wayne State University
School of Medicine

AIDS: THE SECOND DECADE, 1990. (NRC)

Committee on AIDS Research and the Behavioral, Social, and Statistical Sciences

MARSHALL H. BECKER, School of Public Health, University of Michigan, Ann Arbor
ROBERT F. BORUCH, Graduate School of Education and Department of Statistics,
University of Pennsylvania
THOMAS J. COATES, Division of General Internal Medicine, and Center for AIDS
Prevention Studies, University of California at San Francisco
RAMON C. CORTINES, Superintendent of Schools, San Francisco Unified School District
ROBYN M. DAWES, Department of Social and Decision Sciences,
Carnegie Mellon University
DONALD C. DES JARLAIS, Chemical Dependency Institute, Beth Israel Medical Center,
New York
JOHN H. GAGNON, Department of Sociology, State University of New York at Stony Brook
ALBERT R. JONSEN, Department of Medical History and Ethics,
University of Washington at Seattle
SHIRLEY LINDENBAUM, Department of Anthropology, Graduate Center,
City University of New York
JANE MENKEN (*Vice Chair*), Department of Sociology, and Population Studies Center,
University of Pennsylvania
LINCOLN E. MOSES (*Chair*), Department of Statistics, Stanford University
CLADD E. STEVENS, The New York Blood Center
BAILUS WALKER, School of Public Health, University Oklahoma

Panel on AIDS Interventions and Research

MARSHALL H. BECKER (*Chair*), School of Public Health, University of Michigan,
Ann Arbor
PHILIP W. BLUMSTEIN, Department of Sociology, University of Washington at Seattle
MARGARET A. CHESNEY, Department of Epidemiology and Biostatistics, and Center for
AIDS Prevention Studies, University of California at San Francisco
ANKE A. EHRHARDT, HIV Center for Clinical and Behavioral Studies, New York State
Psychiatric Institute, Columbia University
MINDY T. FULLILOVE, HIV Center for Clinical and Behavioral Studies,
New York State Psychiatric Institute, Columbia University
KAREN HEIN, Division of Adolescent Medicine, Albert Einstein College of Medicine, and
Montefiore Medical Center, Bronx, New York
JANE ALLYN PILIAVIN, Department of Sociology, University of Wisconsin at Madison
JAMES L. SORENSEN, Substance Abuse Services, San Francisco General Hospital, and
University of California at San Francisco
REED V. TUCKSON, Charles R. Drew University of Medicine and Sciences
JAMES A. WILEY, Survey Research Center, University of California at Berkeley

**THE AIDS RESEARCH PROGRAM OF
THE NATIONAL INSTITUTES OF HEALTH, 1991. (IOM)**

**Committee to Study the AIDS Research Program
of the National Institutes of Health**

WILLIAM H. DANFORTH (*Chair*), Washington University, St. Louis
LINDA H. AIKEN, University of Pennsylvania, Philadelphia
MARSHALL H. BECKER, School of Public Health, and Department of Behavior and
Health Education, The University of Michigan, Ann Arbor
VICTORIA A. CARGILL, University Hospitals of Cleveland,
Case Western Reserve University, Cleveland, Ohio
JOHN M. COFFIN, Tufts University School of Medicine, Boston
R. GORDON DOUGLAS, Jr., Merck, Sharp & Dohme International, Rahway, New Jersey
JAMES EIGO, ACT UP, New York
HERMAN N. EISEN, Massachusetts Institute of Technology, Cambridge
MELVIN M. GRUMBACH, School of Medicine, University of California, San Francisco
DONALD HOPKINS, Global 2000, Inc., Chicago
C. MAX LANG, College of Medicine, The Milton S. Hershey Medical Center,
The Pennsylvania State University, Hershey
CURTIS MEINERT, School of Hygiene and Public Health, Johns Hopkins University,
Baltimore, Maryland
NEAL NATHANSON, School of Medicine, University of Pennsylvania, Philadelphia
PHILIP S. SCHEIN, U.S. Bioscience, Blue Bell, Pennsylvania
ARTHUR SILVERSTEIN, Institute of the History of Medicine, School of Medicine,
Johns Hopkins University, Baltimore, Maryland

HIV SCREENING OF PREGNANT WOMEN AND NEWBORNS, 1991. (IOM)

**Committee on Prenatal and Newborn
Screening for HIV Infection**

MARIE C. McCORMICK (*Chair*), Harvard School of Public Health, Boston
LORI B. ANDREWS, American Bar Foundation, Chicago
MOLLY J. COYE, Health Dimensions Inc., San Jose, California
ROBERT A. DERZON, Lewin - VHI, Inc., Corte Madera, California
NORMAN C. FOST, University of Wisconsin School of Medicine, Madison
RODNEY HOFF (*government liaison member*), National Institute of Allergy and
Infectious Diseases
MICHAEL M. KABACK, University of California, San Diego
BARBARA J. SABOL, Human Resources Administration, New York, New York
EUGENE WASHINGTON, School of Medicine, University of California, San Francisco

THE SOCIAL IMPACT OF AIDS IN THE UNITED STATES, 1993. (NRC)

Panel on Monitoring the Social Impact of the AIDS Epidemic

ALBERT R. JONSEN (*Chair*), Department of Medical History and Ethics,
School of Medicine, University of Washington

RONALD BAYER, School of Public Health, Columbia University

RICHARD A. BERK, Department of Sociology, University of California,
Los Angeles

ALLAN M. BRANDT, Departments of Social Medicine and History of Science,
Harvard University, and Harvard Medical School

DAVID L. CHAMBERS, School of Law, University of Michigan, Ann Arbor

DEBORAH COTTON, Harvard School of Public Health

JOHN H. GAGNON, Department of Sociology, State University of New York, Stony Brook

SHIRLEY LINDENBAUM, The Graduate Center, City University of New York

EARL E. SHELP, Foundation for Interfaith Research and Ministry, Houston, Texas

MARK D. SMITH, Kaiser Family Foundation, Menlo Park, California

JAMES TRUSSELL, Office of Population Research, Princeton University