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IOM [Institute of Medicine] Roundtable Meeting May 5, 1994

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National Aids Policy
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9 OF 9

MEETING FILES
5/5/94-6/22/94

ENCLOSURES FILED OVERSIZE ATTACHMENTS

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



MAR 31 1994

DIVISION OF HEALTH PROMOTION
AND DISEASE PREVENTION

FAX: 202/334-2939

Call Leslie &
ask her to add
Paul Tran to the
invitees list for
the 6th

MEMORANDUM

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

FROM: Leslie Hardy *LH* and Jennifer Holliday *JH*

DATE: March 29, 1994

SUBJECT: May 5-6, 1994 Roundtable Dinner and Workshop

As you know, the Roundtable will be concluding its activities with the upcoming and final workshop, *Collaboration Between Government and Industry: Challenges and Opportunities for HIV Drug and Vaccine Development*. The meeting will be held on **Friday, May 6, 1994** from 9:00 am to 5:00 pm in the Lecture Room of the National Academy of Sciences building, 2101 Constitution Avenue, N.W. A continental breakfast will be available beginning at 8:30 am outside of the Lecture Room. A workshop agenda and invitation list are enclosed for your information.

We plan to keep the workshop relatively small and closed so that participants may speak frankly about the problems hampering government-industry collaboration and explore possible solutions. Although there will be a number of brief didactic presentations during the workshop, we have set aside substantial blocks of time for general discussion. Among the issues we hope to explore are: potential impediments to government-industry collaboration in drug research and development (e.g., the fair-pricing clauses included in Cooperative Research and Development Agreements [CRADAs], the rules governing intellectual property developed from government-industry collaborative arrangements); the implications for progress toward discovery of novel drug or vaccine candidates and their development into products, particularly when barriers may exist that discourage or prevent government-industry collaboration; and ways to overcome existing obstacles. To inform workshop participants and stimulate discussion, we will be distributing several background items a few weeks before the workshop—for example, brief case histories of the NCI-industry experience with taxol and ddI, a brief historical account of what's happened to the rules that govern intellectual property rights from government-industry collaborations in the U.S., and a written statement documenting or describing the importance and value of government and industry collaboration in HIV drug and vaccine development.

On Thursday evening, May 5, Roundtable members and invited guests (see enclosed list) will meet for dinner beginning at 6:30 pm in the Members Room of the NAS building. As this will be the Roundtable's last meeting, we thought the dinner would provide an opportunity to informally discuss some of the future challenges and opportunities in the AIDS drug and vaccine development arena. The dinner session should conclude around 8:30 pm.

For those of you from out of town, IOM Travel will assist you in making airline reservations; their telephone number is 202-334-3850 or 1-800-235-2210. When speaking with an agent, please reference record locator number 5ZW8F1. A block of rooms has been reserved at the Wyndham Bristol Hotel (2430 Pennsylvania Avenue, N.W.) We will be handling the hotel arrangements through our office. Please complete and fax the attached reservation form to Jennifer Holliday at (202) 334-2939 **by April 18**. The new maximum daily reimbursement for hotel and meals is \$151, with no more than \$34 for meals; receipts must be submitted for any single expense of \$25 or more. You will receive a travel voucher at the meeting.

We look forward to seeing you in May. Please feel free to call me or Jennifer Holliday at (202) 334-2453 if you have any questions.

Institute of Medicine

Roundtable for the Development of Drugs
and Vaccines Against AIDS

**Collaboration Between Government and Industry: Challenges and Opportunities
for HIV Drug and Vaccine Development**

May 6, 1994

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

TENTATIVE AGENDA

8:30 Continental Breakfast

9:00 **Welcome and Introduction**

- Barton Haynes, *F.M. Hanes Professor of Medicine; Director, Duke University Arthritis Center; and Roundtable Co-chair*
- Paul Volberding, *Chief, AIDS Program and Clinical Oncology, San Francisco General Hospital; and Roundtable Co-chair*

9:15 **Importance and Value of Government-Industry Collaboration on HIV Drug and Vaccine Development**

- Edward Scolnick, *President, Merck Sharp & Dohme Research Laboratories*

9:30 **Historical Perspectives on Government Technology Transfer Policy and the Pharmaceutical Industry**

Discussion Leader: Peter Barton Hutt, *Partner, Covington & Burling*

Understanding the Legislative History of Intellectual Property Rights Involving the Pharmaceutical Industry

- Peter Barton Hutt, *Partner, Covington & Burling*

Understanding the History of Fair Pricing Clauses and Their Implementation in Government Licensing of Intellectual Property

- Thomas Mays, *Director, Office of Technology Development, National Cancer Institute*

- 10:00 Discussion
- 10:30 *Break*
- 10:45 **Impediments to Collaboration on HIV Drug and Vaccine Development: Defining the Issues**
- Discussion Leader:** Pat Gage, *Chief Operating Officer, Genetics Institute, Inc.*
- Commentary from a Government/NIH Perspective
- Bruce Chabner, *Director, Division of Cancer Treatment, National Cancer Institute*
- A View from the Pharmaceutical Industry
- Stephen Carter, *Senior Vice President, World Wide Clinical Research & Development, Bristol-Myers Squibb Pharmaceutical Research Institute*
- Practical Implications of Rules Governing Intellectual Property Developed from Collaborative Relationships
- Harold Edgar, *Professor of Law, Columbia University School of Law*
- 11:30 Discussion
- 1:00 *Lunch*
- 2:00 **Overcoming Obstacles to Collaboration and Promoting HIV Drug and Vaccine Development: Proposals for Resolution**
- Discussion Leader:** Martin Delaney, *Co-Executive President and Director, Project Inform*
- Industry Perspective
- David Barry, *Vice President, Research, Development and Medical Affairs, Burroughs Wellcome Co.*
- Government/NIH Perspective
- Anthony Fauci, *Director, National Institute of Allergy and Infectious Diseases*
- Congressional/Legislative Response
- Timothy Westmoreland, *Counsel, Subcommittee on Health and the Environment, U.S. House of Representatives*
 - David Schulke, *Chief Health Policy Advisor, The Honorable Ron Wyden, U.S. House of Representatives*

- 2:40 Discussion
- 4:15 **Consideration of Future Directions: Summary of Salient Issues**
• Daniel Hoth, *Senior Vice President and Chief Medical Officer, Cell Genesys*
- 4:45 **Closing Remarks**
• Paul Volberding, *Chief, AIDS Program and Clinical Oncology, San Francisco General Hospital; and Roundtable Co-chair*
- 5:00 *Adjourn*

INSTITUTE OF MEDICINE

**Collaboration Between Government and Industry: Challenges and Opportunities
for Drug and Vaccine Development**

Roundtable for the Development of Drugs
and Vaccines Against AIDS
May 6, 1994

WORKSHOP

INVITEES

Moises Agosto, *Treatment Research Advocate, Department of Public Policy, National
Minority AIDS Council*

Paul Blake, *Vice President and Medical Director, Clinical Research, Development &
Medical Affairs North America, SmithKline Beecham*

Dani Bolognesi, *James B. Duke Professor and Director, Center for AIDS Research,
Duke University Medical Center*

Samuel Broder, *Director, National Cancer Institute, National Institutes of Health*

Stephen K. Carter, *Senior Vice President, World Wide Clinical Research & Development,
Bristol-Myers Squibb Pharmaceutical Research Institute*

Ben Cheng, *Information Advocacy Associate, Project Inform*

Ellen C. Cooper, *Director of Clinical Research, Community-Based Clinical Trials Program,
American Foundation for AIDS Research*

Deborah J. Cotton, *Assistant Professor of Medicine, Harvard Medical School*

Cornelia Dekker, *Vice President, Clinical Research, Biocine Clinical Research,
Chiron Corporation*

Joseph A. DiMasi, *Senior Research Fellow, Center for the Study of Drug Development,
Tufts University*

Mindy Thompson Fullilove, *Associate Professor of Clinical Psychiatry and Public Health,
Columbia University*

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

Daniel Hoth, *Senior Vice President and Chief Medical Officer, Cell Genesys*

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

Margaret Johnston, *Acting Deputy Director, Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health*

David Kessler, *Commissioner, Food and Drug Administration*

Jack Killen, *Acting Director, Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health*

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

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

Ira Magaziner, *Senior Advisor to the President for Policy Development, The White House*

Thomas Mays, *Director, Office of Technology Development, National Cancer Institute, National Institutes of Health*

Teresa McGovern, *Legal Director, HIV Law Project, AIDS Service Center, Lower Manhattan*

Richard A. Merrill, *Daniel Caplin Professor of Law, University of Virginia School of Law*

Harry M. Meyer, Jr., *President (retired), Medical Research Division, American Cyanamid Company*

Charles Nelson, *Assistant Treatment Research Advocate, National Minority AIDS Council*

John F. Niblack, *President, Pfizer Research, Pfizer Inc.*

William E. Paul, *Director, Office of AIDS Research, National Institutes of Health*

John P. Phair, *Chief, Division of Infectious Diseases and Director, Comprehensive AIDS Center, Northwestern University Medical School*

Michael Saag, *Associate Professor of Medicine, University of Alabama at Birmingham*

David Schulke, *Chief Health Policy Advisor, The Honorable Ron Wyden, United States House of Representatives*

William B. Schultz, *Counsel, House Subcommittee on Health and the Environment,
United States House of Representatives*

Edward Scolnick, *President, Merck Sharp & Dohme Research Laboratories*

John D. Siegfried, *Associate Vice President and Senior Director, Pharmaceutical
Manufacturers Association*

Mervyn Silverman, *President, American Foundation for AIDS Research*

Whaijen Soo, *Assistant Vice President and Senior Director, Clinical Virology and AIDS
Research, Hoffmann-La Roche, Inc.*

Peter Staley, *Founding Director, Treatment Action Group, New York*

Harold Varmus, *Director, National Institutes of Health*

John Vernon, *Professor of Economics, Department of Economics, Duke University*

Timothy Westmoreland, *Counsel, House Subcommittee on Health and the Environment,
United States House of Representatives*

Randy F. Wykoff, *Associate Commissioner for AIDS and Special Health Issues, Food and
Drug Administration*

INSTITUTE OF MEDICINE

**Collaboration Between Government and Industry: Challenges and Opportunities
for Drug and Vaccine Development**

Roundtable for the Development of Drugs
and Vaccines Against AIDS
May 5, 1994

DINNER

INVITED GUESTS

Moises Agosto, *Treatment Research Advocate, Department of Public Policy, National
Minority AIDS Council*

Stephen K. Carter, *Senior Vice President, World Wide Clinical Research & Development,
Bristol-Myers Squibb Pharmaceutical Research Institute*

Ben Cheng, *Information Advocacy Associate, Project Inform*

Deborah J. Cotton, *Assistant Professor of Medicine, Harvard Medical School*

Mindy Thompson Fullilove, *Associate Professor of Clinical Psychiatry and Public Health,
Columbia University*

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Drug Administration*

INSTITUTE OF MEDICINE

Roundtable for the Development of Drugs
and Vaccines Against AIDS

**Collaboration Between Government and Industry: Challenges and Opportunities
for HIV Drug and Vaccine Development**

May 6, 1994

TO: Jennifer Holliday, AIDS Activities
FAX (202) 334-2939

FROM: _____

_____ I **will** be able to attend dinner on Thursday,
May 5, 1994.

_____ I **will not** be able to attend dinner on Thursday,
May 5, 1994.

_____ Please reserve a room for me at the
Wyndham Bristol Hotel for the night
of Thursday, May 5, 1994.

Wyndham Bristol Hotel
2430 Pennsylvania Avenue, N.W.
Washington, DC 20037
Tel: (202) 872-1680 or
1-800-372-8321

_____ I **will not** need a hotel room.

(All rooms are guaranteed for late arrival, so you may check-in after dinner on Thursday night.)