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Future Directions in AIDS Research November 21-23, 1993

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HARVARD AIDS INSTITUTE

Chairman
M. Essex, DVM, PhD

Executive Director
Richard Marlink, MD

8
Story
Street
Cambridge
Massachusetts
02138

617 495-0478
FAX: 617 495-2863

Be sure I have this in my Boston meeting file

TO: Kristine Gebble

FAX #: (202)632-1096

FROM: John Mullaney/Ric Marlink

FAX #: (617) 495-2863

DATE: November 5, 1993

MESSAGE:

Please excuse the informal nature of this correspondence

-Ric

IF THIS TRANSMISSION IF NOT FULLY RECEIVED OR IS UNCLEAR, PLEASE CALL (617) 495-0478.

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M. Essex, DVM, PhD

Executive Director
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Street
Cambridge
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FAX: 617 495-2863

November 5, 1993

Dear Kristine,

I am writing to you in anticipation of our teleconference call concerning working group II for the Future Directions for AIDS Research (FDAR). This call has been scheduled and confirmed between 4:00 and 6:00 p.m. on Monday, November 8, 1993. We have encountered a wealth of information - in fact one of the main problems with information concerning AIDS research is that there is a tremendous amount of information out there. Secondly, much of it is in an unanalyzed or unreviewed state. Therefore to gather experience in this field from the experience of others, over the last three weeks, John Mullaney, Usha Thakrar and I have been conducting interviews with colleagues in the area of AIDS research and of information processing in an attempt to shape the direction of the working group. The attached information gives you a broad overview of where we presently stand with the inquiry. I would like to use this material as a basis for discussing the tasks the working group needs to address before the conference convenes on November 21, 1993.

As the material states, there are really two issues to address in this working group. The first is the level and efficacy of communication between the basic sciences and the clinical applications. Our preliminary inquiry among colleagues reveals a general consensus on this matter. Research information exchange from the basic sciences to the clinical science application is fairly effective. The clinician principal investigator

the point of synthesis among the various research fields. The flow of communication from clinical application back to the basic science research seems to be an area where communication could be much improved. Many questions emerge from a closer analysis of this dynamic and that is presented in diagram I. It is our hope that you will comment and edit freely on these diagrams to fine tune our preliminary analysis.

With regard to the specimen repository and data repository issues, we are continuing our interviews with individuals knowledgeable in this field. There is an immediate need for assembling an inventory of cohorts and the availability of repositories nationally and internationally. The issue of access to these repositories is a spepartate one. This issue will be one that raises serious questions since specimens from some repositories are more easily accessible than others.

Thus far the cooperation of our colleagues in this exercise has been excellent. It has been a pleasure to work with such an enthusiastic group. I think it bodes well for our November conference.

I look forward to speaking with you on Monday.

Sincerely

Richard Marlink, M.D.

WHERE WE ARE PRESENTLY

Mission 1. (A)

Discovering barriers is achieved by describing the present "state" of AIDS research. The models that follow are the result of discussions with several investigators in AIDS research. We provide you these models with questions we are presently asking the working group to address. These models are presented in diagrams I, II and III. Our questions are included in the model itself, and we invite you to edit them as you think appropriate.

Mission 1. (B)

There are several models for mechanisms that can be proposed to overcome the barriers. For the purposes of this telephone conversation, we present three models for discussion: (a) the SPIRATS models from the NIAID, (Diagram IV) and (b) a model for a possible electronic system of information sorting and access that could be utilized in context of a comprehensive system of collaborative or cross-disciplinary research, (Diagram V) ; and (c) A third model for discussion is an idea gleaned from the Strategies for Managing Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command, from the Institute of Medicine in 1993. This report (pp. 24-36) provides recomendations for government allocations for innovations in research. We find that each of these models point to issues of policy around where the locus of such mechanisms. Should the government manage such information or should this task be assigned or contracted to a private entity.

Mission 2.

The inventories of specimen repositories is early at this point; however some key questions we need to ask are included in the graphic presentations.

1. There appear to be repositories that are accessible to other research scientists from the community. Others are less accessible. Diagram VI represents the existing process of input and distribution of specimens from the NIH repository.

2. The divisions for the cohorts are divided by categories: Men, Women, Children, Drug Users, Hemophiliacs, Transfusion recipients as well as a series of international cohorts. Within each of the categories there are many subdivisions. Any individual PI knowledge of what other cohorts exist, is limited to his or her area of research. There is limited formal communication between PI's of cohorts from the different areas.

3. There are examples of smaller cohort studies with specimen repositories that are piggy-backing with larger existing cohorts such as MACS. In some cases biological data is now being enhanced with behavioral data and public health date.

4. There is no comprehensive list of that includes all existing cohorts with repositories.

Working Group II
Outline for Discussion

(This outline is a list of questions that guided our preliminary discussions with colleagues. The results of the discussions have been translated into diagrams for the purposes of discussion.)

In the effort to clarify the many issues underlying the task of working group II we decided first to separate the task itself and ask very specific questions about it. We came up with the following break down. In the subsequent chapters, we will provide a profile of how these "questions" were addressed by individuals involved in AIDS Research.

Mission: 1. (A). Identify barriers to effective communication among AIDS researchers?*

Technical? other areas? e.g. "language" barriers among the disciplines? Competing incentives?

Among the various institutions: govt, academic and industry (pharmaceutical)?

NIH and all systems, intramural research pgms - extramural research and non-NIH sponsored research.

Within the various disciplines?

Immunology, Virology,...

Between, the basic AIDS researchers and those conducting clinical applications (Immunopathogenisis?)

Among (or between) various disciplines?

(B) Propose mechanisms for increased communication

Focus -- limiting redundancy

Where are the areas of redundancy. How to define them? Literature search?
Personal interviews?
both?
Who determines what is redundant. How is the issue of redundancy explained and communicated to researchers.

Increasing productivity
What kind of "productivity?"

To what extent to the above "talk" with one another. What is the forum?
Journals, workshops, annual meetings, news-alerts, brochures, computer "dialogue," e.g. INTERNET, e-mail, others?

Mission 2.

Develop proposals for the establishment and maintenance of better specimen repositories, including collections from long-term, non-progressors and survivors.

Task 1.

Do an inventory of existing specimen repositories.

Where are the repositories located?

Is accessibility to specimen different from access to specimen data?

What access to "AIDS Researchers" have to these repositories. Who determines the access? What is the level of access between people at the government level, i.e. within NIH and its subdivisions but also the access accorded to those outside the NIH extramural or intramural research network.

To the latter inquiry, should we not know the level of demand for access to specimens outside the NIH network.

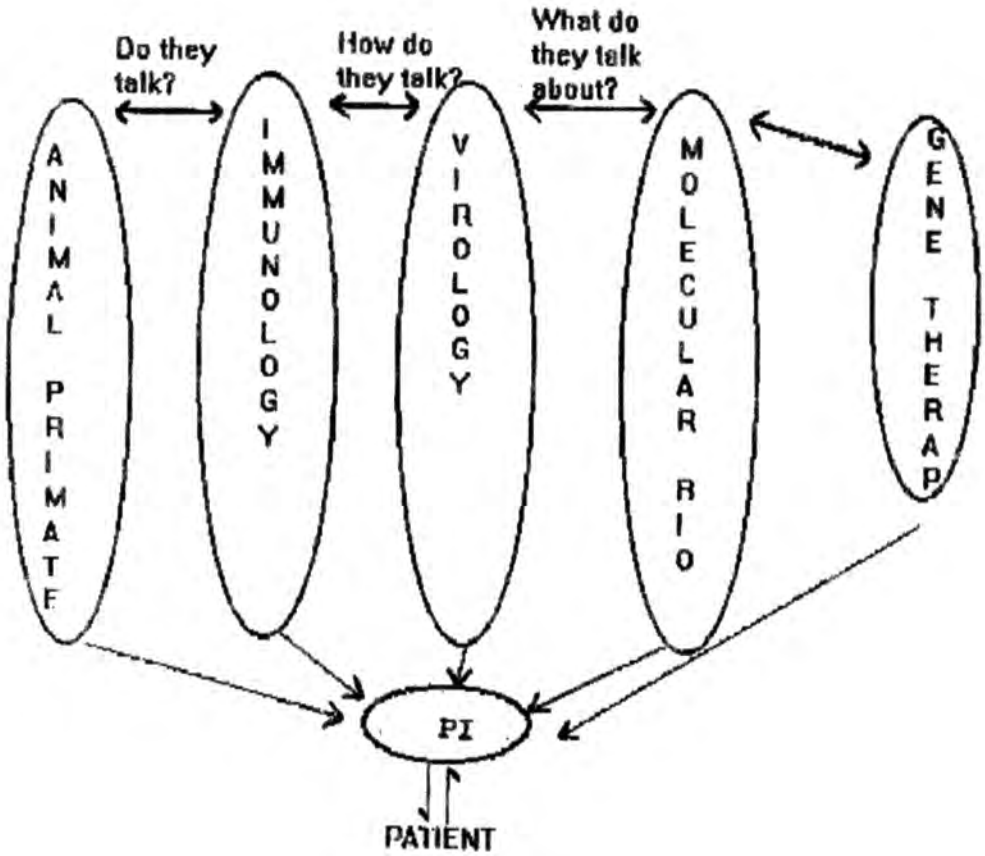
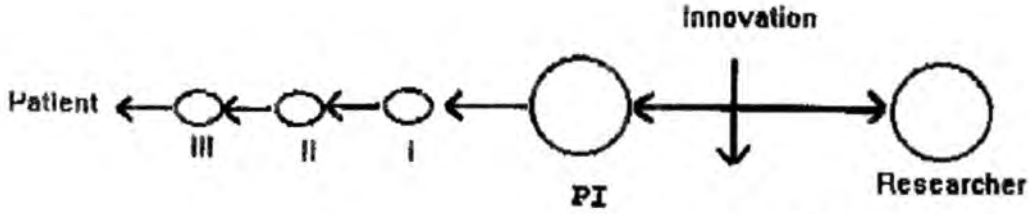

Do they talk?
How do they talk?
What do they talk about?
ANIMAL PRIMATE
IMMUNOLOGY
VIROLOGY
MOLECULAR BIO
GENE THERAP
PI
PATIENT

DIAGRAM I



Workshops

Journals

Informal Network

(Electronic?)

What role if any can advances in technology play in improving this process?

1. Volume of Information
2. Quality of Information
   Raw Preliminary Data -- Peer Review Journal Publication
3. Control
4. Access -- for whom? (Government library, university)
5. Ownership

Is the problem a lack of information or a lack of efficient distribution of this information?

DIAGRAM II

DEVELOPING THERAPEUTIC AGENTS

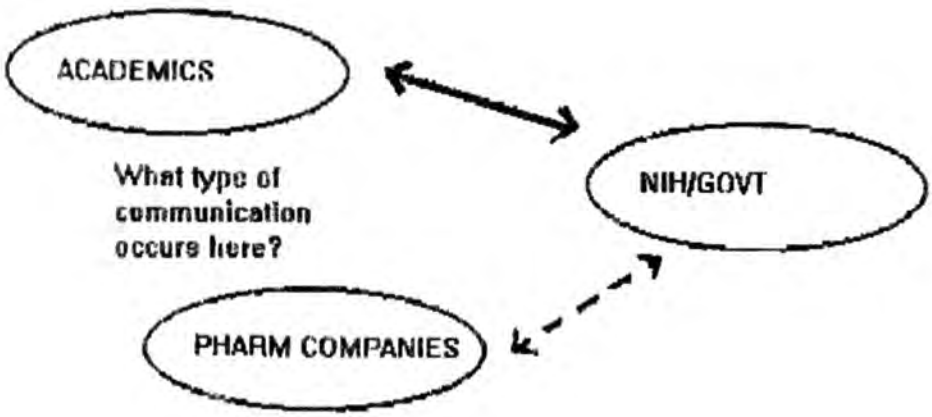


DIAGRAM III

Special Program for Innovative Research on AIDS Treatment Strategies (SPIRATS) model

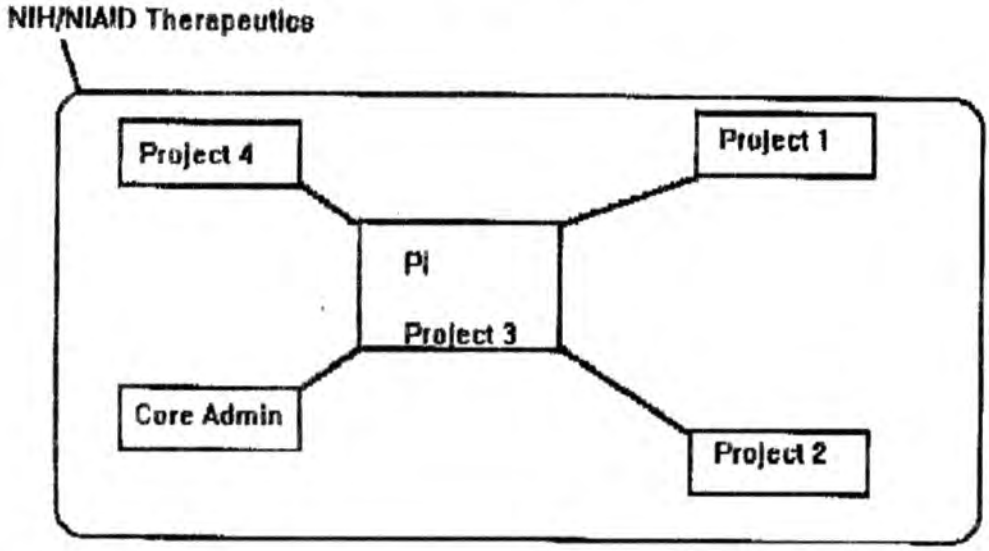


DIAGRAM IV

SPIRATS (cont.)

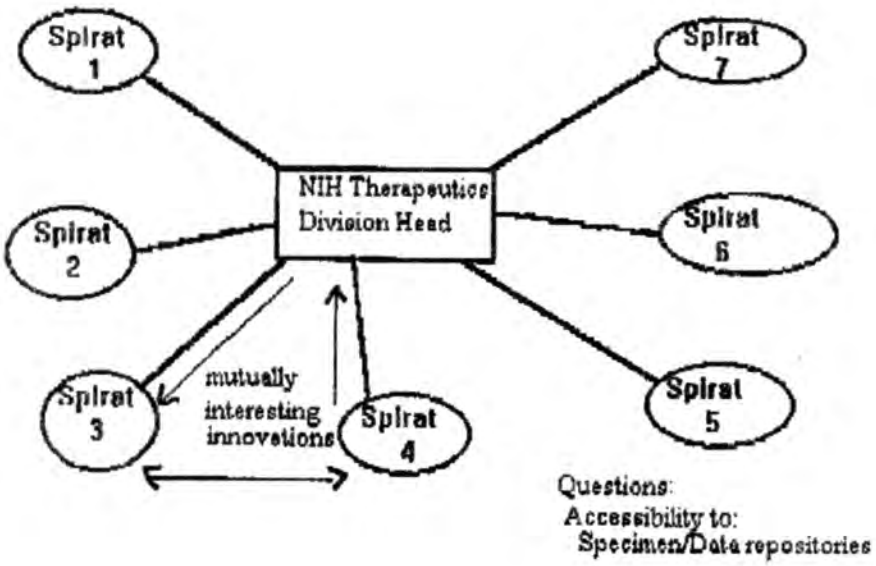


DIAGRAM IVA

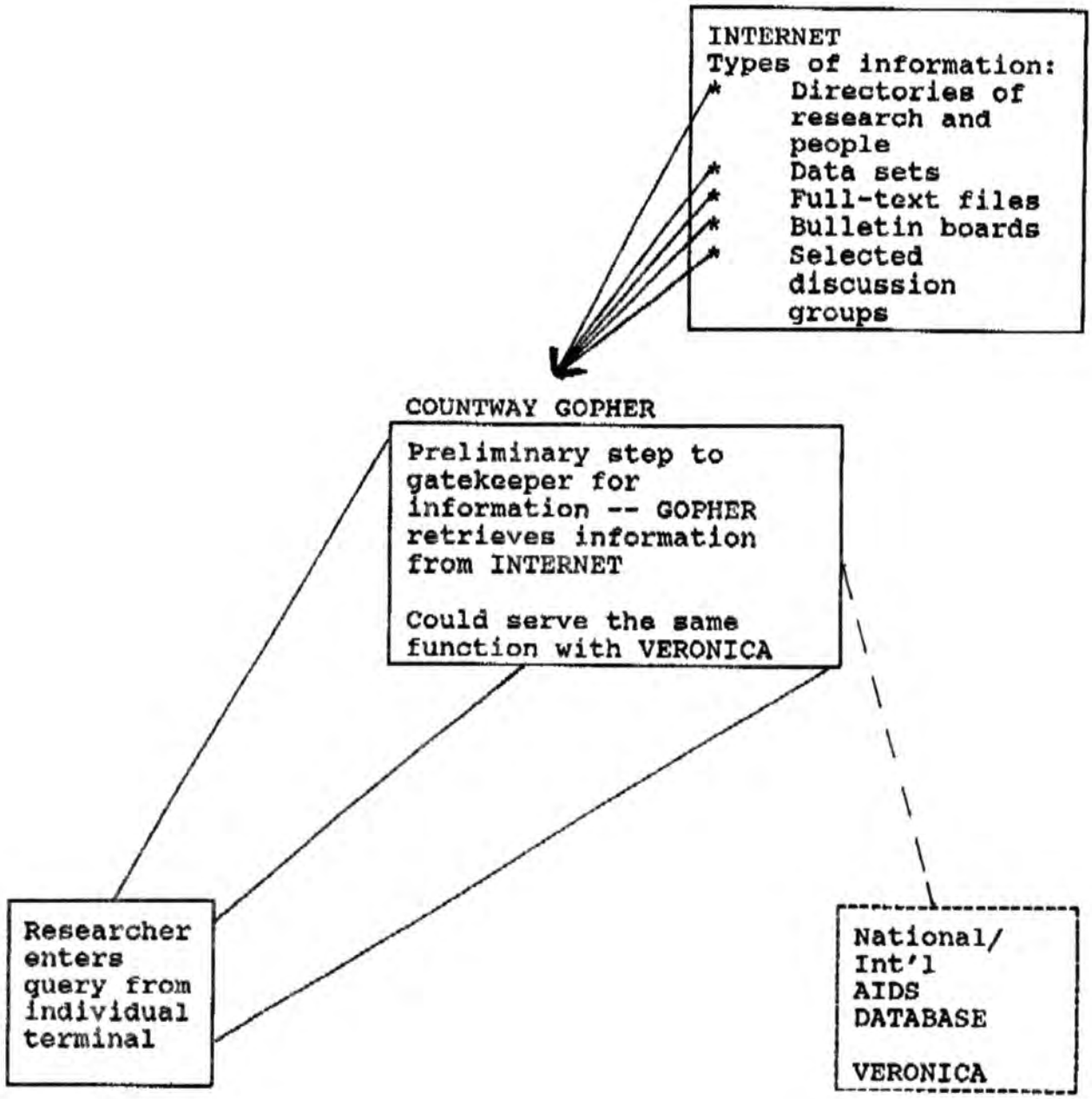
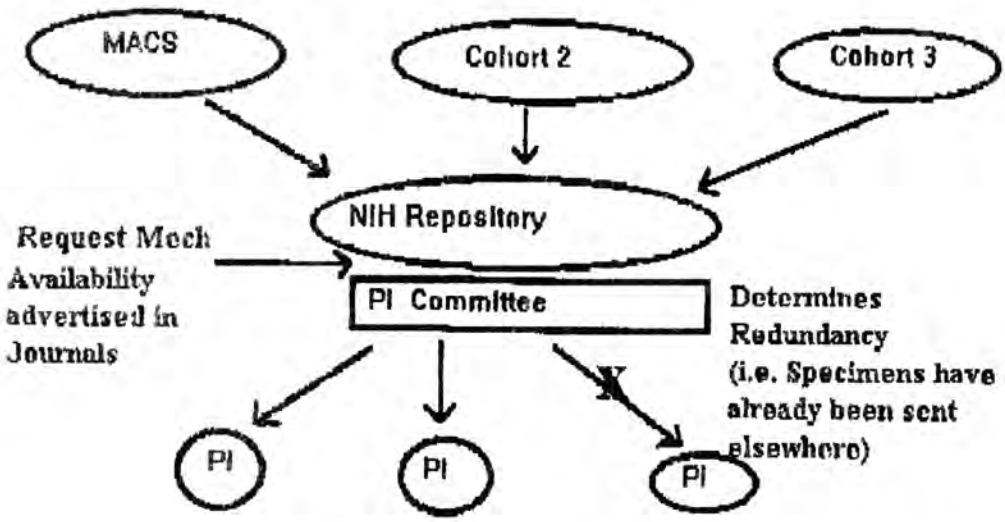

INTERNET
Types of information:
* Directories of research and people
* Data sets
* Full-text files
* Bulletin boards
* Selected discussion groups
COUNTWAY GOPHER
Preliminary step to gatekeeper for information -- GOPHER retrieves information from INTERNET
Could serve the same function with VERONICA
Researcher enters query from individual terminal
National/ Int'l AIDS DATABASE
VERONICA

DIAGRAM V

DATA/SPECIMEN REPOSITORIES



Is information on where the specimens went and the results of the studies, available? (INTERNET Library for data?)

Is redundancy the only issue for being turned down?

DIAGRAM VI

HARVARD AIDS INSTITUTE

FAX

Date: 11/16/93

To: FDAR Participants

From: Ric Marlink
Harvard AIDS Institute

Number of Pages (including cover sheet): 5

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Baltimore, David
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Barrer, Andrew
Barry, David W.
Beswick, Terry
Bolognesi, Dani
Brown, Jr., Laurence
Chen, Irvin
Coates, Tom
Cooper, Ellen C.
Cusick, Dan
Dee, Lynda
Delaney, Martin
Dunlap, Thomas G.
Essex, Max
Fauci, Anthony
Fleming, Patsy
Freiberg, Brenda R.
Gallo, Robert
Gebbie, Kristine
Gonsalves, Gregg
Haas , Greg
Hilleman, Maurice
Hirsch, Martin
Hodel, Derek
Hoth, Daniel F.
Kessler, David
Killen, John K.
Kramer, Larry
Kuropat, Rosemary
Lagakos , Stephen
Laurence, Jeffrey
Lein, Brenda
Letvin, Norman
Marlink, Richard
McFarlane, Rodger
Milano, Mark
Morin, Steve
Niblack, John F.
Osborn, June E.
Pauza, David
Pavlakis, George
Schooley, Robert
Varmus, Harold
Wong-Staal, Flossie
Wykoff, Randolph F.
Yarchoan, Robert

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fax # (617) 495-2863

Future Directions in AIDS Research

Toward a Cure . . .

November 16, 1993

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We are very much looking forward to greeting you here in Boston as a continuation of our meeting in Madison at the end of July. Although presently the sun is shining, and it is very mild in Boston, we all know New England weather can be quite unpredictable, and one should be prepared for that when traveling here. The conference center at Babson College is quite comfortable and the lodging, meals, and meetings are all within one complex, so possible inclement weather should not effect us too much. There is a recreational center near the Center for Executive Education, where the conference will take place. This recreational center has the usual exercise facilities in addition to an indoor pool and facilities for racquetball, tennis, and ice-skating.

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Ric Marlink Marty Delaney Dave Pauza

Facilitating Organizations:
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C. David Pauza
University of Wisconsin Medical School
505 SMI 1300 University Ave.
Madison, WI 53706
608/262.9147
608/262.9148 Fax

FDAR MEETING AGENDA DRAFT

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6:00-7:30	Dinner
7:30-10:00	Working Groups meet

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9:30-11:00	Working Group I Report and Editing
11:00-11:15	Coffee Break
11:15-12:45	Working Group II Report and Editing

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3:15-3:30	Coffee Break
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Press Conference

Center for Exec. Ed. OneWoodland Hill Drive, Wellesley (617) 239-4000

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ADDITIONAL MATERIALS LIST

Title:	*Sent Out to Partic.*	*To Be Available at Meeting*
The AIDS Research Program of the National Institutes of Health. Report of a Study by a Committee of the Institute of Medicine	X	
AIDS research at the NIH: A Critical Review Part I: Summary. Foreword by Larry Kramer. Report by Gregg Gonsalves and Mark Harrington	X	
NIH Reauthorization Act, P.L. 103-43, Title XVIII		X
Basic Research on HIV Infection: A Report from the Front. Prepared by Gregg Gonsalves, Treatment Action Group		X
HIV/AIDS Research Agenda National Institute of Allergy and Infectious Diseases		X
Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command Institute of Medicine		X
Report on ACTG Communication Structures NIAID Office of Communication		X
Report of the NIH/HIV AIDS Information Services Conference National Library of Medicine and the NIH Office of AIDS Research		X
AmFAR Clinical Briefing Ellen Cooper, Rico Viray		X
The Unified Medical Language System, Metathesaurus National Library of Medicine		X

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From: Ric Marlink
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608/262.9148 Fax

FUTURE DIRECTIONS IN AIDS RESEARCH
NOVEMBER 21-23, 1993
BOSTON, MA
AGENDA

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FROM THE SOUTH via ROUTE 128/95: Take Route 128/95 North to Exit 21 (Route 16 West). On Route 16 West continue approximately 2.5 miles and take a left onto Forest Street. (On the corner of Forest Street and Route 16 is an old movie theater that is converted into stores called PLAYHOUSE SQUARE.) Once on Forest Street continue 1 mile, pass through a 4-way stop sign and Babson College will be on the right. Stay on the main road of the campus until signs direct you to The Center for Executive Education. (Note: The Center is located in the back of the campus.)

FROM THE NORTH via ROUTE 128/95: Take Route 128/95 South to Exit 21 (Route 16 West). On Route 16 West continue approximately 2.5 miles and take a left onto Forest Street. (On the Corner of Forest Street and Route 16 is an old theater that is converted into stores called PLAYHOUSE SQUARE.) Once on Forest Street continue 1 mile, pass through a 4-way stop sign and Babson College will be on the right. Stay on the main road of the campus until signs direct you to The Center for Executive Education. (Note: The Center is located in the back of the campus.)

ADDITIONAL MATERIALS LIST

Title:	*Sent Out to Partic.*	*To Be Available at Meeting*
The AIDS Research Program of the National Institutes of Health. Report of a Study by a Committee of the Institute of Medicine	X	
AIDS research at the NIH: A Critical Review Part I: Summary. Foreword by Larry Kramer. Report by Gregg Gonsalves and Mark Harrington	X	
NIH Reauthorization Act, P.L. 103-43, Title XVIII		X
Basic Research on HIV Infection: A Report from the Front. Prepared by Gregg Gonsalves, Treatment Action Group		X
HIV/AIDS Research Agenda National Institute of Allergy and Infectious Diseases		X
Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command Institute of Medicine		X
Report on ACTG Communication Structures NIAID Office of Communication		X
Report of the NIH/HIV AIDS Information Services Conference National Library of Medicine and the NIH Office of AIDS Research		X
AmFAR Clinical Briefing Lilen Cooper, Rico Viray		X
The Unified Medical Language System, Metathesaurus National Library of Medicine		X

for Boston mtg

M E M O R A N D U M

TO: Kristine Gebbie

FROM: Andrew E. Barrer Andrew

DATE: November 10, 1993 - update 11/15/93

RE: Harvard AIDS Institute Working Group II

Notes on the telephone conference call for Working Group II from November 8, 1993: (summary)

The main issue discussed was how could information that is available to the public through on-line services, conferences, journals, abstracts, etc. be made available to all researchers in a simple straight forward manner?

My suggestions:
There needs to be a user friendly central data bank that can input all the information in a way similar to that of MedLine. Who would take on this responsibility? How do we measure, rather than from word of mouth alone, what researchers feel is the weak link in information accessibility? If we implement a new centralized system, how do we measure its effectiveness? (is this a graduate library science thesis ? research project to fund from somewhere ?)

I brought up the issue about information sharing that may be seen as "proprietary". The NIAID "SPIRATS" model helps address this in a limited manner. On 11/9/93 I met with some Patent Office staff. I am looking into their assumptions that information can be both protected and shared. I will follow up on this with Dr. Marlink. (I was told that this is Working Group I's topic - government/industry cooperation)

The 11/15 follow-up call identified the main focus to be the information loop between basic science research → clinical trials → and back to basic. No specific conclusions were arrived at today. More material will be sent to you prior to the Nov 21 Harvard meeting.

Andrew

file: b:confer.hai

Future Directions in AIDS Research

Toward a Cure . . .

October 1 1993

To Participants in Symposium on Future Directions in AIDS Research:

Thank you for your participation to date and your commitment to the continuation of this critical dialogue. We invite you to attend the concluding session of the meeting which has been scheduled according to your availability from Sunday, November 21, through Tuesday November 23, at the Center for Executive Education located in the Boston area.

Future Directions in AIDS Research, as you know, has actually come to represent a unique process. We view our role in this process primarily as facilitators. We have sought to include both the important institutions and the key individuals representing those institutions in a collaborative "meeting of the minds." In doing so, we hope to create both the will and the needed mechanisms to more rapidly defeat this disease.

We are saddened by the recent death of one of our key participants, Mr. Jesse Dobson, and certainly know the urgency and focus he constantly brought to the fight must be continued

This second meeting will be the most essential part of the entire symposium, in that we will be addressing specific plans or responses to the consensus statements developed in the first meeting, and possible ways to achieve the goals inherent in the statements. It is therefore vital that you join in this second challenging and difficult discussion; your contribution is important to the successful outcome of this process

The meeting will begin on Sunday at 5:00 p.m., and will include dinner and the convening of the four working groups that evening. Sessions will run from 8:30a.m., to 5:00p.m. on Monday and Tuesday

Please return the enclosed fax indicating your attendance confirmation by Friday October 15. Your credit card information is required for the Center's billing purposes. the inclusive daily charge of $209 reflects Harvard's discounted rate and includes single occupancy guest room accommodations, all meals through Tuesdays luncheon, continuous coffee service, conference supplies, and the use of recreational facilities. (If you prefer double occupancy @ $159/person/day, please indicate this on the return fax and note with whom you will be sharing the room.) Symposium organizers are seeking funding to defray some of the cost but cannot guarantee anything yet.

The Center for Executive Education is located at Babson College, one Woodland Hill Drive, Wellesley MA. (phone 617/239-4000). Taxi drivers at Logan Airport in Boston should be directed to "Babson College in Wellesley"(fare approx. $30). Once you arrive on campus, the driver can follow the signs to reach the Center. Check-in time is anytime after 2:00p.m. on Sunday. We will make arrangements for a complimentary bus to go from the Center to Logan Airport on Tuesday. Given Boston's traffic we recommend that you make your return plane reservations for no earlier than 7:00 p.m. Tuesday evening if you plan to take the bus.

Facilitating Organizations:
Harvard AIDS Institute
8 Story Street
Cambridge MA 02138
617/495.0478
617/ 495.2863Fax

Project Inform
1965 Market Street #220
San Francisco, CA 94103
415/553.8151
415/558.0684 Fax

University of Wisconsin Medical School
505 SMI 1300 University Ave.
Madison, WI 53706
608/262.9147
608/262.9148 Fax

Future Directions in AIDS Research

Toward a Cure . . .

We are grateful for your efforts to date and look forward to your continued participation in the Future Directions in AIDS Research (FDAR) initiative. Please find attached additional information about the working groups that have been established. An agenda will be sent in advance of the meeting.

Sincerely,

Richard Marlink
Harvard AIDS Institute
Ph: 617/495-0478
Fax: 617/495-2863

C. David Pauza
University of Wisconsin
Ph: 608/262-9147
Fax: 608/2629148

Martin Delaney
Project Inform
Ph: 415/558-8669
Fax: 415/558-0684

RM:dc
enclosures
Appendices A,B,andC

Appendix A:
FUTURE DIRECTIONS IN AIDS RESEARCH

Participant list for July 30-31 meeting

Scientific Participants

Dr. Art Amman; Ariel Project for Prevention of HIV Transmission; Novato, CA
Dr. Dani Bolognesi; Duke University Medical Center, Durham, NC
Dr. Sam Broder; National Cancer Institute, National Institutes of Health, Bethesda, MD
Dr. Irvin Chen; UCLA School of Medicine
Dr. Tom Coates, Center for AIDS Prevention Studies, University of California San Francisco, CA
Dr. Max Essex; Harvard AIDS Institute and Harvard School of Public Health, Cambridge, MA
Dr. Anthony Fauci; National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD
Dr. Robert Gallo; National Cancer Institute, National Institutes of Health, Bethesda, MD
Dr. William Haseltine; Human Genome Sciences, Inc., Rockville, MD
Dr. Maurice Hilleman; Merck Institute for Therapeutic Research, West Point, PA
Dr. Norman Letvin; Harvard Universtiy and the New England Regional Primate Research Center, Southborough, MA
Dr. Richard Marlink; Harvard AIDS Institute and Harvard School of Public Health, Cambridge, MA
Dr. Gary Nabel; Howard Hughes Medical Institute, University of Michigan, Ann Arbor
Dr. John Niblack; Intercompany Collaboration for AIDS Drug Development and Pfizer, Inc., Groton, CT
Dr. June Osborn; School of Public Health, University of Michigan, Ann Arbor, MI
Dr. William Paul; National Institutes of Health, Bethesda, MD
Dr. David Pauza; University of Wisconsin Medical School and Wisconsin Regional Primate Research Center, Madison, WI
Dr. George Pavlakis; National Cancer Institute, Frederick Cancer Research and Development Center, Frederick, MD
Dr. Robert Schooley; University of Colorado Health Sciences Center, Denver, CO
Dr. Flossie Wong-Staal; University of California, San Diego, La Jolla, CA

Community and Political Representatives

Dr. David Kessler; Food and Drug Administration, Washington, DC
Mr. Steve Morin, House Committee on Appropriations, Washington, DC
Ms. Kristine Gebbie, National AIDS Policy Coordinator, Washington, DC
Mr. Moises Agosta; National Minority AIDS Council, Washington, DC
Mr. Terry Beswick; Human Rights Campaign Fund, Washington, DC
Mr. Dan Cusick; ACT UP Golden Gate, San Francisco, CA
Ms. Linda Dee; AIDS Action, Baltimore, MD

Mr. Martin Delaney; Project Inform, San Francisco, CA
Mr. Jesse Dobson; Project Inform, San Francisco, CA
Mr. Greg Gonzalves; Treatment Action Group, New York, NY
Mr. Greg Haas; Committee of 10,000, Minneapolis, MN
Mr. Mark Harrington; Treatment Action Group, New York, NY
Mr. Derek Hodel; AIDS Action Council, Washington, DC
Mr. Larry Kramer; Playwright and AIDS activist, New York, NY
Mr. Mark Milano; ACT UP New York, NY
Dr. Jeffrey Laurence, AmFar, New York, NY

Administrative Assistants and Recorders

Dr. Maria Salvato
Dr. Miroslav Malkovsky
Dr. Rachel Child-Abbott
Ms. Anne Donnelly
Mr. David Lewis
Ms. Brenda Lein
Mr. Joel Thomas
Ms. Keli Shapiro
Mr. Dan Streblow
Ms. Krista Meyer
Mr. Steve Bartz
Ms. MarianneWallace

Appendix B
FUTURE DIRECTIONS IN AIDS RESEARCH
JULY 30-31, 1993
CONSENSUS STATEMENTS

Premise: We believe that effective treatments will be discovered for this disease. We are committed to the belief that it is possible to develop new therapies within a reasonable time capable of providing long-term survival without clinical disease.

1. Insufficient resources inhibit the pace of both general biomedical research and AIDS-specific research. More resources will shorten the time to develope effective treatments

2. There is an unmet need to identify gaps or discontinuities in programs of research and in the implementation of clinically relevant findings.

3. Targeted special programs should be considered for emerging, gap-filling, or risky innovative research areas. Mechanisms for prioritization are possible and should be utilized.

4. There is a need to improve communication pathways and coordination among investigators. One example is the need to develop high quality repositories for defined clinical samples.

5. The urgent challenge of AIDS highlights the problem of constituting complex drug trials using multiple proprietary compounds from distinct public and private sources. A rational and comprehensive strategy should be implemented to overcome barriers at all levels that mitigate against these novel therapeutic trials. This point addresses the crucial problem of initiating therapeutic studies with multiple, simultaneous agents owned by different entities.

6. There is a need for the further stimulation and support of creative thinking in the AIDS research community. This should include an assessment of different management styles and structures and an emphasis on the training of new investigators.

7. There is need to expand and create AIDS research programs by infusion of money and talent from outside the current NIH structure.

8. The government should work with industry to create a mechanism to attract the pharmaceutical industry to participate in these efforts.

9 The President, his Administration and Congress must take a leadership role in educating the American public and world community on why these initiatives are important and urgent.

No amount of structural review or prosposals for change will work without first defining the mechanism for implementation and then finding the will and courage to carry them out.

Appendix C:
Working Groups formed as a result of the July 1993 FDAR Consensus Statements

Discussions at the FDAR meeting identified several important targets for action. In order for participants in the November meeting to propose concrete recommendations and/or suggest viable future action around these target points it will be essential to bring in-depth information to the table for consideration. In an effort to achieve that end, small working groups are being established to pursue the central questions raised at the last meeting and to present their findings to the larger group in November. The mission of each working group is briefly described below and designated group leaders are noted.

We invite your participation in one of the groups described below. Your expertise in one of the four defined areas will be critical to the work the small groups must accomplish in order to bring substantive information to the larger group in November. You will hear from one of the group leaders shortly with more information about their particular group.

Thank you in advance for your continued commitment to this endeavor.

WORKING GROUP I

Mission: 1. Identify barriers to effective communication between public and private sector laboratories 2. Identify mechanisms to improve government and industry cooperation focusing on development of treatments with clinical benefit (for example, mechanisms for facilitating combination drug trials with agents owned by separate private entities)

Chair: John Niblack

WORKING GROUP II

Mission: 1. Identify communication barriers among AIDS researchers and propose mechanisms for increased communication, focusing on limiting redundancy and increasing productivity. 2. Investigate the establishment and maintenance of better specimen repositories including better communication about specimens and data already in existence.

Chair: Ric Marlink

WORKING GROUP III

Mission: 1. Prioritize key gaps in basic research efforts and propose mechanisms designed to eliminate or breach them. 2. Identify administrative structures and funding sources that will interface primary discovery and clinical evaluation of promising therapies.

Chair: David Pauza

WORKING GROUP IV

Mission: 1. Investigate management structures that can encourage new avenues of scientific discovery, including risky areas of research, focusing on clinical benefit. 2. Define an administrative structure for matching non-governmental funding sources with appropriate target areas. 3. Identify key impediments to recruitment of new investigators and propose alternative mechanisms.

Chair: Martin Delaney

annedata/pubpol/wrkgrp.doc

goes w/ Project Inform FAX on Nov. Mtg

Appendix A:
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Chair: Ric Marlink

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Chair: Martin Delaney

annedata/pubpol/wrkgrp.doc

Project INFORM
1965 Market Street, Suite 220
San Francisco, CA 94103

FAX Transmittal Form

Date: 10/

To: All Participants FDAR Fax Number: _____

From: **Dan Cusick**
Public Policy Department
Fax Number: (415)558-0684
Voice Phone: (415)558-8669

Total Pages: 1

put in rest of material for Boston Mtg

Comments

October 25, 1993

To: Future Directions in AIDS Research Participants,

This is a follow up to the background materials sent to you last week by mail. I failed to include a title page for ether report summary, My apologies to the authors. The two pieces were taken from reports entitled:

The AIDS Research Program of the National Institutes of Health, Report of a Study by a Committee of the Institute of Medicine. National Academy Press, Washington, DC., 1991

Gregg Gonsalves + Mark Harrington. AIDS Research at the NIH: A Critical Review Part I: Summary. Foreword by Larry Kramer. Published by TAG, Treatment Action Group, New York, New York, USA, VIII International Conference on AIDS, Amsterdam, the Netherlands, 20 July 1992

Fax by October 15 to

Dr. Richard Marlink
Harvard AIDS Institute
fax: 617/495-2863

I would like to confirm my participation in the Future Directions in AIDS Research meeting, Wellesley, MA.,November 21-23, 1993.

I agree to be responsible for charges below, which include accommodations for two nights, all meals,(Sunday dinner through Tuesday Lunch), continuous coffee service, conference supplies, and use of recreation facilities.

Please specify single or double occupancy,smoking or non-smoking accommodation:

✓ Single occupancy,2 nights total $418

✓ Non-smoking accommodation

___ Double occupancy,2 nights total $318 / person
With whom will you be sharing a room?

___ Smoking accommodation

_____

Name: Kristine M. Gebbie

Address: 750 17th Street NW #1060
Washington, DC 20503

Phone 202. 632.1090

Fax: 202. 632.1096

Credit Card Information
Please specify credit card and credit card number for billing purposes

American Express #_____ exp date_____

Carte Blanche #_____ exp date_____

Diners Club # 3889 2114 32 6404 exp date 8/95

Discover #_____ exp date_____

Mastercard #_____ exp date_____

Visa #_____ exp date_____

Thank you

Project INFORM
1965 Market Street, Suite 220
San Francisco, CA 94103

FAX Transmittal Form

Date: 11/4/93

To: F.D.A.R. Participants Fax Number:

From:

Anne Donnelly
Public Policy Coordinator
Fax Number: (415)558-0684
Voice Phone: (415)558-8669

Total Pages: 2

Did my registration form get sent?

Comments

(Participant List:)

DEE, I.	WONG-STAAL, F	HILLEMAN, M	
HARRINGTON, M	PAUL, W	COATES, T	GONSALVES, G
HODEL, D	BOLOGNESI, D	NIBLACK, J	GONSALVES, G
GONSALVES, G	ESSEX, M	KESSLER, D	MILANO, M
PAUZA, D	FAUCI, A	GEBBIE, K	
MARLINK, R	GALLO, R	SCHOOLEY, R	
PAVLAKIS, G	HASELTINE, W	CHEN, I	
KRAMER, I.	AGOSTA, M	OSBORNE, J	
HAAS, G	LETVIN, N	BRODER, S	
MARTIN DELANEY	BESWICK, T	AMMAN, A	
MORIN, S DC	LAURENCE, J	NABEL, G	
MORIN, S SF			
CUSICK, D			
GONSALVES, G			

Future Directions in AIDS Research

Toward a Cure . . .

FDAR UPDATE

A periodical newsletter for FDAR participants

First and foremost, if you have not yet registered for the November 21-23 continuation of our meeting, you are late and need to do so ASAP. You should have received an invitation with pertinent details; if not, contact organizers for information.

If you are going directly from the airport to the conference center, staff recommends that you contact the Wellesley Carriage Co. at 1-800-836-0006 for transportation. The charge for a coach is between $43.00 and $45.00 each way and it will hold up to 4 people if they don't have a ton of luggage. The coach can pick people up at their respective terminals at limousine (not taxi) stands. If you choose a taxi, keep in mind that if the driver is not too sure about where he/she is taking you, the ride could cost up to $50.

Great news! FDAR has received a joint grant from Design Industries Foundation for AIDS (DIFFA) and Broadway Cares/Equity Fights AIDS. $125,000 will be granted outright with another $125,000 pledged for matching grants from other donors, on a dollar-for-dollar basis. A dispersal mechanism with an expected timeline is in the process of development and the costs of the upcoming meeting (including participant on-site accommodations) will be covered by grant funds. This generous grant indicates the level of public support for this process, and all participants are encouraged to do what you can to bring in the necessary matching fund donations.

Another benefit of grant funding is that some travel reimbursement will be available for participants who cannot cover their costs. Because we do not want to spend a large part of the grant on travel, we encourage you to fly on Saturday (this saves 50-75%) and book your flight **ASAP**. Thanksgiving week is one of the busiest holidays for travel and flights out of Boston will be hard to book. Our travel agent assures us that anyone should be able to get a round trip ticket to Boston for under $500 if flights are ticketed now. If this is not the case for you, please contact organizers. We do not currently know the date we will have access to reimbursement funds but it will probably not be until after the meeting so save any travel or accommodation receipts you would like to see reimbursed.

The four FDAR working groups are all in process, each working in its own way to accomplish its charge. Martin Delaney's Group IV has had a conference call and a meeting of a focus subgroup. John Niblack's Group I has been collecting individual input in preparation for an upcoming conference call. Dave Pauza's group (III) is communicating via the mail, while Group II (Ric Marlink) has been working individually with Ric. . Reports on the progress of each working group will be given at the Boston meeting.

You should have received a description of the mission statements of the four working groups. Please review them and give them some thought, as these issues will make up part of the agenda of the upcoming meeting. If you do not have the mission statements, or if you have questions or comments, feel free to contact either group leaders or organizers.

Facilitating Organizations:
Richard Marlink
Harvard AIDS Institute
8 Story Street
Cambridge MA 02138
617/495.0478
617/495.2863Fax

Martin Delaney
Project Inform
1965 Market Street #220
San Francisco, CA 94103
415/550.8151
415/558.0684 Fax

C. David Pauza
University of Wisconsin Medical School
505 SMI 1300 University Ave.
Madison, WI 53706
608/262.9147
608/262.9148 Fax

Ethics / Report Disclosure

THE WHITE HOUSE

WASHINGTON

NOV 12 1993

Steve / Art / John
fyi - to help me
stay alert —

November 12, 1993

MEMORANDUM FOR KRISTINE GEBBIE
NATIONAL AIDS POLICY COORDINATOR

FROM: KATHLEEN M. WHALEN KMW
SPECIAL COUNSEL TO THE PRESIDENT

SUBJECT: Special Instructions Regarding Potential Conflicts of Interest

In your SF-278 (financial disclosure form) submitted to the Office of the Counsel to the President, you noted several organizations with which you were affiliated in the last year--Washington State Department of Health, Kansas Health Foundation, Seattle University, and American Public Health Association. If any of these organizations is a party to, or represents a party to, a matter in which you are involved, you have a responsibility to evaluate your impartiality.

Specifically, under 5 CFR § 2635.502, for a period of one year after that relationship is terminated, before participating in any particular matter involving parties with whom you had a prior relationship as employee, consultant, trustee, director, etc., you should consider whether a reasonable person, having knowledge of all the relevant facts, would question your impartiality. If you decide that your impartiality would be questioned, you should not participate in the matter unless you have received authorization from the Counsel's Office.

In addition, you should be aware of a criminal statute that prohibits you from participating in any matter in which you have a financial interest. 18 U.S.C. § 208. This includes the financial interests of a spouse and any dependent children.

Without knowing all of the specific issues with which you might be involved, it is difficult to warn you about any particular types of conflicts that could arise. This is just to provide you with general guidance. Please feel free to call this office (x. 6229) if you have any questions, whether of a general nature or regarding specific circumstances.

cc: Beth Nolan, Associate Counsel to the President

National Community AIDS Partnership

RECEIVED

NOV 19 1993

MEMORANDUM

DATE: November 16, 1993

TO: Steve Lee
AIDS Policy Office

FROM: Luis Martinez

RE: Meeting Confirmation

I am so glad that we were able to coordinate our schedules to make this meeting happen. I want to confirm that on Friday, November 19, 1993 at 12:00 p.m. the following persons will meet with Ms. Gebbie in her office at 750 17th Street, NW, Suite 1060:

Harry Hohn
Chair, National Community AIDS Partnership
Chairman and CEO, New York Life Insurance

John Creedon
Trustee, National Community AIDS Partnership
Director, Board of Directors, MetLife Insurance Company
Past President and CEO, MetLife Insurance Company

Paula Van Ness
Executive Director, National Community AIDS Partnership

I understand that the meeting will be approximately 45 minutes.

cc: Buck Buckingham

1140 Connecticut Avenue, NW
Suite 901
Washington, DC 20036-4001
Tel: (202) 429-2820
Fax: (202) 429-2814

Heart Strings 101
1252 W. Peachtree Street
Suite 554
Atlanta, GA 30309
Tel: (404) 876-4673
Fax: (404) 885-9734

Project INFORM
1965 Market Street, Suite 220
San Francisco, CA 94103

FAX Transmittal Form

Date: 10/2/93

To: FDAR PARTICIPANTS Fax Number: _____

From: **Dan Cusick**
Public Policy Department
Fax Number: (415)558-0684
Voice Phone: (415)558-8669

Total Pages: 9

Retiree — see 1st pg for mtg arrangements — Live to AA, George, Ben Carlos, Buck for comments

Comments

ANY QUESTIONS CAN BE REFERED to
My self ANNE DONNELLY OR DAVID LEWIS
AT. 415/558 8669 THANK YOU
DAN CUSICK

Steve—
Jeb need
this for
Boston
trip

CDC - fyi — not for public distribution / comment yet — L.

Leon Panetta
Director
Office of Management and Budget
Old Executive Office Building
Washington, DC 20503

Dear Mr. Panetta:

As you are aware, the Acquired Immunodeficiency Syndrome (AIDS) epidemic is a major public health problem facing our country today. There have been over 300,000 cases of AIDS reported in the United States according to the Federal Centers for Disease Control and Prevention. AIDS is now the ninth leading cause of death for all citizens of our country. Moreover, it is estimated that more than 1 million people in the United States are infected with the human immunodeficiency virus (HIV), the virus that causes AIDS. Despite unprecedented efforts on the part of government and industry, there is no cure or vaccine for this disease currently available. It is crucial that the Federal Government maintain an intensive collaborative effort to find a cure and a vaccine as soon as possible and, particularly, to remove any obstacles that may be delaying this effort.

The President has identified AIDS as a major priority area for coordination and collaboration, and has recently named a National AIDS Policy Coordinator. In keeping with the President's commitment as well as that of the Department of Health and Human Services, I am requesting the formation of an expert advisory committee to conduct an in depth review of all aspects of AIDS drug development. This advisory committee, to be known as the National Task Force on AIDS Drug Development, will be a vital collaboration between government, industry, the medical community, academia, and people infected and affected by this epidemic. The goal of the committee will be to assure that any obstacles to the rapid development of drugs for HIV disease and HIV-related conditions are identified and removed.

We believe that this Task Force will bring together a broad cross-section of experts in AIDS and in drug development in a forum that is not currently available. These experts, both as members and consultants of the Task Force, will be able to aggressively identify any new, creative options for the development of therapies to treat HIV-related disease and to identify and remove any obstacles to the rapid development of such therapies. Particular areas of concentration for the Task Force might include government/industry collaboration, streamlining the discovery and early screening of potential therapies, cooperative approaches to early human studies of potential therapies and many related issues. There is no other existing mechanism for this level of cooperative interaction between government, industry, academia, the medical community and individuals who are HIV-infected or affected.

The advisory committee process is the most cost effective means to receive the cross cutting expert advice that is desperately needed. It is anticipated that this Task Force would exist for at least two years, with recommendations delivered to me throughout this time.

I am therefore requesting that you approve the formation of the National Task Force on AIDS Drug Development. Enclosed are copies of the proposed charter and budget for the committee.

Sincerely,

Donna E. Shalala
Secretary
Department of Health and
Human Services

Enclosures

Assistant Secretary for Health

Request to Establish the National Task Force on Acquired Immune Deficiency Syndrome (AIDS) Drug Development --ACTION

The Secretary
Through: US_____
COS_____
ES_____

ISSUE

Request to establish the National Task Force on Acquired Immune Deficiency Syndrome (AIDS) Drug Development. It is requested that this Task Force be established to assist the Administration, in conjunction with the President's National AIDS Policy Coordinator, in determining how best to proceed in developing drugs to treat AIDS. The objective of the Task Force is to ensure continuity, enhance cooperation, eliminate barriers, and establish a national strategy in all aspects of the development of treatments for AIDS and HIV-related diseases.

DISCUSSION

A number of innovative and creative approaches have been developed and implemented in the effort to find effective treatments and preventatives for HIV-related diseases. These have included a broad range of efforts on the parts of the Public Heath Service, private industry, and community advocacy organizations, as well as a number of important reviews of critical aspects of drug development conducted by both governmental and non-governmental bodies. There has not, however, been a systematic over-arching effort to ensure that all aspects of drug development--from initial drug discovery to the use of the product in the clinical setting are rapidly taking place in a creative coordinated manner, free of unnecessary barriers. The Task Force will have the responsibility of ensuring that all aspects of AIDS drug development are effectively coordinated, that all appropriate avenues of research are pursued, and that all unnecessary barriers to the development of new molecules, new compounds, and new combinations to treat HIV infection and HIV-related

diseases. These critical objectives can not be handled by any currently existing advisory committee within HHS.

RECOMMENDATION

I recommend that the Secretary approve the establishment of the National Task Force on Acquired Immune Deficiency Syndrome (AIDS) Drug Development by signing the charter attached at Tab A and the formal determination attached at Tab B.

Philip R. Lee, M.D.

Tab A: Charter
Tab B: Formal Determination
Tab C: Proposed Plan for Balance
Tab D: Financial Operating Plan
Tab E: Legislative Authority

C H A R T E R

National Task Force on Acquired Immune Deficiency Syndrome (AIDS) Drug Development

Purpose

The Secretary of the Department of Health and Human Services is charged with the administration of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. The National Task Force on AIDS Drug Development will advise the Secretary and, as needed, other parts of the Administration, on how best to proceed in developing drugs to treat AIDS, a major public health problem in the United States today. The Task Force will assist the Administration, including the agencies of the Public Health Service, other agencies within the Department of Health and Human Services, the Department of Defense, and other Departments, as appropriate, in conjunction with the National AIDS Policy Coordinator, in the establishment of a national strategy in all aspects of the development of treatments for human immunodeficiency virus (HIV) infection and HIV-related diseases. The Task Force will be charged with first identifying any barriers that may be preventing the rapid development and evaluation of such treatments, and to then identify steps that can be taken to remove such barriers. Additionally, the Task Force will be charged with identifying creative options to enhance the development and evaluation of useful treatments for treating HIV infection and HIV-related diseases.

Authority

Section 222 of the Public Health Service Act; 42 USC 217a. The Task Force is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. app. 2), which sets forth standards for the formation and use of advisory committees.

Function

The Task Force shall identify any barriers and provide creative options for the rapid development and evaluation of treatments for HIV infection and its sequelae. It shall advise the Secretary, and, as needed, other parts of the Administration, on issues related to such barriers, and provide options for the elimination of such barriers. The Task Force will provide its recommendations through the use of subcommittees, public testimony, and Task Force deliberations.

Structure

The Task Force shall consist of the Assistant Secretary for Health as Chair and a core of 14 members selected by the Secretary from among authorities knowledgeable about AIDS and treatment development issues. Members shall represent the drug development

industry, academic and medical research centers, clinical medicine, government, and HIV-infected and affected communities.

Members shall be invited to serve for overlapping four-year terms except for the first members appointed: four shall serve for a term of two years, five for a term of three years, and five for a term of four years, as designated at the time of appointment.

Terms of more than two years are contingent upon the renewal of the Task Force by appropriate action prior to its expiration. A member may serve after the expiration of his/her term until a successor has taken office.

Subcommittees consisting of two or more committee members may be established, as needed, to address specific and detailed areas of the Task Force mission. The Chair of the Task Force shall make these appointments, as well as appointing a Task Force member to Chair the subcommittees. Consultants may be used to extend the expertise of a given subcommittee with the approval of the Chair of the Task Force. Subcommittees may, in turn, establish temporary working groups, which will consist of highly technically qualified experts, to make recommendations regarding specific technical areas of the subcommittees' interest. All subcommittees will make preliminary recommendations regarding specific issues for subsequent action by the Task Force. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be provided information on its name, membership, function, and estimated frequency of meetings.

Management and support services will be provided by the Office of AIDS and Special Health Issues, Food and Drug Administration, and the Office of AIDS Research, National Institutes of Health.

Meetings

Meetings shall be held approximately four times a year at the call of the Chair with advance approval of a Government official who shall also approve the agenda. A Government official shall be present at all meetings.

Meetings shall be open to the public except as may be determined otherwise by the Secretary or other official to whom the authority has been delegated. Meetings will be closed if, for example, the agenda includes the discussion of confidential/commercial, or trade secret information. Notice of all Task Force meetings shall be given to the public.

Meetings of the Task Force shall be conducted and records of the proceedings kept as required by applicable laws and Departmental regulations.

Compensation

Members who are not full-time Federal employees shall be paid at the rate of $150.00 per day for the time spent at meetings, plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

The estimated annual cost for operating the Task Force and its subcommittees and working groups, including compensation and travel expenses for members, but excluding staff support is $ 122,550. The estimated personyears of staff support is 3.0, at an estimated annual cost of $ 175,104.

Reports

In the event a protion of the meeting is closed to the public, a report shall be prepared not later than November 1 of each year which shall contain as a minimum the function of the Task Force, a list of members and their business addresses, the dates and places of meetings, and a summary of the Task Force's activities and recommendations during the preceding year. A copy of the report shall be provided to the Department Committee Management Officer.

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Termination Date

Unless renewed by appropriation action prior to its expiration, the National Task Force on AIDS Drug Development will terminate two years from the date this charter is approved.

APPROVED:

_____ _____

Date Secretary

FORMAL DETERMINATION

I determine that the formation of the National Task Force on AIDS Drug Development is in the public interest in connection with the duties imposed on the Department by law, and that such duties can best be performed through the advice and counsel of such a group.

I deem that it is not feasible for the Department or any of its existing committees to perform these duties, and that a satisfactory plan for appropriate balance of the Task Force membership has been submitted.

_____ _____

Date Secretary

PROPOSED PLAN FOR APPROPRIATE BALANCE

OF TASK FORCE MEMBERSHIP

The National Task Force on Acquired Immune Deficiency Syndrome (AIDS) Drug Development will consist of the Assistant Secretary for Health as Chair and a core of 14 members selected by the Secretary from among authorities knowledgeable about AIDS and drug development issues. Members shall represent the drug development industry, academic and medical research centers, clinical medicine, government, and the HIV-infected and affected communities.

The Department of Health and Human Services, in conjunction with the National AIDS Policy Coordinator and other appropriate governmental agencies, shall give close attention to equitable geographic distribution and to minority and female representation so long as the effectiveness of the Task Force is not impaired.

Appointments shall be made without discrimination on the basis of age, race, sex, cultural, religious, or socioeconomic status.

~~Sexual~~ / ~~HIV Status~~

include

Sexual orientation /

HIV status

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMITTEES; NATIONAL TASK FORCE ON ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) Therapies DEVELOPMENT; ESTABLISHMENT

AGENCY: THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, PHS

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS), in conjunction with the National AIDS Policy Coordinator, is announcing the establishment by the Secretary HHS of the National Task Force on Acquired Immune Deficiency Syndrome (AIDS) Drug Development. Elsewhere is this issue of the FEDERAL REGISTER, the Department is publishing a notice requesting nominations for membership on this Task Force.

DATES: This rule becomes effective [Insert Date of Publication in the Federal Register]. Authorization for the Task Force being established will end on _____ unless the Secretary HHS formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:
Donna M. Combs,
Committee Management Office (HFA-306),
Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857,
301-443-2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972, Pub. L. 92-463, as amended (5 U.S.C. app. 2), and 21 CFR 14.40(b), the Department, in conjunction with the National AIDS Policy Coordinator, is announcing the establishment by the Secretary HHS (the Secretary) of the National Task Force on AIDS Drug Development.

The Task Force shall advise the Secretary and, as needed, other parts of the Administration, on how best to proceed in developing therapies to treat AIDS, a major pubic health problem in the United States today. The Task Force will assist the Administration, including the agencies of the Public Health Service, other agencies within HHS, the Department of Defense, and other Departments as appropriate, in the establishment of a national strategy in all aspects of the development of treatments for human immunodeficiency virus (HIV) infection and HIV-related diseases. It will be charged with first identifying any barriers that may be preventing the rapid development and evaluation of such treatments, and to then identify steps that can be taken to remove such barriers. Additionally, the Task Force will be charged with identifying creative options to enhance the development and evaluation of useful treatments for treating HIV infection and HIV-related diseases.

Dated:[ ]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

REQUEST FOR NOMINATIONS FOR MEMBERS ON PUBLIC ADVISORY COMMITTEES; NATIONAL TASK FORCE ON ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) DRUG DEVELOPMENT

AGENCY: The Department of Health and Human Services, PHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services, PHS, in conjunction with the National AIDS Policy Coordinator is requesting nominations for 14 members to serve on the National Task Force on Acquired Immune Deficiency Syndrome (AIDS) Drug Development. Elsewhere in this issue of the FEDERAL REGISTER, the Department is publishing a final rule announcing the establishment of this Task Force.

The Department and the National AIDS Policy Coordinator has special interest in ensuring that women, minority groups, and the physically handicapped are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or physically handicapped candidates.

DATES: Nominations should be received on or before [Insert Date 30 days after the publication in the Federal Register].

Addresses: All nominations for membership, except for nominations should be sent to Randolph F. Wykoff (address below)

FOR FURTHER INFORMATION CONTACT:
Regarding all nominations

Randolph F. Wykoff
Office of AIDS and Special Health Issues (HF-12),
Food and Drug Administration
5600 Fishers Lane,
Rockville, MD 20857,
301-443-0104

SUPPLEMENTARY INFORMATION: The Department, in conjunction with the National AIDS Policy Coordinator, is requesting nominations for 14 members to serve on the National Task Force on AIDS Drug Development. The function of the Task Force is to identify any barriers and provide creative options for the rapid development and evaluation of treatments of HIV infection and its sequelae. It shall advise the Secretary, and, as needed, other parts of the Administration, on issues related to such barriers, and provide options for the elimination of such barriers. The Task Force will provide its recommendations through the use of subcommittees, public testimony, and Task Force deliberations.

Persons nominated for membership should be from among authorities knowledgeable about AIDS and treatment development

issues. Members shall represent the drug development industry, academic and medical research centers, clinical medicine, government, and the HIV-infected and affected communities.

Members shall be invited to serve for overlapping four-year terms except for the first members appointed: four shall serve for a term of two years, five for a term of three years, and five for a term of four years, as designated at the time of appointment.

Terms of more than two years are contingent upon the renewal of the Task Force by appropriate action prior to its expiration. A member may serve after the expiration of a member's term until a successor has taken office.

Nominations Procedures

Interested persons may nominate one or more qualified persons for membership on the Task Force. Nominations shall state that the nominee is willing to serve as a member of the Task Force and appears to have no conflict of interest that would preclude Task Force membership. The Department, in conjunction with the National AIDS Policy Coordinator, will ask the potential candidates to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: [ ]