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Series/Staff Member: Kristine Gebbie

Subseries:

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Folder Title:
First Conference on Human Retroviruses December 12, 1993

Stack:	Row:	Section:	Shelf:	Position:
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Kristine -

If no one else does it - you might mention the passing of Jesse Dobson, a member of Scientific Committee, of AIDS. Jesse was a committed and demanding advocate for research on immune restoration of people with advanced HIV disease. He battled for better communication among all of you. We will miss him as we continue. →

continue the fight.

(As you know, he was a principle organizer of "Future Directions" and many other "think tanks", etc.)

Terry

ps. Will you be on e-mail at all next week? Have a good trip!

Research Policy and Process: the Impact of AIDS

I. Introduction

A. Congratulation on the conference

B. "disclaimer" on technicality of talk

C. "informed consent" on attempt to be clear

Relationship of science & policy / level of policy

II. The role of mythology

A. Shapes our expectations and our concerns

B. Affects our ability to hear one another

C. We are more sensitive to the flaws in the myths of others than our own

1. Government bureaucracy
2. Academia + perfects in search of truth — grubbers for grants, publ., tenure
3. Pharmaceutical industry + $$, brains — profiteers
4. Advocates and activists + light & energy — fads & fancies

III. Research Policy

A. That the Federal government will fund

1. $ in NIH
2. $ elsewhere
   a. other PHS agencies
   b. other agencies (Defense, Energy)

B. That we can/will find answers to reasonable human questions

1. epidemiology of the disease

2.causal agent and pathophysiology

3.natural history

4.treatments and cures

5.prevention

IV.Research Process

A.Respect for the scientific process

1.As it has revolved in bench sciences

2.as it has been applied to medical treatment

3.with difficulty in the social sciences

B.Respect for "peer review"

C.Respect for "academic freedom"

D.relationship to pharmaceutical industry

V.The Impact of HIV and AIDS

A.funding

1.increases

2.distortions (HIV in CDC budget)

B.process

OAR / director

1.the role of the advocacy community

2.the process of regulation and review

3.the blurring of the lines

a.Drug Development Task Force as example

C.Changes that have yet to happen

~~1.relationship to industry~~

2."Manhattan project"

One project ?

One boss ?

One laboratory ?

find out what we need to know

The First National Conference on Human Retroviruses and Related Infections

cosponsored by the National Foundation for Infectious Diseases and the American Society for Microbiology in collaboration with NIH and CDC

December 12-16, 1993, Washington, D.C.

December 2, 1993

Kristine Gebbie, R.N.
National AIDS Policy Coordinator
Executive Office of the President
750 17th Street, N.W., Suite 1060
Washington, D.C. 20500

Dear Ms. Gebbie:

On behalf of the Scientific Program Committee, I am most appreciative that you have agreed to be a keynote speaker at the Opening Session of the First National Conference on Human Retroviruses and Related Infections. I am writing to let you know that Robin Weiss of the Chester Beatty Laboratories will also speak at the Opening Session, and his presentation will follow yours. His talk will address the unanswered questions in HIV pathogenesis. The Opening Session will convene at 7 pm on Sunday, December 12 in the Sheraton Washington Ballroom at the Sheraton Washington Hotel located at 2660 Woodley Road, NW. You should plan on speaking for 30 to 45 minutes.

Please feel free to contact Ms. Melissa Sordyl at the ASM Headquarters should you have any questions. We look forward to seeing you on December 12.

Sincerely,

Robert Schooley

Robert Schooley
Chair, Scientific Program Committee

cc: Melissa Sordyl, Director of Meetings, ASM

American Society for Microbiology
Meetings Department
Attn: Melissa Sordyl
1325 Massachusetts Ave., NW
Washington, DC 20005-4171

202/737-3600

Fax 202/942-9340

Meetings Direct Line
202/942-9248

The First National Conference on Human Retroviruses and Related Infections

cosponsored by
the National Foundation for Infectious Diseases and the American Society for Microbiology

in collaboration with NIH and CDC

December 12-16, 1993
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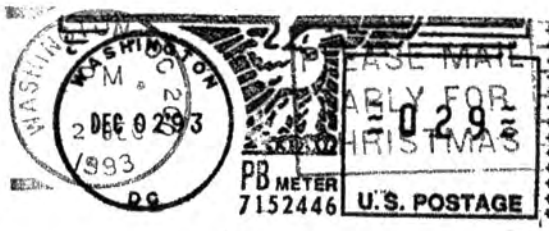
American Society for Microbiology
Meetings Department
1325 Massachusetts Ave, NW
Washington, DC 20005-4171



Kristine Gebbie, R.N.
National AIDS Policy Coordinator
Executive Office of the President
750 17th Street, N.W., Suite 1060
Washington, D.C. 20500

DEC 13 1993

Office of the National AIDS Policy Coordinator

Executive Office of the President
750 17th Street, N.W. Suite 1060
Washington, D.C. 20500

Phone: (202)632-1090
Fax: (202)632-1096

Deliver To: ASM

Sent From:

X Kristine Gebbie, RN, MN, National AIDS Policy Coordinator

Number of Pages: 1 + Cover Fax Number: (202)942-9340 Date: 12-13

Message:

Steve — I faxed this this morning / KG has seen it & I lost to Jerry last night!

AUDIOTAPE WAIVER
1ST NATIONAL CONFERENCE ON HUMAN RETROVIRUSES AND RELATED INFECTIONS

I, Kristine Gebbie

X will

____ will not

grant permission to the American Society for Microbiology (ASM) to record and distribute my presentation at the 1st National Conference on Human Retroviruses and Related Infections in Washington, DC, December 12-16, 1993. *(Please note: if one individual in a session does not return or will not sign an audiotape waiver, the entire session will not be recorded.)*

I understand that presentations given by federal employees are governed by the U.S. Copyright Act of "United States Government Work". In these cases, ASM may NOT hold sole copyright for any recordings. Nevertheless, I am being asked to sign the waiver form indicating my personal willingness to have my presentation recorded and distributed.

Speaker Name: Kristine M. Gebbie
Session Title: Opening Session
Session Date: December 12, 1993
Session Time: 7:00 p.m.
Session Room: Sheraton Washington Ballroom

Signature

12/12/93
Date

KRISTINE GEBBIE
Printed Name

Return by **December 6, 1993** to:

Meetings Department - WAIVER
ASM
1325 Massachusetts Avenue, NW
Washington, DC 20005

Fax: (202) 942-9340

NATIONAL AIDS POLICY OFFICE
OFFICE OF THE COORDINATOR

ROUTING SLIP

DATE: 11/9

TO: Kristine

FROM: ✓ W. STEVE LEE

____ For your information

✓ For your action they need a title for your talk 11/10.

____ Review and comment by (date) ____

____ Prepare reply for Coordinator's signature

____ Reply directly and blind copy Coordinator

____ **Circulate**/forward to: ____

____ File

COMMENTS:

(note to SL. Betty on 301.6560003)

~~Development~~

~~AIDS Research Policies~~

Research Policy & Process:

the impact of AIDS

NATIONAL FOUNDATION FOR INFECTIOUS DISEASES

RESEARCH • PREVENTION • EDUCATION

NFID 20th YEAR 20 1973-1993

July 15, 1993

For: Dec. 12th

Ms. Kristine M. Gebbie
National AIDS Policy Coordinator
200 Independence Avenue, SW, Room 38-G
Washington, DC 20201

Dear Ms. Gebbie:

This letter is to invite you to be the keynote speaker at the opening ceremony of the First National Conference on Human Retroviruses and Related Infections on Sunday evening, December 12, 1993, at the Sheraton Washington Hotel in Washington, DC. We believe this major meeting may provide you and the administration with an excellent opportunity to announce to the nation its position on AIDS research, and an opportunity to encourage everyone involved in the meeting to increase their efforts to defeat this terrible disease. The audience will contain 2,000 to 3,000 of America's best researchers and would be most receptive to your presence.

The conference is cosponsored by the National Foundation for Infectious Diseases (a public, non-profit organization) and the American Society for Microbiology, in collaboration with the National Institutes of Health and the Centers for Disease Control and Prevention. It was created to provide a forum for scientists and medical researchers primarily in the United States and North America (but worldwide) to present, discuss and critique their latest research into the epidemiology and biology of human retroviruses (especially HIV-1) and the diseases they produce or with which they are associated, e.g. AIDS. The meeting will catalyze free exchange of information and ideas, and spawn new data, collaborative studies and research efforts among the nation's brightest scientists to hasten our understanding of these relatively new agents and their diseases, ultimately to the benefit of all our citizens and mankind.

The meeting will feature "state-of-the-art" lectures that will be highly scientific in nature; special symposia panels comprised of nationally and internationally known scientists to present and debate selected controversial scientific issues; original presentations of new data and science; and "late-breakers" consisting of important developments and preliminary research findings that need to be brought to everyone's attention immediately.

4733 BETHESDA AVENUE • SUITE 750 • BETHESDA, MARYLAND 20814

TELEPHONE: 301/656-0003 • FACSIMILE: 301/907-0878

Many scientists, physicians, and health care and public policy officials from all sectors (government, academia, industry, and practice) of the nation's health care and research system will be participating in and attending the conference. Others who have been invited are infectious disease specialists, clinical researchers, epidemiologists, infection control practitioners, risk management experts, nurses, and clinical pharmacists.

The administration's leadership in health care issues has not been ignored by organizers of this first national conference, and your presence there will signify a willingness to address head–on this important topic.

A copy of the "Call for Abstracts" is enclosed for your information. The First National Conference promises to be an exciting, highly informative and news–making meeting. If you have any questions, please do not hesitate to contact me at (301) 656–0003. I look forward to hearing from you at your earliest possible convenience.

Sincerely yours,

Richard J. Duma, MD, PhD
Executive Director

RJD/bwo 8/3/93 Recommend attendance – a cross-profession, scientific meeting

Enc.

Clinton Presidential Records
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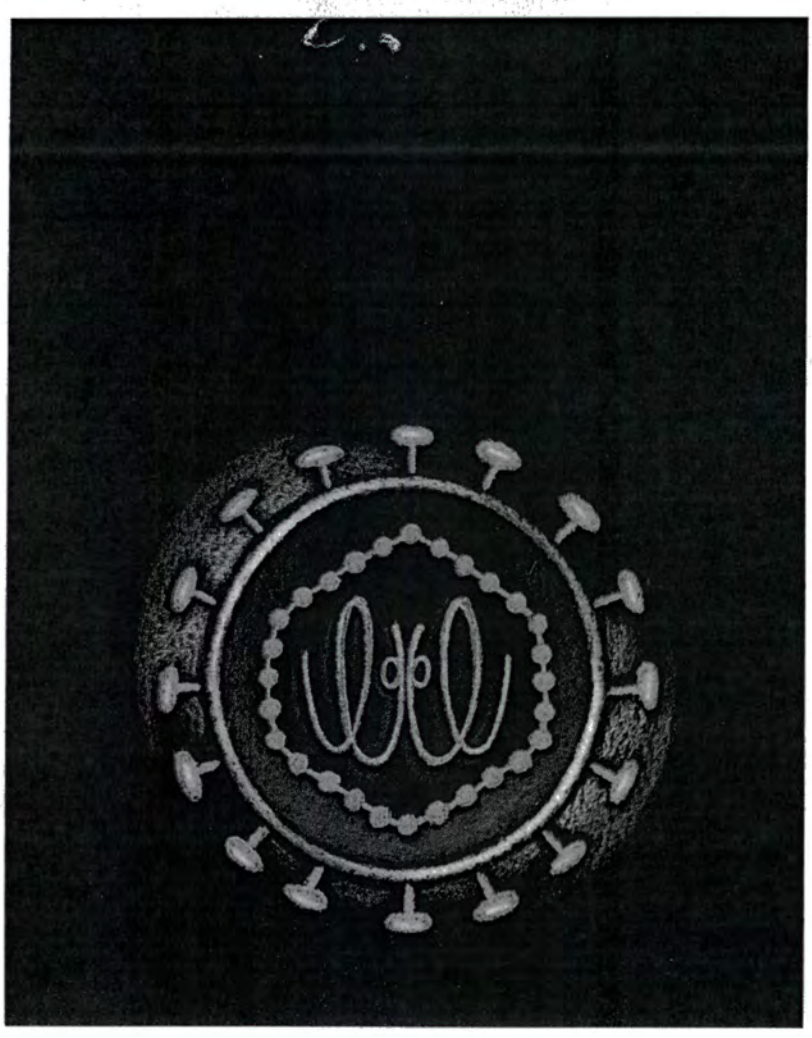

The First National Conference on Human Retroviruses and Related Infections

CALL FOR ABSTRACTS

cosponsored by
the National Foundation for Infectious Diseases
and the American Society for Microbiology
in collaboration with NIH and CDC

December 12-16, 1993
Washington, D.C.

SUPPLEMENT TO THE ASM NEWS

NATIONAL FOUNDATION FOR INFECTIOUS DISEASES
RESEARCH • PREVENTION • EDUCATION
Founded 1973

FACSIMILE TRANSMISSION

NFID Fax # 301-907-0878

TO: Dr. Art Lawrence
Office of National AIDS Policy Coordinator

FROM: Dr. Richard Duma
Executive Director

DATE: 8/5/93

TIME:

FAX #

Number of Pages (including cover sheet) 3

(Call 301-656-0003 if there are problems.)

Attached is list of speakers for the Retrovirus Conference Dec 12-16, as we discussed.

4733 BETHESDA AVENUE • SUITE 750 • BETHESDA, MARYLAND 20814
TELEPHONE: 301/656-0003 • FACSIMILE: 301/907-0878

AS of 8/4/93

First National Conference on Human Retroviruses and Related Infections

ROUND TABLE SYMPOSIA and CHAIRPERSONS

Monday (December 13)	Tuesday (December 14)	Wednesday (December 15)
1. How to Use Antivirals in Clinical Practice Robert T. Schooley Infectious Diseases Division, University of Colorado Health Sciences Center	1. Regulator Genes and Proteins Flossie Wong-Staal AIDS Research, University of California, Los Angeles	1. Clinical Drug Trials-Surrogate Markers and Disease Progression David W. Feigal Division of Antiviral Drug Products U.S. Food and Drug Administation
2. Tuberculosis Michael D. Iseman Division of Infectious Diseases National Jewish Center for Immunology and Respiratory Medicine, Denver	2. Immune-Based Therapy Richard B. Pollard AIDS Clinic, The University of Texas Medical Branch	2. Animal Models for Retroviral Pathogenesis-Lessons Learned Ronald C. Desrosiers Division of Microbiology, New England Regional Primate Research Center, Harvard Medical School
3. Early Detection of HIV Infection in Infants Thomas C. Quinn National Institute of Allergy and Infectious Diseases, National Institutes of Health	3. Potential Interventions of Perinatal Transmission of Human Immunodeficiency Virus Type 1 Lynne M. Mofenson Pediatric, Adolescent and Maternal AIDS Branch, National Institute of Child Health and Human Development, National Institutes of Health	3. Strategies of Vaccine Testing Sten H. Vermund Vaccine Trials and Epidemiology Branch, Clinical Research Program, Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health

4. HIV Infections in Women	4. Molecular Epidemiology of HIV and SIV	4. CD4 Depletion
Constance R. Wofsy AIDS Activities Division, San Francisco General Hospital	Harold W. Jaffe Division of HIV/AIDS, National Center for Infectious Diseases, Centers for Disease Control and Prevention	Anthony S. Fauci National Institute of Allergy and Infectious Diseases, National Institutes of Health
5. Primary HIV Infection	5. Transmission and Prevention of HIV Infection in the Health Care Worker	5. Management of the HIV-Infected Child
David D. Ho Aaron Diamond AIDS Research Center for the City of New York	Julie L. Gerberding Center for Hospital Epidemiology and Infection Prevention, San Francisco General Hospital	Philip A. Pizzo Infectious Disease Section, National Cancer Institute, National Institutes of Health
6. Controversial Topics in Retroviral Resistance	6. Rational Drug Development	6. Long Term HIV-1 Survival
Victoria A. Johnson Infectious Diseases University of Alabama School of Medicine	Joshua S. Boger Vertex Pharmaceuticals Cambridge, Massachusetts	John P. Phair Infection Diseases Section Northwestern University Medical School

[redacted]

update — As of 8/9/93

STATE-OF-THE-ART LECTURES and SPEAKERS

First National Conference on Human Retroviruses and Related Infections

	Monday (December 13)	Tuesday (December 14)	Wednesday (December 15)	Thursd
1.	Human Retroviruses: An Overview	1. Retroviral Assembly	1. Retroviral Protease	1. Process Presen Class 1 (Cytoto
	Robert C. Gallo Laboratory of Tumor Cell Biology, National Cancer Institute, National Institutes of Health	Eric Hunter AIDS Center, University of Alabama at Birmingham	Daniel W. Norbeck Antiviral Discovery, Abbott Laboratories Abbott Park, Illinois	John J. Depart Biochen Univers
2.	STD As a Co-Factor in HIV Infection	2. Neutralizing Epitopes	2. Immunopathogenic Mechanisms of HIV Infection	2. HPV-As in HIV
	King K. Holmes Centers for AIDS and STD University of Washington	Joseph G. Sodroski Dana Farber Cancer Institute, Harvard Medical School	Anthony S. Fauci National Institute of Allergy and Infectious Diseases, National Institutes of Health	Joel Pa Laborat Universi
3.	Antiviral Resistance	3. Update on Combination Therapy	3. Molecular Approaches to HIV Therapy	3. Reverse Structu
	Douglas D. Richman Pathology and Medicine, Veterans Affairs Medical Center University of California, San Diego	Martin S. Hirsch Massachusetts General Hospital Harvard Medical School	Flossie Wong-Staal AIDS Research, University of California, Los Angeles	Dr. Step Departm Molecul Universi

4.	Role of Adjuvants in Retroviral Vaccines Frederick R. Vogel Division of AIDS Vaccine R&D, National Institute of Allergy and Infectious Diseases, National Institutes of Health	4.	Viral Vectors in Vaccines Maurice R. Hilleman Merck Institute for Therapeutic Research West Point, Pennsylvania	4.	Role of Animal Models in Retroviral Vaccines Ronald C. Desrosiers Division of Microbiology, New England Regional Primate Research Center, Harvard Medical School	4.	Novel to HIV Barton Divisic Duke
5.	New Applications of PCR Technology John J. Sninsky Roche Molecular Systems, Inc. Alameda, California	5.	HIV-Associated Lymphoma Lawrence Kaplan AIDS Program/Oncology Division, University of California, San Francisco	5.	HIV Prevention: What Works James Curran HIV/AIDS, Office of the Director, Centers for Disease Control and Prevention	5.	The R in the and T Roy M Depart Imperi Londor
6.	Role of Interleukins in Retroviral Infections William E. Paul Laboratory of Immunology, National Institute of Allergy and Infectious Diseases, National Institutes of Health	6.	Clinical, Epidemiological and Therapeutic Advancements in Management of HTLV-I Infections Thomas A. Waldmann Metabolism Branch, National Cancer Institute, National Institutes of Health	6.	HTLV-1 Transformation Warner C. Greene Gladstone Institute of Virology and Immunology, University of California, San Francisco	6.	Immun Interve Gary J. Howar Ann Ar

ay (December 16)

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-Restricted
dc) T-Cells

Monaco, Jr.
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Jniversity Medical Center

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THE WHITE HOUSE

WASHINGTON

November 10, 1993

MEMORANDUM

TO: David Kessler, Commissioner
Food and Drug Administration

FROM: Kristine M. Gebbie W. Steve Lee for
National AIDS Policy Coordinator

SUBJECT: National Foundation for Infectious Diseases speech

I am going to be talking to the First National Conference on Human Retroviruses and Related Infections, sponsored by the National Foundation for Infectious Diseases on December 12, under the title of "Research Policy and Process: The Impact of AIDS."

If you have any ideas or talking points you think pertinent to this discussion, I'd appreciate receiving them by December 5.

Thank you.

THE WHITE HOUSE

WASHINGTON

November 12, 1993

MEMORANDUM

TO: Donald S. Burke, M.D.
Colonel, Medical Corps, U.S. Army
Director Division of Retrovirus

FROM: Kristine M. Gebbie N. Gene Lee for.
National AIDS Policy Coordinator

SUBJECT: National Foundation for Infectious Diseases speech

I am going to be talking to the First National Conference on Human Retroviruses and Related Infections, sponsored by the National Foundation for Infectious Diseases on December 12, under the title of "Research Policy and Process: The Impact of AIDS."

If you have any ideas or talking points you think pertinent to this discussion, I'd appreciate receiving them by December 5.

Thank you.

THE WHITE HOUSE

WASHINGTON

November 10, 1993

MEMORANDUM

TO: Anthony Fauci, Director
National Institute of Allergy and Infectious Diseases

FROM: Kristine M. Gebbie W. Steve Lee for
National AIDS Policy Coordinator

SUBJECT: National Foundation for Infectious Diseases speech

I am going to be talking to the First National Conference on Human Retroviruses and Related Infections, sponsored by the National Foundation for Infectious Diseases on December 12, under the title of "Research Policy and Process: The Impact of AIDS."

If you have any ideas or talking points you think pertinent to this discussion, I'd appreciate receiving them by December 5.

Thank you.

[187] From: Kristine Gebbie 11/19/93 3:56PM (1703 bytes: 20 ln)
To: Steve Lee
Subject: 1st Nat. Retroviris Conf.
---------- Forwarded with Changes ----------
From: Johanne Messore 11/17/93 2:34PM (1296 bytes: 17 ln)
To: Kristine Gebbie
Subject: 1st Nat. Retroviris Conf.
---------- Message Contents ----------

Text item 1:

This is in response to your written request for suggestions for your speech at the First National Retrovirus Conference..since this conference covers retroviruses and related infections, it is much broader than AIDS. I think the speech presents an excellent opportunity for you to acknowledge the contribution of basic research (in this case, basic retrovirology research) to the rapid identification of HIV as the causative agent for AIDS and to make a pitch for the continued support of basic research as a necessary component of the AIDS research agenda. The subject of your speech also lends itself to a discussion of the impact of AIDS on research policy and process through such examples as the role of people living with AIDS and their advocates on the NIH OAR S1 reauthorization, parallel track, and the new AIDS Drug Development Task Force. If you need talking points developed on any of these issues let me know and Alice and I can work on it.

Text item 2:

Steve--if Jo has any critical points on the issues in her memo, a brief paragraph would be helpful--otherwise, just print off her memo and put it in my file--thanks.

FIRST NATIONAL CONFERENCE ON
HUMAN RETROVIRUSES AND RELATED INFECTIONS
TALKING POINTS FOR MS. GEBBIE

- Despite the lack of a curative therapy and a vaccine, it is clear that the scientific community has risen to the challenge of HIV infection. Unprecedented gains in knowledge have come about in a very short time: knowledge of how HIV is transmitted; basic and clinical knowledge of the disease itself; and knowledge that is applicable to other disease areas, such as knowledge of the functioning of the immune system.

- However, much still needs to be done and we must underscore the need to follow the basic principles of scientific investigation. The results of basic research in fields such as virology, immunology, and pathogenesis provide the foundation necessary for the development of vaccines to prevent HIV infection and the development of therapies to help manage the disease and improve the quality of life of infected persons.

- It is important for us to make decisions about accelerating areas of research in the context of a comprehensive research program that is grounded in basic science, is rapidly responsive to scientific developments and changes in the epidemic, and is planned to eliminate information gaps.

- AIDS has impacted on the conduct of science at many levels.

  - The complex nature of HIV disease has created the opportunity and need for increased emphasis on multidisciplinary research, combining research areas such as behavioral research with research on disease progression and clinical trials. While not a focus of this meeting, behavioral research will be related to many of the research areas discussed during the ensuing days.

  - The social and cultural context of HIV infection and AIDS has demanded that we consider them in the conduct of research such as clinical trials. Also in this regard, we must continue to work to close the gaps between research and health care delivery by linking clinical research with delivery programs.

  - We have learned to work with AIDS advocates, including them in our planning process and finding that they have many good ideas to offer.

- It is important to ensure that the results from research are translated into clinical practice and are made available to HIV-infected people and their advocates. We must continue to explore ways to innovatively and effectively disseminate research information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

DEC 0 6 1993

TO: National AIDS Policy Coordinator

FROM: Director, Office of AIDS Research

SUBJECT: Talking Points: First National Conference on Human Retroviruses and Related Infections

Attached are talking points that you may wish to consider as you prepare remarks for your presentation on "Research Policy and Process: The Impact of AIDS" at the subject conference.

We hope these talking points are helpful. Best personal regards.

Anthony S. Fauci, M.D.

Attachment

FOOD AND DRUG ADMINISTRATION

Office of the Commissioner
Office of Executive Secretariat
5600 Fishers Lane, HF-40
Rockville, Maryland 20857

Fax No. (301) 443-1863 Telephone No. (301) 443-3900

RECEIVED
DEC - 3 1993

FACSIMILE TRANSMISSION RECORD

NUMBER OF PAGES (not including coversheet) - 8

TO: Kristine Gebbie

Fax No. (202) 632-1096 Telephone No. (202) 632-1090

FROM: Dennis Myers

MESSAGE:

FOOD AND DRUG ADMINISTRATION Office of Executive Secretariat

Memorandum

December 3, 1993

NOTE TO: Kristine M. Gebbie
National AIDS Policy Coordinator

FROM: Dennis Myers, Director
Office of Executive Secretariat

SUBJECT: National Foundation for Infectious Diseases Speech

In response to your November 10, 1993, memorandum to Commissioner David Kessler, FDA's Office of AIDS and Special Health Issues has prepared the enclosed talking points for your consideration in connection with your December 12 speech. Also enclosed for your quick reference is a copy of the November 30 HHS News Release on the National Task Force on AIDS Drug Development.

Please feel free to contact me if you have any questions or require additional assistance.

Dennis Myers
Director

Enclosures

The Food and Drug Administration has implemented a variety of innovations to improve its services to people with AIDS and HIV infection. Generally, these innovations fall into two categories: a) Efforts to provide promising agents to people with life threatening disease who have no satisfactory alternative therapies; and b) Efforts to speed the review and approval process for the most promising agents.

To meet the specific challenges of the HIV epidemic, FDA has implemented a variety of organizational changes, including the creation of the Division of Antiviral Drug Products, the Office of AIDS and Special Health Issues and the Laboratory of Retrovirology. Additionally, several Advisory Committees have been created to provide the Agency with outside advice on important regulatory decisions.

1. Expanded Access Mechanisms

Expanded access mechanisms are designed to make promising products available as early in the drug evaluation process as possible. Expanded access mechanisms include Treatment IND protocols and parallel track protocols. In addition, the ordinary development of drugs under an IND includes a variety of open studies that also provide access to drugs. To date, tens of thousands of people have received products under expanded access mechanisms.

- Treatment INDs

  Final regulations were issued in May of 1987 establishing conditions under which promising new drugs and biologics that have not yet been approved or licensed may be made available to persons with serious or life-threatening illnesses. Treatment INDs have generally been granted when the product is well into the clinical testing phase or when all clinical trials have been completed, after the development of some reliable evidence that the product is effective. Nine Treatment IND protocols for promising AIDS-related products have been allowed to proceed since the Treatment IND regulations became effective.

- Parallel Track

  The final PHS policy statement on the parallel track mechanism was published in the Federal Register on April 15, 1992. The purpose of the parallel track policy is to expand the availability of promising investigational drugs to those persons with AIDS and HIV-related diseases who are without satisfactory alternative therapy and who cannot participate in controlled clinical trials. Stavudine (d4T) was the first drug submitted for consideration under the parallel track policy. The protocol was allowed to proceed on October 5, 1992.

2. Expedited Procedures

- In 1987, FDA created a "AA" priority category to classify all applications for potential AIDS therapies to ensure that these products receive the highest priority in the review process.

- In October, 1988, FDA issued interim regulations designed to expedite marketing approval of new drugs intended for life-threatening and severely-debilitating diseases, by facilitating the clinical testing and evaluation processes. Under the expedited procedures, early consultation with FDA by drug manufacturers, with agreement on the proper design of clinical trials, can lead to phase 2 studies with adequate data to support approval. In some instances, then, the need for Phase 3 testing can be virtually eliminated.

- On December 11, 1992 FDA published the final rule to accelerate the approval of new drugs for serious and life-threatening diseases when the drug provides meaningful therapeutic benefit over existing products. Under these procedures FDA may approve drugs based on surrogate endpoints that reasonably predict that a drug provides clinical benefit. This clinical benefit is then confirmed through additional human studies that will be carried out after marketing approval. The accelerated approval approach provides for removal of the drug from the market if further studies do not confirm the clinical benefit of the therapy.

As of September 30, 1993, FDA had received over 500 IND applications for more than 150 products to be used in the treatment of HIV/AIDS. Many of the ongoing clinical trials are using combinations of two or more agents.

FDA has approved 14 applications for products to treat HIV/AIDS. Three drugs are to treat HIV infection and eleven are to treat HIV/AIDS-related illnesses. There are no antiretroviral new drug applications pending review at FDA.

- **Zidovudine** (formerly AZT) - the first drug to go through the "AA" priority review designation, approved March, 1987 to treat AIDS.

- **Human Interferon alpha**, approved November, 1988 for the treatment of Kaposi's Sarcoma, a cancer affecting many persons with AIDS.

- **Aerosolized pentamidine**, approved June, 1989, for the prevention of Pneumocystis carinii pneumonia in immunocompromised patients.

- **Ganciclovir**, approved June 1989, for the treatment of cytomegalovirus retinitis, a sight-threatening opportunistic infection from AIDS.

- **Fluconazole**, approved January, 1990, for use in the treatment of candidiasis and cryptococcal meningitis which are fungal infections.

- **Erythropoietin**, approved December, 1990, for the treatment of zidovudine-related anemia.

- **Foscarnet**, approved September, 1991, for use in the treatment of cytomegalovirus retinal infections in persons with AIDS.

- **ddI (didanosine)**, approved October 1991, for the treatment of adult and pediatric patients (over 6 months of age) with advanced HIV infection who are intolerant of zidovudine therapy or who have demonstrated significant clinical or immunologic deterioration during zidovudine therapy.

- **ddC (zalcitabine)**, approved June 1992, for use in combination with zidovudine (AZT) as a treatment option for adult patients with advanced HIV infection who show signs of clinical or immunological deterioration.

- **Itraconazole**, approved September 1992, for the treatment of blastomycosis and histoplasmosis in immunocompromised and non-immunocompromised patients.

- **Atovaquone**, approved November 1992, for the treatment of mild to moderate PCP in patients who are intolerant of trimethoprim-sulfamethoxazole, the standard therapy.

- **Dronabinol**, approved December 1992, (supplemental application) for anorexia and weight loss associated with AIDS.

- **Rifabutin**, approved December 1992, for the prophylaxis of Mycobacterium avium complex, a severe infection that often afflicts AIDS patients.

- **Megestrol acetate**, approved September 1993, (supplemental application), for anorexia, cachexia, or an unexplained weight loss in patients with AIDS.

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
Tuesday, Nov. 30, 1993

Contact: Victor Zonana
(202) 690-6343

HHS Secretary Donna E. Shalala today announced the formation of a National Task Force on AIDS Drug Development to expedite the search for new therapies against AIDS and the underlying human immunodeficiency virus (HIV).

The expert panel will be highly focused, seeking new and innovative approaches to the development of AIDS drugs.

"The task force has a clear and critical mission: to identify, and remove, any barriers or obstacles to developing effective treatments," Shalala said.

The 15-member panel will be drawn from government, the pharmaceutical industry, academia, medicine and the AIDS-affected communities. "This represents unprecedented high-level collaboration among leaders in the field," Shalala said.

"It is time to refocus and re-energize our best minds for a concerted attack on this killer," Shalala said.

"None of us can guarantee success," Shalala added. "HIV is a vicious and cunning adversary. But history will judge us harshly if we fail to give it our best shot."

Shalala was joined at the announcement by Assistant Secretary for Health Dr. Philip Lee, who will chair the panel; Dr. P. Roy Vagelos, chairman and chief executive officer of Merck & Co., Inc.; Kristine M. Gebbie, national AIDS policy coordinator; and Moises

- More -

Agosto, research and treatment advocacy manager at the National Minority AIDS Council.

Also attending the National Institutes of Health press conference were Dr. David Kessler, commissioner of food and drugs; Dr. Harold Varmus, newly sworn in as director of the National Institutes of Health; and Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases.

"The FDA has made great strides in streamlining the approval process for drugs to treat life-threatening conditions, and the NIH has contributed mightily to our understanding of AIDS and HIV," Shalala said.

"In addition, the Clinton administration and Congress have raised the NIH AIDS research budget 21 percent this year, to $1.3 billion," she added.

"But the sad fact remains that not a single New Drug Application for an antiretroviral drug is currently before the FDA. No matter how much we shorten the pipeline, we cannot achieve our goal unless we start filling that pipeline with promising compounds," Shalala said.

At least one million U.S. citizens are infected with HIV. Some 340,000 have been reported to the CDC with full-blown AIDS, and over 200,000 have died.

"Unfortunately, none of the drugs we have today are curative," Dr. Lee said.

"The task force, which will be appointed by and report to the secretary, will bring together many of the top people in the field.

It will raise the level and intensity of collaboration," Dr. Lee continued.

"The group we envision will be constantly evaluating the process -- identifying obstacles, charting strategy, and asking: 'What are our options? Is anything falling through the cracks? Are we doing everything we possibly can?'" Lee said.

"We're not just talking about antivirals," Dr. Lee added. "We need an across-the-board strategy to develop drugs to treat all aspects of HIV disease. We need immune modulators, anticancer compounds, and agents to treat and prevent opportunitic infections."

"The Centers for Disease Control and Prevention inform me that AIDS and HIV, on average, kill 92 people in this country every day," Shalala said. "With so many people being held hostage by this virus, we must explore all possible options."

Shalala said she expects to begin receiving nominations for task force membership immediately.

Said Gebbie: "The mere creation of a new task force does not halt an epidemic, and if this new group were allowed to become a mere bureaucratic space-filler, it could even become counterproductive. I am confident, however, that neither of these things will occur."

Added Shalala: "This is is not just another government panel appointed to study an issue and write a report that gathers dust.

"I expect the task force to report to me personally, rapidly and regularly, and I pledge to work with all its members to eliminate any obstacles to finding effective treatments," she said.

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[15] From: Robert Moran 11/29/93 12:18PM (1859 bytes: 32 ln)
To: Kristine Gebbie
cc: George Walter, Robert Moran
Subject: National Foundation for Infectious Diseases speech
---------- Message Contents ----------

On November 10, you asked for suggestions for talking points on the subject of "research policy and process: the impact of AIDS."

Suggested talking points:

1. Use of community groups and the use of government, community group coalitions to bring research findings rapidly into the care arena ("translation"). Illustrative are applicant guidelines and application processes for HRSA CARE funding and for CDC funding of health agencies and community organizations.

2. Involvement of community interests and affected populations in the development of the research agenda and in the conduct of community research.

Possible themes:

1. The impact of this epidemic and its associated assembly have changed public health in ways still unfolding. The vastness of the change and the implications for the future are only glimmers from here, yet we have already witnessed the influences of an organized, learned, and concerned alliance on research have been to subject, protocol, terminology, and priority. You could speculate, with minimal clairvoyance, that others will emulate.

2. Much of the external (to the government) power structure resulted from a perceived vacuum left when it was concluded that government by choice and circumstance could not and would not lead. Possible avenues that might be developed could run from irony on the cynical side to an affirmation of democracy on the inspirational side. However, I would suggest a discussion of your role in bringing community and government together.

THE WHITE HOUSE

WASHINGTON

November 10, 1993

Betty Orr
National Foundation for Infectious Diseases
4733 Bethesda Avenue
Suite 750
Bethesda, MD 20814

Dear Betty:

This letter confirms Kristine Gebbie's keynote address at the First National Conference on Human Retrovirus and Related Infections, on Sunday, December 12 1993 in Washington, DC at the Sheraton Washington.

Ms. Gebbie will arrive at 7:00 for dinner, following which she will deliver a keynote address, "Research Policy and Process: The Impact of AIDS."

Please call me at (202) 632-1090 with any questions or for further clarification. I am enclosing a biographical sketch and curriculum vitae for your reference.

Sincerely,

W. Steve Lee

W. Steve Lee, Executive Assistant to
National AIDS Policy Coordinator

Enclosure

from Dr Burke — Steve - for file for Space

SUGGESTIONS FOR NATIONAL FOUNDATION FOR ~~INFECTIOUS~~ DISEASES
SPEECH ON ~~"RESEARCH~~ POLICY AND PROCESS"

1. The need for "targeted" research.

2. The respective research roles of industry, government, and academia, and coordination of their efforts.

3. A crucial gap in the process: transition from academic research to pilot product

4. The problem of non-profitability of products intended for public health usage, especially vaccines.

5. The timid approach to vaccine development being taken by US industry (related to #4).

6. Imbalances in the federal government research "investment strategy" in the face of an epidemic:

   therapeutic (much) > preventive

   basic > applied

The First National Conference on Human Retroviruses and Related Infections

cosponsored by the National Foundation for Infectious Diseases and the American Society for Microbiology in collaboration with NIH and CDC

December 12-16, 1993, Washington, D.C.

March 23, 1994

Ms. Kristine M. Gebbie
National AIDS Policy Coordinator
200 Independence Avenue, SW, Room 38-G
Washington, DC 20201

Dear Ms. Gebbie:

This letter is a belated but genuinely sincere "thank you" for your participation in the "First National Conference on Human Retroviruses and Related Infections" held in Washington, DC, December 12-16, 1993.

From all reports we believe the conference was well-received and was an outstanding success. Of course, all the credit for its success goes to people such as yourself who unselfishly contributed their time and expertise to the program.

Again, many thanks for doing such a splendid job and for sharing your knowledge with those interested in this very important subject.

With best personal regards,

Sincerely yours,

Richard J. Duma, MD, PhD
Executive Director
National Foundation for Infectious Diseases

RJD/bwo

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