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THE WHITE HOUSE

WASHINGTON

MEMORANDUM FOR JACK WEITZCARVER AND WENDY WERTHEIMER

From: Todd Summers
Deputy Director
Office of National AIDS Policy
(202) 632-1090

Date: December 3, 1997

Re: President's Advisory Council on HIV/AIDS and its Vaccine Recommendations

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Attached is a draft of recommendations prepared by the Research Committee of the President's Advisory Council on HIV/AIDS (PACHA).

I would appreciate it if you would review the document and provide me with a brief written response to these recommendations. This response is for internal use only, and will not be shared with the PACHA unless you subsequently authorize such release.

The PACHA meeting is starting tomorrow, so if your comments could be prepared by the end of the day today that would be very helpful.

Also, I mentioned that the Department of Energy may have some time available on its supercomputers to assist in vaccine modeling. Can you tell me whether or not we should work with DOE to obtain a time allocation?

Please call me if you have any questions. Thank you!

.ACHIEVING THE AIDS VACCINE GOAL

Recommendations from the Presidential Advisory Council on HIV and AIDS

Background

Since late 1995, the Research Committee of the Presidential Advisory Council on HIV and AIDS (PACHA) has devoted significant time and effort to issues concerning the development of an AIDS vaccine. The committee consulted with numerous experts in AIDS research and vaccinology (see Appendix A: List of Informants). The committee also solicited and received written input from these and other experts (see Appendix B: Sources of Additional Written Input). The Committee focused on identifying the obstacles and impediments to an AIDS vaccine, and analyzed the complex, diverse issues that must be addressed in order to achieve the President's goal of an AIDS vaccine within a decade.

Comprehensive Plan

It has become increasingly clear that a comprehensive plan is essential to achieve the goal of an AIDS vaccine, and that no federal agency, national or international organization, nor private sector corporation alone has the expertise, the capacity, or the resources to accomplish all the steps needed to achieve this goal. These include, but are not limited to: (1) basic scientific research in order to better understand the human immune response to HIV; (2) product development of vaccine candidates suitably manufactured and approved for human testing; (3) small-scale (phase I and II) clinical studies in humans to determine the safety and immune response of candidate vaccines; (4) large-scale (phase III) longitudinal field trials to determine efficacy; and (5) resolution of various supporting issues, such as product liability, incentives for private research and development investment, and financing mechanisms to ensure access to successful vaccines worldwide.

Leadership

It has also become obvious that strong, visible, high-level leadership is desperately needed to accelerate the vaccine effort by overseeing the development and implementation of a comprehensive plan, and by elevating the vaccine effort to the highest priority in order to stop an epidemic that continues to infect 8,000 - 10,000 people every day world-wide. The Vice President has the necessary interest and standing to engage the cooperation and collaboration of the private sector, the international community, and the appropriate federal agencies in order to oversee the development of an effective plan. The Office of the Vice President also

has the authority to hold the relevant Federal agencies accountable for their vaccine efforts and their willingness to collaborate with other essential agencies, organizations and participants.

To complement the Vice-President's role, the President should appoint a respected and accomplished leader in public health/medical science as the National Director for AIDS Vaccine Development. This should be a full time position in a semi-autonomous environment sufficiently high in the Government hierarchy to: (1) be an advocate for AIDS vaccine development, (2) have fiscal authority over all government AIDS vaccine efforts, (3) provide strong leadership and coordinate all government organizations involved in this field, (4) maintain close relationships with vaccine developers in the private sector, and (5) martial the resources and cooperation of other nations, international organizations, and the philanthropic community.

Planning Process and Goals

The development and implementation of a comprehensive plan for accelerated AIDS vaccine development will require a systematic, coordinated process, with defined timelines, and must include all appropriate constituencies representing relevant federal agencies/institutions [e.g. National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Department of Defense (DOD), United States Agency for International Development (USAID)], the private sector (biotechnology and pharmaceutical industries), and the international community [e.g. United Nations Programme on AIDS (UNAIDS), International AIDS Vaccine Initiative (IAVI), World Bank, G-7 countries]. The first phase would include a series of focused meetings, with establishment of working groups and committees, each with specific objectives and deadlines for action and performance.

The comprehensive plan must include not only the vision and process for vaccine development but also the specific objectives, responsibilities, strategies and outcomes for the implementation of the plan. It is essential that the plan reflect the integration of the special skills and expertise of all appropriate federal agencies, non-governmental organizations, and the international community, as well as set forth a process for collaboration among the various participants. Some of the issues which must be addressed include: (1) how to coordinate the relationships and form partnerships with other major industrialized nations, UNAIDS, and nongovernmental organizations; (2) funding and financial incentives; (3) management controls; (4) clear milestones and target goals; (5) regulatory issues; (6) intellectual property rights; (7) liability issues; and (8) defining the roles of the various U.S. Federal agencies, taking advantage of established programs and experience in field testing of candidate vaccine products.

Basic Science Research

A major area which must be addressed within the comprehensive plan concerns basic scientific research. The National Institutes of Health (NIH), the world's premier biomedical research agency, should maintain it's essential role in promoting basic research in virology, immunology, behavioral, and related sciences which provides the knowledge base for vaccine development. However, NIH should utilize more of its in-house experience and expertise

in vaccine development for this effort. NIH experts outside of the Division of AIDS could provide much needed knowledge and advice in vaccine development.

The establishment of the proposed [AIDS] Vaccine Center within NIH may facilitate expansion of basic scientific knowledge. It is essential that the director of this Center be an accomplished vaccinologist, and that this director have full responsibility and authority to allocate, prioritize, and manage all NIH funding designated as "AIDS vaccine" research. Additionally, NIH must substantially increase the amount of AIDS research funds allocated to vaccines.

Vaccine Development Approach

There is a serious lack of candidate AIDS vaccines in the "pipeline" to test in clinical trials, and it is imperative to overcome this lack. Basic science research may not reveal, within the desired timelines, all the answers to the complex mechanisms of immune control of HIV-1 to permit the rational design of an AIDS vaccine certain to work in advance of human testing. Without knowing the "correlates of protection" (the human immune responses to a vaccine that indicates protection from HIV-1 if exposed), and without having a laboratory animal that closely mimics human HIV infection, it will be necessary to test various traditional and novel vaccine design strategies in human clinical trials to assess safety, immune response, and efficacy. This process of "thoughtful empiricism", a hallmark in the history of vaccine development, may provide vitally needed answers. The risk that a tested vaccine may fail to work is a reality, but the benefit for future studies from the knowledge gained may outweigh the time, cost, and effort in determining a vaccine unsuccessful.

Product Development

Product development refers to the translation of promising concepts from laboratory and animal experiments to actual vaccine products made according to "good manufacturing practices" (GMP) under Food and Drug Administration (FDA) guidelines before they are approved by the FDA for human testing under "investigational new drug" (IND) protocols.

Product development requires the infrastructure and expertise residing primarily in the private sector (pharmaceutical and biotechnology industries) and is an area in need of leadership and innovation. Government leadership may be required to effectively subsidize private industry needs. Such support would ideally involve the commissioning of targeted applied research, the facilitation of cooperative agreements for pilot manufacture of new vaccine candidates, and the support of Phase I, II, and III trials. This could be accomplished by experienced companies or non-governmental research institutes working with a minimal amount of governmental interference. Federal leadership will also be required to address a host of essential related issues, such as intellectual property rights, financial incentives for the government vaccine purchase market, international vaccine development and purchase funds, tax

rebates, subsidies for vaccine approaches not commercially attractive, patent extensions, and liability issues. These are issues which are not within the traditional role of NIH, but are essential to the development of an effective vaccine.

Phase III Field Efficacy Trials

A third major area of concern relates to the implementation of large scale field trials to determine vaccine efficacy. It will be important to conduct multiple field trials of various candidate vaccines concurrently, not waiting for the results of one before starting others. Many such trials will likely occur in developing countries, where the incidence of new infections is higher. As a result, true partnerships with investigators in these countries must be developed. Critical to the success of large field trials in developing countries will be the involvement and "ownership" of the testing program by scientists living in these developing countries.

Agencies such as CDC, DOD, and USAID have extensive experience and expertise in field epidemiology, surveillance, and the conduct of vaccine efficacy trials, especially in developing countries. In addition, DOD and CDC currently maintain several long term overseas field research infrastructures operating through government-to-government collaborations with foreign ministries of health and other agencies. These ongoing field research stations can provide tremendous capacity for the multiple vaccine trials which are likely to extend over decades. To facilitate this process, the comprehensive plan must address the complex issues of communication, cooperation, and collaboration among the diverse agencies and organizations which will be required in this international effort.

PACHA Research Subcommittee Members:

Alexandra Levine, Chairperson
Jerry Cade
Debra Fraser-Howze
Phyllis Greenberger
Bob Hattoy
Scott Hitt
Ron Johnson
Helen Miramontes
Bruce Weniger

Submit written comments to Daniel Montoya, Executive Director, PACHA
Office of National AIDS Policy
Executive Office of the President
808 17th Street, NW, Suite 820
Washington, DC 20006 FAX: (202) 632-1096

APPENDIX A: LIST OF INFORMANTS

The following invited individuals formally discussed AIDS vaccine issues with the Committee or the Council on one or more occasions between April 1996 and October 1997. Listing here is solely to indicate the breadth of expertise and opinion received, and does not necessarily imply agreement or endorsement with the above analyses and recommendations.

1. David Baltimore, PhD
   Professor, Massachusetts Institute of Technology
   President-elect, California Institute of Technology
   Chair, NIH AIDS Vaccine Research Committee

2. Seth Berkley, MD
   Rockefeller Foundation
   President, International AIDS Vaccine Initiative (IAVI)

3. Deborah Birx, MD
   Director of Retrovirology
   Walter Reed Army Institute of Research

4. Dani Bolognesi, PhD
   Director, Center for AIDS Research
   Duke University
   Co-Director, Human Vaccine Institute

5. Larry Brilliant, MD
   Founder
   Seva Foundation

6. Donald S. Burke, MD
Director, Center for Immunization Research
School of Public Health
John Hopkins University

7. Margaret Chesney, PhD
Center for AIDS Prevention Studies
University of California, San Francisco

8. Mary-Lou Clements-Mann, MD, MPH
Center for Immunization Research
School of Public Health
John Hopkins University

9. Chris Collins
Center for AIDS Prevention Studies (CAPS)
UCSF & VACT-UP

10. Dino Dina, MD
President
Chiron Vaccines Corporation

11. Burt Dorman, PhD
President & CEO,
Acrogen Inc.

12. Jose Esparza, MD, PhD
Chief, Vaccine Development
United Nations Programme on AIDS (UNAIDS)

13. Max Essex, DVM, PhD
Professor of Virology,
Chairman, Harvard AIDS Institute
Harvard School of Public Health

14. Anthony S. Fauci, MD
Director
NIAID, NIH

15. Richard G. A. Feachem, PhD
Senior Advisor Human Development
World Bank
Board of Directors, IAVI

16. Donald P. Francis, MD, ScD
President
VaxGen, Inc.

17. David Gold, JD
AIDS Vaccine Advocacy Coalition

18. William L. Heyward, MD
HIV Vaccine Coordinator
National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention

19. Maurice R. Hilleman, PhD
Director
Merck Institute of Therapeutic Research

20. Margaret "Peggy" Johnston, PhD
Scientific Director
International AIDS Vaccine Initiative (IAVI)

21. John Y. Killen, MD
Director, Division of AIDS
NIAID, NIH

22. Wayne Koff, MD, PhD
United Biomedical, Inc.

23. Yichen Lu, PhD
Senior Scientist & Manager
HIV Program
Virus Research Institute, Inc

24. Richard T. Mahoney, PhD
Director, Institutional Development
International Vaccine Institute, Seoul, Korea

25. John G. McNeil, MD
Director
DOD, HIV-1/AIDS Vaccine Development Program

26. Ronald Moss, MD
Medical Director
Immune Response Corporation

27. Kenrad E. Nelson, MD
Professor of Epidemiology
School of Public Health
John Hopkins University

28. William E. Paul, MD
Director
Office of AIDS Research
NIH

29. Peter Piot, MD
Executive Director
United Nations Programme on AIDS (UNAIDS)

30. Bryan Roberts, PhD
Vice President of Research
Virus Research Institute, Inc.

31. Philip K. Russell, MD
John Hopkins University
Founding President, Albert B. Sabin Vaccine Foundation
Board of Directors, International AIDS Vaccine Initiative (IAVI)

32. Jerald C. Sadoff, MD
Executive Director, Vaccine Research
Merck Research Laboratories

33. Allan Schultz, PhD
Chief
Vaccine Research & Development Branch
Division of AIDS, NIAID, NIH

34. Haynes "Chip" Sheppard, PhD
Cellular Immunologist
Virus Laboratory
California Department of Health

35. William Snow
ACT-UP-Golden Gate
Co-founder, AIDS Vaccine Advocacy Coalition (AVAC)
Member, NIH AIDS Vaccine Research Committee

36. Sten Vermund, MD, PhD
Professor of Epidemiology
President, Gorgas Memorial Institute for Tropical and Geographic Medicine
University of Alabama

APPENDIX B: SOURCES OF ADDITIONAL WRITTEN INPUT

In response to a public solicitation by the Research Committee for comment and opinion, the following individuals provided written input between September and December 1995 (written documentation was also received by some of the informants listed above to supplement their verbal input). Listing is solely to indicate the breadth of opinion received, and does not necessarily imply agreement or endorsement with the above analyses and recommendations.

37. Abul K. Abbas, MD
Professor of Pathology
Harvard Medical School

38. Arthur J. Ammann, MD
Director of Research
American Foundation for AIDS Research (AMFAR)

39. Dana Cappiello
Co-founder
Until There's a Cure Foundation

40. Scott B. Halstead, MD
Director, Infectious Disease Research
Department of the Navy
(formerly head of Health Sciences Division, Rockefeller Foundation)

41. Norman L. Letvin, MD
Chief, Division of Viral Pathogenesis, Beth Israel Hospital
Professor of Medicine, Harvard Medical School

42. John Moore, PhD
Staff Investigator

Aaron Diamond AIDS Research Center

43. Lendon Payne, MD, PhD
Director of Research,
Virus Research Institute, Inc.

44. Kathleen Scutchfield
Co-founder
Until There's a Cure Foundation

45. Robert T. Schooley, MD
Professor of AIDS Research
University of Colorado Health Sciences Center

46. Jonathan T. Warren, PhD
Immunologist, AIDS Vaccine Evaluation Group
The EMMES Corporation

47. Peter F. Wright, MD
Director, AIDS Vaccine Evaluation Unit
Professor of Pediatrics, Vanderbilt University School of Medicine

APPENDIX C: REFERENCE DOCUMENTATION

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Mascola, J. R., McNeil, J. G., Burke, D. S. (1994). AIDS vaccines: Are we ready for human efficacy trials? JAMA, 272, 488-489.

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THE WHITE HOUSE

WASHINGTON

December 3, 1997

The Honorable Juanita Millender-McDonald
United States House of Representatives
Washington, DC 20515

Dear Ms. Millender-McDonald:

Enclosed is some information on available grants to assist people living with HIV/AIDS which are or may be available to the City and County of Los Angeles. The information includes descriptions of:

(1) grants available through the Ryan White CARE Act program administered by the Health Resources and Services Administration (HRSA) in the Department of Health and Human Services, including information on the amount of funds received by the State of California and the County of Los Angeles under this program, and

(2) funds available through the Housing Opportunities for Persons with AIDS (HOPWA) program available from the Office of Community Planning and Development in the Department of Housing and Urban Development.

I am also enclosing a copy of the HRSA Grants Preview, which provides information on other HRSA programs, such as the Community and Migrant Health Center program. which while not specifically directed to people with HIV/AIDS, can provide assistance to them.

I will be glad to provide you with any additional information which you may need. You should also call each program directly to obtain specific information about eligibility and application requirements. For information on the Ryan White CARE Act programs, you should contact Dr. Joseph O'Neill, Associate Administrator, HIV/AIDS Bureau, HRSA, telephone number (301) 443-1993, and for information on the HOPWA program, you should contact Mr. David Vos, Director, Office of HIV/AIDS Housing, HUD, telephone number (202) 708-1934.

Thank you.

Sincerely,

Todd Summers
Deputy Director, Office of National AIDS Policy

THE WHITE HOUSE

WASHINGTON

December 11, 1997

Ms. Jennifer Sleboda
The George Washington University
Women's Studies Program
2201 G Street, N.W.
Funger Hall, Room 506-I
Washington, DC 20052

Dear Ms. Sleboda:

The following is in response to your November 19, 1997 letter requesting internship information from the Office of National AIDS Policy:

- general contact person: Deputy Director Todd Summers
- current address: 808 17th Street, N.W. Suite 820 Washington, DC 20006
- phone number: (202)632-1090
- fax number: (202)632-1096
- internship opportunities: All interns to this office must go through the White House Intern Program. There are fall, spring, and two summer sessions.
- activities and goals: See the enclosed sheet. Role of ONAP paper

Interns to this office do a number of substantive tasks for the staff which include: compiling briefing materials, creating and maintaining briefing books on a number of AIDS-related issues, assisting the Executive Director of the Presidential Advisory Council on HIV and AIDS in administrative tasks, and aiding correspondence with the public.

I hope this helps in the formulation of your directory.

Sincerely,

Todd Summers
Deputy Director
Office of National AIDS Policy

The George Washington University
WASHINGTON DC

WOMEN'S STUDIES PROGRAM

November 19, 1997

Dr. Arthur Lawrence
AIDS Policy Office
750 17th Street, N.W., Suite 1060
Washington, DC 20503

RE: Gender and Social Policy Institution Directory

Dear Ms./Mr./Dr. Lawrence:

The Women's Studies Program at the George Washington University would like to obtain information about your organization, association, or institution, as we are preparing a directory of gender and social policy institutions in the Washington, D.C. area. We have your name listed as a contact in our internship directory, however we need additional information from you. We are also updating our listing of internship sites for our graduate students. We would like to have the following information for our directory:

- general contact person (as opposed to internship contact)
- current address
- phone/fax number
- e-mail address (if you have one)
- web site (if you have one)
- information on internship opportunities
- information about the activities and goals of your organization
- any relevant brochures

This directory will allow students to learn about the wide range of gender and social policy institutions in the Washington, D.C. area. Additionally, in the future we hope to develop a course on Gender and Social Policy Institutions in the Washington Area, which would involve site visits and interviews with organizational leaders.

We would greatly appreciate your help in providing this information as we feel it will be a great resource for our students as well as the public. If you have any questions, please contact me. Thank you.

Sincerely,

Jennifer Sleboda
Student Research Assistant

2201 G STREET., N.W. • FUNGER HALL • ROOM 506-I • WASHINGTON, DC 20052 • (202) 994-6942 • FAX (202) 994-7249 • E-MAIL: wstu@gwis2.circ.gwu.edu