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PRESIDENTIAL

ADVISORY

COUNCIL ON

HIV/AIDS

August 17, 1998

MEMORANDUM TO NEAL NATHANSON, M.D.

FROM: Daniel C. Montoya, Executive Director 

RE: AIDS Vaccine Initiative

In follow-up to our conversation this morning, I would appreciate the opportunity to be invited to the upcoming and subsequent meetings of the Office of AIDS Research (OAR) Advisory Committee, as it deals with the AIDS Vaccine Initiative. In order to assist the Council in providing recommendations to the President and Secretary of the Department of Health and Human Services (HHS), my role is to act as liaison between the Council and the Office of National AIDS Policy (ONAP) and Secretary of HHS. I can be reached at (202) 395-1445; or you can E-mail me at <montoya_dc@al.eop.gov>.

I have attached information regarding the Presidential Advisory Council on HIV/AIDS (Council) including a "confidential" address listing with members' business and home addresses (not for public distribution), a list of each subcommittee and its members, as well as past research related recommendations.

As I mentioned on the call, Sandra Thurman is on travel status. Todd Summers, Deputy Director of the Office of National AIDS Policy, is available at (202) 456-2444. He will be calling you regarding the upcoming OAR Advisory Committee meeting and ONAP's participation.

Enclosures

cc: Sandra Thurman
Todd Summers ✓

Presidential Advisory Council on HIV/AIDS

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DATE: 8/16/14

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August 17, 1998

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Kathleen Gerus, *Prevention Liaison*
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PACHA Recommendations - Unresolved Only

Research

PACHA Recommendations - Unresolved Only

ILR.1

Date Passed 12/8/95

Resolved? No

Description

The Vice President's leadership and technological expertise should be sought to bring together the resources and expertise of various Government agencies, the private sector, community groups, and other nations in the effort to develop HIV vaccines and microbicides and to "reinvent" the Government's involvement in development of these products.

Date	Action Type	Formal?
	Administration Response	☒
	On February 20, 1996, Vice President Gore met with representatives of the pharmaceutical industry regarding expanded collaboration between the public and private sectors on AIDS research. The meeting included a discussion of the need for greater industry and Government involvement in the development of microbicides. The Vice President has expressed interest in a continued role in furthering this area of research and development. December 1997: PACHA members believe this recommendation is not complete. They expressed concern that microbicide research has lost momentum. They will address this issue during the March 1998 PACHA meeting. They expressed concern that the meeting with the Vice President did not occur.	
	Assessment of Response	☒
	The meeting between Vice President Gore, Government scientists, and industry representatives was seen as a productive and useful first step in the process of reinventing the partnership between Government and private industry in the development of HIV vaccines, microbicides, and other new therapies.	
	Follow-up Action Recommended	☒
	It is imperative that this dialogue continue. Another meeting between the Vice President and other concerned groups should be convened by September 1 in order to keep the momentum for this partnership thriving. Furthermore, it is essential that community groups be included in future discussions, and that the Council be informed of these meetings.	

PACHA Recommendations - Unresolved Only

II.R.2

Date Passed 12/8/95

Resolved? No

Description

The priority for funding by the OAR for microbicide research and development, as well as such funding within CDC, must be increased substantially, with a concomitant increase of full-time equivalents (FTEs) allocated for this priority.

Date	Action Type	Formal?
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Administration Response



NIH funding for research on microbicides has increased over the past several years and will continue to increase. The priority accorded to this important area of research has been determined through the OAR planning process, which included consultation with NIH and non-government scientists, clinicians, academicians, industry representatives, and AIDS community advocates. These experts reached a consensus on the scientific priorities included in the consolidated NIH Plan and Budget Request. OAR anticipates that this research will continue to receive high priority for funding.

At CDC, the Epidemiology Branch, Division of HIV/AIDS Prevention (DHAP), in collaboration with the Division of Reproductive Health, the Division of STD, and the Women's Health Program Office, coordinated a meeting in mid-April to discuss policy, research, and program issues concerning microbicide research relative to CDC's mission of HIV prevention. This meeting was attended by CDC researchers, outside consultants, and representatives from NIH and FDA. Regarding ongoing research, the CDC HIV/AIDS Epidemiology Branch, in collaboration with the Division of Viral and Rickettsial Diseases, is currently conducting a three-year prospective study of HIV in female genital tract secretions. Studies are also being conducted within the Epidemiology Branch to examine women's interpretation of HIV prevention messages as a function of relevant beliefs and goals concerning close relationships and potential biases in message interpretation due to contextual framing information and the hierarchical presentation of message content.

Assessment of Response



The Administration is certainly moving in the right direction regarding this area, although these concrete increases have not yet been seen. The President has used his leadership to emphasize the importance of this area to the public. Two meetings have been held (CDC, 4/15/96, with Patsy Fleming, Director, Office of National AIDS Policy, and others in attendance, and the International Working Group on Microbicides, in Virginia, 4/11/96).

Follow-up Action Recommended



The Administration should require each relevant agency and NIH institute to provide, on an annual basis, information on specific funding and FTE allocations being applied for microbicide research. Tracking of this information should include the specific types and nature of the research being conducted.

Current efforts should be continued, and overall funding for microbicide research must significantly increase.

PACHA Recommendations - Unresolved Only

ILR.3

Date Passed 12/8/95

Resolved? No

Description

The Government should develop mechanisms to increase the pool of investigators in microbicide research and development, especially those involved in biomedical and behavioral aspects.

Date	Action Type	Formal?
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Administration Response



Attracting new investigators into the field of AIDS research is a high priority for the NIH. Several mechanisms are already in place, such as the AIDS Loan Repayment Program, and others are under development. There are at present no special initiatives to increase investigators in any specific areas related to AIDS research, such as microbicides.

Assessment of Response



While two recent meetings on microbicide research may have generated interest in this area by biomedical and behavioral researchers at the involved institutions, as yet there has been no evidence of specific mechanisms to increase the pool of investigators in this area.

Follow-up Action Recommended



The NIH, OAR, and CDC should issue Requests for Applications for training grants and for focused research projects related to microbicides.

Federal agencies and institutes should track the monies being spent on training of potential investigators in the field of microbicide research.

PACHA Recommendations - Unresolved Only

ILR.4

Date Passed 12/8/95

Resolved? No

Description

In HIV/AIDS clinical research, the NIH must ensure the early and fundamental involvement of behavioral and social scientists in the process of initial study development, design, and implementation.

Date	Action Type	Formal?
	Administration Response	☒
	The NIH has identified the issues of recruitment, retention, and adherence to clinical trial protocols and therapeutic regimens as important behavioral and social science research components of clinical research. These issues are critical to the outcome of these studies. The NIH is encouraging projects that link these important behavioral and clinical research issues. This is an important element of current NIH vaccine efficacy trials.	
	Assessment of Response	☒
	This recommendation has not been implemented. The four recommendations listed in the Executive Summary of the NIH AIDS Research Program Evaluation Working Group Report (page 18) do not address this recommendation. However, NIH has identified the issue as an important component of clinical trial protocols and vaccine efficacy trials.	
	Follow-up Action Recommended	☒
	The Council will postpone recommendations for action until the report from the Behavioral, Social Science, and Prevention Area Review Panel of the NIH AIDS Research Program Evaluation Working Group is reviewed by the Council.	

PACHA Recommendations - Unresolved Only

IX.R.2

Date Passed 3/15/98

Resolved? No

Description

Federal leadership at the highest level will be required, through the Office of National AIDS Policy, ensuring that adequate resources are provided for the coordination process necessary to achieve the goal of an effective AIDS vaccine.

Date	Action Type	Formal?
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PACHA Recommendations - Unresolved Only

IX.R.3

Date Passed 3/15/98

Resolved? No

Description

The Office of National AIDS Policy should ensure the development and implementation of a comprehensive federal plan to achieve the goal of an effective AIDS vaccine.

Date	Action Type	Formal?
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PACHA Recommendations - Unresolved Only

IX.R.4

Date Passed 3/15/98

Resolved? No

Description

The process of defining the structure and mission of the proposed (AIDS) Vaccine Center at NIH, and the appointment of a director with the highest level of expertise, should proceed promptly.

Date

Action Type

Formal?



PACHA Recommendations - Unresolved Only

IX.R.5

Date Passed 3/15/98

Resolved? No

Description

The urgent need for an AIDS vaccine mandates the simultaneous implementation of both basic and empiric scientific approaches.

Date	Action Type	Formal?
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☐

PACHA Recommendations - Unresolved Only

VLR.2

Date Passed 4/5/97

Resolved? No

Description

A significant and sustained increase in funds must be made available for HIV/AIDS vaccine research and development. These funds must be derived from NEW sources from both government and industry, and must not be taken from existing programs aimed at prevention, research, care, services, and/or treatment for persons with HIV/AIDS. Innovative use of such funds is essential, as seed money to initiate new and creative hypotheses in vaccine research; to support product development; to expand the proportion of successfully funded grant applications; and to bring additional entities into the HIV/AIDS vaccine field.

Date	Action Type	Formal?
11/26/97	Administration Response	☒
	No response given to date.	