

NLWJC - Kagan

DPC - Box 002 - Folder 007

AIDS - Vaccine

THE WHITE HOUSE
WASHINGTON

November 30, 1998

WORLD AIDS DAY EVENT

DATE: December 1, 1998
LOCATION: 450 OEOB
BRIEFING TIME: 12:00 pm - 12:25 pm
EVENT: 12:30 pm - 1:15 pm
FROM: Bruce Reed/Chris Jennings/Sandy Thurman

I. PURPOSE

To commemorate World AIDS Day by unveiling new steps to address the growing number of children being orphaned by HIV/AIDS -- estimated to be as many as 40 million by the year 2010.

II. BACKGROUND

You will be joined by Secretary of State Madeleine Albright and U.S. Agency for International Development (USAID) Administrator Brian Atwood to commemorate World AIDS Day by launching a series of new initiatives to address the growing crisis of children affected by AIDS. You will announce: (1) historic new increases of NIH funding dedicated to new research aimed at developing an effective AIDS vaccine and to new prevention strategies to help address the problem of HIV/AIDS throughout the world; (2) new emergency funding from USAID to support international community-based AIDS orphan programs; and (3) a delegation to Sub-Saharan Africa, led by your AIDS Policy Advisor, Sandra Thurman, to assess the growing problem of AIDS orphans and recommend new strategies for responding.

In your remarks, you will announce the following:

- **USAID projection that up to 40 million children will be orphaned by HIV/AIDS by the year 2010.** (NOTE: this projection is of children who will lose one or both parents to AIDS) Over 90 percent of AIDS orphans live in developing countries that have too few resources to provide for their care and support. Over 33 million people around the world now have HIV or AIDS, with another 5.8 million becoming infected every year. As with so many epidemics, children and young people bear much of the terrible burden of AIDS. In the United States, as many as 80,000 children already have been orphaned by AIDS.

- **Increase in funding by the National Institutes of Health on research to prevent and treat HIV around the world.** NIH will undertake the largest single public investment in AIDS research in the world by supporting a comprehensive program of basic, clinical, and behavioral research on HIV infection and its related illnesses. This program will include:
 - * **\$200 million for research on AIDS vaccines to prevent transmission around the world, which represents a 33 percent increase from last year's funding.** The development of a safe and effective AIDS vaccine is critical to stemming the growing problem of HIV/AIDS and AIDS orphans across the world. NIH will dedicate \$200 million in vaccine research in FY1999 -- a \$47 million increase from FY1998 and an 100 percent increase since FY1995. This investment is critical to meeting your challenge to develop an effective AIDS vaccine.
 - * **\$164 million for other new research critical to addressing the HIV/AIDS epidemic across the world.** NIH will invest \$164 million in FY1999, a \$38 million increase over last year, for critical projects to reduce the number of AIDS orphans by preventing and treating HIV/AIDS internationally, including: a new prevention trials network to reduce adult and perinatal transmission of HIV/AIDS; new strategies to prevent and treat HIV infection in children; funding to train more foreign scientists to collaborate on this epidemic; research on the prevention and treatment of the opportunistic infections, such as tuberculosis, that commonly kill people with HIV/AIDS; and research on topical microbicides and other female-controlled barrier methods of HIV prevention.
- **\$10 million in emergency relief funding at USAID to provide support for AIDS orphans.** USAID will make available \$10 million in emergency funding to support community-based efforts for orphans, including training and support for foster families, initiatives to keep children in school, vocational training, and nutritional enhancements. In addition, USAID will take steps to help prevent the spread of HIV from mothers to children and to improve medical care for children already infected with HIV.
- **AIDS Policy Advisor Sandra Thurman to lead fact-finding delegation to raise awareness and make recommendations to address growing problem of AIDS orphans.** You will announce that you have asked Sandra Thurman, Director of the Office of National AIDS Policy, to lead a fact-finding delegation to southern Africa, where 90 percent of AIDS orphans reside. The delegation will include representatives from across the Clinton Administration, key Congressional offices, and the national media to raise awareness about this emerging problem and to develop recommendations for action.

- **New steps to address the continued need of those living with HIV/AIDS in the United States.** While the problem of AIDS orphans is most acute internationally, you will also underscore that HIV/AIDS affects families in this country as well. You will announce that the Vice President will unveil over \$200 million in funds for the Housing Opportunities for People With AIDS (HOPWA) program this year to assist communities around the country to prevent individuals affected by HIV/AIDS and their families from becoming homeless. The Vice President will announce these grants at a meeting with local community leaders who provide housing and other support services for people living with HIV/AIDS, as well as several individuals and families who have benefited from these services.

This is also an opportunity to highlight the Administration's record of achievement on HIV/AIDS. In this year, you have:

- **Declared HIV/AIDS in racial and ethnic minority communities to be a severe and ongoing health care crisis and unveiled a new \$156 million initiative to address this problem,** including crisis response teams, enhanced prevention efforts, and assistance in accessing state-of-the-art therapies all targeted toward ethnic and racial minorities in communities across the country.
- **Worked with Congress to secure historic increases in a wide range of effective HIV/AIDS programs.** Increases this year alone include: a \$262 million increase in the Ryan White CARE Act; a \$1.79 billion increase in AIDS research funding at the NIH; a \$32 million increase for HIV prevention programs at the CDC; and a \$21 million increase in the Housing Opportunities for People With AIDS (HOPWA) program at HUD.

III. PARTICIPANTS

Briefing Participants:

Secretary Albright
 Brian Atwood, Administrator USAID
 Bruce Reed
 Chris Jennings
 Sandy Thurman
 Richard Socarides

Program Participants:

YOU
 Secretary Madeleine Albright
 Administrator Brian Atwood
 Amy Slemmer, adoptive mother and Washington Representative for Mother's Voices Against AIDS

* Several adoptive families from the local area will be seated on stage.

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- **YOU** will be announced onto the stage accompanied by program participants.
- Secretary Albright will make welcoming remarks and introduce Administrator Atwood.
- Administrator Atwood will make remarks and will introduce Amy Slemmer.
- Amy Slemmer will make remarks and introduce **YOU**.
- **YOU** will make remarks, work a ropeline, and then depart.

VI. REMARKS

Provided by Speechwriting.

**PRESIDENT CLINTON COMMEMORATES WORLD AIDS DAY BY UNVEILING NEW STEPS
TO ADDRESS THE GROWING CRISIS OF CHILDREN ORPHANED BY AIDS**

December 1, 1998

Today, President Clinton joined Secretary of State Madeleine Albright and U.S. Agency for International Development (USAID) Administrator Brian Atwood to commemorate World AIDS Day by launching a series of new initiatives to address the growing crisis of children orphaned by AIDS. The President unveiled historic new increases at the National Institutes of Health dedicated to fund new research aimed at developing an effective AIDS vaccine and new prevention strategies to help address the problem of HIV/AIDS throughout the world; announced new emergency funding from USAID to support international community-based AIDS orphan programs; and directed his AIDS policy advisor Sandra Thurman to lead a delegation to southern Africa to assess the growing problem of AIDS orphans and recommend new strategies for responding. The President:

- ✓ **Highlighted USAID projection that up to 40 million children will be orphaned by HIV/AIDS by the year 2010**, over 90 percent of whom live in developing countries with few resources to provide for their care and support. Over 33 million people around the world now have HIV or AIDS, with another 5.8 million becoming infected every year. As with so many epidemics, children and young people bear much of the terrible burden of AIDS. In the United States, as many as 80,000 children already have been orphaned by AIDS.
- ✓ **Announced 30 percent increase this year in funding by the National Institutes of Health on research to prevent and treat HIV around the world.** The National Institutes of Health will undertake the largest single public investment in AIDS research in the world by supporting a comprehensive program of basic, clinical, and behavioral research on HIV infection and its related illnesses. This program will include:
 - **\$200 million for research on AIDS vaccines to prevent transmission around the world, which represents a 33 percent increase from last year's funding.** The development of a safe and effective AIDS vaccine is critical to stemming the growing problem of HIV/AIDS and AIDS orphans across the world. The President announced that NIH will dedicate \$200 million in vaccine research in Fiscal Year (FY) 1999, a \$47 million or 33 percent increase from FY1998 and an 100 percent increase since FY1995. This investment is critical in meeting the President's challenge to develop an effective AIDS vaccine.
 - **\$164 million for other new research critical to addressing the HIV/AIDS epidemic across the world.** The President also announced that the NIH will invest \$164 million in FY1999, a \$38 million increase over last year, for critical projects to reduce the number of AIDS orphans by preventing and treating HIV/AIDS internationally, including: a new prevention trials network to reduce adult and perinatal transmission of HIV/AIDS; new strategies to prevent and treat HIV infection in children; funding to train more foreign scientists to collaborate on this epidemic; research on the prevention and treatment of the opportunistic infections, such as tuberculosis, that commonly kill people with HIV/AIDS; and research on topical microbicides and other female-controlled barrier methods of HIV prevention.
- ✓ **Unveiled \$10 million in emergency relief funding at USAID to provide support for AIDS orphans.** USAID will make available \$10 million in emergency funding to support community-based efforts for orphans, including training and support for foster families, initiatives to keep children in school, vocational training, and nutritional enhancements. In addition, USAID will take steps to help prevent the spread of HIV from mothers to children and to improve medical care for children already infected with HIV.

- ✓ **Directed AIDS Policy Advisor Sandra Thurman to lead fact-finding delegation to raise awareness and make recommendations to address growing problem of AIDS orphans.** President Clinton asked Sandra Thurman, Director of the Office of National AIDS Policy, to lead a fact-finding delegation to southern Africa, where 90 percent of AIDS orphans reside. The delegation will include representatives from across the Clinton Administration, key Congressional offices, and the national media to raise awareness about this emerging problem and to develop recommendations for action.

- ✓ **Unveiled new steps to address the continued need of those living with HIV/AIDS in the United States.** While the problem of AIDS orphans is most acute internationally, the President underscored that HIV/AIDS affects families in this country as well. The President highlighted that today the Vice President will unveil over \$200 million in funds for the Housing Opportunities for People With AIDS (HOPWA) program this year to assist communities around the country to prevent individuals affected by HIV/AIDS and their families from becoming homeless. The Vice President will announce these grants at a meeting with local community leaders who provide housing and other support services for people living with HIV/AIDS, as well as several individuals and families who have benefited from these services.

- ✓ **Built on a solid record of achievement in HIV/AIDS.** Today's announcements build on a deep and ongoing commitment by the Clinton Administration to respond to the AIDS crisis both in the United States and across the world. The Administration has fought for other critical investments in HIV/AIDS. This year alone, the President:
 - Declared HIV/AIDS in racial and ethnic minority communities to be a severe and ongoing health care crisis and unveiled a new \$156 million initiative to address this problem, including crisis response teams, enhanced prevention efforts, and assistance in accessing state-of-the-art therapies;
 - Worked with Congress to secure historic increases in a wide range of effective HIV/AIDS programs. Increases this year alone include: a \$262 million increase in the Ryan White CARE Act; a \$1.79 billion increase in AIDS research funding at the NIH; a \$32 million increase for HIV prevention programs at the CDC; and a \$21 million increase in the Housing Opportunities for People With AIDS (HOPWA) program at HUD.

Richard Socarides 11/08/98 02:23:19 PM

Record Type: Record

To: See the distribution list at the bottom of this message
cc:
Subject: AIDS vaccine

This would put us ahead of the 10 year plan!

----- Forwarded by Richard Socarides/WHO/EOP on 11/08/98 02:23 PM -----



rwockner @ netcom.com
11/07/98 12:54:00 PM

Record Type: Record

To: Stuart D. Rosenstein, Richard Socarides
cc:
Subject: NC8562: FLASH! Gallo: HIV vaccine in 4 years

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AIDS Researcher Hopes for Vaccine

.c The Associated Press

BANGKOK, Thailand (AP) -- American AIDS researcher Robert Gallo has said that recent work has raised his confidence that a vaccine can be developed against the deadly disease in four years.

Speaking to Thai researchers Friday at Bangkok's Chulalongkorn University, Gallo, credited for co-discovering HIV, the virus that causes AIDS, said he was more confident of a vaccine than a year ago.

"Recent researches make me confident that we will have something in the form of a preventive vaccine, say, in the coming three or four years," Gallo was quoted by The Nation newspaper as saying.

Gallo said recent laboratory studies show that a protein in the urine of women early in pregnancy can inhibit the replication of HIV virus in the test tube.

Study on a vaccine is meanwhile under way on 80 volunteers in several European countries and Israel made by combining interferon, used in treating Hepatitis B and cancer, with TAT, an HIV-generated protein.

Trials are likely to begin in the United States after it receives approval by the U.S. Food and Drug Administration, possibly in February, Gallo was quoted by the Bangkok Post as saying.

Clinical trials could begin in Thailand after that, he said.

Gallo is a director of the Institute of Human Virology in Baltimore, Maryland.

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AIDS - vaccine

EK -
Our weekly covered this,
didn't you think?
-Br

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MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Chris Jennings, Deputy Assistant to the President for Health Policy
Sandra Thurman, National AIDS Policy Coordinator

SUBJECT: AIDS Vaccine Initiative - Next Steps

P. 1 to Bruce -
Yes - we didn't
send it in did we?
What we have to
do, though, is to get some -
thing in the schedule this
summer - e.g. a Pres.
mtg w/ scientists
or a VP mtg
w/ the
pharmaceutical companies.
Let's remind Chris.
Etera

This memorandum will summarize the broad response to the announcement of your commitment to developing an AIDS vaccine, and lay out a strategy to sustain momentum and solidify support for this initiative.

Response to Announcement

There has been broad-based and enthusiastic appreciation for your commitment to developing an AIDS vaccine. The Morgan State speech positively showcased your leadership and willingness to take on a critical research task with vital domestic and international implications. Prior to the announcement, we contacted major constituency groups and several industry leaders to ensure their support for this initiative. Attached are several comments that have been received.

AIDS Groups You have received a great response from the vast majority of national AIDS organizations. The AIDS Action Council, based in Washington and representing 1,400 community-based organizations (CBOs) across the country, and the National Association of People with AIDS have both written strong letters of support. The San Francisco AIDS Foundation, one of the largest CBOs in the country, and the Center for AIDS Prevention Studies, the leader in the prevention arena, continue to provide good comments for the media. The CAEAR Coalition, representing the 49 major cities receiving Ryan White CARE Act funding, are praising this initiative. Additional verbal and written responses are equally positive.

Some community groups and activists are expressing their concern around resource issues: a) will real resources be committed to this effort, and b) will funding or personnel be redirected from current treatment and prevention activities? Unfortunately, the timing of the Morgan State speech coincided with the Administration not requesting additional funds for AIDS drug assistance programs, and not placing AIDS funds in the "protected" category during the Budget discussions.

Consequently, the AIDS community feels that it is getting a mixed message. In their view, the Administration is focusing its efforts and dollars on a new initiative for vaccine development while at the same time de-prioritizing AIDS funding and underfunding treatment.

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Foundations and Industry The Rockefeller Foundation has taken the lead in coordinating an international project known as the International AIDS Vaccine Initiative (IAVI). They strongly support Presidential leadership in this arena, and are anxious to participate in an international effort. UNAIDS, based in the World Health Organization in Geneva, has pledged to work with you to make this effort a success, and are delighted with your leadership. They are writing an op-ed piece to place in the Washington Post or NY Times.

The American Foundation for AIDS Research (AmFAR) in New York has put its support behind the initiative, as has the Albert Sabin Vaccine Foundation. Industry leaders, including those from Merck Pharmaceuticals, have been positive in their comments, but are waiting to see how this dialogue will evolve in the proposed White House meeting.

Next Steps

National Institutes of Health (NIH) Proposal The NIH has put forward more specifics around their proposed role in vaccine development. NIH has begun development of a Vaccine Research Center (VRC) as a joint venture of the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID). The VRC will begin incorporating a core group of NIH scientists with expertise in immunology, virology and vaccine research already on-site at NIH. The primary focus of VRC will be to stimulate multidisciplinary research from basic science through to vaccine design and production.

Initially the VRC will be a "laboratory without walls," while laboratory space is sought in the vicinity of the NIH campus to bring the scientists together. Later, as scientists are recruited from outside the NIH ranks, NIH will consider constructing new space on campus to house the VRC. The funding and support for the VRC will be jointly provided by NCI and NIAID. As you know, funds for AIDS research are allocated according to the plans developed by the Office of AIDS Research (OAR) with the NIH Institutes. The OAR has proposed \$17 million in FY 1998 for the VRC, bringing the overall NIH support to AIDS vaccines to \$150 million. A search committee will be named before the end of May to conduct a nationwide search for a scientist with specific expertise in vaccine development to serve as Director for the new VRC.

Plans to Address Community Concerns To demonstrate that this is a serious proposal, we have set up several meetings to provide information to the community and walk through their concerns. On Wednesday, Sandy Thurman will have a news briefing in her office with Dr. Harold Varmus, Director of the NIH, Dr. Bill Paul of the Office of AIDS Research, and Dr. Tony Fauci of NIAID to provide more details about NIH's plan for a vaccine research center. A follow-up meeting with the community will take place after the news briefing. Sandy has already met with most of the national AIDS organizations individually this week. We are also setting up a meeting next week for the community with OMB to explain FY'97 and FY'98

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budgetary issues and reaffirm the Administration's full and equal commitment to all of the AIDS programs -- prevention, research and care.

To continue in a consistent and positive direction, we will identify opportunities to reaffirm the breadth of the Administration's commitment to HIV/AIDS. By early June, the expert panel sponsored by HHS and Kaiser Family Foundation to develop model clinical practices for care of adult HIV infection will be ready to publish their recommendations in the Federal Register for public comment. This has been an anxiously awaited document, given the increasing complexity of HIV care with many new drug combinations and laboratory tests to monitor HIV disease. This is a clear demonstration of the Administration's commitment to translating research gains into improved care for all persons living with HIV. A White House roll-out could be orchestrated with both health care providers and community groups.

Many of the leading national AIDS organizations come together in Washington, DC on June 23, 1997 to kick off the HIV Testing Project -- an initiative to encourage people to voluntarily learn their HIV status so they can benefit from effective new treatments. This would be another opportunity to announce the expert panel recommendations to visibly cement your support for the spectrum of AIDS prevention and care issues in addition to active research and vaccine development components.

Sustaining Momentum on Vaccine Initiative The U.S. has proposed that the leaders of the eight major industrialized nations meeting at the Denver Summit in June agree to support a worldwide AIDS vaccine research initiative. The UNAIDS program and the International AIDS Vaccine Initiative (IAVI) are working with us to fashion a proposal acceptable to participating countries. Four countries have already contacted UNAIDS around what specifics could be developed. A few satellite meetings with the scientific and research communities could be put together in Denver to highlight this initiative. We are coordinating with Dan Tarullo of the NEC around the possibility of coordinating an announcement at the Summit.

In the next few months, a White House meeting to bring together vaccine development experts, government scientists, community leaders, and representatives of biotech and vaccine manufacturing companies can be put together. This would create an opportunity for you to deliver brief remarks, and for the Vice President to engage biotechnology and pharmaceutical industry partners in AIDS drug and vaccines development efforts.

We are working on a follow-up memo that will provide additional information, including plans relative to the June G8 Summit in Denver.



May 20, 1997

The Honorable Bill Clinton
 President of the United States
 The White House
 1600 Pennsylvania Avenue, N.W.
 Washington, D.C. 20515

Dear Mr. President:

On behalf of the 1,400 community-based organizations AIDS Action Council represents, I would like to take this opportunity to applaud your call this past Sunday, May 18, to make the development of an AIDS vaccine a "new national goal for science." By likening your challenge to find an AIDS vaccine within the next decade to President John F. Kennedy's call to put an American on the moon, you have reminded the country, indeed, the world, that much remains to be done before this terrible epidemic is truly over.

Mr. President, AIDS Action Council recognizes your leadership in the fight against this dread disease. Sixteen years into the AIDS epidemic, the AIDS community is enjoying the new hope that promising AIDS drug therapies represent. Thousands of people living with HIV and AIDS are benefiting from state-of-the-art care, which has contributed to an historic decline in AIDS deaths in the United States. History will record these two advancements, as well as your AIDS vaccine announcement last Sunday, as a part of your legacy on AIDS.

AIDS Action Council urges you to expand that legacy by continuing to make funding for AIDS research, care, prevention, and housing a budgetary priority in fiscal year 1998 and beyond. Research to find more effective treatments, a vaccine, and a cure must continue to be a priority. All Americans living with HIV and AIDS must have access to the health care and the social services they need to stay alive and healthy. Every weapon at our disposal, including needle exchange programs, must be put to good use to curb the further spread of HIV. And no individual living with HIV disease should want for adequate, stable housing. AIDS Action Council is anxious to work with you to ensure that this era of hope - raised to a new level by your call to re-energize our nation's search for an AIDS vaccine - touches the life of every American living with, and affected by, HIV and AIDS.

Best Regards,

A handwritten signature in black ink that reads "Daniel Zingale". The signature is written in a cursive, flowing style.

Daniel Zingale
 Executive Director

cc The Honorable Donna Shalala
 Sandra Thurman, Director, Office of National AIDS Policy

1875

Connecticut Ave NW

Suite 700

Washington DC

20009

Fax 202 986 1345

Tel 202 986 1300



NAPWA

**NATIONAL
ASSOCIATION
OF PEOPLE
WITH AIDS**

May 21, 1997

The President
The White House
Washington, DC 20500

Dear Mr. President:

I am writing on behalf of the National Association of People with AIDS (NAPWA), to commend you on the announcement of a rational initiative to develop a protective vaccine against the Human Immunodeficiency Virus (HIV) in the next ten years. NAPWA salutes your commitment to making this a serious national priority.

As the national voice of people living with HIV, NAPWA represents the needs of countless thousands of Americans who face the day-to-day challenges of living with HIV disease. We remain committed to working for a cure for AIDS. We have never strayed from our responsibility, however, to promote and support effective HIV prevention and education. For millions of people at-risk for HIV infection across the globe, the simple knowledge that the greatest nation on earth will lead the effort to develop a preventive vaccine is very powerful.

We applaud your leadership and the leadership of Vice President Gore. In announcing this initiative, NAPWA strongly urges you to renew your commitment to maintaining and expanding HIV/AIDS Housing, Prevention, Research, Medicaid and Medicare and CARE Act services.

Sincerely,

A. Cornelius Baker

A. Cornelius Baker
Executive Director



UNAIDS
 (UNICEF • UNDP • UNFPA)
 UNESCO • WHO • WORLD BANK

The Executive Director

Joint United Nations Programme on HIV/AIDS

Reference: ext

President William J. Clinton
 The White House
 Washington, D.C.

20 May 1997

Mr President,

Your extraordinary leadership in setting the goal for the development of an AIDS vaccine in the next ten years merits sincere praise. For too long, the research agenda has been turned on its head, with ninety percent of research funds in AIDS going towards cures and only ten percent to vaccines. Important as the new developments in therapy are in reducing the suffering and prolonging lives of people living with HIV/AIDS in the few countries where treatment is possible and affordable, they are doing nothing to halt the relentless march of this disease in Africa, Asia, Latin America and Eastern Europe.

For a vaccine to be brought to the parts of the world where the disease is having its greatest impact, the countries of the industrialized world and the developing world will need to work closely together. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has a Vaccine Advisory Committee, which is chaired by Dr Barry Bloom of the Albert Einstein College of Medicine in New York, and includes representatives from several industrialized and developing countries. UNAIDS and its Committee have as their mission to promote and facilitate the scientific, ethical, legal, and practical involvement of developing countries in vaccine research and testing.

Mr President, we pledge UNAIDS to work with you, Secretary Shalala, the National Institutes of Health and other U.S. institutions in the forefront of this crusade against AIDS. A vaccine which effectively addresses a virus which is devastating the world, must be tested and proven in the most affected countries in accordance with the highest standards of science and ethics.

Again, Mr President, I should like to congratulate you for your bold step forward. By directing the scientific community to leap beyond the tested borders of biology in the 21st century, you do much to ensure your own place in the history of our planet.

Please accept, Mr President, the assurance of my highest consideration.

Peter Piot



May 19, 1997

The Honorable William Jefferson Clinton
President
The White House
Washington, DC 20510

Dear Mr. President:

The Cities Advocating Emergency AIDS Relief (CAEAR) Coalition commends you on the announcement of a ten year federal initiative to develop a vaccine for the Human Immunodeficiency Virus (HIV). We salute your use of the Presidency to keep issues related to the worldwide AIDS pandemic at the forefront.

The CAEAR Coalition represents the federal policy and appropriations interests of the 49 U.S. epicenters of the AIDS epidemic that receive funding through Title I of the Ryan White CARE Act. We are people living with HIV and AIDS, medical providers, support service providers, and health planners who are on the front lines of the U.S. AIDS epidemic. We acknowledge the importance of a targeted initiative for vaccine development and recognize that a vaccine is critical to preventing new infections in youth and adults at risk for infection. We trust that the leadership of the United States in this initiative will have a ripple effect in governments and communities around the world--encouraging them to increase their efforts to end this devastating pandemic.

As consumers and providers of CARE services for people living with HIV, we ask that you continue to use the Presidency as a bully pulpit to keep the issues of people living with HIV in the hearts and minds of the American people. CARE programs will continue to need significant increases in support from the federal government as more people live longer with HIV disease. Medical care, housing, substance use treatment, mental health treatment, transportation, nutrition, and of course new antiretroviral drug therapies continue to be critical to the quality of life and survival of people living with HIV. Your ongoing support for increased funding for CARE programs is paramount to our success in filling these needs.

Thank you for your leadership and the leadership of Vice President Gore. We encourage you to continue to clearly articulate your commitment to ending this epidemic while caring for those living with HIV. The CAEAR Coalition looks forward to working with you to realize the goal of this laudable initiative.

The CAEAR Coalition
1413 K Street N.W., Suite 700
Washington, D.C. 20005

202 789 3565
202 789 4277 fax

Executive Committee

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Suzi Rodriguez, *Vice Chair*
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Kathy Cerra, *At-Large*
Luanna Clark, *At-Large*

**Administrator of
Federal Affairs**
H. Alexander Robinson

**Governmental Relations
Representative**
The Sheridan Group

MEMORANDUM

June 2, 1997

TO: Bruce, Elena

FR: Chris and Sarah

RE: POTUS Investments in AIDS Prevention and Treatment

CC: Nancy-Ann

Attached is a one-pager that we are giving to the AIDS office to use to counter criticisms that we have received from some AIDS activists (although most have been supportive) and a few editorial writers that the President's commitment to developing an AIDS vaccine undermines investments in other areas of AIDS funding. As you will note, the President has consistently increased funding for most AIDS treatment and prevention programs and these commitments are in no way undermined by the President's call for the development of an AIDS vaccine in the next decade.

We have also attached a list of quotes both from the scientific community and the AIDS community supporting the President's call to develop an AIDS vaccine. To highlight support for this initiative, we are also working with Eric to have UNAIDS submit an editorial to *The Washington Post* on the importance of developing a vaccine.

In addition, we are currently working with the AIDS office on a memo to the President describing the status of all of the Administration's initiatives on AIDS, including the AIDS vaccine initiative, pediatric labeling, as well as the Gore Medicaid Demo (which, as you may know, was the subject of Robert Pear's Sunday *New York Times* piece). HCFA is scheduled to give their report to the Vice President early next week. From initial reports at HHS, it does not appear that this proposal will be able to be offered as a budget neutral Medicaid waiver as originally proposed, as HCFA estimates that this proposal would definitely have costs associated with it. We are working with Nancy-Ann on this issue and plan to meet with the Vice President's staff later this week to discuss possible responses to the HCFA analysis.

We hope you find this information helpful. We will keep you up to date as this moves forward. Please call with any questions or comments.

President Clinton's Challenge to Develop an AIDS Vaccine Does Not Undermine But Rather Builds on His Strong Record on AIDS Research, Treatment, and Prevention

President Clinton's announcement to increase efforts to develop an AIDS vaccine in no way undermines his commitment to funding AIDS prevention and treatment. Developing a successful vaccine is the only way to stop this epidemic that is killing millions of people around the world each year. The President believes that we also must increase our commitment to investing in treatment for people with HIV/AIDS and improve our prevention efforts. Since he took office, funding for all AIDS investments has increased in research, treatment, and prevention each year. Since President Clinton took office, he has:

- **Increased Ryan White by 168 percent.** The President's FY 1998 Budget proposes to spend \$1 billion on Ryan White, an 168 percent increase over the FY 1993 Budget, to help our hardest hit cities, States, and local clinics provide medical and support services for people with AIDS.
- **Accelerated Federal Medicaid spending on HIV/AIDS.** Federal Medicaid spending on AIDS/HIV treatment has increased 53 percent since FY 1993, spending \$2 billion in FY 1997. At least 50 percent of people with AIDS and more than 90 percent of children with AIDS are covered by Medicaid, making Medicaid the largest single payor of direct medical services for people living with AIDS. Currently, approximately 100,000 Medicaid beneficiaries are HIV positive.
- **Increased funding for State AIDS Drug Assistance Programs (ADAP).** As soon as the Food and Drug Administration began approving Protease Inhibitors in early 1996, the Administration proposed two budget amendments -- \$52 million in FY 1996 and \$65 million in FY 1997 -- to increase funding for ADAP which provides access to medicine for people with HIV who are not covered by Medicaid but do not have access to private health care coverage. The President's FY 1998 budget proposes \$167 million for ADAP.
- **Ensured that Medicaid covers Protease Inhibitors.** Under the President's leadership, the Health Care Financing Administration has advised all States that they are required to cover Protease Inhibitors and encouraged them to ensure that appropriate nutritional services are provided to persons living with HIV/AIDS.
- **Doubled funding for Housing for People with AIDS.** Without stable housing a person living with HIV has diminished access to care and services. It is estimated that up to 50 percent of people living with HIV and AIDS are or will be at risk of becoming homeless during the course of their illness. The President has proposed \$200 million for HOPWA, more than 100 percent of what was spent in FY 1993.
- **Increased commitment to CDC prevention programs by 27 percent.** The President's FY 1998 Budget proposes \$634 million for CDC prevention efforts, a 27 percent increase over the FY 1993 Budget. CDC works with states and communities to provide the information and tools needed to design and implement effective local prevention programs.

**QUOTES SUPPORTING THE PRESIDENT'S CHALLENGE FOR AMERICA TO
DEVELOP AN AIDS VACCINE WITHIN TEN YEARS**

"AIDS Action Council is anxious to work with you to ensure that this era of hope--raised to a new level by your call to re-energize our nation's search for an AIDS vaccine--touches the life of every American living with, and affected by, HIV and AIDS."

-- AIDS Action Council 5/20/97

"The International AIDS epidemic will only be overcome by the development of an effective HIV vaccine, and American science has a critical role to play in developing one. But this vaccine can be made only if the scientific community receives strong support from the federal government to overcome the very real obstacles that will exist for years to come. The President's intellectual endorsement of our efforts is very welcome."

-- David D. Ho, M.D.

"For millions of people at-risk for HIV infection across the globe, the simple knowledge that the greatest nation on earth will lead the effort to develop a preventive vaccine is very powerful."

-- National Association of People With AIDS 5/21/97

"Your extraordinary leadership in setting the goal for the development of an AIDS vaccine in the next ten years merits sincere praise. Mr. President, we pledge UNAIDS to work with you...in the forefront of this crusade against AIDS."

-- UNAIDS 5/20/97

"I am absolutely convinced that we will have a vaccine (for AIDS) that is safe and effective."

-- Dr. Anthony Fauci, National Institute of Health 5/19/97

"It's like polio in the iron lung days. People were overjoyed to have the iron lungs, but that was no way to live if you had the opportunity to be protected. So protection is the right response."

-- David Baltimore, chairman of the NIH Vaccine Commission 5/19/97

"I like the idea of setting a goal."

-- Robert C. Gallo, co-discoverer of HIV 5/19/97

"We salute your use of the Presidency to keep issues related to the worldwide AIDS pandemic at the forefront...We acknowledge the importance of a targeted initiative for vaccine development and recognize that a vaccine is critical to preventing new infections in youth and adults at risk for infection."

-- Cities Advocating Emergency AIDS Relief 5/19/97

"The IAVI strongly supports your call for an urgent increased and time-bound effort to develop safe and effective HIV vaccines. We also applaud your plans to call for the leaders of the G-7 countries and Russia to join the U.S. in a global effort to create a vaccine."

-- International AIDS Vaccine Initiative 5/19/97

"There are still many unexplored or only partly explored avenues of research that could lead to an effective vaccine within a few years...Our planned research institute will be eager to participate with the U.S. government in its effort to speed up the development of an AIDS vaccine."

-- Luc Montagnier, discoverer of the virus that causes AIDS and head of the Swiss-based World Foundation for AIDS Research

"Mr. President, AMFAR strongly supports your goal to develop a successful vaccine for the prevention of HIV infection by the year 2007. We believe that this is a realistic goal...AMFAR will provide grant support for selected promising research projects...We hope to join with the federal government in further increasing our financial commitment until, like smallpox and polio, HIV infection is brought under full control throughout the world."

-- The American Foundation for AIDS Research (AMFAR)

Varmus Meeting With NIH Advisory Council to Discuss AIDS Vaccine Status

- Today, Dr. Varmus will meet with the NIH Advisory Council to discuss the status of the new AIDS Vaccine initiative. He will particularly focus on the establishment of the NIH Vaccine Research Center (VRC) and the new funds dedicated to the new vaccine research effort.
- The Vaccine Research Center, a joint venture between the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID), will incorporate a core of NIH scientists with expertise in immunology, virology, and HIV vaccine research.
- Physical, financial, and human resources for the VRC will be funded by NCI and NIAID. Funds for AIDS research will be allocated by the Office of AIDS Research, which has dedicated \$10 million for the VRC in FY 1998. (The total proposed for the AIDS vaccine is \$150 million, a 33 percent increase in the last two years).
- A special search committee will be named shortly to identify a director for the new center. It will be a scientist with expertise in vaccine development.
- Dr. Varmus will announce where the building will be housed within the NIH campus. He will also announce his desire to construct a new building at NIH to house all of the scientists who are coming together to focus on the vaccine. (However, this may require congressional approval and he cannot make a firm commitment at this time).

Background

- More than 29 million men, women, and children around the world have been infected with HIV. More than 3 million of those infections have occurred in the last year, with 95 percent in the poorest parts of the world. AIDS is also the leading cause of death for people ages 29-45 in the United States. Even countries like the United States where new treatments have recently become available desperately need an AIDS vaccine, as these treatments can never reach and help all of the people suffering from this disease.

Other Initiatives on the Vaccine

- The VRC is only one aspect of the vaccine development challenge issued by the President at Morgan State. The President also announced that at the G-7 summit in Denver in June, he will enlist other nations to join the U.S. in a worldwide effort to develop an AIDS vaccine. Dr. Varmus has already contacted his counterparts in these nations to elicit their support for this effort and the response has been very positive. There is also explicit language in the Communique which discusses the importance of this commitment.
- NIH and other Administration officials are also working to meet the President's challenge to find ways to increase the pharmaceutical industry's investment in developing an AIDS vaccine. There have been discussions a possible meeting with industry officials and the President or Vice President that would potentially be followed by a series of meetings to address how to overcome obstacles to developing a vaccine.

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AIDS-vaccine

Joint United Nations Programme on HIV/AIDS

FAX TRANSMISSION

6/2/97

9:56 AM

TO: Eric Goosby

FAX: 202-690-7560

FROM: Lisa Jacobs tel.: (212) 880-5325

PAGES: 4 (including cover sheet)

Job Number 1604-02

MESSAGE

Per the request of Sally Cowal at UNAIDS, attached please find an op-ed by Dr. Peter Piot, for submission to the *Washington Post*. The essay applauds President Clinton's call for an AIDS vaccine within 10 years, and discusses strategies to achieve that goal.

Please call me at 212-880-5325 when you receive this. If you have any questions or need additional information, you can contact me directly.



UNAIDS

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Joint United Nations Programme on HIV/AIDS

COMMITMENT IS THE FIRST, CRUCIAL STEP TOWARD AN AIDS VACCINE

by Peter Piot, M.D., Ph.D.

Executive Director, Joint United Nations Programme on HIV/AIDS (UNAIDS)

During a recent visit to a health clinic in a city in Sub-Saharan Africa, I was approached by a young woman with two small children. She told me she had been infected with HIV by her late husband, and though her children were not infected, she worried about their future.

"What is happening with the AIDS vaccine?" she asked me. Unfortunately, there wasn't much to report. The woman frowned. "Don't come back with more of your speeches," she said, grabbing the hands of her children. "Come back when you have a vaccine."

For most people in the industrialized world, it is difficult to grasp the overwhelming impact of AIDS felt by many developing countries. There are African cities where one in three young adults are infected with HIV, and hospitals where 70% of their beds are occupied by patients with AIDS. India today has more people with HIV infection than any country in the world, and most of those infections occurred in just the past two years. The epidemic extends far beyond those infected; Uganda, with a population of just over 20 million, already has 1.2 million AIDS orphans. Last year, more than 1.5 million people died of AIDS in the world, and the death rate continues to accelerate.

AIDS has been an unprecedented reversal of human health progress. This disease has not only drained health services in these countries, the loss of so many young adults -- the backbone of the workforce -- is further obstructing Africa's struggle toward economic development. And AIDS is sure to threaten the developing economies of Asia and Latin America, where the epidemic looks as if it will follow the same rapid path it has taken in Africa. Unless we find a vaccine.

President Clinton's public call for an AIDS vaccine within ten years is a hopeful message for people around the world -- in both industrialized and developing countries. As a leader in medical research, the U.S. stands poised to lead the way toward an AIDS vaccine. The recent advances in anti-HIV treatment AIDS

AIDS Vaccine / Page 2

demonstrates the power of science and political will. An organized community exerted pressure on decision makers to find drugs that would help those afflicted. The same has not happened for vaccine research.

Furthermore, the pharmaceutical industry invested billions in AIDS drug development, recognizing their economic potential. The prospect for profits from AIDS vaccine research is not as clear. Governments should therefore develop financial incentives for private industry to ensure that AIDS vaccine research can

be an economically viable undertaking. In addition, measures are needed to remove potential legal and regulatory obstacles that discourage companies from engaging in vaccine research.

Aside from the political and economic hurdles, there are many scientific uncertainties. HIV is perhaps the most cunning virus we have ever encountered; it remains to be seen whether our immune systems could ever be equipped to evade infection. The difficulties in conducting large-scale HIV vaccine trials cannot be overstated. The search will only be productive through a combination of leadership and scientific capacity.

While more basic scientific research should be conducted to better understand the fight between HIV and our immune system, more money needs to be allocated to directed, applied vaccine development. With 8,500 people becoming infected every day, we cannot sit passively and wait for the good ideas to come; we need to seize promising candidates and enlist research institutions to proceed with human trials in both developed and developing countries. We must test different types of vaccines at the same time, not one after the other. Perhaps the first vaccines will not be very effective, but we will learn from these trials to improve the next generation of vaccines.

Look to the past: Most vaccines available today were developed through a combination of basic scientific knowledge and thoughtful experimentation. And the fact that we have been able to control HIV in the body at all is a monumental victory.

AIDS Vaccine / Page 3

UNAIDS recognizes the importance of President Clinton's declaration and pledges to work with him on this difficult challenge. As a consortium of six UN agencies, UNAIDS is uniquely placed to assure that the vaccine effort is global, and includes participation of developing countries.

We are already developing partnerships between the research community and the public and private sectors to encourage vaccine development, and are AIDS

preparing to assist developing countries in conducting human vaccine trials with the highest scientific and ethical standards. And when an effective vaccine is discovered, UNAIDS will work by creating private/public partnerships to make it available in the countries around the world where today there is no hope.

It is tragic that combination drug therapy is not available to many people with HIV/AIDS in the U.S. and in Europe, much less in developing countries. And for people fortunate enough to have access to the drugs, the demanding regimen is far from ideal. New, better, more accessible treatments are needed. But anti-

HIV drugs will never eradicate HIV from the the planet. A vaccine is our best possible hope.

I have a vision: A vibrant manufacturing sector in downtown Kampala, Uganda returns to its traditional activity of making furniture, after more than a decade of only making coffins.



Sherman G. Boone
05/28/97 10:57:11 AM

Record Type: Record

To: Christopher C. Jennings/OPD/EOP, Sandra Thurman/OPD/EOP
cc: Elena Kagan/OPD/EOP, Elizabeth Drye/OPD/EOP
Subject: Denver Summit Communique re: AIDS Vaccine

Elizabeth Drye suggested that you should be seeing proposed Denver Summit Communique language re: the AIDS Vaccine. I am forwarding the relevant paragraphs from the current draft on AIDS, as well as those on infectious disease and on children's environmental health issues. Language in brackets, for the most part, includes reference to the country proposing the revision.

Regarding process, I have been coordinating primarily with HHS on AIDS, OSTP on infectious diseases, and EPA on children's health. Our office will be receiving comments from various Summit countries on the current draft today and tomorrow, and will be turning around a revised draft over the week-end. Materials for the President's briefing book are due to us from various agencies on Monday.

Please let me know if you would like to be included on Denver Summit distribution list(s); ideally, however, you should already be providing policy guidance through the inter-agency clearance process.

....

Children's Environmental Health

Protecting the health of our children is a shared fundamental value. Children throughout the world face significant threats to their health from an array of environmental hazards, and we recognize particular vulnerabilities of children to environmental threats[, including impacts of global climate change]. Together, our governments will explicitly incorporate children into work to improve science and risk assessments, strengthen information exchange, and provide for microbiologically safe drinking water.

....

Infectious Diseases

Infectious diseases, such as drug-resistant tuberculosis, malaria, and HIV/AIDS [F: are responsible for a third of all deaths from disease in the world], pose significant challenges to the health, security, and financial resources of the global community. In many parts of the world, infectious diseases and deaths from infectious disease have risen sharply in the last decade for a variety of reasons, including the emergence of drug-resistant microbes and the increased movement of people and products. In the coming year, our governments will promote more effective coordination of international responses to outbreaks; promote development of a

global surveillance network, [UK: building on existing regional surveillance systems]; strengthen research; and help to build medical and institutional capacity to prevent, detect and control infectious diseases globally. [F alternative: In the coming year, our governments will enhance scientific research in view of better control of infectious diseases; promote the coordination of existing efforts to develop a global surveillance network; improve the international response to outbreaks; and help to build medical and institutional capacities, including availability of international standard products to prevent, detect and control infectious diseases globally.] Central to this work will be strengthening and linking existing activities in and among each of our countries, and in other fora, especially the World Health Organization (WHO).

[EC: While insisting on prevention and promoting new treatment of AIDS for the benefit of the greatest number, developing ...] Developing a safe and effective vaccine against AIDS holds the best chance of limiting, and eventually eliminating, the threat of this disease. This remains an urgent global public health imperative. We will [work to] provide the investments necessary to accelerate AIDS vaccine research, and together will enhance international scientific cooperation and collaboration. Cooperation among scientists, governments in the developed and developing world, and international agencies will be critical. We call on other states to join us in this endeavor.

The Joint United Nations Program on HIV/AIDS (UNAIDS) must help expand the scale and quality of the response to HIV/AIDS. As a group and with others, we will work to assure that it has resources adequate to fulfill its mandate.

AIDS Vaccine Using Nasal Spray Shows Promise

Inoculated Chimps Resist Infection a Year Later, but Costs May Stall Additional Testing

By Rick Weiss
Washington Post Staff Writer

Chimpanzees inoculated with an experimental AIDS vaccine have successfully fought off repeated exposures to the AIDS virus up to a year after they were vaccinated, a research team reported yesterday.

The novel vaccine, which consists of a series of nasal sprays followed weeks later by a booster shot in the arm, is the latest addition to a small but growing arsenal of experimental AIDS vaccines showing early signs of promise after many years of mostly disappointing results.

Scientists cautioned that other vaccines have looked similarly effective in chimpanzees, only to fail in human clinical trials. But researchers said they were encouraged by the strength of the immune response triggered by this vaccine, and especially impressed with its ability to confer protection so long after vaccination.

In previous tests of AIDS vaccines, chimps or monkeys have been exposed to the AIDS virus, HIV, soon after they were vaccinated—an unrealistic scenario. The new vaccine worked even when chimps were challenged with a big HIV dose 50 weeks after they were vaccinated—longer than has worked in any other study.

Unfortunately, several researchers said, the company that helped develop the vaccine—Wyeth-Ayerst Research of Radnor, Penn.—has, like other

vaccine developers, been questioning the cost-effectiveness of ushering its vaccine through the expensive and time-consuming labyrinth of clinical trials and regulatory approval. Key Wyeth scientists who spearheaded the work have been removed from the project, leaving its future uncertain.

Given the latest chimpanzee results and President Clinton's recent call for a renewed national commitment to developing an AIDS vaccine within the next decade, however, scientists said they hoped the company would reconsider financing the necessary work that could lead to early safety tests in human volunteers.

"There is no doubt that a good percent of the pharmaceutical industry, for reasons that are in part understandable and obvious, have become in recent years less interested in financing development of an AIDS vaccine," said Robert C. Gallo of the Institute of Human Virology in Baltimore, who co-discovered HIV and was involved in the latest chimpanzee studies. "It's possible, and we hope it's true, that these and other recent promising findings will renew their interest."

Representatives for Wyeth-Ayerst did not return phone calls this week-end. But study leader Marjorie Robert-Guroff, of the National Cancer Institute, said the possibility of working toward a small safety trial in people was "under discussion."

The new vaccine was made from

an adenovirus—a kind of virus that can cause colds in people—that was genetically engineered to contain an extra gene called gp160, normally found only in HIV. When sprayed into the nasal passages of chimps, the modified virus settled into the animals' upper respiratory tracts and intestines.

During the next week or so, the viruses multiplied in the chimps' mucous membranes, and spewed out gp160 proteins. As predicted, the chimps' immune systems responded to the HIV proteins by making antibodies and white blood cells programmed to attack HIV.

The researchers boosted that protective immune response by giving the chimps a shot in the arm containing laboratory-made versions of a different HIV protein, gp120. More than 11 months later, they subjected the chimps to intravenous infusions of HIV.

Robert-Guroff and her colleagues reported in the June issue of *Nature Medicine*, released yesterday, that unvaccinated chimps became infected with the deadly virus within a month, but vaccinated chimps remained healthy and apparently uninfected until the study ended, almost a year later.

Adenovirus-based vaccines have a potential advantage over other kinds of AIDS vaccines because adenoviruses can stimulate a potent immune system response in mucous membranes, including the urinary tract, and vagi-

nal and rectal tissues. "We'd like to induce mucosal immunity," Robert-Guroff said, "because worldwide, transmission of HIV is predominantly across mucosal barriers" through intercourse, rather than by intravenous infection.

The new report does not specifically reveal whether mucosal antibodies were generated in the chimps, but the U.S. military has given soldiers oral adenovirus vaccines for years to protect against upper respiratory tract infections, generating mucosal immunity and very few complications.

Nonetheless, researchers warned, any AIDS vaccine made from a live virus that is capable of causing disease in people, as adenoviruses can, will have to be tested carefully for safety. Several said they hoped that will happen soon.

"Eight thousand people a day and 3 million a year are being infected with HIV despite all the education and counseling, so most experts believe that to get control worldwide we are going to need a safe, affordable and effective vaccine," said Mark Mulligan, director of the HIV vaccine evaluation unit at the University of Alabama at Birmingham.

"This vaccine is an encouraging step in the pathway to getting there," Mulligan said. "My feeling is that adenovaccines should be given serious review for advancing into small, Phase 1 human trials where their safety and human immune response can be evaluated."

MONDAY, JUNE 2, 1997
The Washington Post

AIDS - AIDS Vaccine

Unwelfare Reform?

By Mike Causey
Washington Post Staff Writer

Federal officials are confident that the government can absorb 10,000 new workers from the welfare rolls without disrupting regular personnel operations and office routines or harming the quality of government work. Even members of Congress who often are skeptical of social engineering programs, especially in government, express little concern that this effort will do any harm.

But some rank-and-file federal workers, not to mention ex-feds who were downsized into the unemployment ranks, are less than happy about the White House's welfare-to-work program.

The program will hardly be noticeable in most federal agencies. The Census Bureau will take the largest number of the welfare-to-work hires (about 40 percent of the total hires), with the Defense Department hiring most of the rest.

Most of the new hires will go into temporary jobs outside the regular civil service system. They will do basic office work and will be paid at Grade 1, or about \$13,500 a year. Agencies also expect that they will have to provide low- or no-cost day care and transit subsidies.

Career officials in several agencies say they have been instructed to be upbeat about the plan, which is supposed to prompt private industry to hire many thousands more from the welfare rolls. The idea is to get some people off welfare and pay them while they pick up basic office skills and develop work habits that could lead to full-time jobs in private industry. It is yet to be determined how many welfare recipients—if any—will be hired by officials who developed the program.

Some personnel officials say they are concerned that the welfare hires will require excessive supervision and mentoring.

But although bosses are reluctant to go public on the practical implications of the welfare-to-work program, some

rank-and-file employees are more upfront. This is what some readers have to say on the subject:

■ "I've been reading about the welfare-to-work program, and I'm curious about a couple of things. In your May 14 column you say that government agencies have been told by the White House to hire 10,000 people off the welfare rolls. . . . What nobody says is what, if anything, the government plans to do about people, like me, who were laid off last year because of downsizing.

" . . . Are our leaders now advocating a program of welfare rotation? That is, first you have a federal job. Then you get laid off because of downsizing. Then you go on the welfare rolls. Then you get hired for a federal job. Is that the way this is supposed to work? I'm curious."

Cassandra Hall

■ "Has anybody else noticed that the welfare-to-work program, at least as it applies to the federal government, doesn't make much sense? The last time I checked there were about 6,000 former federal civil servants drawing state unemployment benefits. President Clinton says that U.S. government agencies are to hire 10,000 people, who are welfare recipients. Does that mean the 6,000 who were fired who are still drawing unemployment will be taken off unemployment and put into federal jobs paying \$13,000 to \$15,000 a year? I originally planned to ask you for the name of the person who is in charge of this program. But after careful consideration, I will not pose the question because obviously nobody is in charge of this baby. For purposes of job security, just identify me with the initials: B.S."

■ "Is it now a requirement for federal employment that the person receiving a federal appointment must be someone who had a federal government job, lost it because of a reduction-in-force and was forced to go on welfare [and] then qualified for a federal job?"

Frosty Williams

Monday, June 2, 1997

The Washington Post

MONDAY, JUNE 2, 1997

AIDS - AIDS vaccine

DRAFT -- DRAFT -- DRAFT -- DRAFT -- DRAFT -- DRAFT -- DRAFT

MEMORANDUM FOR THE PRESIDENT

FROM: Bruce Reed, Assistant to the President for Domestic Policy
Chris Jennings, Deputy Assistant to the President for Health Policy
Sandra Thurman, National AIDS Policy Coordinator

SUBJECT: AIDS Vaccine Initiative - Next Steps

This memorandum will summarize the broad response to the announcement of your commitment to developing an AIDS vaccine, and lay out a strategy to sustain momentum and solidify support for this initiative.

Response to Announcement

There has been broad-based and enthusiastic appreciation for your commitment to developing an AIDS vaccine. The Morgan State speech positively showcased your leadership and willingness to take on a critical research task with vital domestic and international implications. Prior to the announcement, we contacted major constituency groups and several industry leaders to ensure their support for this initiative. Attached are several comments that have been received.

AIDS Groups You have received a great response from the vast majority of national AIDS organizations. The AIDS Action Council, based in Washington and representing 1,400 community-based organizations (CBOs) across the country, and the National Association of People with AIDS have both written strong letters of support. The San Francisco AIDS Foundation, one of the largest CBOs in the country, and the Center for AIDS Prevention Studies, the leader in the prevention arena, continue to provide good comments for the media. The CAEAR Coalition, representing the 49 major cities receiving Ryan White CARE Act funding, are praising this initiative. Additional verbal and written responses are equally positive.

Some community groups and activists are expressing their concern around resource issues: a) will real resources be committed to this effort, and b) will funding or personnel be redirected from current treatment and prevention activities? Unfortunately, the timing of the Morgan State speech coincided with the Administration not requesting additional funds for AIDS drug assistance programs, and not placing AIDS funds in the "protected" category during the Budget discussions.

Consequently, the AIDS community feels that it is getting a mixed message. In their view, the Administration is focusing its efforts and dollars on a new initiative for vaccine development while at the same time de-prioritizing AIDS funding and underfunding treatment.

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Page 2 - The President

Foundations and Industry The Rockefeller Foundation has taken the lead in coordinating an international project known as the International AIDS Vaccine Initiative (IAVI). They strongly support Presidential leadership in this arena, and are anxious to participate in an international effort. UNAIDS, based in the World Health Organization in Geneva, has pledged to work with you to make this effort a success, and are delighted with your leadership. They are writing an op-ed piece to place in the Washington Post or NY Times.

The American Foundation for AIDS Research (AmFAR) in New York has put its support behind the initiative, as has the Albert Sabin Vaccine Foundation. Industry leaders, including those from Merck Pharmaceuticals, have been positive in their comments, but are waiting to see how this dialogue will evolve in the proposed White House meeting.

Next Steps

National Institutes of Health (NIH) Proposal The NIH has put forward more specifics around their proposed role in vaccine development. NIH has begun development of a Vaccine Research Center (VRC) as a joint venture of the National Cancer Institute (NCI) and the National Institute of Allergy and Infectious Diseases (NIAID). The VRC will begin incorporating a core group of NIH scientists with expertise in immunology, virology and vaccine research already on-site at NIH. The primary focus of VRC will be to stimulate multidisciplinary research from basic science through to vaccine design and production.

Initially the VRC will be a "laboratory without walls," while laboratory space is sought in the vicinity of the NIH campus to bring the scientists together. Later, as scientists are recruited from outside the NIH ranks, NIH will consider constructing new space on campus to house the VRC. The funding and support for the VRC will be jointly provided by NCI and NIAID. As you know, funds for AIDS research are allocated according to the plans developed by the Office of AIDS Research (OAR) with the NIH Institutes. The OAR has proposed \$17 million in FY 1998 for the VRC, bringing the overall NIH support to AIDS vaccines to \$150 million. A search committee will be named before the end of May to conduct a nationwide search for a scientist with specific expertise in vaccine development to serve as Director for the new VRC.

Plans to Address Community Concerns To demonstrate that this is a serious proposal, we have set up several meetings to provide information to the community and walk through their concerns. On Wednesday, Sandy Thurman will have a news briefing in her office with Dr. Harold Varmus, Director of the NIH, Dr. Bill Paul of the Office of AIDS Research, and Dr. Tony Fauci of NIAID to provide more details about NIH's plan for a vaccine research center. A follow-up meeting with the community will take place after the news briefing. Sandy has already met with most of the national AIDS organizations individually this week. We are also setting up a meeting next week for the community with OMB to explain FY'97 and FY'98

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Page 3 - The President

budgetary issues and reaffirm the Administration's full and equal commitment to all of the AIDS programs -- prevention, research and care.

To continue in a consistent and positive direction, we will identify opportunities to reaffirm the breadth of the Administration's commitment to HIV/AIDS. By early June, the expert panel sponsored by HHS and Kaiser Family Foundation to develop model clinical practices for care of adult HIV infection will be ready to publish their recommendations in the Federal Register for public comment. This has been an anxiously awaited document, given the increasing complexity of HIV care with many new drug combinations and laboratory tests to monitor HIV disease. This is a clear demonstration of the Administration's commitment to translating research gains into improved care for all persons living with HIV. A White House roll-out could be orchestrated with both health care providers and community groups.

Many of the leading national AIDS organizations come together in Washington, DC on June 23, 1997 to kick off the HIV Testing Project -- an initiative to encourage people to voluntarily learn their HIV status so they can benefit from effective new treatments. This would be another opportunity to announce the expert panel recommendations to visibly cement your support for the spectrum of AIDS prevention and care issues in addition to active research and vaccine development components;

Sustaining Momentum on Vaccine Initiative The U.S. has proposed that the leaders of the eight major industrialized nations meeting at the Denver Summit in June agree to support a worldwide AIDS vaccine research initiative. The UNAIDS program and the International AIDS Vaccine Initiative (IAVI) are working with us to fashion a proposal acceptable to participating countries. Four countries have already contacted UNAIDS around what specifics could be developed. A few satellite meetings with the scientific and research communities could be put together in Denver to highlight this initiative. We are coordinating with Dan Tarullo of the NEC around the possibility of coordinating an announcement at the Summit.

In the next few months, a White House meeting to bring together vaccine development experts, government scientists, community leaders, and representatives of biotech and vaccine manufacturing companies can be put together. This would create an opportunity for you to deliver brief remarks, and for the Vice President to engage biotechnology and pharmaceutical industry partners in AIDS drug and vaccines development efforts.

We are working on a follow-up memo that will provide additional information, including plans relative to the June G8 Summit in Denver.



May 20, 1997

The Honorable Bill Clinton
 President of the United States
 The White House
 1600 Pennsylvania Avenue, N.W.
 Washington, D.C. 20515

Dear Mr. President:

On behalf of the 1,400 community-based organizations AIDS Action Council represents, I would like to take this opportunity to applaud your call this past Sunday, May 18, to make the development of an AIDS vaccine a "new national goal for science." By likening your challenge to find an AIDS vaccine within the next decade to President John F. Kennedy's call to put an American on the moon, you have reminded the country, indeed, the world, that much remains to be done before this terrible epidemic is truly over.

Mr. President, AIDS Action Council recognizes your leadership in the fight against this dread disease. Sixteen years into the AIDS epidemic, the AIDS community is enjoying the new hope that promising AIDS drug therapies represent. Thousands of people living with HIV and AIDS are benefiting from state-of-the-art care, which has contributed to an historic decline in AIDS deaths in the United States. History will record these two advancements, as well as your AIDS vaccine announcement last Sunday, as a part of your legacy on AIDS.

AIDS Action Council urges you to expand that legacy by continuing to make funding for AIDS research, care, prevention, and housing a budgetary priority in fiscal year 1998 and beyond. Research to find more effective treatments, a vaccine, and a cure must continue to be a priority. All Americans living with HIV and AIDS must have access to the health care and the social services they need to stay alive and healthy. Every weapon at our disposal, including needle exchange programs, must be put to good use to curb the further spread of HIV. And no individual living with HIV disease should want for adequate, stable housing. AIDS Action Council is anxious to work with you to ensure that this era of hope - raised to a new level by your call to re-energize our nation's search for an AIDS vaccine - touches the life of every American living with, and affected by, HIV and AIDS.

Best Regards,

A handwritten signature in cursive script that reads "Daniel Zingale".

Daniel Zingale
 Executive Director

cc The Honorable Donna Shalala
 Sandra Thurman, Director, Office of National AIDS Policy

1875

Connecticut Ave NW

Suite 700

Washington DC

20009

Fax 202 986 1345

Tel 202 986 1300



NAPWA

**NATIONAL
ASSOCIATION
OF PEOPLE
WITH AIDS**

May 21, 1997

The President
The White House
Washington, DC 20500

Dear Mr. President:

I am writing on behalf of the National Association of People with AIDS (NAPWA), to commend you on the announcement of a national initiative to develop a protective vaccine against the Human Immunodeficiency Virus (HIV) in the next ten years. NAPWA salutes your commitment to making this a serious national priority.

As the national voice of people living with HIV, NAPWA represents the needs of countless thousands of Americans who face the day-to-day challenges of living with HIV disease. We remain committed to working for a cure for AIDS. We have never strayed from our responsibility, however, to promote and support effective HIV prevention and education. For millions of people at-risk for HIV infection across the globe, the simple knowledge that the greatest nation on earth will lead the effort to develop a preventive vaccine is very powerful.

We applaud your leadership and the leadership of Vice President Gore. In announcing this initiative, NAPWA strongly urges you to renew your commitment to maintaining and expanding HIV/AIDS Housing, Prevention, Research, Medicaid and Medicare and CARE Act services.

Sincerely,

A. Cornelius Baker

A. Cornelius Baker
Executive Director



UNAIDS
 UNICEF • UNDP • UNFPA
 UNESCO • WHO • WORLD BANK

The Executive Director

Joint United Nations Programme on HIV/AIDS

President William J. Clinton
 The White House
 Washington, D.C.

Reference: exr

20 May 1997

Mr President,

Your extraordinary leadership in setting the goal for the development of an AIDS vaccine in the next ten years merits sincere praise. For too long, the research agenda has been turned on its head, with ninety percent of research funds in AIDS going towards cures and only ten percent to vaccines. Important as the new developments in therapy are in reducing the suffering and prolonging lives of people living with HIV/AIDS in the few countries where treatment is possible and affordable, they are doing nothing to halt the relentless march of this disease in Africa, Asia, Latin America and Eastern Europe.

For a vaccine to be brought to the parts of the world where the disease is having its greatest impact, the countries of the industrialized world and the developing world will need to work closely together. The Joint United Nations Programme on HIV/AIDS (UNAIDS) has a Vaccine Advisory Committee, which is chaired by Dr Barry Bloom of the Albert Einstein College of Medicine in New York, and includes representatives from several industrialized and developing countries. UNAIDS and its Committee have as their mission to promote and facilitate the scientific, ethical, legal, and practical involvement of developing countries in vaccine research and testing.

Mr President, we pledge UNAIDS to work with you, Secretary Shalala, the National Institutes of Health and other U.S. institutions in the forefront of this crusade against AIDS. A vaccine which effectively addresses a virus which is devastating the world, must be tested and proven in the most affected countries in accordance with the highest standards of science and ethics.

Again, Mr President, I should like to congratulate you for your bold step forward. By directing the scientific community to leap beyond the tested borders of biology in the 21st century, you do much to ensure your own place in the history of our planet.

Please accept, Mr President, the assurance of my highest consideration.

Peter Piot



May 19, 1997

The Honorable William Jefferson Clinton
President
The White House
Washington, DC 20510

Dear Mr. President:

The Cities Advocating Emergency AIDS Relief (CAEAR) Coalition commends you on the announcement of a ten year federal initiative to develop a vaccine for the Human Immunodeficiency Virus (HIV). We salute your use of the Presidency to keep issues related to the worldwide AIDS pandemic at the forefront.

The CAEAR Coalition represents the federal policy and appropriations interests of the 49 U.S. epicenters of the AIDS epidemic that receive funding through Title I of the Ryan White CARE Act. We are people living with HIV and AIDS, medical providers, support service providers, and health planners who are on the front lines of the U.S. AIDS epidemic. We acknowledge the importance of a targeted initiative for vaccine development and recognize that a vaccine is critical to preventing new infections in youth and adults at risk for infection. We trust that the leadership of the United States in this initiative will have a ripple effect in governments and communities around the world--encouraging them to increase their efforts to end this devastating pandemic.

As consumers and providers of CARE services for people living with HIV, we ask that you continue to use the Presidency as a bully pulpit to keep the issues of people living with HIV in the hearts and minds of the American people. CARE programs will continue to need significant increases in support from the federal government as more people live longer with HIV disease. Medical care, housing, substance use treatment, mental health treatment, transportation, nutrition, and of course new antiretroviral drug therapies continue to be critical to the quality of life and survival of people living with HIV. Your ongoing support for increased funding for CARE programs is paramount to our success in filling these needs.

Thank you for your leadership and the leadership of Vice President Gore. We encourage you to continue to clearly articulate your commitment to ending this epidemic while caring for those living with HIV. The CAEAR Coalition looks forward to working with you to realize the goal of this laudable initiative.

The CAEAR Coalition
1413 K Street N.W., Suite 700
Washington, D.C. 20005

202 789 3565
202 789 4277 fax

Executive Committee

Ernest Hopkins, *Chair*
Suzi Rodriguez, *Vice Chair*
Robert Rybicki, *Treasurer*
Jacqueline Muther, *Southern*
Marc Halpert, *Southwestern*
Rex Sandborg, *Midwestern*
A. Gene Copello, *Northwestern*
Matthew McClain, *Mid-Atlantic*
Paul DiDonato, *Ar-Large*
Shawn Griffin, *Ar-Large*
Kathy Cerro, *Ar-Large*
Luanna Clark, *Ar-Large*

**Administrator of
Federal Affairs**

H. Alexander Robinson

Governmental Relations

Representative
The Sheridan Group



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

AIDS vaccine

'97 MAY 16 AM 10:39

MAY 15 1997

MEMORANDUM FOR THE PRESIDENT

FROM: Donna E. Shalala *Donna E Shalala*
SUBJECT: AIDS Vaccine Development

Recent advances in biomedical research supported by the National Institutes of Health (NIH) have created new opportunities and encouragement in our search for an effective vaccine against HIV infection. These advances are a direct result of our sustained investment in both basic scientific research and clinical investigation in the area of HIV/AIDS. This era of important scientific progress and renewed hope for the possibility of an AIDS vaccine provides a unique opportunity for you to consider ways to further this critical scientific endeavor.

To sustain this progress and capitalize on new scientific opportunities, we have increased the NIH budget for AIDS vaccine research by 33.6 percent over the past two years to nearly \$150 million in the fiscal year 1998 proposed budget. For now, the funding level is sufficient to maintain the ongoing momentum. Further increases are anticipated in the coming fiscal years. Recently, NIH also established a new NIH AIDS Vaccine Research Committee, chaired by Nobel Laureate Dr. David Baltimore, to provide leadership and guidance to an intensified comprehensive search for an AIDS vaccine.

A safe and effective AIDS vaccine is a global public health imperative. More than 29 million men, women, and children around the world have been infected with HIV. More than 3 million of these infections occurred in just the past year, with nearly 95% in the poorest parts of the world. Without an effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading infectious cause of death in the world. Even in the U.S., where new and effective anti-HIV therapies are available, complacency is not an option. HIV is capable of mutating and becoming resistant to therapies, and could well become even more dangerous. Only a truly effective preventive anti-HIV vaccine can limit and eventually eliminate the threat of AIDS.

I envision several options to demonstrate a strong Presidential commitment to this priority over several years that will serve to galvanize the worldwide scientific community, renew the commitment of the pharmaceutical industry to AIDS vaccine development, and restate the unwavering commitment of the United States to develop a preventive vaccine:

1. **U.S. Proposal for a Global AIDS Vaccine Research Initiative at Denver Summit.** The United States has proposed that the leaders of the eight major industrialized nations, meeting at the Denver Summit in June, agree to support a worldwide AIDS vaccine research initiative. This proposal has been discussed by the representatives who are organizing the Summit agenda, and proposed language for the final Summit Communique has been prepared and approved by the "Sherpas."

The proposal calls for the eight participating nations to make a political commitment to provide, in their own countries, the investments necessary to accelerate research toward the development of an HIV/AIDS vaccine as a scientific and public health priority. In the Communique, the nations also will pledge to work together to enhance international scientific cooperation and collaboration in this global initiative, and to work with the Joint United National Program on AIDS (UNAIDS) to address the legal and ethical issues related to vaccine testing.

To facilitate this scientific collaboration, our proposal also calls for meetings of key scientists from the nations participating in the Summit and from other nations integral to AIDS vaccine development. These meetings would take place in concert with that of the NIH AIDS Vaccine Research Committee, chaired by Dr. David Baltimore. This joint group will discuss research progress, identify scientific gaps and opportunities, design collaborative programs aimed at utilizing the unique scientific and clinical resources of each participant, and share scientific information related to the development of AIDS vaccine candidates for worldwide use. At the recommendation of the "Sherpas," the Director of NIH has written to his counterparts in the eight nations to seek their support and collaboration in this initiative.

2. **White House Briefing by Key Scientists on Progress towards a Vaccine.** The report of a year-long evaluation by more than 100 eminent scientists, known as the Levine Report, called for a reinvigorated and restructured NIH AIDS vaccine research program. The NIH has taken a number of steps to make AIDS vaccine research a top priority, including the initiation of studies to test a new vaccine strategy. You could invite the key scientists to brief you at the White House or at NIH regarding research progress and prospects for the future. If current research leads to a promising vaccine candidate for large-scale clinical testing, additional resources will be necessary to support clinical trials in the U.S. and at international sites.

3. **Announcement of New NIH AIDS Vaccine Laboratory.** We are in the process of establishing a dedicated intramural HIV vaccine research and development center on the NIH campus, a major new initiative capitalizing on remarkable advances in immunology not previously applied to vaccine development. You could announce

Page 3 - Memorandum for the President

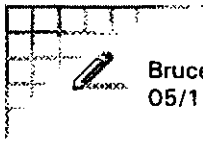
this initiative with the leadership of the NIH AIDS vaccine research program in attendance. In addition, you could visit one of several university-based vaccine labs supported by NIH throughout the country.

4. Announcement of Awards for New NIH AIDS Vaccine Innovation Grants. NIH has recently established a new funding mechanism, the "Innovation Grant Program for Approaches in AIDS Vaccine Research." In September 1997, NIH will award grants totaling \$6 million for this new program to encourage novel research in AIDS vaccines. You could announce these grants with those scientists on hand.

5. White House Meeting to Challenge Industry. Another option would be to convene a meeting at the White House, to follow-up a meeting held by the Vice President last year, bringing together leading government scientists and CEOs of vaccine manufacturers, to seek solutions to important but complex concerns that have deterred the sustained participation of these companies in HIV vaccine development, such as cost of development, potential market, and legal liability issues.

6. Presidential Address. This is an opportune moment for you to deliver a major address on our continuing national commitment to ending the AIDS epidemic with the ultimate goal of developing a preventive vaccine. This could be the focus of one of your upcoming speeches or it could be done in conjunction with the announcement of new initiatives. A good site for such an address could be the National Institutes of Health campus in Bethesda, MD.

I look forward to working with you on these initiatives to speed the pace of progress toward the development of a safe and effective AIDS vaccine. Although no one can predict when such a vaccine may be developed, your efforts would constitute a real legacy to the U.S. and to the world.



Bruce N. Reed
05/15/97 11:47:13 AM

Record Type: Record

To: Michael Waldman/WHO/EOP, James T. Edmonds/WHO/EOP
cc: Elena Kagan/OPD/EOP, Christopher C. Jennings/OPD/EOP
Subject: Comments on Morgan St. draft

Excellent work -- it reads very well, and has a lot of real thoughts in it.

My only suggestion is that the graph on the vaccine challenge is not quite right. I think you need to be more specific here about what we're doing -- otherwise the challenge has no credibility and won't get picked up. Also, the emphasis shouldn't be on "yes, it will take money" and "we're willing to commit the public resources necessary" because that implies we're coming up with more money, which we're not -- and our own scientists will go to great pains to say that it's not a function of more money anyway. So I would say something like:

"...the inner space of the human body. Today, let us commit ourselves to developing an AIDS vaccine within the next ten years. There are no guarantees; it will take energy, it will take focus; it will take great effort from our greatest minds. But we have made great strides in recent years. [We can get you a DNA monkey example if you want it] It is no longer a question of whether we can develop an AIDS vaccine -- it is a question of when. And if America commits to find an AIDS vaccine within the next decade, we will do it.

"I am prepared to do all I can to make this happen. Our scientists at NIH have been at the forefront of this battle. Today, I am pleased to announce that NIH will establish a new AIDS vaccine laboratory dedicated to this crusade. At the summit in Denver next month, I will enlist other nations to join us in a worldwide effort to find a vaccine to stop one of the world's greatest killers. And we will challenge America's pharmaceutical industry, which leads the world in innovative research and development, to work with us and make the successful development of an AIDS vaccine part of its basic mission.

"The 21st century will be the century of biology. Together, we can make an AIDS vaccine its first great triumph."

I know you don't want to load the speech down with specifics, but I think our challenge is B.S. without at least some evidence we're doing something to make it happen.

Great job all around. Let me know if you need anything else.

AIDS - vaccine

THE PRESIDENT INTRODUCES INITIATIVES TO FULFILL HIS COMMITMENT TO DEVELOP AN AIDS VACCINE

Today President Clinton challenged the nation to commit itself to the goal of developing an AIDS vaccine within the next ten years. The President also announced a number of important initiatives to help fulfill this commitment, including high-level international collaboration, a dedicated research center for AIDS vaccine research at the National Institutes of Health (NIH), and outreach to scientists, pharmaceutical companies, and patient advocates to maximize the involvement of both the private and public sectors in the development of an AIDS vaccine. The President has already taken steps to enhance the possibility of developing an AIDS vaccine by increasing funding for NIH vaccine research and development over 33 percent in the last two years. The initiatives the President announced today, which build on an exceptional commitment to develop better ways to prevent, diagnose, treat, and eventually cure AIDS, include:

- **A New NIH AIDS Vaccine Center.** A dedicated intramural HIV vaccine research and development center is being established at the National Institutes of Health. This vaccine center, which will be fully operational within the next several months, is uniting outstanding scientists in immunology, virology, and vaccinology to join in a highly-collaborative effort to develop an AIDS vaccine. Bringing together a broad array of researchers in an intensely-focused environment has been a successful way of developing vaccines in the past.
- **A Global AIDS Vaccine Research Initiative.** The United States is proposing that the leaders of the eight major industrialized nations meeting at the Denver Summit in June agree to support a worldwide AIDS vaccine research initiative. The proposal calls for each nation to make a commitment to provide the necessary investments in their country to accelerate research toward the development of an HIV/AIDS vaccine as a scientific and public health priority. Joint meetings of key scientists from participating nations will address research progress, identify scientific gaps and opportunities, and design collaborative programs.
- **A Challenge to Pharmaceutical Manufacture Industry to Invest in Innovative Research to Develop an AIDS Vaccine.** We can only be successful in developing an AIDS vaccine if private and public sectors make this goal a priority. The President is challenging the pharmaceutical industry to join the government in a partnership to realize this important goal.

Background on HIV/AIDS. HIV/AIDS remains a global public health threat. More than 29 million men, women and children around the world have been infected with HIV -- more than 3 million infections occurring within the last year. Without an

effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading cause of death among persons between 25-44 years of age. Between 650,000-900,000 Americans are estimated to be living with HIV disease, and over 300,000 Americans have already died from AIDS.

Clinton Administration Accomplishments on HIV/AIDS. The Clinton Administration has made a sustained commitment to addressing the HIV epidemic through investments in prevention, research and treatment.

- **Increased funding for the NIH vaccine by 33 percent.** Funding for NIH vaccine research and development has increased over 33 percent in the last two years -- from \$111.1 million in FY 1996 to \$148 million proposed in the President's FY 1998 budget.
- **Funding for AIDS research, prevention and care increased by more than 50 percent in the first four years of the Clinton Administration.** Funding for AIDS Drug Assistance Programs (ADAP), which help low-income people purchase needed therapies, has tripled, while funding for the Ryan White CARE Act increased 158 percent. The approval of new AIDS drugs has greatly accelerated, with 16 new AIDS drugs and two diagnostic tests.

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AIDS VACCINE Q&AS

Q: DOESN'T THE PRESIDENT'S CHALLENGE RING HOLLOW SINCE YOU ARE NOT INVESTING ANY NEW RESOURCES DEVELOPING AN AIDS VACCINE?

A: The President has committed additional resources to developing an AIDS vaccine. In the last two years, he has increased funding for the AIDS vaccine by 33 percent and his FY 1998 budget increases spending for AIDS vaccine research by \$17 million.

Moreover, scientists have informed the President that it is not only money that we need to meet the challenge of finding an AIDS vaccine, but that we also need to promote collaboration between experts in this area. That is why the President has announced that there will be a new AIDS Vaccine Center at NIH which will unite scientists in immunology, virology, and vaccinology to join in a highly collaborative effort to develop an AIDS vaccine.

That is also why he is calling on the leaders of the eight major industrialized nations meeting at the Denver summit in June to support a worldwide AIDS vaccine research initiative. These important initiatives are what scientists believe we need to do to fully commit ourselves to the goal of developing an AIDS vaccine.

Q: IN 1985, MARGARET HECKLER PREDICTED THAT WE WOULD HAVE AN AIDS VACCINE IN TWO YEARS. THAT WAS OVER TEN YEARS AGO. MOREOVER, AT A RECENT CONFERENCE, DR. ROBERT GALLO INDICATED THAT WE MAY NEVER SEE AN EFFECTIVE AIDS VACCINE. WHY SHOULD WE BELIEVE THAT THE PRESIDENT'S PROMISE THAT WE CAN DEVELOP AN AIDS VACCINE IN A DECADE?

A: We know much more about the AIDS virus today than we knew in 1985 or even in 1995. Recent scientific advances have taught a great deal about how the AIDS virus infiltrates the human and begins to destroy the human immune system. We have developed a whole new series of drugs that inhibit the reproduction of the AIDS virus.

There are many credible scientists and medical researchers who believe that it is not a question of whether we will ever get an AIDS vaccine but when. The scientific leaders at the National Institutes of Health have said that are extremely encouraged by recent progress in the AIDS vaccine and believe that the development of a vaccine is feasible. In fact, there were numerous presentations at the conference that spoke about the tremendous progress we have made in the AIDS vaccine development and in vaccine development in general.

The President announced today that we should commit ourselves to developing an AIDS vaccine in the next ten years. He acknowledged that there are no guarantees. But he believes that we should commit our energy, our focus, and the efforts from our greatest minds to finding an AIDS vaccine.

Q: HOW ARE THE INITIATIVES THE PRESIDENT ANNOUNCED TODAY BEING PAID FOR? ARE THEY A PART OF THE BALANCED BUDGET AGREEMENT?

A: All of the costs for developing an AIDS vaccine are being paid for by NIH's existing budget. NIH has already increased funding for AIDS vaccine research by 33 percent in the last two years -- from \$111 million in FY 1996 to \$148 million proposed in the President's FY 1998 budget. The President's FY 1998 budget alone calls for a \$17 million increase.

Q: IF WE ARE INVESTING MORE TO DEVELOP AN AID VACCINE AREN'T WE TAKING AWAY FROM INVESTMENTS ON TREATING PEOPLE WHO ALREADY SUFFER FROM THIS DISEASE?

A: Since he took office, the President has made an extraordinary commitment to increasing our investments in AIDS. Funding for AIDS research, prevention and care increased by more than 50 percent in the first four years of the Clinton Administration. Funding for AIDS Drug Assistance Programs (ADAP), which help low-income people purchase needed therapies, has tripled, while funding for the Ryan White CARE Act increased 158 percent. The President believes that we need to continue to increase our investments in all of these areas and his FY 1998 budget reflects that commitment, with additional investments in AIDS research, prevention and care.

Q: THE BALANCED BUDGET AGREEMENT CALLS FOR CAPS ON DISCRETIONARY DOMESTIC SPENDING. WON'T ADDITIONAL FUNDING FOR AN AIDS VACCINE MEAN LESS FOR OTHER IMPORTANT PRIORITIES? WHY NOT EXPEND THIS KIND OF ENERGY AND RESOURCES ON A CURE FOR BREAST CANCER OR HEART DISEASE OR DIABETES?

A: This Administration has made a strong improving biomedical research an extremely important priority. We have increased investments in biomedical research at the National Institutes of Health by an impressive 16 percent since the President took office.

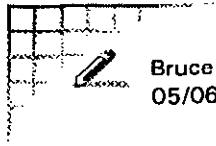
These additional investments has been used to increase investments in biomedical research in a number of important areas. For example, funding for breast cancer research has increased by 76 percent since the President took office .

Developing an AIDS vaccine is one important priority in our investments in biomedical research. Without an effective vaccine, AIDS will soon take over as the leading cause of

death for persons between the ages of 25 and 44. Between 650,00 and 900,000 Americans are estimated to be living with HIV and over 300,000 have died of AIDS.

While we have made enormous strides in the last year in treating AIDS, these treatments are not always effective and are often prohibitively expensive both for Americans and throughout the world. Also scientists at NIH believe that it is only a matter of time before we develop an AIDS vaccine. Increasing our commitment to developing a vaccine could make an enormous difference and save millions of lives both in this country and throughout the world.

File: ~~HHS~~ - AIDS vaccine
and
~~HHS~~
Heath - Diabetes



Bruce N. Reed
05/06/97 07:52:28 PM

Record Type: Record

To: Victoria Radd/WHO/EOP
cc: Christopher C. Jennings/OPD/EOP, Sylvia M. Mathews/WHO/EOP, Elena Kagan/OPD/EOP, John Podesta/WHO/EOP
Subject: AIDS Vaccine & Diabetes Update

As you may recall, we have been going back and forth with HHS and NIH in an effort to accelerate research on an AIDS vaccine and a cure for diabetes. We are finally making some progress, although still slower than we would like. Erskine had expressed a particular interest in the diabetes issue, so here's where we stand.

On both issues, we have repeatedly told HHS and NIH that the White House was ready to seek significant additional funding for NIH research targeted toward finding an AIDS vaccine and/or a cure for diabetes. In both cases, NIH raised strong objections both to our seeking additional funding (they say they have enough) and to any attempt to earmark that funding toward a specific purpose. They don't like the idea of politicians telling scientists how to spend their money, and they insist that scientific breakthroughs aren't a function of how much money they spend. HHS is loathe to make NIH do anything that NIH doesn't want to do.

Happily, after much prodding, NIH and HHS have finally come up with a list of actions we CAN take to advance the search for an AIDS vaccine. Shalala will be sending a memo to us later this week. The proposed actions include announcement of a new NIH AIDS vaccine laboratory, a new set of AIDS vaccine research and innovation grants (\$6 million), and an international commitment to AIDS vaccine research as part of the Denver Summit Communique (which Varmus has apparently been working on with his counterparts in the other 8 nations). We think we're also in a position now for the President to call for an AIDS vaccine by a date certain (within the next 8-10 years) without the entire scientific community attacking the idea. Together, these steps would make an excellent package for the President to unveil in his Morgan State commencement address on science May 18th.

Diabetes is taking longer, but the long-term prognosis is good. NIH has scheduled a major diabetes research conference for this fall, which is the mechanism Varmus uses when he needs an excuse to spend more than he's been spending on something. Around the same time, the Labor/HHS appropriations bill will be enacted, presumably with a major increase in overall NIH funding that will enable him to devote more resources to diabetes research. CDC is also seeking increases for diabetes prevention. So we should be in good shape in September to make a major push on diabetes, pegged to the NIH conference.

It will be difficult to do more in the short run, for 3 reasons: 1) Varmus will object; 2) we would have to file an amended budget request that spells out what we would give up in order to pay for the diabetes increase; and 3) the Republicans will still give NIH far more than we can promise. These obstacles are not impossible to overcome, but they would be difficult to pull off in time for Morgan State -- and it's perhaps the wrong time to propose new discretionary initiatives when we're in the midst of debating a tight budget resolution.

At some point, to ensure that this all turns out right, it might be a good idea to bring Varmus in to get to know Erskine. Kevin Thurm says that while Varmus is as prickly as they come, a little face time with the powers that be here might soften him up over time.

Let me know if you would like us to set that up sometime.

cc: Elena
return

BR

MEMORANDUM FOR THE PRESIDENT

FROM: Donna E. Shalala
SUBJECT: AIDS Vaccine Development

DRAFT

Recent advances in biomedical research supported by the National Institutes of Health (NIH) have created new opportunities and encouragement in our search for an effective vaccine against HIV infection. These advances are a direct result of our sustained investment in both basic scientific research and clinical investigation in the area of HIV/AIDS. This era of important scientific progress and renewed hope for the possibility of an AIDS vaccine provides an unique opportunity for you to consider ways to further this critical scientific endeavor.

To sustain this progress and capitalize on new scientific opportunities, we have increased the NIH budget for AIDS vaccine research by 33.6 percent over the past two years to nearly \$150 million in the fiscal year 1998 proposed budget. Recently, NIH also established a new NIH AIDS Vaccine Research Committee, chaired by Nobel Laureate Dr. David Baltimore of MIT, to provide leadership and guidance to an intensified comprehensive search for an AIDS vaccine.

A safe and effective AIDS vaccine is a global public health imperative. More than 29 million men, women, and children around the world have been infected with HIV. More than 3 million of these infections occurred in just the past year, with nearly 95% in the poorest parts of the world. Without an effective vaccine, AIDS will soon overtake tuberculosis and malaria as the leading infectious cause of death in the world. Even in the U.S., where new and effective anti-HIV therapies are available, complacency is not an option. HIV is capable of mutating and becoming resistant to therapies, and could well become even more dangerous. Only a truly effective preventive anti-HIV vaccine can limit and eventually eliminate the threat of AIDS.

I envision several options for a strong Presidential statement on this priority that will serve to galvanize the worldwide scientific community, renew the commitment of the pharmaceutical industry to AIDS vaccine development, and restate the unwavering commitment of the United States to develop a preventive vaccine:

1. **Presidential Address.** This is an opportune moment for you to deliver a major address on our continuing national commitment to ending the AIDS epidemic with the ultimate goal of developing a preventive vaccine. This could be the focus of one of your upcoming commencement addresses or it could be done in conjunction with the announcement of new initiatives. A good site for such an address could be the National Institutes of Health campus in Bethesda, MD.

DRAFT

- 2. White House Meeting to Challenge Industry.** Another option would be to convene a meeting at the White House, to follow-up a meeting held by the Vice President last year, bringing together leading government scientists and CBOs of vaccine manufacturers, to seek solutions to concerns that have deterred the sustained participation of these companies in HIV vaccine development, such as cost of development, potential market, and legal liability issues.
- 3. Announcement of New NIH AIDS Vaccine Laboratory.** We are prepared to establish a dedicated intramural HIV vaccine research and development center on the NIH campus, a major new initiative capitalizing on remarkable advances in immunology not previously applied to vaccine development. You could announce this initiative with the leadership of the NIH AIDS vaccine research program in attendance. In addition, you could visit one of several university-based vaccine labs supported by NIH throughout the country, including the University of Alabama, University of Washington, and Vanderbilt.
- 4. Announcement of Awards for New NIH AIDS Vaccine Innovation Grants.** NIH has recently established a new funding mechanism to encourage novel research in AIDS vaccines. This new "Innovation Grant Program for Approaches in AIDS Vaccine Research" will award grants totaling \$6 million later this year. You could announce these grants with those scientists on hand.
- 5. U.S. Proposal for an International AIDS Vaccine Research Initiative at Denver Summit.** At the Denver Summit in June, the U.S. will propose that the Eight nations make the political commitment to provide, in their own countries, the investments necessary to accelerate research toward the development of an AIDS vaccine as a scientific and public health priority. We will also propose that the U.S. NIH AIDS Vaccine Research Committee, chaired by Nobel Laureate Dr. David Baltimore, serve as the convener of vaccine researchers from around the world to discuss progress in research, identify scientific gaps and opportunities, design collaborative programs, and share scientific information. The Director of NIH is already contacting his counterparts in the eight nations to seek their consultation regarding this initiative. This will become part of the Communique of the Summit, and you could highlight this initiative as part of the Summit agreements.
- 6. White House Briefing by Key Scientists on Progress towards a Vaccine.** The report of a year-long evaluation by more than 100 eminent scientists, known as the Levine Report, called for a reinvigorated and restructured NIH AIDS vaccine research program. The NIH has taken a number of steps to make AIDS vaccine research a top priority, including the initiation of studies to test a new vaccine strategy. You could invite the key scientists to brief you at the White House or at NIH regarding research progress and prospects for the future. If current research leads to a promising vaccine candidate for large-scale clinical testing, additional resources will be necessary to support clinical trials in the U.S. and at international sites.

In addition to these opportunities for leadership in the area of AIDS vaccine research, this is also an opportune moment to demonstrate our further commitment in the area of AIDS therapies. The HHS, with the advice of non-government clinical scientists and community

DRAFT

representatives, has prepared a document providing principles, guidelines and recommendations for clinicians and their patients regarding the most effective use of new anti-HIV therapies, including protease inhibitors. This draft is in final review and could be ready for release for public comment shortly. Your participation would highlight not only the importance of these guidelines, but your Administration's commitment to research and treatment. The release of these guidelines will require additional actions to assure access to these critical treatment regimens by those in need. As the Vice President recently announced, HCFA is developing a demonstration program to test the concept of providing Medicaid coverage at an earlier stage of HIV infection. In conjunction with this coverage, you could also announce a request to Congress for additional PY 1998 funds for the AIDS Drug Assistance Programs (ADAP), which helps uninsured and underinsured low-income individuals purchase AIDS drugs.

effects on insurance/liability etc?

- **Cloning:** On May 2, the National Bioethics Advisory Commission will meet to review commissioned papers on selected topics related to the prospect of human cloning and to continue development of its report to you. The Commission is on a schedule to produce its report by early June.
- **Immunization Program:** On May 6, the Senate Labor and Human Resources Subcommittee on Public Health and Safety will hold a hearing on the reauthorization of the immunization program. Walter Orenstein, Director, National Immunization Program, CDC, will testify.
- **Medicare Fraud:** On May 6, the House Ways and Means Subcommittee on Health will hold a hearing on the President's proposals to eliminate Medicare fraud and abuse. Bruce Vladeck, Administrator, HCFA, and Michael Mangano, Principal Deputy Inspector General, HHS, will testify.
- **Informed Consent Procedures:** On May 8, the House Government Reform and Oversight Subcommittee on Human Resources and Intergovernmental Relations will hold a hearing on the processes for securing informed consent in clinical trials.
- **Medicare for Veterans:** On May 8, the House Veterans' Affairs Subcommittee on Health will hold a hearing on the Veterans Medicare Reimbursement Demonstration Act which would establish a demonstration project to provide Medicare reimbursement for health care services offered to certain Medicare-eligible veterans in VA selected facilities. Kathy Buto, Associate Administrator for Policy, HCFA, will testify.
- **AIDS Vaccine Research:** The May issue of *Nature Medicine* includes a report from a team of researchers, supported by the National Institute of Allergy and Infectious Diseases (NIAID), on a new DNA-based vaccine which protected two chimpanzees against HIV-1, the virus that causes AIDS. Unlike standard vaccines, which are formulated from dead or weakened viruses, the new vaccine directly incorporates attenuated HIV-1 genes rather than proteins produced by viral genes. The researchers suggest that further studies of the method are warranted. NIAID has not issued a formal response to the report. Researchers suggest that this reduced diversity and the resulting reduced ability of the immune system to recognize certain antigens may be key to the development of immunodeficiency in patients with HIV. These findings support early treatment of the disease, before elements of the immune system are significantly depleted.

OK -
For weekly?
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AIDS - vaccine

Genetic Vaccine Keeps Chimps Protected Against AIDS Virus

Researchers Conducting Safety Testing in Humans

By Rick Weiss
Washington Post Staff Writer

An experimental vaccine containing genetic material from the AIDS virus has protected two chimpanzees against the deadly virus, suggesting the novel technique might someday be used to make an effective AIDS vaccine for people.

Two months after they were vaccinated, both of the chimpanzees fought off intravenous doses of the AIDS virus that normally would have been sufficient to infect 250 of the animals. The chimps remain healthy more than a year later, with tests indicating they are completely free of the virus, said David B. Weiner, the University of Pennsylvania molecular immunologist who led the study.

The finding gives a boost to the relatively new technique—known as genetic or “naked DNA” vaccination—and to the company that made the vaccine, Apollon Inc. of Malvern, Pa. The company is already conducting safety tests of the vaccine in a small number of healthy, uninfected men.

“Chimps have very similar immune systems to people,” Weiner said. “It would be a wonderful thing if this led to a usable vaccine.”

Researchers warned, however, that many other AIDS vaccines have looked similarly promising at the same early stage of development, only to fail in humans. Some scientists also criticized the study for its use of a “wimpy” strain of HIV to challenge the animals after vaccination. The strain, known as SF2, has a reputation for being relatively easy to fight off.

“It’s incremental progress,” said Alan Schultz, chief of preclinical AIDS vaccine development at the National Institute of Allergy and Infectious Diseases. “It’s not clear what the significance is, and it’s not the home run we’re all hoping for.”

Drug therapies are proving increasingly effective against AIDS, but many public health officials believe that a protective vaccine remains the best hope for conquering AIDS, which has killed more than 6.4 million people worldwide in the past decade—more than a quarter of those in the last year alone.

Genetic vaccination is one of several approaches under investigation in what has remained a mostly disappointing effort to develop an AIDS vaccine. Success has been hampered by HIV’s great variability, which makes it a moving target for vaccine developers, and by the lack of a good animal model for testing candidate vaccines.

Equally frustrating, scientists still don’t know what, precisely, an AIDS vaccine ought to do in the body to be effective. Neither of

the immune system’s two armies for fending off microbial invaders—antibodies and killer T cells—reliably win the battle against HIV. Vaccines seek to boost the strength of one or both of those immune system armies, but no one knows which is more important.

The first AIDS vaccines were made from purified HIV proteins, which mostly stimulated antibody production when injected into people. The National Institutes of Health has deemed the approach not sufficiently promising at this time to warrant government funding for large-scale human testing.

A second kind of vaccine contains live but weakened strains of HIV, which stimulate both arms of the immune system in animals. But some researchers worry that such a virus could spontaneously regain its disease-causing potential and cause AIDS in some recipients, so testing in people has not begun.

The newly tested vaccine contains four HIV genes—snippets of DNA containing the genetic code that tells a cell how to make four HIV proteins. When muscle cells around the injection site absorb the genes and start making the proteins, the immune system responds by producing swarms of antibodies and killer T cells that are primed to attack HIV should it ever appear.

That’s what happened in the two chimps, which received a total of eight shots over the course of a year before getting infused with overwhelming doses of HIV. Within two months after that challenge, the animals fought off their infections. Sensitive blood tests and lymph node biopsies have confirmed the absence of virus in the year since then, according to a report in the May issue of *Nature Medicine*, released yesterday.

By contrast, an unvaccinated control chimp remains infected with the virus. (Chimpanzees can get infected with HIV but rarely get AIDS.)

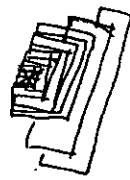
Harold McClure, who studies AIDS vaccines at the Yerkes Regional Primate Research Center in Atlanta, called the results “exciting and very promising.” But he said it remained to be seen whether the vaccine could prevent infection through mucous membranes, as occurs when AIDS is transmitted sexually, the major route of infection among people.

Marc Girard, chief of molecular virology at the Pasteur Institute near Paris, was among several who criticized use of the SF2 strain to test AIDS vaccines. “The challenge they used is not a strong challenge,” he said. “It’s a wimpy virus and this vaccine may not be strong enough for a more virulent virus.”

Weiner said Apollon plans to add other HIV genes to the vaccine to make it stronger.

The Washington Post

WEDNESDAY, APRIL 30, 1997



Verdict Deepens Divisions Over Women in Uniform

While Some Hail Army's Prosecution, Critics Say Crime of Rape Has Been Redefined

By Dana Priest
Washington Post Staff Writer

NEWS ANALYSIS

The guilty verdict at Aberdeen yesterday was an overwhelming victory for the Army's effort to punish men in authority who abuse women in their charge. But it has also widened the divide between those who believe the Army hasn't done enough to accommodate women and those who believe it has done far too much.

For women's groups and others who have criticized the military for too often ignoring sex crimes, the verdicts were a hopeful sign of a turnaround. The military jury of five men and one woman yesterday found Staff Sgt. Delmar G. Simpson guilty of 18 of the 19 counts of rape against him involving six female trainees. Simpson did not physically brutalize the women, and some did not resist his advances. But as the women's drill sergeant he had near-total power over their every move.

"This basically sends a strong message that these cases are about authority, not sex," said Nancy Duff Campbell, co-chair of the National Women's Law Center. "These were not romantic relationships or where people were in it for fun. It was someone saying, 'Show up, do what you're told.'"

For groups opposed to the accelerated integration of women in the military in the last five years, the verdict was proof that the Army has become subservient to wrong-headed congressional masters.

"You've sacrificed another [non-commissioned] officer at the feminist altar of political correctness," argued Henry Hamilton, a former military judge. He said he believes that what was described in court was consensual sex between Simpson and the trainees, and redefined as rape by the judge and the Army leadership that publicly vowed to prosecute the cases aggressively.

"It's just like before and after Watergate when the rules shifted," he said. "Now it's before and after Aberdeen, it's a redefinition of rape."

There is no dispute that Simpson had intercourse with the six women. He admitted to having

had consensual sexual relations with them—by itself a crime in the military because of the difference in rank.

But the Army accused Simpson of the much more serious crime of rape. His actions did not involve the kind of violence and resistance typically associated with rape. Instead, they fell into a military definition called "constructive force" rape.

Under the military code of justice—and the judge's instruction to the jury—rape can occur if the woman believes in her mind that she might be

are very loyal to their drill sergeant. They want to please their drill sergeant."

Eugene R. Fidell, president of the nonprofit National Institute of Military Justice, said the verdict is a "tribute to the recognition that the training environment is really different than what we're accustomed to in the civilian world."

It was clear from the reaction to yesterday's verdict that court rulings will not settle the dispute that has grown around the Aberdeen cases.

Elaine Donnelly, president of the Center for Military Preparedness and a one-woman campaign against sex integration in the military, said the verdict could set a dangerous precedent if the jurors believed they had to find Simpson guilty of rape just because the women were of lower rank. "It would cheapen the definition of rape," she said, and cause military men to wonder whether they should even have normal friendships with women.

But Rep. Carolyn B. Maloney (D-N.Y.), who has introduced legislation to review the military court system, said she was pleased with the verdict while still skeptical of the system. "At least it's one case that the Army followed through on," she said, referring to four other cases that were dealt with out of court. "But they'll always be second-guessed on it. Some people are saying he's a scapegoat; others are saying this has happened because of the media attention."

The NAACP, which has expressed concern that black drill sergeants have been targeted for prosecution, yesterday renewed its calls for an independent post-trial investigation. "We are withholding comment regarding the recent verdict until we receive more detailed facts about the verdict," NAACP president Kweisi Mfume said in a statement. "If necessary, the NAACP will proceed with its own investigation and hearing."

Rep. Earl F. Hilliard (D-Ala.), first vice chairman of the Congressional Black Caucus, said yesterday that he distrusted the Army's case against Simpson and other black drill sergeants. "The cases were tainted in the beginning," he said, alleging with the defense that the women were pressured to embellish their accusations.

"It's not over," Hilliard said.

"This basically sends a strong message that these cases are about authority, not sex. These were not romantic relationships or where people were in it for fun. It was someone saying, 'Show up, do what you're told.'"

— Nancy Duff Campbell, co-chair,
National Women's Law Center

seriously hurt or killed if she resists. She need not resist or fight back, and in some of the cases against Simpson the women did not tell him to stop.

A crucial factor in determining whether the women would have been too afraid to resist is the disparity in their ranks and the unique power that drill sergeants have over trainees. The prosecution's first witness, Warrant Officer Paul Wiatr, a former drill sergeant of the year at Aberdeen, was meant to drive home that point to the jury.

"If a drill sergeant wearing a drill sergeant hat approaches a young soldier, it intimidates the soldier. It instills fear in them," he testified. "Soldiers

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