FOIA Number: 2018-0758-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Todd Summers

Subseries:

OA/ID Number: 21090

FolderID:

Folder Title:
Issues - Vaccines - POTUS

Stack:	Row:	Section:	Shelf:	Position:
S	66	6	3	2

THE WHITE HOUSE

WASHINGTON

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, identity 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.

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 President has set a difficult goal for the research community, but NIH is ready to bring its scientific expertise and resources into play...recent advances in immunology and virology have increased optimism that (creating an AIDS vaccine) can be done."

-- Dr. Harold H. Varmus, NIH Director

"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)

"The development of a vaccine against AIDS will be an accomplishment of the greatest importance to humankind. Advances in biomedical research supported by the National Institutes of Health have created new opportunities and encouragement in our search for an effective AIDS vaccine. The NIH is committed to allocating the resources necessary to move us forward."

-- Dr. William E. Paul, Director of Office of AIDS Research of NIH

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.

A: The federal government will continue to assume a leadership role –it spends $3 billion on HIV/AIDS care through Ryan White and Medicaid alone -- but this is a broader societal issue. As it has in the past, the AIDS epidemic is again shining a spotlight on cracks and inequities in our health-care delivery system.

The federal government cannot solve the AIDS drug issue alone. The solution must be system-wide, combining private, federal and state resources. No single federal or state program can provide a total solution. Federal and state policy makers must work closely with the private sector to ensure that our resources are maximized.

Q: How do you intend to maximize these resources?

A: In a number of ways. In the Ryan White program, for example, the Health Resources and Services Administration intends to require all states to use the 340b mechanism to achieve reliable and consistent levels of cost-savings on all medications in their ADAP formularies.

This is expected to reduce not only the cost of drugs purchased by ADAPs, but the level of burden on States associated with individually negotiating discounts with multiple manufacturers.

We will also encourage states to contribute additional funds to ADAPS. Currently about 20 states do not contribute any funding at all. And we will encourage ADAPs to target resources to low-income individuals.

Q: When do you intend to change your 1998 budget request for ADAP?

A: The Administration's request $1.036 billion for Ryan White is $40 million (4%) over FY 1997, and 168% over FY 1993. Much of the requested increase over FY 1997 could be used for AIDS drugs and related primary care services.

The Administration's commitment to providing access to AIDS drugs has been demonstrated by its submission of two budget amendments to increase ADAP funding in the past year. We will continue to monitor ADAP funding levels and are prepared to seek additional funds if needed to perform the Federal role.

Q: What about the 1997 budget? Is it adequate? Aren't some states, such as Mississippi, cutting people off their ADAP programs?

A: We believe the FY 1997 budget is adequate, but some states have reported limited formularies, waiting lists, and restricted access to specific drugs because of increased demand on these programs.

Q: What is being issued today?

A: The Department of Health and Human Services is publishing in the Federal Register for public comment a comprehensive set of draft "Guidelines for the Use of Antiretroviral Agents in HIV-infected Adults and Adolescents."

These guidelines were drafted by panels of experts convened by HHS, and will provide doctors the most up-to-date information about how new protease inhibitor drugs and combination therapy should be used in the treatment of HIV disease. They are recommendations, not requirements, and do not have the force of administrative regulation or law.

"Q: How can the government publish these guidelines, without saying how it will pay for the costly drugs the guidelines recommend?

A: There is considerable confusion in the medical community about how these drugs should be used and we think it is important to provide the best information we can. HHS has published guidelines on the treatment of other diseases, such as diabetes, without specifically paying for the medical care described in those guidelines.

As Secretary Shalala said, these medical guidelines raise important public policy issues, and we are working diligently to address them. But the important point today is that our scientists are setting standards of care for HIV disease that prolong and enhance life. Our national investment in AIDS research is paying off.

Q: How are you working to address the public policy issues?

A: Among other things, the Department is reviewing the budget implication of the new treatment guidelines for the AIDS Drug Assistance Program. (The current request for fiscal 1998 is for $167 million.) Since taking office, the Clinton Administration has nearly tripled spending for this program.

State ADAPs are funded by a variety of sources – the ADAP set-aside in Title II of Ryan White provides only 45% of the total $368 million spent on ADAP in FY 1997. So while the federal government is a major contributor to state ADAP budgets, we will continue to look to our partners at the State and local level in addressing this situation as well.

Q: Doesn't the federal government have a moral obligation to provide these treatments to all who need them?

INTERNATIONAL AIDS VACCINE INITIATIVE

MEMORANDUM

DATE: June 18, 1997

TO: Eric P. Goosby, MD
Director, Office of HIV/AIDS Policy

FROM: Betsy Kovacs, Program Manager

SUBJECT: International Call for Action on HIV Vaccine Development

Seth Berkley asked us to forward the attached materials to you for your information in advance of their distribution to the media on Friday. The Call for Action is signed by over 50 organizations from around the world, endorsing President Clinton's challenge to the G-7 for HIV vaccine development.

We appreciate your understanding and support of the need for vaccines to stem the spread of this dreadful pandemic. We hope you find these materials of interest and that you will call if you have any questions or need further information.

BK

PS Dr Goosby:
Seth wanted to especially thank you for your "vision" in this orchestration.
BK

AIDS virus which are resistant to and untreatable by these drugs.

Q: Are the drugs hard to use?

A: Use of the drugs requires a thorough understanding of HIV disease and how these drugs work and interact, and many doctors with HIV+ patients may not fully understand how these drugs should be used and the risks associated with them. The guidelines are intended to help those doctors with their treatment decisions, benefiting the patient by providing the best possible therapy and everyone by reducing the likelihood that resistant strains will develop.

Q: Does HHS usually tell doctors how to use new therapies?

A: HHS has convened in the past similar panels and issued similar guidelines to provide doctors with the best possible medical information. For example, the Public Health Service has issued guidelines on the treatment of diabetes, NIH consensus panels have provided recommendations on when women should begin receiving mammograms, and the Agency for Health Care Policy and Research has issued a number of guidelines on treatment and management of a number of diseases.

Q: How much would it cost if all Federal grantees were to fully "implement" these guidelines?

A: We aren't sure what the final cost would be. The guidelines recommend that more people should receive combination therapy than is currently accepted practice, and that many of these people may have no means of their own to pay for these drugs. The federal government already spends about $3 billion on AIDS care through Ryan White and Medicaid in FY 1997. We are committed to working with State and local governments, private insurers and drug companies to first identify how many people are appropriate for these drugs and unable to afford them, and then work together to make this treatment available to as many people who could benefit as possible within existing resources.

International Call for Action on HIV Vaccine Development

Summit of the Industrialized Nations
Denver, Colorado USA

On May 18, 1997, United States President Bill Clinton asked that we "commit ourselves to developing an AIDS vaccine within the next decade."

AIDS has already taken the lives of millions of men, women and children. More than 29 million individuals have been infected with HIV. Each day, approximately 10,000 new infections occur, almost 95 percent of these in the developing world.

The investment of substantial government and private sector funds, over a sustained period of time, enabled researchers to make extraordinary progress in developing new HIV therapeutics. Tragically, these advances are far beyond the reach of most HIV-infected individuals in the world. An effort of similar magnitude is needed to develop HIV vaccines, without which AIDS will continue its relentless march of destruction.

President Clinton stated that at the Summit of the Industrialized Nations in Denver, he will seek to "enlist other nations to join in a worldwide effort to find a vaccine to stop one of the world's greatest killers."

We, the undersigned, believe that HIV disease is a global disease and requires a global response. No single country or company has the resources to go it alone. Therefore, we call upon the industrialized nations of the world to support a global effort to develop safe, effective, preventive HIV vaccines for use throughout the world by 2007. We call upon the nations participating in the Denver Summit to agree on a specific plan to meet this goal.

We also call upon the large industrialized nations to devote new resources to this vaccine development effort, including assuring that vaccines are produced for developing countries, creating incentives for maximum participation of the pharmaceutical/vaccine industry, and agreement on specific mechanisms to ensure mutual cooperation and coordination of the effort. The excruciating burden of this disease demands that funds not be diverted from research for HIV therapeutics or prevention. The creation of new financing mechanisms, such as an AIDS Vaccine Development Fund and AIDS Vaccine Purchase Fund, should be considered.

Finally, we call upon the large industrialized nations to expand this effort to other international forums, including the G-77 nations. The industrialized nations must begin working with each other and less developed countries, private industry, international agencies, and non-governmental organizations to lay the groundwork for maximizing the research effort and securing broad international access to any HIV vaccines that are developed.

All countries around the world will gain by this effort and each has a unique contribution to make, such as providing funding, scientists, testing sites, and vaccine production. A global effort of this magnitude would demonstrate how the world can come together in an era of globalization for the good of all humankind -- a noble goal for the next century.

Signatories to International Call for Action on HIV Vaccines

United States

AIDS Action Baltimore, Inc.
AIDS Action Council
AIDS Education Global Information System (AEGIS)
AIDS Treatment News
AIDS Vaccine Advocacy Coalition (AVAC)
Albert B. Sabin Vaccine Foundation, Inc.
Center for AIDS Prevention Studies (CAPS)
Gay Men's Health Crisis (GMHC)
Global AIDS Action Network (GAAN)
Holistic Health Center
International AIDS Vaccine Initiative
International Center for Research on Women
Jonas Salk Foundation
Marathon of Mothers
Mothers Organizing Mothers (MOMS)
National AIDS Fund
National Association of People with AIDS (NAPWA)
National Lesbian and Gay Health Association (NLGHA)
People with AIDS Health Group
Project Inform
San Francisco AIDS Foundation
Title II Community AIDS National Network
Treatment Action Group
UCSF AIDS Research Institute
Until There's A Cure Foundation
Vaccine Advocates

Venezuela

Accion Ciudadana Contra el SIDA (ACCSI)

Zambia

Family Health Trust

Zimbabwe

Southern Africa AIDS Information Dissemination Service (SAfAIDS)

Signatories to International Call for Action on HIV Vaccines

Australia
International Union against the Venereal Disease and the Treponematoses

Bangladesh
HIV/AIDS STD Activities in Bangladesh (HASAB)

Belgium
International Lesbian and Gay Association

Brazil
Fundação Oswaldo Cruz (FIOCRUZ)

Canada
International Council of AIDS Service Organizations (ICASO)

Chile
Corporacion Chilena de Prevencion del Sida (CChPS)

France
Fondation Marcel Mérieux

Germany
Deutsche AIDS-Stiftung

India
St. Paul's Trust Initiative for AIDS-free India

Japan
Agency for Cooperation in International Health

Kenya
Kenya National AIDS Control Programme

Mexico
Center of Research and Advanced Treatment in AIDS and HIV (CITAID)

Netherlands
AIDS Coordination Group
EuroCASO Secretariat
Nederlandse Vereniging tot Integratie van Homoseksualiteit COC

Thailand
Center for Vaccine Development, Institute of Sciences and Technology for

Uganda
Uganda Cancer Institute

United Kingdom
AIDS Helpline N.I.
European Public Policy Network on AIDS (EPPNA)
International Community of Women Living with AIDS (ICW)
London Lighthouse
National AIDS Trust
Network of Self-Help HIV and AIDS Groups
Scottish Voluntary HIV and AIDS Forum
The Terrence Higgins Trust
UK Coalition of People Living with HIV & AIDS