



AIDS
vaccine

December 30, 1998

Hon. Bruce Reed
Assistant to the President
Office of Domestic Policy
The White House
Washington, DC 20050

Dear Mr. Reed:

The beginning of a New Year is traditionally a time for reflection, renewal and hope. As 1999 dawns, I'd like to take this moment to reflect on some of the progress the world has made -- and the challenges that remain -- in the quest for a safe, accessible AIDS vaccine for use throughout the world.

Consider some of the highlights of 1998:

- Seventeen years into the epidemic, an AIDS vaccine candidate was finally launched into Phase III clinical trials.
- IAVI released its *Scientific Blueprint for AIDS Vaccine Development* and began implementing its strategies by investing \$9.1 million in two new International AIDS Vaccine Development Partnerships, significantly widening the product development pipeline.
- The World Bank formed a bank-wide task force with IAVI to consider new financial instruments to accelerate AIDS vaccine R & D for the world's poorest countries and assure their access to a vaccine once it is successfully developed.
- The seeds of national AIDS vaccine programs were planted and began flowering in South Africa, India and China.
- AIDS vaccine R & D commanded increased attention and resources around the world.

We at IAVI are particularly proud of our new Vaccine Development Partnerships, which we believe represent a new paradigm for public-private cooperation. Vaccines are being created specifically for use in developing countries, with scientists from developing countries (Kenya and South Africa) enlisted as full partners in the effort. Moreover, for the first time, intellectual property agreements have been negotiated to help ensure access to these vaccines at a reasonable price in developing countries should they prove

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Organizationally, IAVI strengthened its staff and broadened its funding base this year, adding to our list of donors the government of the United Kingdom, the William H. Gates Foundation, Levi Strauss, Crusaid, the Elton John AIDS Foundation, the Belotsky Foundation, Angel Music, Ltd. and the UK's AIDS Crisis Trust. We also strengthened and deepened our partnership with the U.K.'s National AIDS Trust.

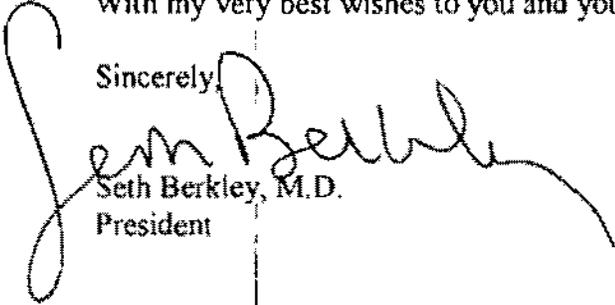
But 1998 was also a year of great loss. Worldwide, 2.5 million people died of AIDS, and 5.8 million were newly infected. Over 95% of those newly infected live in developing countries without access to the antiviral drugs that are prolonging lives in industrialized countries. We at IAVI suffered a personal loss when Dr. Mary Lou Clements-Mann, a cherished member of our Scientific Advisory Committee, and Dr. Jonathan Mann, an unyielding defender of human rights, perished aboard Swissair flight 111.

Clearly, our work is far from done. While 1998 saw the start of the first efficacy trials, scientists agree that we will need multiple trials, of multiple vaccine candidates, in many different parts of the world in order to succeed. While IAVI's funding base grew, we only had resources to finance two of the six to ten International Vaccine Development Partnerships envisioned by the *Scientific Blueprint*. IAVI's mission is to *ensure* vaccine development, and we do not have to launch all of the partnerships ourselves; still, the fact remains that many exciting approaches have not yet been funded.

In short, despite all the reasons for hope, the scientific, political and economic hurdles to developing an AIDS vaccine are enduring, as are the challenges of ensuring worldwide access to a vaccine once it is developed. As we begin the countdown to the Millenium, I ask that we all rededicate ourselves to the goal of developing safe, effective, accessible HIV vaccines for use throughout the world. We could leave no better legacy for future generations.

With my very best wishes to you and your loved ones,

Sincerely,



Seth Berkley, M.D.
President

THE WHITE HOUSE
WASHINGTON

MEMORANDUM FOR BRUCE REED
CHRIS JENNINGS
DANIEL MENDELSON
LAURA EFROS

From: Sandra L. Thurman 
Director
Office of National AIDS Policy
(202) 456-2437

Date: October 13, 1999

Subject: **Resolution by Presidential Advisory Council on HIV/AIDS Regarding Pelosi
Vaccine Bill**

Attached is a copy of a resolution just approved by the Presidential Advisory Council on HIV and AIDS relative to the Pelosi vaccine bill. They are certainly interested in having the Administration supportive of efforts to promote industry engagement in vaccine research.

PRESIDENTIAL

October 5, 1999

ADVISORY

COUNCIL ON

HIV/AIDS

The following resolution was unanimously adopted by the Presidential Advisory Council on HIV/AIDS during their 14th meeting on Tuesday October 5, 1999

**RESOLUTION IN SUPPORT OF H.R. 1274
THE LIFESAVING VACCINE TECHNOLOGY ACT**

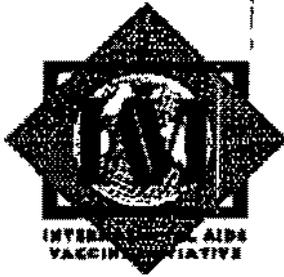
The development, testing, and implementation of a vaccine against HIV will require the concerted and coordinated effort of relevant branches of the Federal government, as well as the strong commitment of private-sector industry. Numerous financial impediments currently discourage the pharmaceutical industry to participate fully in the generation of vaccines against AIDS, malaria, TB, and other catastrophic infections.

The Lifesaving Vaccine Technology Act of 1999 (H.R. 1274) would provide tax credit for qualified research and development costs associated with generation of these vaccines, similar to the research and development credits which are currently provided to other types of technology. Further, since the vast majority of HIV-, TB-, and malaria-infected individuals reside in resource-poor areas of the world, the Act also requires companies that use the tax credit to establish a good faith plan for the widest possible global access to any efficacious vaccine which may be developed.

The Presidential Advisory Council on HIV/AIDS strongly supports the intent of H.R. 1274, and hereby urges the Administration to support and work strongly toward passage of this Act in the Congress.

Presidential Advisory Council on HIV and AIDS

Stephen N. Abel, DDS
Mr. Terje Anderson
Ms. Regina Aragon
Barbara Aranda-Naranjo, PhD, RN
Ms. Judith Billings
Mr. Charles Blackwell
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Rep. Charles Quincy Troupe
Bruce Weniger, MD



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If you have not received all of this transmission or have encountered difficulties with it, please contact the sender.

DATE: April 29, 1998

TO: *Bruce Reed / The White House*

FAX NUMBER: *456-5557*

NUMBER OF PAGES: (including this page) *2878*

FROM:

TELEPHONE NUMBER: 1-212-655-0201

SUBJECT:

MESSAGE:

Bruce —

Per our conversation Monday, attached is a memo on AIDS vaccine ideas for the 5/18 anniversary, proposed language for the G-7/8, and an article describing the purchase fund. idea.

Best, Victor

April 29, 1998

Memorandum to: Bruce Reed
The White House
Washington, DC

From: Victor Zonana
Vice President, International AIDS Vaccine Initiative
New York, NY

With the May 18 anniversary of the President's AIDS Vaccine speech at Morgan State rapidly approaching, I am writing to offer IAVI's assistance in coming up with a suitable announcement the Administration could make to mark the anniversary.

The enclosed concept paper sketches out the two-pronged strategy IAVI is championing in order to more fully engage private industry in the search for an HIV vaccine.

The first part of our strategy envisions the creation of a Vaccine Purchase Fund to assure commercial vaccine companies that a viable market will exist in developing nations when a vaccine is ready. Funds would only be made available to purchase a vaccine once it is developed. One approach would be for donor nations to guarantee a line of credit through the World Bank, where Dr. Richard Feachem has already convened a Task Force on New Instruments to help make this happen. (Dr. Seth Berkley, IAVI's president, sits on the Task Force.)

The second part of our strategy envisions a much smaller Vaccine Development Fund to support industrial development and testing of vaccines specifically designed for developing countries. Suggested contributions are \$2 million per G-8 country for the first two years, rising to \$5-\$10 million for the next five years.

It would be a huge step forward for the President to announce his support, even in principle, of AIDS vaccine development and purchase funds. It would send a powerful signal to the biotech industry, and the venture capitalists who finance it, that the President's commitment to develop an AIDS vaccine within a decade was a serious one, and that he recognizes that private industry must be part of the solution.

Barring a statement of support, the President could ask Vice President Gore to convene an interagency working group to examine and overcome commercial obstacles that stand in the way of an AIDS vaccine, especially the lack of a guaranteed market in developing countries. Participants could include Sandy Thurman and officials of HHS, NIH, Treasury, State, AID and, perhaps, OSTP.

I am sending copies of this note to Chris Jennings and Sandy Thurman.

Best,
Victor

~~CONFIDENTIAL~~ 200
not to be given circulation
without specific
authorization.

Summary of an
HIV vaccine development proposal for the May 1998 G-8 meeting,
Birmingham, United Kingdom

"Preventing the transmission of HIV infection and the development of AIDS is an urgent global public health imperative. While other prevention and treatment methods must be pursued, in the long term, the development of safe, accessible and effective vaccines against AIDS holds the best chance of limiting and eventually eliminating, the threat of this disease. We will work to provide the resources necessary to accelerate AIDS vaccine research, and together will enhance international scientific cooperation and collaboration. Cooperation among scientists, and governments in the developed and developing world and international agencies will be critical. We call on other states to join us in this endeavor."

**--Denver Summit of the Eight Communiqué,
Paragraph 33, June 22, 1997**

On June 22, 1997, the leaders of the eight largest economies pledged to provide the resources necessary to accelerate AIDS vaccine research and to enhance global cooperation toward this end. What follows is a summary of a bold plan to fulfill this worthwhile promise.

The Challenge

Despite a decade long global effort to control HIV, the epidemic continues to spread. More than 30 million persons are infected with HIV, and it is estimated that 16,000 people are newly-infected each day, 90% of whom live in developing countries. New therapeutic advances are, in general, only available in industrialized countries, are expensive (costing \$15,000 to \$20,000 per person annually), are complicated to use, and are now failing a growing number of the persons taking them. A vaccine is the only feasible means to control the global epidemic, yet vaccine development is proceeding far too slowly.

Relevant Issues

A number of key scientific advances have created a sense of optimism within the scientific community that a vaccine can indeed be developed. The challenges, however, are still formidable. Because science lacks either a good animal model for HIV disease or correlates of immunologic protection, it is only through testing vaccines in humans that we will be able to determine what works and ultimately develop an effective tool.

Although the public sector research institutions play a key role in basic research, vaccine product development is almost exclusively a commercial enterprise. There are not adequate commercial incentives for large amounts of private sector capital to be invested in HIV vaccines particularly those for developing countries. AIDS is currently costing the world community approximately \$18 billion a year in research, prevention and treatment of those afflicted. While the cost-effectiveness of vaccines is unassailable, less than 1% of global AIDS resources have been devoted to vaccine research. Vaccines receive less than 10% of overall HIV research expenditures and only a small percentage of that is directed at vaccine product development. Thus, the slow progress in vaccine development can be attributed to the combination of industry's reluctance to invest heavily in the HIV vaccine research and development process coupled with the continuing low priority given to vaccine product development by the public sector.

In the past, the world has relied on an iterative process to create vaccines. Vaccine candidate products have been developed based upon the best scientific knowledge. These products have then been clinically tested, with the results used to improve vaccine designs. Eventually a safe and effective vaccine has resulted. In the case of HIV, however, this usual mechanism of vaccine development has been abandoned for a more basic science approach to the understanding of pathogenesis and immunology that has so far been unsuccessful. It is an approach without precedence in the history of vaccine development.

Because of the uncertainties as to what will eventually work, a variety of different vaccine approaches must be investigated in parallel and not serially. Although new vaccine product development has slowed, there is, fortunately, a substantial backlog of untested vaccine products. In fact, over 25 vaccine candidates have been developed and found safe in small scale human studies. Many of these have stimulated some type of immune

response in the human body. Despite evidence of their immunogenicity, none of these vaccines has yet been tested for efficacy. The decision not to test these candidate vaccines turns on clear political and social considerations rather than any specific scientific barrier. These can be overcome. A rational and thorough approach to vaccine development would call for rapidly testing a range of the best of these existing products for efficacy while continuing to improve vaccine designs.

Vaccine development costs are high. Given the uncertainty involved, the financial risks to any industrial developer to move a single approach forward are unacceptably high. The risks become especially acute in view of the fact that more than 90% of the potential market for vaccines will be in developing countries. Developing countries not only have the greatest need for vaccines, but it is in these countries where vaccines can be most effectively tested. Vaccine candidates may need to be specifically devised for particular developing countries because the virus strains circulating in these populations differ from those in industrialized countries as are the vaccine characteristics, such as cost, ease of administration and stability, that will need to be considered for successful deployment in developing nations. For all of these reasons, commercial market forces are inadequate to ensure vaccine development in a timely fashion – and without public sector cooperation and support, they never will be. This market failure is not unique to HIV vaccines; many successful vaccine development efforts were previously stimulated by a strong public sector investment in partnership with industry.

Suggested strategies for the G-8

To advance HIV vaccine research and development, the G-8 nations have an historic opportunity to overcome the problem of a potentially unprofitable market for HIV vaccines. By providing crucial public financing to develop and test HIV vaccines, particularly those with limited commercial potential, the G-8 can push promising HIV vaccines off their blocked path and onto an efficient road leading ultimately to protection from this growing epidemic. If an end to the AIDS epidemic is the ultimate destination, then only one vehicle, a preventive vaccine, can get us there. What follows is a two-pronged strategy to do just this.

The first prong of the strategy seeks to assure commercial vaccine companies of a commercially viable market in developing countries by establishing a Vaccine Purchase Fund. Such a fund can create a guaranteed paying market in the developing world of known minimum size. By encouraging industrial investment in vaccine development, the Vaccine Purchase Fund will help to mobilize private capital and allow market forces to work, incorporating the efficiency of the private sector in creating vaccines for the developing world. The Vaccine Purchase Fund could be financed by current country or donor funds, or by a guaranteed line of credit through the World Bank. Ten to 15 participating countries, providing \$50 - \$100 million each, would create a \$0.5 - 1.0 billion dollar developing country vaccine market. Funds would only be made available to purchase a vaccine once it was successfully developed. A World Bank line of credit is a particularly attractive approach as current funds allocated to HIV could continue to be used for prevention and treatment until a vaccine was developed. Ultimately, having subsidized funds available for purchase will be essential for assuring vaccine availability for the poorest populations, but by itself will most likely not be adequate to fully overcome the

reluctance of major vaccine companies to invest in developing HIV vaccines for low income countries.

The second prong of the strategy seeks to provide direct public sector financing of vaccine development and testing. This can be accomplished by creating a Vaccine Development Fund to support industrial development and testing of vaccines specifically designed for developing countries and for those vaccines with limited commercial potential. This approach is based on the traditional means of promoting vaccine development. Such a fund can create a rapid response from the vaccine industry; be targeted toward vaccines of greatest potential for use in lower income countries; and also be used for vaccine testing as well as targeting the development of vaccines that would otherwise have no commercial potential. (Examples of these include vaccine vectors whose intellectual property is already in the public sector, such as BCG vectors or vaccines with risk/benefit ratios which would make them not commercially viable in low HIV incidence countries). Suggested amounts are \$2 million per G-8 country for the first two years, rising to \$5-10 million for the next five years. This would allow the world to move forward multiple approaches in parallel. Such a fund would be very effective at accelerating development of specific products, but would require making tough up-front strategic decisions about which products should receive investment.

Conclusions

Over the last decade, the global community has devoted major resources to developing HIV basic science and therapeutic drugs. The dramatic advances that we have made reflect this worthwhile investment. At the same time, the long-term need of developing better preventive technologies has yet to win adequate world attention and investment. Preventive vaccine development, the most cost-effective approach in combating and ultimately eliminating viral diseases, is best advanced through the industrial sector. However, without a new public/private effort, vaccine development will remain a low priority, allowing the epidemic to grow unchecked with rising health care and impact costs throughout the world. This status quo is far too costly.

To most effectively accelerate vaccine development, the G-8 countries can build both the Development and Purchase Funds. By quickly advancing vaccine product research and assuring the private sector reliable HIV vaccine markets in developing nations, these funding vehicles can provide the synergy to fully mobilize the world's scientific and industrial potential to finally meet the AIDS vaccine challenge.

By adopting this proposal, the leaders of the Group of Eight countries will make good on their pledge to undertake one of the single greatest leadership challenges of this century and the next. A vaccine is our only hope of eliminating this disease — not just in developing countries where the epidemic is spreading unchecked, but also in industrialized countries where HIV drug regimens are already failing and are barely affordable to the majority of people with AIDS. The G-8 nations can create the pathway to solving a health and economic problem that will continue to defeat us until we finally harness the world's finest science and industrial efforts. This approach offers a new model of economic and scientific cooperation in this era of globalization. It is a model the world urgently needs as we face a new millennium. Tens of millions of lives can be saved through this effort. There is no greater promise to be kept.



Suggested language for the G-8 Communique at Birmingham:

"The Denver Summit of Eight Communique (Paragraph 33, June 22, 1997) declared that to meet the "urgent global public health imperative" of AIDS, Summit members would "work to provide the resources necessary to accelerate AIDS vaccine research, and together will enhance international scientific cooperation and collaboration". The Birmingham Summit determined the next step in meeting this aim is to enhance both the supply and demand mechanisms for vaccine development. To ensure necessary economic conditions to encourage industrial investment in HIV vaccines, the G-8 leaders ask the World Bank to work with countries to investigate and develop effective mechanisms to finance the purchase of HIV vaccines for developing countries. The G-8 leaders also support the creation of a vaccine development fund which would assure the development of vaccines appropriate for use in developing countries. We ask other states to support this effort."



Article from our
news letter

IAVI Launches Campaign for Global HIV Vaccine Purchase Fund

In an effort to stimulate private sector investment in HIV development and help ensure access to HIV vaccines once they are developed, IAVI has launched an international campaign to create a Global HIV Vaccine Purchase Fund.

Over the past year, IAVI leaders have worked to build support for a Vaccine Purchase Fund among international agencies and G-8 and G-77 governments. The fund would provide developing countries with funds to purchase HIV vaccines, once candidate vaccines are demonstrated to be effective in humans.

The fund would also help assure pharmaceutical and vaccine companies of a commercially viable market for HIV vaccines in developing countries. Through grants and/or loans provided by industrial nations and international agencies, the Purchase Fund would, in effect, create a worldwide guaranteed paying market for HIV vaccines.

Historically, vaccines have been created primarily for industrialized country markets and have only "trickled down" to those in developing countries years after receiving marketing approval (usually only after they come "off-patent" and have paid off the industrial research investments). If this paradigm were to continue, once an HIV vaccine is developed, the results would be disastrous for poorer countries hard-hit by the epidemic.

For this reason, a growing number of public health authorities are suggesting that mechanisms must be created so that HIV vaccines can be made available in developing countries at the same time they are made available in industrialized countries (where HIV treatment and other forms of prevention are readily available).

According to Seth Berkley, IAVI's President, creation of the fund will stimulate industrial investment in HIV vaccine development. "A Global HIV Vaccine Purchase Fund would help mobilize private capital and provide real incentives for companies that have the experience and expertise to produce vaccines. It is absolutely vital that we encourage real market forces to develop in the area of HIV vaccines," says Berkley.

As envisioned, funding for the HIV Vaccine Purchase Fund would be provided by developing country contributions, industrialized country grants and/or guaranteed lines of credit arranged through international agencies such as the World Bank. According to Berkley, if 10 to 15 countries each provide US\$100 million, a US\$1.5 billion guaranteed market for HIV vaccines would be created in developing countries.

The World Bank is currently exploring different potential models for structuring the Purchase Fund. One model would be to obtain commitments from wealthy nations to provide direct grants or low cost financing for the purchase of HIV vaccines once they are developed. Funds and credit would be provided to countries according to need with the poorest, and those hardest hit by HIV, receiving the most funds. Another more innovative and attractive model would be to create an approved line of credit for countries at the World Bank which would be used to purchase vaccines of a specified nature when they became available. A key advantage of this plan would be that funds need not be made available until a safe and effective HIV vaccine is

developed. Thus current funds could continue to be used for short-term prevention and treatment needs.

The senior management of the World Bank has embraced the idea of creating an environment more conducive to industrial investment in HIV vaccines and convened a Bank-wide task force to look at potential financing options. The European Commission has also indicated support for such an idea and is investigating possible participation.

In order to further stimulate HIV vaccine development, IAVI is also pushing the G-8 and G-77 nations to create an HIV vaccine development fund or provide direct funding for HIV vaccine research and development. Such funding would stimulate the development of approaches that may not have a viable commercial market at this time because of intellectual property issues or unfavorable risk-benefit profiles for industrialized countries with relatively low rates of HIV infection. Moreover, issues such as ease of use, temperature stability and the cost of production may be critical in some of the more impoverished markets and, therefore, vaccines with these characteristics, even if shown to have lower efficacy, may have an important role to play.

In the Final Communiqué at the Denver Summit of the Eight in June 1997, the G-8 nations agreed that "the development of a safe, accessible and effective vaccines against AIDS holds the best chance of limiting and eventually eliminating the threat of this disease. We will work to provide the resources necessary to accelerate AIDS vaccine research, and together will enhance international scientific cooperation and collaboration. We call on other states to join us in this endeavor." (Denver Summit of the Eight Communiqué, Paragraph 33, 22 June 1997).

The G-8's agreement to act on HIV vaccine development was, according to many observers, a response to U.S. President Bill Clinton's call for development of an AIDS vaccine by 2007 just one month before the meeting. It was also brought about by international pressure generated by IAVI's Call to Action, an international consensus statement endorsed by more than 80 leading organizations in 52 countries. However, since the Denver Summit, the G-8 nations have done little, if anything, in the area of joint action on HIV vaccines.

IAVI is marshalling worldwide support for the Vaccine Purchase Fund. "We are committed to encouraging real private sector investment in HIV vaccines and to guaranteeing that all the countries of the world have full access to any HIV vaccines that are developed," says Berkley. "We must begin working now to ensure that the huge disparity that we see in terms of access to HIV treatments never happens with HIV vaccines."

AIDS Vaccine

MEMORANDUM

To: Bruce Reed

From: Sandy Thurman

RE: Denver Summit

Date: June 2, 1997

It has come to my attention that the only AIDS vaccine related activity planned for the upcoming Denver is the general release of the communique.

Expectations have been elevated following the President's remarks about an AIDS vaccine in the Morgan State speech. There is a looming PR crisis within the AIDS community because they feel that the Administration has "de-prioritized" AIDS in budget discussions and may place funds for prevention and treatment in competition with AIDS vaccine research. I think the Denver Summit offers a good opportunity to be more proactive and concrete in defining the President's vaccine initiative for the domestic groups and the press. I would propose that we do the following:

- o Hold a satellite meeting in Denver involving major foundations (Rockefeller Foundation, International AIDS Vaccine Initiative), UNAIDS, vaccine experts, some vaccine manufacturers, advocacy groups, scientific and general press.
- o Purpose of the meeting will be to clarify details of the U.S. vaccine initiative, hear from participating scientists and manufacturers on their ideas of next steps to realize vaccine development, and put out the word to the community that the Administration is committed to both treatment and prevention funding as well as vaccine research. Major support for the President's initiative can be demonstrated.
- o IAVI and UNAIDS can get international public health people to the meeting to show the international component of other countries' commitment, activities to realize it, and the enormous impact of HIV on the economies of developing countries. A leadership role of the G7/G8 countries is initiatives that sustain economic development and health of economies of all nations.
- o At the meeting, a plan for the Vice President to hold a White House meeting with manufacturers and scientists can be announced.
- o Press materials will be developed for the scientific press, which would clearly outline the NIH plans for the Vaccine Center, plans to bring together the right blend of

expertise, and a discussion of the status of current vaccine science as it relates to this initiative.

- o Press materials will also be developed for the general national press, which clearly explains the Administration's commitment to an overall strategy on AIDS. This would lay out the fact that no recent epidemic has been eradicated without a vaccine, and that the Administration will never turn its back on providing care and services to people already living with HIV.

AIDS Vaccine

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, a 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 5/1997

"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 5/1997

"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."

-- Lue 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 WHITE HOUSE
WASHINGTON

May 17, 1997

PRE-COMMENCEMENT BREAKFAST

DATE: May 18, 1997
LOCATION: Edward P. Hurt Gymnasium
Morgan State University
EVENT TIME: 9:05 am - 9:25 am
FROM: Bruce Reed

I. PURPOSE

To attend the annual pre-commencement breakfast of supporters of the university.

II. BACKGROUND

You will make very brief remarks to a group of approximately 300 faculty, parents, alumni, corporate representatives, etc. who have made significant contributions over the last year to enhance the university. All of the attendees will be present at the commencement ceremony. This is an opportunity to personally congratulate and thank these supporters of the University for their efforts.

You will be greeted by Judge Harry Cole, Chairman of the Board of Regents and Earl Richardson, President of Morgan State University. Judge Harry Cole is a retired judge and an alumnus of Morgan State. He was Maryland's first black state senator. Earl Richardson has been President of Morgan State University for 14 years, and previously worked as the Executive Assistant to the President of the University of Maryland College Park. He is a graduate of the University of Maryland Eastern Shore.

Following your remarks at the breakfast you will meet briefly with the families of Judge Harry Cole and President Earl Richardson.

III. PARTICIPANTS

Event Participants: (in speaking order)

Representative Elijah Cummings

Earl Richardson, President, Morgan State University.

Participants in photos following the breakfast:

Dr. Earl S. Richardson, President Morgan State University

Mrs. Sheila Richardson, wife
Mr. Eric A. Richardson, son
Judge Harry A. Cole, Chairman, Morgan State University Board of Regents
Mrs. Doris Cole, wife

IV. PRESS PLAN

Closed Press.

V. SEQUENCE OF EVENTS

- You will enter the breakfast accompanied by Representative Elijah Cummings and Earl Richardson, President, Morgan State University, and proceed to the stage.
- Earl Richardson makes brief remarks and introduces Representative Elijah Cummings.
- Representative Elijah Cummings makes brief remarks and introduces you.
- You make very brief remarks.
- You will depart and proceed to holding room.
- You will take photos with President Earl Richardson and Judge Harry Cole and their families.
- You will then robe and depart for the commencement address by motorcade.

VI. REMARKS

Talking points provided by Laura Capps in Speech writing.

THE WHITE HOUSE
WASHINGTON

May 16, 1997

MORGAN STATE UNIVERSITY COMMENCEMENT ADDRESS

DATE: May 18, 1997
LOCATION: Morgan State University, Hughes Field
EVENT TIME: 10:00 am - 12:00 pm
FROM: Bruce Reed

I. PURPOSE

To deliver a commencement address and receive an honorary degree from Morgan State University, and to make new policy announcements on genetic testing and the development of an AIDS vaccine.

II. BACKGROUND

You will be delivering the commencement address of Morgan State University's graduating class of approximately 850 students. There will be an audience of approximately 10,000 family members and friends of the graduates. The University has also invited 500 high school and elementary students from Baltimore to attend.

This is your first commencement address of an historically black college. Morgan State is one of two public universities in the state of Maryland and one of the nation's most respected historically black colleges. Morgan State traces its roots to the 1860s when it was founded as the Centenary Biblical Institute which educated men for the ministry. As it broadened its mission, it was renamed Morgan College in honor of the Reverend Lyttleton Morgan, the first Chairman of its Board of Trustees. In 1939 the State purchased the college in response to a study that found the State needed to provide more higher education opportunities for African-Americans. In 1975 the Legislature designated Morgan as a university, and the Legislature created an independent Board of Regents to govern the institution. In 1988 Maryland reorganized its higher education system by merging most campuses into the University of Maryland System. However, Morgan retained its independence and was designated by the Legislature as Maryland's Public Urban University -- which gave Morgan State the responsibility for offering programs at all degree levels, carrying out research, and developing programs that addressed the needs of the City of Baltimore.

Morgan State currently enrolls 6,000 students, up from 3,500 a decade ago. At the undergraduate level, Morgan offers programs in the arts and sciences and in professional

fields including business, teacher education, engineering, and social work. At the graduate level it awards degrees in fields such as architecture and business, and boasts doctorate programs in five fields of study.

Some notable alumni of Morgan State include: **Kweisi Mfume**, President of the NAACP and former Chairman of the CBC; **Richard Dixon**, Maryland State Treasurer (first African-American to hold that post); **Robert Bell**, Chief Judge of Maryland's highest court (first African-American to hold the position); **Earl Graves**, Publisher of Black Enterprise Magazine; Maryland State Senator **Clareuce Blount**, Senate Majority Leader, (first African-American to hold the position); **Major General Arthur Dean**, US Army Director of Military Personnel Management, Office of Deputy Chief of Staff for Personnel; **Major General Larry Ellis**, Assistant Deputy Chief of Staff for Personnel, Department of the Army; **Brigadier General William E. Ward**, 92nd Airborne Division.

Morgan State has made the following commitments to the Administration's national priorities:

- Committed Federal Work Study students to America Reads
- Participates in the Direct Lending program
- Participates in the Community Empowerment Initiative to revitalize Baltimore's poorest neighborhoods.
- Leads several Science Education and Education Technology initiatives, including managing the Baltimore Urban Systemic Initiative, which reforms mathematics and science education in the city's schools. It is also responsible for bringing city schools on-line, tutoring students in math and science, and sponsoring the City's Science Fair.
- Morgan is the site of the federally-funded National Transportation Center, which educates minorities for jobs in the transportation field.

III. PARTICIPANTS

Event Participants: (in speaking order)

Earl Richardson, President, Morgan State University
Judge Harry Cole, Chairman, Board of Regents
Reverend Dennis Proctor, Pastor, Pennsylvania Avenue A.M.E. Zion Church
Governor Parris Glendening
Bernie Hollis, Dean of the School of Arts and Science
Dr. Clara Adams, Vice President for Academic Affairs
Dr. Richard Ochillo, Dean of Graduate Studies
LTC Joseph Bozeman, Jr., Department of Military Science
Nashad Warfield, Senior Class Graduate
Dr. Hildbert Stanley, President, National Alumni Association.
Dr. Richard McKinney, Professor of Philosophy Emeritus.

Also Seated on Stage:

Mayor Kurt Schmoke, Baltimore
Senator Paul S. Sarbanes
Representative Elijah Cummings

Speaker Casper Taylor, Maryland House of Delegates
State Senator Thomas V. Mike Miller, President, Maryland Senate

Chief Judge Robert Bell, Maryland Court of Appeals
 Councilman Lawrence Bell, President, Baltimore City Council
 Mrs. Shirely Marcus-Allen, University Regent
 Mrs. Anne C. Boucher, University Regent
 Ms. Gwendolyn Burrell, University Regent
 Mrs. Frances Draper, University Regent
 Mr. Dallas R. Evans, University Regent
 Dr. Charles W. Griffin, University Regent
 Mr. James J. Hanks, University Regent
 Mr. Neal M. Janey, University Regent
 Mr. Francis X. Kelly, University Regent
 Mr. Kweisi Mfume, University Regent
 Mr. Martin R. Resnick, University Regent
 Mr. Abraham Moore, Univ. Vice President
 Dr. Joseph Popovich, Univ. Vice President

Ms. Julie Goodwin, University Counsel
 Dr. Cecil Payton, Executive Assistant to the President
 Dr. Levi Watkins, Honorary Degree Recipient
 Dr. Otis Thomas, Dean, Business and Management
 Dr. Patricia Morris, Dean Education and Urban Studies
 Dr. Eugene DeLouch, Dean Engineering
 Rev. Douglass Sands, Director Morgan Christian Ch.
 Mr. Bernard Jennings, University Vice President
 Mr. Ricardo Perry, University Vice President
 Dr. JoAnn Rodenhauser, Chair, University Council
 Mr. Anthony Johns, Director Architecture
 Mr. Anthony McPhail, Alumnus of the Year
 Mr. Earl Graves, Black Enterprise Magazine
 Ms. Dana Govan, Student Government Association
 Ms. Tanya McDuffie, Student Government Association
 Dr. Edith Booker, Director of State Relations
 Dr. Herbert Klinghoffer, Registrar

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- You will motorcade to the commencement site, while the processional of graduation class and faculty is underway.
- You will be announced onto the stage by President Earl Richardson.
- Reverend Dr. Dennis Proctor, Pastor, Pennsylvania Avenue A.M.E. Zion Church, will give the invocation.
- Morgan State University Choir will perform "Lift Every Voice and Sing."
- Governor Parris Glendening makes remarks.
- Judge Harry Cole, Chairman, Board of Regents, makes remarks.
- **President Earl Richardson makes remarks and introduces you.**
- **You will make remarks.**
- Judge Harry Cole announces that he will present you with an honorary degree.
- Bernie Holis, Dean, School of Arts and Science, presents you with the hood.
- President Earl Richardson presents you with the Honorary Doctorate of Law.
- **You will accept the honorary degree and return to your seat.**
- Honorary Degrees are conferred by President Richardson and Judge Harry Cole.
- Degrees in Course are conferred by Dr. Clara Adams, Vice President, Academic Affairs.
- Doctorate and Masters Degrees are conferred by Dr. Richard Ochillo, Dean of Graduate Studies.
- Undergraduate Degrees are conferred.
- Commissioned officers are recognized by Joseph Bozeman, Dept. of Military Science.
- Senior Honor Graduates and class awardees are recognized by Dr. Clara Adams.
- Nashad Warfield, member, Morgan State University Senior Class, makes remarks.
- Alumnus of the Year Award is presented by Dr. Hilbert Stanley, Pres., Alumni Assoc.

- Morgan State University Choir performs "I Believe I Can Fly."
- The Alma Mater is led by the choir.
- Dr. Richard McKinney, Professor of Philosophy, Emeritus delivers the benediction.
- Recessional begins.
- Upon completion of the recessional, you will depart the stage and enter the motorcade.

VI. REMARKS

Remarks Provided by Terry Edmonds in Speechwriting.

VII. ATTACHMENTS

Background on policy announcements is attached.

BACKGROUND ON POLICY ANNOUNCEMENTS

I. GENETIC TESTING

Call on Congress to pass bipartisan legislation to prevent insurance companies from making improper use of genetic information. While genetic testing has the potential to identify hidden genetic disorders and spur early treatment, but genetic testing also can be used by insurance companies and others to discriminate and stigmatize groups of people. For example, in the early 1970's, health insurance coverage and jobs were denied to many African-Americans who were identified as carriers of sickle-cell anemia.

Several bills have been introduced in this Congress, which prohibit health plans from requesting or using genetic information as a basis to deny health care coverage or raise premiums. The Administration is today announcing its support for the bipartisan legislation introduced by Rep. Louise Slaughter, which contains strict protections against disclosure an improper use by any health plan of an individual's genetic information.

More than a dozen states have already enacted laws to restrict the use of genetic information in health insurance, and at least thirty-one others have introduced legislation in 1997. However, state legislation is insufficient to solve this problem. The variability among state bills will lead to a lack of uniformity across the nation as to whether and how genetic information may be used by health plans.

II. AIDS VACCINE WITHIN THE NEXT TEN YEARS

You will announce three important initiatives to help fulfill your commitment to developing an AIDS vaccine:

- 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. You will announce that you are 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.

The Administration 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 -- from \$111.1 million in FY 1996 to \$148 million proposed in the President's FY 1998 budget. Overall 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 also greatly accelerated, with 16 new AIDS drugs and two diagnostic tests.



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

MAY 15 1997

'97 MAY 16 AM 10:39

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

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.

AIDS Vaccine

MEMORANDUM

May 18, 1997

TO: Bruce Reed, Elena Kagan
FR: Chris Jennings and Sarah Bianchi
RE: Background Information on POTUS Announcement on AIDS Vaccine and Genetic Screening

Attached are the materials that were used in yesterday's commencement address at Morgan State including:

- (1) One-page fact sheet on AIDS vaccine
- (2) Questions and answers on AIDS vaccine
- (3) National and International trends on AIDS
- (4) One-page fact sheet on genetic screening
- (5) Questions and answers on genetic screening
- (6) Fact sheet on what genetic screening protection legislation would do
- (7) List of Members and Groups who support the Slaughter legislation.

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.

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.

STATISTICS ON THE AIDS EPIDEMIC

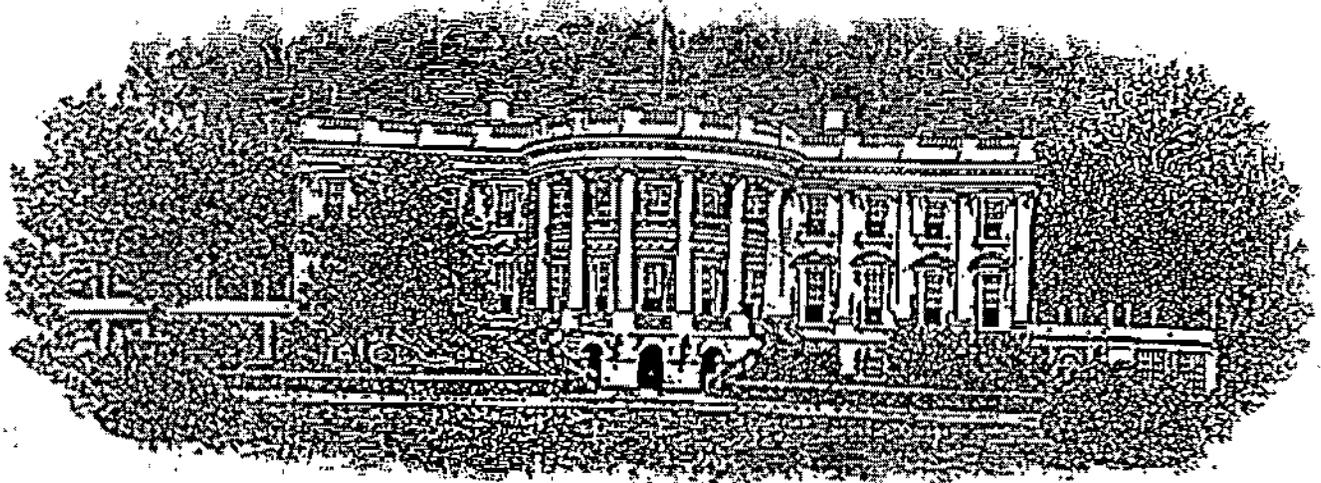
National Trends

- Between 650,000 and 900,000 Americans are living with HIV.
- Since the AIDS epidemic began 500,000 Americans have been reported with AIDS -- 300,000 have died.
- An estimated 40,000 to 60,000 Americans are being infected with HIV each year.
- It is the leading cause of death among Americans aged 25 to 44.
- Women now comprise 14% of people with AIDS. If the current trends continue, an estimated 80,000 children will have been orphaned as a result of this disease by the end of the decade.
- In 1994 alone, 1,000 new pediatric cases of AIDS were reported.
- One in four new HIV infections in the U.S. occur among people under the age of 21. Between 27 and 54 Americans under the age of 21 are infected with HIV each day.
- People of color have been disproportionately impacted by AIDS. As of October 1995, 38 percent of newly reported AIDS cases were with people of color.

International Trends

- 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.
- In 1995, 1.1 million adults and 350,000 children in the world died of AIDS.
- It has been estimated in some countries in sub-Saharan Africa that life expectancy has decreased by up to twenty years because of the AIDS epidemic.
- In 1992, in South Africa 2% of all women who came in for prenatal treatment were HIV positive and that number is up to 14%.
- 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.

THE WHITE HOUSE



Christopher C. Jennings
Deputy Assistant to the President for Health Policy
216 Old Executive Office Building
Washington, DC 20502
phone: (202) 456-5560
fax: (202) 456-5557

Facsimile Transmission Cover Sheet

To: Bruce Reed

Fax Number: 6-2878

Telephone Number: _____

Pages (Including Cover): _____

Comments: Updated version of

genetic screening of AIDS vaccine

*Aids
Vaccine*

Today, let us look within and step up to the challenge of our times -- a challenge with consequences far more immediate for the life and death of millions around the world. AIDS will soon overtake tuberculosis and malaria as the leading infectious killer in the world. Even here in this country, where new and effective anti-HIV strategies 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 HIV vaccine will totally eliminate the threat of AIDS.

Today, let us set a new national goal of developing an AIDS vaccine within the next ten years. There are no guarantees; it will take energy, it will take focus; it will demand great effort from our greatest minds. But we have made strides in recent years. 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, 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 of industrialized nations 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.

With stunning speed, scientists are now moving to unlock the secrets of our genetic code. Genetic testing has the potential to identify hidden genetic disorders and spur early treatment. But, it can also be used by insurance companies and others to discriminate and stigmatize groups of people. We know that in the 1970s some African Americans were denied health care coverage by insurers and jobs by employers because they were identified as sickle cell anemia carriers. We also know that one of the main reasons women refuse genetic testing for susceptibility to breast cancer is their fear that insurance companies may either deny them coverage or raise their rates. No insurer should be able to use genetic data to underwrite or discriminate against any American seeking health insurance. This should not just be a matter of principle, it should be a matter of law. In the coming weeks, I will send legislation to the Congress to prohibit insurance companies from using genetic screening information to determine premium rates or eligibility for health insurance.

Office of HIV/AIDS Policy

Office of the Assistant Secretary for Health
U.S. Public Health Service/DHHS
200 Independence Avenue, S.W.
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DRAFT

New AIDS Vaccine Development Initiatives

The White House will announce a new multi-faceted commitment to developing an effective AIDS vaccine, involving high-level international collaboration, a dedicated research center for AIDS vaccine research at the National Institutes of Health, and outreach to industry partners to maximize the involvement of the private sector in AIDS vaccine development.

o Global AIDS Vaccine Research Initiative 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. The proposal calls for each nation to make a political commitment to provide the investments necessary within 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 discuss research progress, identify scientific gaps and opportunities, and design collaborative programs. The proposal has the support of the Summit organizers, and a Summit Communique is being prepared outlining this pledge to work together to enhance international scientific cooperation and collaboration.

o New NIH AIDS Vaccine Laboratory A dedicated intramural HIV vaccine research and development center will be established at the National Institutes of Health. This laboratory will allow the remarkable advances in immunology and virology to be brought to bear in a highly focused fashion on the development of AIDS vaccines.

o White House Meeting With Industry on AIDS Vaccines A White House meeting will bring together leading government scientists and the CEOs of vaccine manufacturers to seek solutions to the important but complex issues that have deterred sustained participation of these companies in HIV vaccine development.

AIDS Facts 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 in the world. In the United States, AIDS is the leading cause of death among persons between 25-44 years of age, and the eighth leading cause of death for all Americans. Between 650,000 - 900,000 Americans are estimated to be living with HIV disease, and over 300,000 Americans have already died from AIDS.

Accomplishments under Clinton Administration The Clinton Administration has made a sustained commitment to addressing the HIV epidemic through investments in prevention, research and treatment. Funding for AIDS research, prevention and care increased by more than 50% in the first four years. Funding for AIDS Drug Assistance Programs which help low-income people purchase needed therapies has tripled, while funding for the Ryan White CARE Act increased 158%. Approval of new AIDS drugs has greatly accelerated, with 16 new AIDS drugs and two new diagnostic tests approved since 1993. The Office of AIDS Research has been strengthened to plan and carry out the AIDS research agenda. Focused new investments in prevention involve community planning to maximize local efforts.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Melissa T. Skolfield

Assistant Secretary for Public Affairs

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Los Angeles Times

May 11, 1997, Sunday, Home Edition

SECTION: Part A, Page 1; National Desk

LENGTH: 1476 words

HEADLINE: AIDS VACCINE PROVING TO BE AN ELUSIVE GOAL

BYLINE: MARLENE CIMONS, TIMES STAFF WRITER

DATELINE: WASHINGTON

BODY:

Even today, the memory makes scientists cringe. On a spring day in 1984, Health and Human Services Secretary Margaret Heckler, surrounded by prominent AIDS researchers and public health officials, announced that the virus responsible for causing AIDS had been found.

Brimming with optimism, she declared that a vaccine would be ready for testing within two years.

It was a remarkable display of scientific hubris that most AIDS specialists would prefer to forget.

"No viral vaccine has ever been made in two years," said Haynes Sheppard, a researcher with the California Department of Health Services. "Vaccine development is part science, part art and part luck--and if we don't get lucky, it might take a very long time."

In the recent euphoria resulting from the introduction of life-extending AIDS drugs, it is easy to forget the more frustrating side of AIDS research: that 13 years after the discovery of the human immunodeficiency virus, there is still no effective preventive vaccine on the horizon.

"One must keep in mind that there were no breakthrough AIDS drugs for many years--and then, suddenly, there were," said Sheppard, one of hundreds of AIDS researchers who met at the National Institutes of Health last week for an update on vaccine progress.

The news is not all bad.

Researchers have gained new information from animal studies about the breadth of the immune response to different candidate vaccines. And at least one human trial is poised to expand to 420 volunteers to begin testing two promising experimental vaccines simultaneously, an approach known as "prime-boost."

But none of the dozens of products under scrutiny has proved compelling enough for a large-scale efficacy trial, in which tens of thousands of high-risk individuals would be studied to see whether a vaccine actually protects them against infection.

*File to
Bruce Reed
ASAP -
plus 2 copies*

Los Angeles Times, May 11, 1997

There are many complex reasons why it is taking so long, chief among them is that HIV is a formidable and crafty foe.

Multifaceted Enemy

One of the biggest challenges facing researchers is the fact that the major target of HIV is the immune system itself. The virus infects the critical T-cells that regulate the immune response, weakening their ability to function. (The virus uses these cells as "virus factories" to copy itself.)

Also, HIV mutates, meaning that any effective vaccine must protect against all strains, both within infected individuals and among different populations.

This cannot always be accomplished, as the influenza vaccine has shown. There are two basic types of flu, but different variations appear every year, requiring new vaccine formulations.

Furthermore, because HIV can be transmitted--and can exist in the body--both as free virus and within cells, a successful vaccine must be able to elicit at least two kinds of immune response.

First, it must stimulate "neutralizing" antibodies that will destroy any free virus before it has a chance to infect the body's cells. Second, as a backup, it must provoke the production of killer T-cells that "poison" any cells that have become infected.

The soon-to-be launched "prime-boost" trial, sponsored by the National Institute of Allergy and Infectious Diseases, will attempt to stimulate both responses by using two compounds at once.

One vaccine, vCP205, is made from a weakened canary-pox virus used to carry specific HIV genes into the body. It will be given to provoke the production of the killer T-cells. The second compound, rgp120, is a genetically engineered copy of an HIV surface protein. It will be given to provoke the antibodies.

It still might not be enough.

Because AIDS is most often a sexually transmitted disease, an effective vaccine also will probably have to stimulate an immune response from the mucosal immune cells that line the reproductive tract. This aspect of vaccine development is proving especially difficult.

"We don't understand the principles of mucosal immunity particularly well, and haven't been successful in developing vaccines directed at mucosally transmitted pathogens," said Dr. Robert T. Schooley, who chairs the executive committee of NIAID's AIDS Clinical Trials Group. "For example, we have no effective vaccines for syphilis or for gonorrhea."

There is much debate over the best ways to proceed.

In developing vaccines, researchers typically look to which immune responses protect against infection--known as "correlates of immunity"--and try to create a product that will elicit those responses.

Los Angeles Times, May 11, 1997

Put another way, scientists study the immune responses of people who have suffered and recovered from viral illnesses. In developing vaccines for chicken pox and polio, for example, researchers learned much from cases of people who recovered.

Dispute Over Next Step

However, unlike other viral diseases, no one is known to have recovered from HIV and become immune. In fact, it is not known whether a natural protective state against HIV even exists.

Some wonder whether it might be valuable to launch a large human trial of a marginal experimental vaccine, hoping that a few individuals would develop immunity so they could be studied.

"Do we really want to blow \$ 30 million on a candidate vaccine that we're not sure will work to get more information about correlates of immunity?" Sheppard asked. "Some believe it's not worth it. Others believe it's absolutely critical to get to the next level of protection. That's where some of the tension is."

Unfortunately, only limited information can be obtained from animal studies. There is no ideal animal model for studying HIV vaccines. Chimpanzees can become infected with HIV, but only one chimpanzee is known to have become ill. Moreover, chimpanzees are an endangered species.

So most HIV animal studies use macaque monkeys. They can be infected with simian immunodeficiency virus, which is similar to HIV and causes an AIDS-like disease. But results cannot always confidently be applied to humans.

During last week's forum, Dr. Opendra Narayan of the University of Kansas Medical Center in Kansas City reported that he had developed a live-virus candidate vaccine that appeared to protect a small number of macaques from exposure to a lethal, lab-created hybrid virus that contained an HIV component.

Fears of Mutating Virus

The virus, dubbed SHIV, was made by combining SIV with a piece of HIV taken from its envelope, or outer coat.

Researchers would be delighted to end up with a live-virus vaccine but have shied away from that approach because of serious concerns about safety.

Historically, the best vaccines are often made from live, attenuated viruses. These are living viruses that have been altered to make them harmless, or capable of causing only mild disease.

But AIDS researchers worry that a live-virus vaccine, even crippled in some way, might find a way to repair itself once in the body or, even worse, meld with another HIV strain to form a more dangerous "mosaic" virus.

HIV is a retrovirus--its genetic material is RNA rather than the usual DNA. Upon infecting a cell, it undergoes a special process to turn its RNA into DNA, integrating with the DNA of the host (human) cell.

Los Angeles Times, May 11, 1997

"We don't know how the body would handle" an attenuated vaccine, said Dr. Larry Arthur of the National Cancer Institute. "Theoretically, once you're infected with a retrovirus, you're infected for life."

"I've always been a strong proponent of attenuated vaccines," he added. "There are certainly enough areas of the world with high-risk people that would warrant testing one. But there is a big potential safety risk."

Arthur has been developing DNA-based vaccines, which use pure--but noninfectious--genetic material from HIV.

Other strategies under study include using a live but harmless "vector," such as a bacterium or another virus, to "carry" an HIV protein gene; using chemically synthesized pieces of HIV proteins, known as peptides, and using a noninfectious HIV look-alike.

No one has yet put a live HIV vaccine in humans, although some experts point to a fascinating case in Australia as evidence that such a trial might not prove as dangerous as many people think.

More than a decade ago, a handful of individuals received transfused blood from an Australian infected with a genetically impaired strain of HIV. One recipient died, but it was unclear whether AIDS was the cause.

None of the others has developed AIDS, raising the possibility that giving individuals a live vaccine using HIV with this same genetic defect might, at least, be safe.

But would it result in immunity?

"Some say: 'Look at these people, they don't get sick. Given the apparent failure of other approaches, do the trial,' " Sheppard said. "But others say: 'No. Safety issues are paramount. We just can't do it.'"

"And who knows who is right?"

LANGUAGE: English

LOAD-DATE: May 11, 1997

**PHOTOCOPY
PRESERVATION**

**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 200,000 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.

PREVENTING INSURANCE DISCRIMINATION BASED ON GENETIC INFORMATION

In his commencement address at Morgan State University today, the President highlighted the great potential and possible perils of recent advances in genetic research. To address widespread concerns about potential abuses, President Clinton called upon Congress to pass bipartisan legislation that would prohibit insurance companies from using genetic information to determine premium rates or eligibility for health plans.

ADVANCES IN SCIENCE: POTENTIALS AND PERILS

Genetic testing has the potential to identify hidden genetic disorders and spur early treatment. Tests for genetic predisposition to certain diseases and conditions -- such as Huntington's disease and certain types of breast cancer -- are already available and more genetic tests are on the horizon. But genetic testing also can be used by insurance companies and others to discriminate and stigmatize groups of people. We know that genetic information has been used to discriminate against people in the past. In the early 1970's, health insurance coverage and jobs were denied to many African-Americans who were identified as carriers of sickle-cell anemia. Studies have shown that many Americans are extremely concerned with the possibility that their genetic makeup will be used to discriminate against them or a member of their family.

ADDITIONAL PROTECTIONS NEEDED

The new legislation will build on the important anti-discrimination insurance laws in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It would strengthen HIPAA by ensuring that in all cases genetic information will not be inappropriately used or disclosed by health plans. This would not only apply to health plans covered under ERISA but also provides blanket protections for all Americans who purchase individual policies.

More than a dozen states have already enacted laws to restrict the use of genetic information in health insurance and at least thirty-one others have introduced legislation in 1997. However, state legislation is insufficient to solve this problem. The variability among state bills will lead to a lack of uniformity across the nation as to whether and how genetic information may be used by health plans.

BUILDING ON THE EXISTING BIPARTISAN LEGISLATION

Several bills have been introduced in this Congress, which prohibit health plans from requesting or using genetic information as a basis to deny health care coverage or raise premiums. The President believes that the bipartisan legislation introduced by Rep. Louise Slaughter (H.R. 306) represents a strong foundation for this much-needed reform. The Slaughter bill contains strict protections against disclosure of an individual's genetic information by health plans. The President looks forward to working with Rep. Slaughter and other members in both parties to pass legislation on this important issue in this Congress.

PHOTOCOPY
PRESERVATION

AIDS vaccine

Merck Plans to Test AIDS Vaccines in Humans

By MICHAEL WALDBOLZ

Staff Reporter of THE WALL STREET JOURNAL

As the AIDS pandemic spreads largely unabated outside the U.S., public-health officials have been waiting hopefully for a breakthrough in the development of a vaccine.

New Merck & Co., after numerous years of effort and failed attempts, appears to have made one.

Merck scientists are laying plans to begin the first human tests of two promising experimental vaccines developed as part of an intense top-secret research effort.

Merck's top vaccine-research executive, in a telephone interview this week, confirmed the vaccines' existence and the company's plans to begin administering them in a small number of healthy, uninfected volunteers by year's end.

The official, Emilio Emini, said he didn't want to raise undue expectations. He said the human tests will be undertaken simply to help Merck scientists determine if the vaccines can produce in people the kind of immune-system reaction generated in animal studies. Those studies themselves are so preliminary that the company hasn't completed their analysis, or presented their results to the AIDS-vaccine research community, Dr. Emini noted.

Still, researchers familiar with the project say that if Merck's vaccines produce a powerful immune reaction, the company is capable of swiftly embarking upon larger trials. Merck, based in Whitehouse Station, N.J., is one of the world's premier commercial vaccine makers.

"The studies are designed to help us quickly see if we are on the right track," said Dr. Emini, director of Merck's infectious-disease research operations. He added: "We are at the point in our research where we need to know if they will trigger the response in people we've seen in animals. And the only way to learn that is by giving them to people." Still, Merck is uncertain if the immune response it has gen-

erated in animals is of the type that will protect people against infection.

Several other companies are testing prototype vaccines in large and small trials in the U.S. and abroad. But one of the Merck vaccines will be among the first of a class of so-called "naked DNA" vaccines for HIV to go into humans. These are vaccines composed of a gene or genes extracted from the virus. No naked DNA vaccines yet exist, and Merck and others have to date been unsuccessful in testing such agents against the flu and other microbes.

Merck declined to provide much detail about the AIDS vaccines. Rumors of the company's testing plans have surfaced in

Please Turn to Page B4, Column 3

the last week or so, and limited information about them has been shared with some research groups and research physicians who will help conduct the small trials. Information from scientists familiar with the company's program suggests that Merck's efforts incorporate the latest technology and knowledge emerging in recent months about what's needed to produce a protective response in people.

"What's exciting and important is that Merck believes it's far enough along to test something," says Margaret Johnston, assistant director for AIDS-vaccine research at the federal government's National Institute of Allergies and Infectious Diseases. "It's good to see Merck involved, and testing an approach that is right now thought to be on the cutting edge."

Specifically, Merck wants to see if its DNA vaccine can stimulate the immune system to release white blood cells often referred to as killer or cytotoxic T-cells. Recent studies by several other research groups show that people exposed to HIV, the virus that causes AIDS, who produce large amounts of killer T-cells and other so-called helper T-cells are able to keep the disease in check. Additional recent studies in monkey show that triggering such T-cells can also keep the virus at bay for limited periods.

Dr. Emini says animal studies Merck is conducting show that the company has been able to make a DNA vaccine that can prompt a killer and helper T-cell response. The company's trials are designed to see if the same biological response occurs in humans, a test that could be accomplished within a few months.

The human trial will be watched closely by AIDS-vaccine researchers because it will provide a critical test of whether DNA vaccines are useful. Most other experimental vaccines have produced antibodies against HIV that, while able to neutralize the virus outside of infected cells, don't appear to be powerful enough to overcome infection. Scientists are hopeful about the DNA approach because such vaccines also stimulate a cascade of T-cells that are able to target and destroy virus particles that enter the cells during a viral infection.

The trick in making a DNA vaccine, however, is identifying which genes from HIV to put into the vaccine. While Merck declined to disclose the gene or genes it is using, Dr. Emini confirmed that the company is using genetic material from the virus that it has altered in an effort to elicit a desired response.

Information about Merck's efforts will appear in the soon-to-be-published August newsletter of the International AIDS Vaccine Initiative, a private New York organization that promotes vaccine development. David Gold, who monitors AIDS-vaccine research for the organization, will report that Merck has been able to "humanize" the genes, making the DNA produce a more powerful immune response than has been produced in any previous efforts by Merck or others.

Mr. Gold will also report that at a recent meeting of vaccine researchers, Merck said that in monkey studies, the altered DNA induced a stronger and longer T-cell response than other test vaccines. Dr. Emini confirmed Mr. Gold's account.

Recent research, however, suggests that a DNA vaccine alone likely won't be powerful enough to fully protect against infection. As a result, Merck confirms that it also will test a vaccine in which bits of the virus are inserted into a defused animal or human virus. The company declined to identify the composition of its virus-based vaccine. "The current sense is that a vaccine against AIDS will require a combination of a DNA vaccine to prime the immune

system followed by a booster of a vaccine involving another virus," says Dr. Johnston of the government's NIAID.

Indeed, several weeks ago Pasteur Merieux Connaught, the vaccine-making unit of the French drug company Rhone-Poulenc SA, reported results of a phase-two test of vaccine in which parts of the AIDS virus are inserted into a weakened virus that causes canarypox, a bird virus. Michel Klein, who directs Pasteur Merieux's HIV-vaccine effort, says the company's test vaccine produced some T-cell response, and it expects to test the vaccine further. The company also is developing a DNA vaccine, Dr. Klein says.

Marsh & McLennan Unit Agrees to Settle EEOC's Age-Bias Case for \$28 Million

By MICHAEL RAPPOFORT

Our Times News Service

NEW YORK—Johnson & Higgins Inc. has agreed to pay \$28 million to settle Equal Employment Opportunity Commission allegations that it illegally forced its directors into early retirement.

The EEOC said the agreement with Johnson & Higgins, an insurance-brokerage concern that is now part of Marsh & McLennan Cos., is one of the largest age-discrimination settlements in the U.S. "It's definitely one of the top five settlements," said Sonya LeCount-McClanahan, an EEOC senior trial attorney.

The EEOC sued Johnson & Higgins in 1993 in federal district court in New York alleging its policy of forcing directors to retire before age 65 violated federal age-discrimination law. Under the policy, directors had to retire by the end of the year in which they turned 62, or by the end of the year in which they turned 60 if they had been on the firm's board for 15 years.

Previously, courts had agreed with the EEOC that the mandatory-retirement policy was illegal, but the level of damages to be paid by Johnson & Higgins hadn't been established.

The settlement "sends a message to the

entire community how age discrimination in any form can be an expensive proposition," Ms. LeCount-McClanahan said.

Barbara Perlmutter, a Marsh & McLennan spokeswoman, said the New York insurance-brokerage, investment-management and consulting company is "pleased to have this matter behind us." Johnson & Higgins was acquired by Marsh & McLennan in 1997, and the retirement policy in question hasn't existed for years, the spokeswoman said.

The \$28 million will be divided among 13 retired Johnson & Higgins directors on whose behalf the EEOC brought the case. The directors had contended they were due millions of dollars in back pay from the firm; they will each receive amounts ranging from \$1.22 million to \$3.57 million.

Some retired Johnson & Higgins directors are continuing to pursue separate litigation against Marsh & McLennan and other Johnson & Higgins directors, alleging they were cheated out of their fair share of the proceeds when Marsh & McLennan bought Johnson & Higgins for \$1.8 billion. Attorneys involved in the litigation couldn't be reached for comment.

Justice Department Examines Remedies In the Microsoft Case

By a WALL STREET JOURNAL Staff Reporter

WASHINGTON—The Justice Department is examining a broad range of potential remedies in the Microsoft Corp. antitrust case and has sought advice from outside experts to evaluate these options if it prevails in the case, a department official said.

Microsoft, however, has said it expects to win the case and dismissed speculation about a possible remedy as premature and unfair. The department spokeswoman called any public speculation about a remedy premature, noting that the U.S. district judge deciding the case, Thomas Penfield Jackson, hasn't yet ruled.

Two investment banks were approached in recent days to provide an analysis of how to break up the company and value its operations, USA Today reported yesterday. The Justice Department spokeswoman acknowledged that the department approached Wall Street firms to evaluate a number of remedies. But she said no one remedy had been singled out and no investment banker has been retained.

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THE WHITE HOUSE

WASHINGTON

December 17, 1998

**MEETING WITH THE
PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS**

DATE: December 18, 1998
LOCATION: Cabinet Room
BRIEFING TIME: 5:15 pm to 5:45 pm
EVENT: 5:45 pm to 6:15 pm
FROM: Bruce Reed/Chris Jennings/Sandy Thurman

I. PURPOSE

You will be meeting with members of the President's Advisory Council on HIV/AIDS to discuss the Administration's progress in addressing the AIDS epidemic.

II. BACKGROUND

The Council requested a meeting with you to address its recommendations on ways to improve the Administration's response to the HIV/AIDS epidemic. The Council recognizes your commitment to improving HIV/AIDS care, research, and prevention. They support recent efforts to highlight international efforts to fight HIV/AIDS, the new initiative on HIV/AIDS in the minority communities, and on increases in research investments. However, the Council has been publicly critical of the Administration in some areas, particularly its commitment to HIV prevention. This meeting provides an opportunity for you to personally reaffirm your commitment to the Council and the seriousness with which you take the issue.

Questions from the Council will focus on four areas:

- **Access to Treatment:** The Council will seek your leadership on expanding access to treatment for indigent persons with HIV who under current law must wait until they reach a level of disability to qualify for Medicaid, which covers the treatments that would likely have forestalled their progression to AIDS. Initial reviews, prompted by a request by the Vice President, determined that such an expansion is not cost neutral and therefore cannot be done administratively through a Medicaid 1115 waiver. However, the Administration has worked extremely hard to expand access to promising HIV/AIDS therapies by supporting substantial increases in the AIDS Drug Assistance Program and advocating for the Jeffords-Kennedy legislation (which includes a demonstration program that would allow states to define disability, substantially increasing access to Medicaid by persons who would become disabled but

for care). Support of this legislation by the Council and the AIDS community would be very beneficial. [Council presenter: Thomas Henderson]

- **Promoting HIV Testing:** Approximately 30% of persons infected with HIV do not know they are infected, complicating prevention efforts and delaying helpful treatments. The Council will ask for your support of a national "get tested" campaign focusing on higher-risk populations (youth, persons of color, women). This is a reasonable proposal, and one which is already under consideration through the budget process. [Council presenter: Alexander Robinson]
- **Vaccine Research:** Last spring, you announced your desire to find a vaccine for HIV within ten years. Two weeks ago, on World AIDS Day, you announced a 33% increase in vaccine research funding at the NIH (up \$47 million to \$200 million). The Council is highly supportive of your ongoing leadership on this issue, but has some concern about the 18 months it is taking to find a director for NIH's new vaccine research center and about the need for increased inter-agency coordination. NIH has assured us that its progress on vaccine research has not been hampered by this vacancy and that filling the position is a top priority for NIH Director Dr. Varmus. [Council presenter: Helen Miramontes]
- **Increased AIDS Funding:** Funding for HIV/AIDS programs has more than doubled during your Administration, with Ryan White funding up 266% and AIDS research up 67%. The Council is concerned that prevention and international funding have not benefited from similar increases. CDC's prevention budget is over \$640 million and has increased 34% since you took office; the Administration is focusing on insuring that prevention funds are used effectively and are targeted to those at highest risk. As for international funding, USAID's AIDS budget has increased 64% during your Administration. You also just announced on World AIDS Day a new \$10 million effort to help developing countries respond to the needs of children orphaned by AIDS. Finally, may announce \$479 million in Ryan White Title I grants to 50 metropolitan areas most heavily impacted by HIV/AIDS; these grants include extra funds for minorities that are part of your recently announced initiative on HIV/AIDS in racial and ethnic minorities. [Council presenter: Regina Aragón]

In your closing remarks (see attached talking points), you may highlight recent Administration activities on HIV/AIDS, including:

- World AIDS Day event at which you announced an AIDS orphan initiative at USAID, increased vaccine research funding from the NIH, and a delegation to Africa led by Sandy Thurman.
- Minority initiative announcement on October 28th at which you declared HIV/AIDS to be an ongoing and severe crisis in racial and ethnic minorities and announced \$156

million in additional funding to address the crisis.

- Historic HIV/AIDS funding achievements in the FY99 budget negotiations with Congress.
- Strongly advocated for other policies that help people with HIV/AIDS, including an enforceable patient bill of rights; the Jeffords-Kennedy legislation that allows people with disabilities -- including people with AIDS -- to stay in or return to work; and substantial increases in research funding at the NIH.

III. PARTICIPANTS

Briefing Participants:

Bruce Reed
Virginia Appuzo
Karen Tramontano
Chris Jennings
Sandy Thurman
Richard Socarides

Program Participants:

YOU
Sandy Thurman
Bruce Reed
Virginia Appuzo
Karen Tramontano
Chris Jennings
Sandy Thurman
Richard Socarides
Dr. Scott Hitt, Council Chairperson
Members of the Council

IV. PRESS PLAN

Pool still photographers at the top of meeting; single print reporter thereafter. Verbatim transcript to be provided to press following meeting.

V. SEQUENCE OF EVENTS

- Sandy Thurman will introduce **YOU** to members of the Council.
- Dr. Scott Hitt will make a brief opening statement.
- Council member Rabbi Joseph Edelheit will provide an overview of the message of the Council to you.

- Four members of the Council will provide brief background statements and identify specific issues on which they seek Administration action. (You will have the option to seek clarification or respond--see attached Q & A.)
- **YOU** will make brief closing remarks, thanking the Council for its hard work and reaffirming your commitment to continuing the fight against AIDS--see attached talking points.

VI. REMARKS

Talking points provided by the Office of National AIDS Policy.

VII. ATTACHMENTS

- Talking points for closing remarks.
- Q & A for discussion purposes.
- List of Council members and brief biographies.

President's Advisory Council on HIV/AIDS

Member List

CHAIR

R. Scott Hitt, M.D.

Dr. Hitt, is a physician at the Pacific Oaks Medical Group in Beverly Hills, California. He is the Chair of PACHA.

PRESENTERS

Regina Aragón

Ms. Aragon serves as the Public Policy Director for the San Francisco AIDS Foundation. She was an attendee of the 1995 White House Conference on AIDS.

Rabbi Joseph Edelheit

Rabbi Edelheit serves at the Temple Israel in Minneapolis, Minnesota.

B. Thomas Henderson

Mr. Henderson, a person living with HIV, serves at the Texas General Land Office in Austin, Texas. He has been active in AIDS and human rights issues for numerous years.

Helen Miramontes, M.S.N., R.N., FAAN

Ms. Miramontes is an Associate Clinical Professor and Deputy Director of the International Center for HIV/AIDS Research and Clinical Training in Nursing, at the School of Nursing at the University of California at San Francisco. She has a son living with AIDS.

H. Alexander Robinson, M.B.A., C.P.A.

Mr. Robinson, a person living with HIV, is a private consultant. He formerly served as the ACLU's chief lobbyist for AIDS, gay/lesbian civil rights, disability issues. He serves as the Co-Chair for the Prevention Subcommittee of the PACHA.

ATTENDEES

Stephen Neal Abel, D.D.S.

Dr. Abel is the former Director of Dentistry at the Spellman Center of St. Clare's Hospital in New York City. Dr. Abel now serves as the Oral Health Policy Liaison in the Office of the Medical Director at the New York State Department of Health/AIDS Institute.

Terje Anderson

Mr. Anderson is the Chair of the Health Resources Services Administration Advisory Committee and is currently the Deputy Executive Director of the National Association of People with AIDS (NAPWA). He was an attendee of the 1995 White House Conference on AIDS.

Barbara Aranda Naranjo, Ph.D., R.N.

Dr. Aranda Naranjo serves at the University of the Incarnate Word, School of Nursing in San Antonio, Texas. She was an attendee of the 1995 White House Conference on AIDS.

Judith Billings, J.D.

Ms. Billings, a woman living with HIV, is the former superintendent of schools for a Washington State school system. She now serves at Targeted Alliances, Education Consulting Services.

Ambassador Charles W. Blackwell

Charles W. Blackwell is the founder of Native Affairs and Development Group and serves as its President and Director. He is also the Chickasaw National Ambassador to the United States of America by appointment of the Chickasaw Governor with confirmation by the Chickasaw Legislature.

Nicholas Bollman [NOT ATTENDING]

Mr. Bollman is presently a Senior Program Director for the James Irvine Foundation. He was an attendee of the 1995 White House Conference on AIDS.

Jerry Cade, M.D.

Dr. Cade, a person living with HIV, is the Co-Founder and Medical Director of University Medical Center's HIV Inpatient Unit and Outpatient Clinic in Las Vegas, Nevada. He was an attendee of the 1995 White House Conference on AIDS.

Lynne M. Cooper, D.MIN.

Dr. Cooper has served as the President of Doorways, an interfaith AIDS residence program, for the past nine years. She is also the director of the National AIDS Housing Coalition Board.

Robert Fogel

Mr. Fogel is an attorney at Hilfman and Fogel in Chicago, Illinois. He is the Chair of the International Subcommittee of the PACHA.

Debra Fraser-Howze

Ms. Fraser-Howze is the founder/director of the National Black Leadership Commission on AIDS in New York City. She is also the Co-Chair of the Racial Ethnic Populations Subcommittee of the PACHA.

Kathleen Gerus

Ms. Gerus, a person living with HIV, currently serves at the Midwest AIDS Prevention Project in Sterling Heights, Michigan. She has served as co-chair of the Women's Advisory Committee of the National Hemophilia Foundation.

Phyllis Greenberger

Ms. Greenberger is currently serving at the Society for the Advancement of Women's Health Research in Washington, D.C. She is the former Associate Director for Government Relations at the American Psychiatric Association.

Nilsa Gutierrez, M.D., M.P.H.

Dr. Gutierrez is the former director of the New York State AIDS Institute, and is currently the medical director of the Health Care Financing Administration's New York Regional Office.

Bob Hattoy

Mr. Hattoy, a person living with AIDS, currently serves as the White House Liaison at the U.S. Department of Interior.

Michael T. Isbell, J.D.

Mr. Isbell is the former deputy executive director of the Gay Men's Health Crisis in New York City, and currently practices law at a private law firm in New York City. He is the Co-Chair for the Prevention Subcommittee of the PACHA.

Ronald Johnson

Mr. Johnson, a person living with HIV, is currently managing director for public policy, communications, and community relations at the Gay Men's Health Crisis in New York City. He formerly served as the Citywide coordinator for AIDS policy in the Office of the Mayor, City of New York.

Jeremy Landau

Mr. Landau, a person living with HIV, resides in Santa Fe, New Mexico. He is currently the Chair of the Prisons Subcommittee of the PACHA. He is the former director of the National Rural AIDS Network.

Alexandra Mary Levine, M.D. [NOT ATTENDING]

Dr. Levine serves as a Professor of Medicine, Chief of Hematology, and Medical Director at the University of Southern California School of Medicine in Los Angeles, California. She is the Chair for the Research Subcommittee of the PACHA.

Steve Lew

Mr. Lew, a person living with HIV, is the Director of Research and Technical Assistance at the Asian and Pacific Islander Wellness Center in San Francisco. He is the co-chair of San Francisco's Ryan White HIV Services Planning Council.

Miguel Milanes

Mr. Milanes is the former HIV/AIDS Program Coordinator and current Executive Assistant to the District Administrator for Dade/Monroe Counties (Miami), in the Office of HIV/AIDS Services, Florida Department of Health.

Reverend Altigracia Perez, STM

Reverend Perez is currently serving at the Church of Saint Phillip the Evangelist in Los Angeles, California. She is also the Co-Chair for the Racial Ethnic Populations Subcommittee of the PACHA.

Michael Rankin, M.D., M.P.H.

Dr. Rankin is Chief, Psychiatry and Mental Health Services, VA Northern California Health Care System in San Francisco, California.

Debbie Runions

Ms. Runions is a person living with HIV, is a community advocate from Nashville, Tennessee. She serves on numerous boards and advisory commissions.

Sean Sasser

Mr. Sasser, a person living with HIV, tested positive for HIV at the age of 19. He was an attendee of the 1995 White House Conference on AIDS.

Benjamin Schatz, J.D.

Mr. Schatz is currently executive director of the Gay and Lesbian Medical Association in San Francisco, California. He was a founder/director of the AIDS Civil Rights Project at the National Gay Rights Advocates.

Richard Stafford

Mr. Stafford, a person living with HIV, is from Minneapolis, Minnesota.

Denise Stokes

Ms. Stokes, a person living with HIV, is a community activist dedicated to HIV education, awareness and prevention. Ms. Stokes joined YOU as keynote speaker at the October White House event announcing \$156 million in funding targeted to African American and other minority populations.

Bruce Weniger, M.D.

Dr. Weniger is a physician at the National Immunization Program in the federal Centers for Disease Control and Prevention in Atlanta, Georgia.

**PRESIDENT WILLIAM J. CLINTON
MEETING WITH THE
PRESIDENT'S ADVISORY COUNCIL ON HIV/AIDS
DECEMBER 18, 1998**

Talking Points

- Thank you for all of the good work that you have been doing.
- Over the past six years, we have made a lot of progress, and I appreciate your recognition of that. Together, we have steered resources toward research, prevention and treatment efforts that have made an incredible difference in the lives of so many.
- We all know there is much more to do, in boosting prevention and international support, and in developing an HIV vaccine. I will make sure this vaccine remains a top priority for my administration.
- You've made a number of good suggestions, and I'm going to ask Sandy to help us move forward on them.
- You have a lot of friends and advocates here - the First Lady, the Vice President, Mrs. Gore, Secretaries Shalala and Cuomo, and certainly Sandy - who have done a tremendous amount to increase awareness of AIDS. I want you to know that we will always be committed to the fight.
- Together, we will beat this epidemic both here at home and around the world.

December 16, 1998

**MEETING WITH THE
PRESIDENT'S ADVISORY COUNCIL ON HIV/AIDS**

QUESTIONS AND ANSWERS

Q: Current HHS guidelines encourage early treatment of HIV to forestall the onset of AIDS, yet access to Medicaid coverage for that treatment is generally restricted to those who have progressed to AIDS. How are you going to help increase access to treatment?

A: This is a difficult challenge and we are taking steps to address it. You know I tried to solve this problem with universal health care.

The Vice President has taken leadership in this area, asking HCFA to look at solutions. Unfortunately, what we thought might be fixed quickly has turned out to be more difficult than expected. While we are committed to continuing our work to look at long term responses, we've also been working on interim solutions:

- Sandy Thurman has set up an internal task force to develop solutions
- we've succeeded in getting significant increases in the AIDS Drug Assistance Program--\$175 million (61%) increase in FY99--and the Ryan White CARE Act overall--\$271 million (23%) increase in FY99 and 266% since FY93
- we strongly supported the Jeffords-Kennedy legislation, which includes a demonstration program that helps states provide Medicaid coverage to people with HIV before they get AIDS - I hope you'll continue to work with us to get legislation like this passed in the coming year
- HCFA has been working with States that are seeking to develop waivers to expand their coverage to people living with HIV. We have talked with HCFA, and they have assured us that they will continue to aggressively provide support and assistance to States that want to develop demonstration programs that work.

I recognize the need and promise you that I and the Vice President will stay on top of this issue and do everything in our power to see that people with HIV don't have to get sick before they get treatment.

Q: We are concerned that our national effort to stop the spread of HIV is not working, and that the number of new HIV infections in this country has stayed at 40,000 per year. In addition, at least 30% of those that are HIV positive don't know it, which means they are likely to continue the activities that spread the infection. The Council would like to recommend a new national "get tested" campaign to encourage people at risk to seek HIV counseling and testing services. Will you

support that request?

A: I think it sounds like a good idea. Let me ask Sandy to take a look at the proposal and give me her recommendations. I do believe we need to do a better job with our work on prevention, not only for HIV but for a variety of preventable illnesses. Secretary Shalala and Surgeon General Satcher have been focusing a great deal of energy on prevention, particularly in racial and ethnic minorities. Dr. Satcher has been helping to lead their Race and Health Disparities initiative, which includes HIV and AIDS as one of six targeted illnesses.

Young people are also in need of greater attention. I believe that some of the impact of the anti-drug campaign by our Office of National Drug Control Policy will help since the abuse of drugs and alcohol plays a key role in young people taking risks with HIV.

Q: Last March, you announced your commitment to finding a vaccine for HIV within ten years. That was 18 months ago. The Council is concerned that the effort to develop a vaccine is not progressing fast enough. NIH has yet to hire a director for its new vaccine center and the different Federal agencies that are involved in vaccine research aren't coordinated. Will you encourage NIH Director Varmus to get the vaccine center director position filled? Will you support Sandy Thurman's office in facilitating cross-agency coordination?

A: I certainly appreciate the need for an HIV vaccine. This past World AIDS Day we did an event here that focused on the international epidemic, and I am just staggered by the impact that AIDS is having on so many nations around the world. I have asked Sandy to go to Africa in January to look at the AIDS orphan issue and to report back to me with recommendations on further actions we might consider. I know that a vaccine is our best and maybe only hope of stopping this terrible disease.

As for the vaccine center director, we have talked with Dr. Varmus and he has assured us that he is being very aggressive in his efforts to find just the right person for the position. Part of the delay has been his commitment to finding the very best person. He also assures us that the vaccine research effort has not been slowed down by this vacancy, and that in fact they are very pleased with their progress. NIH is increasing its vaccine research funding this year, up \$47 million (33%) to \$200 million. I also know that Dr. Nathanson, the new director of the Office of AIDS Research at NIH, is very committed to vaccine research and is providing great leadership.

As for the interagency coordination, Sandy and Dr. Varmus have talked about that. I understand that they're initiating regular vaccine research meetings that will be open to all the different agencies, and the community groups working on this issue. I will talk with Sandy about this and see if there is more that we can do.

Q: While we have had great success in AIDS funding with your leadership, the Council is concerned that there are still a great many unmet needs. We are particularly concerned that HIV prevention activities at the CDC and international assistance through USAID have not received needed increases. Will you commit to increasing AIDS funding in FY2000, particularly in prevention and international relief?

A: We are working on developing the FY2000 budget now, so it is a work-in-progress. I do know that you have a great team of advocates at OMB. Jack Lew, Josh Gotbaum, Sylvia Matthews, and Dan Mendelson are all committed to doing the best that we can in addressing the need for additional AIDS funding.

With respect to prevention funding, I can say that we fully understand the need to increase and improve our HIV prevention activities, and to pay particular attention to communities of color, to women, and to young people who are at highest risk. We're taking a look not only at the need for increased funding, but making sure that what we are already investing is being used most effectively.

As for international funding, we've gotten good support from USAID although I know Brian Atwood would like more. This is going to be a very challenging budget year for us, and I don't want to be overly optimistic about our ability to repeat the kind of increases we were able to obtain in FY99. Nevertheless, we will do our very best to support appropriate funding levels for our international AIDS efforts, and the other AIDS programs as well.

SELECTED HIV/AIDS INVESTMENTS	FY99	Increase from FY98	Increase from FY93
Ryan White CARE Act	\$1.4 billion	23%	266%
<i>AIDS Drug Assistance</i>	<i>\$461 million</i>	<i>61%</i>	<i>787%*</i>
HIV Prevention (CDC)	\$657 million	5%	34%
AIDS Research (NIH)	\$1.8 billion	12%	67%
<i>Vaccine Research</i>	<i>\$200 million</i>	<i>33%</i>	<i>145%</i>
Housing (HUD)	\$225 million	10%	125%
International (USAID)	\$131 million**	8%	64%

*since FY96, when separate program established

**includes \$10 million emergency funding for AIDS orphan initiative

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