

June , 1997

MEMORANDUM TO THE PRESIDENT

FR: Bruce Reed
Sandy Thurman
Chris Jennings

RE: Status of Current AIDS Initiatives

This memo provides a status report on all of your current AIDS initiatives, including your commitment to developing an AIDS vaccine in the next ten years, the Vice President's request for HCFA to assess the feasibility of a budget neutral waiver which would enable Medicaid to cover people with HIV before they become disabled enough to meet the current eligibility criteria allowing them to begin their treatment earlier, and the FDA's proposal to ensure that new drugs and biological products carry adequate pediatric labeling at the time of, or soon after, their approval.

AIDS Vaccine

Your Morgan State announcement to increase our commitment to develop an AIDS vaccine in the next ten years, has received overwhelmingly positive support both in the scientific community and in the AIDS community. (see attached list of supportive quotes). As you know, some activists (mostly on the fringe of the AIDS community) and a few editorial writers have criticized your announcements. Their criticisms have been two-fold: 1) this commitment lacks the necessary funding to increase the likelihood of the development of a vaccine; and 2) this commitment comes at the expense of much-needed funding for people who have already contracted HIV and from funding to prevent more people from contracting the virus.

Both these criticisms are unfounded. You have increased funding for the AIDS vaccine by over 33% over the past two years. Moreover, Dr. Varmus and other experts in this area have stated that the current level of funding is adequate for their efforts. The real need, they argue, is for more collaboration in the scientific community, both among AIDS experts and vaccine experts. The initiatives you announced at Morgan State -- to open a AIDS vaccine center at NIH and to have the countries involved in the Denver Summit to increase their commitment to the development of the vaccine -- would do just that.

You have an excellent record with regard to funding AIDS prevention and treatment. Your FY 1998 Budget proposes to spend \$1 billion on Ryan White, an 168 percent increase over the FY 1993 Budget. You have also taken significant steps to increase support for State AIDS Drug Assistance Programs (ADAP), including proposing to budget amendments in 1996 - \$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. Your FY 1998 proposes \$167 million for ADAP, and we are currently reviewing proposals to offer another budget amendment.

To get these messages across to the AIDS community and others, Sandy Thurman is arranging meetings with the AIDS community and Dr. Varmus, and we are also working with UNAIDS to write an editorial for either *The New York Times* or *The Washington Post* which discusses the real need for an AIDS vaccine.

We are also making significant progress with regard to the three initiatives you announced at Morgan State:

AIDS Vaccine Center. Dr. Varmus is currently assembling the committee to select the new Director of the AIDS vaccine center. He hopes to announce the Director in approximately three months. They plan to announce the status of the center along with the new Director and hope to open it shortly thereafter. We are having ongoing discussions with them about their plans for the center and about any possible events we might want to announce surrounding its opening.

Commitment of the Nations at the G-7 in Denver. We have reviewed the language on the AIDS vaccine in the Communique for the Summit and believe that it is quite strong. Dr. Varmus is following up with his counterparts in various nations to encourage them to actively participate in this international commitment. So far, we have received positive responses from Canada, England, Japan, and Italy, and Dr. Varmus is still involved in negotiations with the remaining nations. We are with Dr. Baltimore, the head of the Committee on the AIDS Vaccine, Dr. Paul and others at NIH to determine the best way for these nations to state their commitment to collaborate on this issue, and also on the most appropriate way to announce this commitment at Denver.

Meeting with the Pharmaceutical Industry. To respond to your call to increase the level of involvement of the pharmaceutical industry, we are working with Dr. Baltimore to determine what the best role the Administration can play to increase their involvement. Possible options include, ??????

Medicaid Demonstration for Protease Inhibitors

In April, the Vice President announced that he was asking HCFA look into the feasibility of doing a budget neutral demonstration to allow people with HIV to receive Medicaid coverage so that can began receiving protease inhibitors before they reach the current disability requirement. This not only will help prolong the lives of thousands of people with HIV, as most experts

believe that earlier treatment is far more effective, but many believe in the long-run it could be cost-effective as Medicaid covers the high costs of many AIDS patients during the last and costliest years of their lives.

The Department plans to send its analysis to the Vice President this week. However, this analysis concludes that this initiative is not budget neutral. This leaves us with a number of options, all of which are laid out in the HHS report including: (1) waiving the budget neutrality requirement for this Medicaid demonstration. (This has the obvious disadvantage of undermining our position that all Medicaid waivers should be budget neutral and will undoubtedly encourage numerous groups and states to apply for waivers that no longer meet the neutrality test); (2) asking HHS to offer this proposal as legislation, which could potentially be added in the budget legislation or through another legislative vehicle. This has the advantage of allowing a cost associated with this initiative but could be politically difficult given the sensitive politics surrounding Medicaid savings in the budget; and (3) the Vice President could say that the Department had met his goals by assessing the feasibility of this demonstration and since they have determined that it is not budget neutral that the Administration will not support this initiative at this time. The obvious problem with this alternative is the widespread press coverage this issue has already received, including a story by Robert Pear in this Sunday's *New York Times*.

Pediatric AIDS

Finally, we are looking at the possibility of announcing the FDA's proposal for new regulations to address the lack of pediatric use information by requiring, for the first time, that applications for certain new drug and biological products contain pediatric data. While children suffer from most of the same diseases as adults, and, by necessity, are treated with most of the same drugs as adults. The majority of new drugs and biological products, however, have not been tested on pediatric populations. As a result, product labeling frequently fails to provide directions for safe and effective use in children, despite widespread use.

In recent years, FDA has undertaken several initiatives to encourage the voluntary addition of pediatric use of information to drug labels, including implementing a "Pediatric Plan" designed to focus attention on and encourage voluntary development of pediatric data during drug development. FDA has also issued a rule that allows pediatric use information to appear on the label on the basis of substantially less data than before. However, these efforts have not resulted in significant gain, particularly with respect to the new drugs entering the marketplace.

Under the new proposal, the FDA would require pediatric studies of a marketed drug when the drug was widely used in children or offers significant therapeutic advantage to children and the lack of adequate labeling poses significant risks to children or additional information is needed to permit safe and effective use. Pediatric studies could be delayed until sufficient data were collected in adults.

The AIDS community strongly supports this initiative. However, there are some at the Department who believe that this initiative could undermine FDA reform, as Senator Dodd opposes any administrative action on this issue. (Status??) He wants this to be handled through legislation and has threatened to oppose FDA reform if we move forward on this issue.

TO: Nancy-Ann

FR: Sarah

RE: My Notes on AIDS Vaccine Meetings

Status of the Vaccine: Scientists currently have a number of different ongoing tests including, on humans, extremely promising testing in monkeys, as well as in the laboratory. None of these tests are currently ready to go to trial. The testing, particularly in monkeys looks very promising, although there is some controversy surrounding the ethics of this testing because there are cloning issues involved.

Time-Scale: Neither Dr Varmus, Dr. Paul, or Dr. Baltimore wanted to give a specific time frame for when an AIDS vaccine might be available. They are quite certain that a viable vaccine will not be ready during the President's second term and maybe not even within the next seven to eight years. They do not want to be held accountable to any specific date that the President would announce.

How important is finding a vaccine? All of the scientists agreed that finding an AIDS vaccine should be a top priority for NIH and the public health community. While protease inhibitors are now successfully treating thousands of AIDS patients, the drug is prohibitively expensive. It will continue to be too expensive and an inappropriate drug for many AIDS/HIV patients in this country and for an even higher percentage of the population in third world countries.

Where do scientists believe the President could be most useful? The first issue that was addressed was whether the President should allocate more resources towards developing a vaccine. NIH is extremely committed to stepping up efforts to move towards a vaccine. They currently only allocate a small portion of its AIDS budget to research on the vaccine. However, Dr. Paul said that they intend to commit a larger portion of their budget to the vaccine next year.

NIH scientists agreed that increasing our investments in developing an AIDS vaccine will help make important strides to developing a vaccine within the shortest possible time frame. This will be particularly useful when scientists get to the stage where they are ready to begin clinical trials, which can be extremely expensive. They agreed that an increase of \$50 million and \$100 million would be necessary to make a substantial difference in current efforts at NIH.

Dr. Varmus suggested that a budget amendment that would be specifically allocated to funding an AIDS vaccine would help NIH reach its funding goals. However, he also noted that this kind of an amendment may be difficult given the political environment in the Appropriations committee, which is extremely supportive of NIH but somewhat reluctant to increase what they believe is an already excessive AIDS budget.

Other ways the President could move forward a vaccine. While the President will not be able to take any actions that will lead to the discovery of the AIDS vaccine in his term or even in any definable time, NIH scientists believe that he could do a number of things to boost this development.

1) Dr. Varmus, Dr. Baltimore and Dr. Paul all strongly believed that the Administration may want to market the development of an AIDS vaccine as an international issue that is in the interest of our national security. In the absence of a viable vaccine, AIDS will severely damage the health and the economy of many countries, including India, Russia, and many African nations. They believe that President Clinton can help make America the world leader in this fight to eradicate this disease.

They suggested that the President may want to consider bringing scientists in this area with him on a possible trip to Africa or any other nation facing large increases in people with HIV/AIDS and highlight the United States commitment to this issue.

They also recommended that perhaps the State Department should consider funding some of the possible additional investments to vaccine research. Using funding from outside of the NIH budget would help circumvent the problem Dr. Varmus would face with the Congress if we were to propose additional money for this issue in the NIH budget.

There was also some interest in characterizing this issue as part of a larger problem of infectious diseases. Dr. Paul suggested that we might lump the AIDS vaccine along with the need for better protection against tuberculosis and malaria.

2) Involving the Industry. Both Dr. Varmus and Dr. Paul believed that the President could help the industry become more invested in this issue. Since the industry often funds clinical trials and in certain stages of the development of a vaccine, it would be extremely helpful in the President would indicate his deep commitment to this issue to elevate the level of interest. This would also help increase the expectation for success. They believe this would urge the industry to step up their level of involvement and at the same time provide an opportunity for the Administration to improve our relationship with the industry. They were very supportive of the idea of a Presidential event with the industry.

3) Bully Pulpit. They also believe that a few Presidential events where the President communicates that this developing a viable vaccine is indeed a high priority for this Administration would help raise interest and awareness of this issue both in the scientific community, the business community, and with the public.

Helping people with HIV/AIDS

They also thought we should consider the fact that finding a viable vaccine may not be the highest priority for people with HIV/AIDS, who are the most vocal and well organized on this issue, since a vaccine will not necessarily cure AIDS. However, NIH scientists believe that there may be a possibility that we will first discover a vaccine that lowers the level of HIV to the point where it cannot be transmitted and where one could live with it. They recommended that we

consider this in our message since it may alleviate some concerns that a vaccine will come at the expense of the cure.



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

MAY 15 1997

McPherson Sq.
11:50 15th St.
3:00
Arrive by 2:45

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:

Page 2 - Memorandum for the President

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

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

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

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

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

Page 3 - Memorandum for the President

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

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

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

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

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

File Sarah
Morgan State

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.

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, the 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.

QUESTIONS AND ANSWERS ON GENETIC TESTING

Q: DIDN'T WE ALREADY TAKE CARE OF THIS PROBLEM IN THE KASSEBAUM-KENNEDY HEALTH REFORM LEGISLATION?

A: The Kassebaum-Kennedy legislation did take important steps to prevent health insurers from discriminating on the basis of genetic information. However, this legislation builds on these provisions in three important areas: (1) prevents insurers in the individual market from discriminating on the basis of genetic information (2) assures the premiums setting is in no way based on genetic information both in the group and individual market; and (3) prevents insurance from disclosing genetic information.

- **Access in the Individual Market.** The Kassebaum-Kennedy law says that employers may not use genetic information as a pre-existing condition unless the illness associated with the pre-existing condition has already been diagnosed. In that case, the health plan could deny health care coverage for a maximum of twelve months.

However, Kassebaum-Kennedy did not address the issue of genetic information for Americans who are part of the individual insurance market. This legislation would take the next step by protecting Americans who have an health insurance in the individual market from being denied health care coverage based on their genetic information.

- **Affordability in the Individual and the Group Market.** The Kassebaum-Kennedy legislation did not address the issue of affordability in the insurance market. Thus it does not prevent insurers from increasing group premium rates based on knowledge about genetic information. (It would prevent health plans from charging an individual higher premiums based on their genetic information).

This new legislation would prevent health plans from setting premium rates based on genetic information, both in group health plans and in the individual market.

- **Disclosing Genetic Information.** This new legislation would also prevent health plans from releasing genetic information. If genetic information from health plans were accessible, it would make it much easier for other parties (probably employers and other non-health insurers) to misuse this information.

Q: AREN'T LOTS OF STATES TAKING ACTION ON THIS ISSUE. WHY DO WE NEED FEDERAL LEGISLATION?

A: More than a dozen states have taken action in this area and 31 more have proposed legislation. 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. Moreover, Employer Retirement Income Security Act (ERISA) exempts self-funded plans from state insurance laws. Thus even if states enact legislation to build on Kassebaum-Kennedy legislation, a large fraction of the population in self-funded plans would not be protected.

Q: IS THERE ANY EVIDENCE THAT INSURANCE COMPANIES ARE DISCRIMINATING AGAINST PEOPLE WITH A GENETIC PREDISPOSITION TO A DISEASE?

A: Medical researchers and physicians have reported that people are refusing to get genetic testing or to participate in medical research because they fear that this information could be used against them or a member of their family. 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. We also know that a leading reason women refuse genetic testing for breast cancer is because they fear that insurance companies may deny health care coverage for either themselves or members of their families or charge excessively high premiums. Moreover, 22 percent of people who live in families where someone has a genetic disorder report that they have been discriminated against by an insurance plan. (Lapham et al., Science, Oct 1996).

Q: HOW WAS GENETIC TESTING USED IN THE 1970s TO DISCRIMINATE AGAINST AFRICAN-AMERICANS?

A: Genetic testing was used both by employers and health insurance plans to discriminate against African-Americans who had one or two altered copies of the sickle cell gene. There were newborn screening programs, pre-employment tests done, and other widespread screening done to test for this genetic disorder. However, most people mistakenly believed that if an individual had at least one altered gene, they would likely develop sickle cell anemia. In fact, both of the genes must be altered to be vulnerable to this disorder.

Q: THERE ARE LOTS OF BILLS OUT ON THE HILL ON THIS ISSUE. WHY DOES THE PRESIDENT LIKE THE ONE INTRODUCED BY REPRESENTATIVE SLAUGHTER?

A: The Slaughter Bill is based on the joint recommendations made by the National Institutes of Health's Working Group on Ethical, Legal, Social Implications of Human Genome Research (ELSI Working Group) and the National Action Plan on Breast Cancer (NAPBC) to address the issue of genetic discrimination and health insurance. It addresses all of the central issues: using genetic information to deny or limit any coverage; establishing premium payments based on genetic information or an individual's request for genetic information; and disclosure of genetic information.

Q: HOW MUCH WOULD THIS LEGISLATION COST?

A: We do not have any formal estimates on how much this legislation would cost. However, states who have enacted legislation in this area have not experienced any major costs associated with this.

Q: HOW MANY AMERICANS WOULD BE AFFECTED BY THIS LEGISLATION?

A: This legislation would protect all Americans from having to pay higher premiums based on genetic information and from having their genetic information disclosed.

Genetic Screening Protection Legislation Would:

- 1) Prohibit insurers and other health plans from using genetic information, or an individual's request for genetic services, to deny or limit any coverage or establish eligibility for insurance.
- 2) Prohibit health plans from establishing differential rates or premium payments for individual insurance policies or group-wide plans based on genetic information.
- 3) Prohibit health plans from requesting or requiring collection or disclosure of genetic information.
- 4) Prohibit health plans or other holders of genetic information from releasing genetic information without prior written authorization of the individual.

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 subsaharan 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.

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, the 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.

QUESTIONS AND ANSWERS ON GENETIC TESTING

Q: DIDN'T WE ALREADY TAKE CARE OF THIS PROBLEM IN THE KASSEBAUM-KENNEDY HEALTH REFORM LEGISLATION?

A: The Kassebaum-Kennedy legislation did take important steps to prevent health insurers from discriminating on the basis of genetic information. However, this legislation builds on these provisions in three important areas: (1) prevents insurers in the individual market from discriminating on the basis of genetic information (2) assures the premiums setting is in no way based on genetic information both in the group and individual market; and (3) prevents insurance from disclosing genetic information.

- **Access in the Individual Market.** The Kassebaum-Kennedy law says that employers may not use genetic information as a pre-existing condition unless the illness associated with the pre-existing condition has already been diagnosed. In that case, the health plan could deny health care coverage for a maximum of twelve months.

However, Kassebaum-Kennedy did not address the issue of genetic information for Americans who are part of the individual insurance market. This legislation would take the next step by protecting Americans who have an health insurance in the individual market from being denied health care coverage based on their genetic information.

- **Affordability in the Individual and the Group Market.** The Kassebaum-Kennedy legislation did not address the issue of affordability in the insurance market. Thus it does not prevent insurers from increasing group premium rates based on knowledge about genetic information. (It would prevent health plans from charging an individual higher premiums based on their genetic information).

This new legislation would prevent health plans from setting premium rates based on genetic information, both in group health plans and in the individual market.

- **Disclosing Genetic Information.** This new legislation would also prevent health plans from releasing genetic information. If genetic information from health plans were accessible, it would make it much easier for other parties (probably employers and other non-health insurers) to misuse this information.

Q: AREN'T LOTS OF STATES TAKING ACTION ON THIS ISSUE. WHY DO WE NEED FEDERAL LEGISLATION?

A: More than a dozen states have taken action in this area and 31 more have proposed legislation. 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. Moreover, Employer Retirement Income Security Act (ERISA) exempts self-funded plans from state insurance laws. Thus even if states enact legislation to build on Kassebaum-Kennedy legislation, a large fraction of the population in self-funded plans would not be protected.

Q: IS THERE ANY EVIDENCE THAT INSURANCE COMPANIES ARE DISCRIMINATING AGAINST PEOPLE WITH A GENETIC PREDISPOSITION TO A DISEASE?

A: Medical researchers and physicians have reported that people are refusing to get genetic testing or to participate in medical research because they fear that this information could be used against them or a member of their family. 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. We also know that a leading reason women refuse genetic testing for breast cancer is because they fear that insurance companies may deny health care coverage for either themselves or members of their families or charge excessively high premiums. Moreover, 22 percent of people who live in families where someone has a genetic disorder report that they have been discriminated against by an insurance plan. (Lapham et al., Science, Oct 1996).

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

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

-- AIDS Action Council 5/20/97

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

-- Dr. Harold H. Varmus, NIH Director

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

-- David D. Ho, M.D.

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

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

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

-- UNAIDS 5/20/97

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

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

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

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

"I like the idea of setting a goal."

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

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

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

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

-- International AIDS Vaccine Initiative 5/19/97

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

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

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

-- The American Foundation for AIDS Research (AMFAR)

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

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

transmission in specific populations; the study of the natural history of HIV-related disease in women, men, adolescents, and children; and the study of transmission from mother to infant. New challenges and scientific opportunities in this area require investigation. Study is needed of new HIV strains and subtypes in the United States that may impact transmission rates and disease progression.

Women and AIDS

NIH has placed high priority on studies focused on women and AIDS and on characterizing clinical manifestations of HIV specific to women. The Women's Interagency HIV Study (WIHS), a major study conducted by several NIH Institutes and Centers in collaboration with other DHHS agencies, is investigating the nature and rate of disease progression in women to better characterize the clinical manifestations of HIV infection in women, determine the effects of therapeutic regimens, and identify the sociocultural and health-care-access factors that affect disease outcomes in women.

Participants in Women's Interagency HIV Study		
	HIV Seropositive (2054 women)	HIV Seronegative (568 women)
<u>Race/Ethnicity</u>		
White	18%	15%
African American	56%	54%
Latina/Hispanic	23%	28%
Other	2%	3%
<u>Exposure Category</u>		
IV drug use	34%	28%
Heterosexual risk	42%	26%
Blood transfusion risk	4%	3%
No identified risk	20%	43%

For example, adolescent females exposed to HIV and other sexually transmitted infections may be at higher risk of infection because of the immaturity of the cells of the genital tract. Research to develop chemical and barrier methods, including topical microbicides, is critical to help women prevent transmission of HIV and other sexually transmitted infections.

NIH supports the HIV Network for Prevention Trials (HIVNET) in preparation for vaccine and other prevention trials of biomedical and behavioral interventions. This network has already begun to evaluate STD treatments, microbicides, and perinatal interventions with antiretrovirals and immunotherapy, as well as other behavioral and biomedical interventions. Another area of primary prevention research is focusing on developing new or improved means of reducing perinatal transmission, with particular emphasis on methods appropriate to the developing world.

Disease Progression

Studies of HIV disease progression are critical for determining how HIV causes destruction of the immune system and subsequent illness. These studies, performed in the United States as well as in other countries that may exhibit different patterns of the epidemic, afford scientists the opportunity to describe the biologic, psychological, clinical, socioeconomic, and medical-care-access consequences of HIV infection and HIV-associated disease. NIH is supporting research on individuals who (1) do not become infected despite repeated exposure to HIV, (2) appear to show clearing of the virus after initial documented infection, (3) manifest infection without immunologic progression (long-term nonprogressors), and (4) maintain stable clinical state even with prolonged immunosuppression (long-term survivors).

TRAINING, INFRASTRUCTURE, AND INFORMATION DISSEMINATION

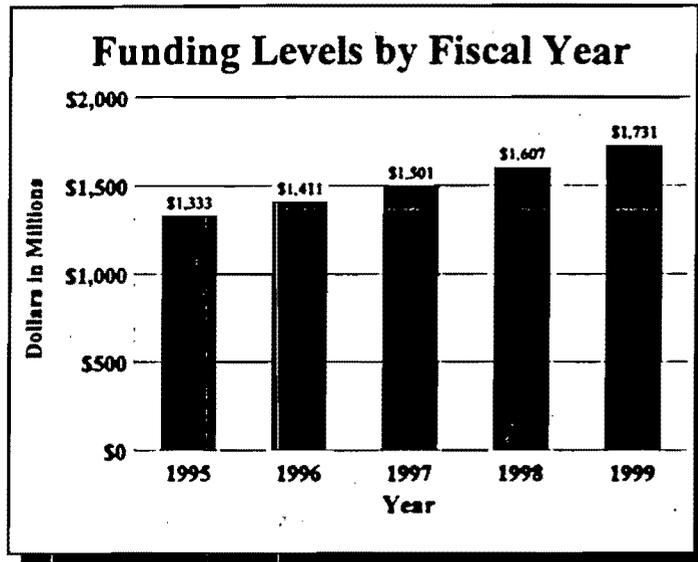
NIH will continue to support training of domestic and international biomedical and behavioral researchers to conduct AIDS-related research and improve facilities and equipment for the conduct of AIDS research. The NIH Loan Repayment Program (LRP) was mandated by Congress under Public-Law 100-607 in 1988 and was authorized to encourage health professionals to engage in AIDS-related research at the NIH. The FY 1999 request includes \$1,000,000 for this program. The dissemination of state-of-the-art research findings for domestic and international audiences also continues to be an important goal.

Conclusion

In summary, the FY 1999 NIH AIDS research plan and budget request is framed on the scientific priorities included in the findings and recommendation of the NIH AIDS Research Program Evaluation. The process to develop this plan and budget involved an intensive outside evaluation of the NIH by hundreds of scientific experts and community representatives and a deliberative and comprehensive implementation of their recommendations. Because of the legislative authorities provided to OAR for planning and budgeting for AIDS research, it has been possible to set new scientific priorities and to reshape and restructure the research enterprise toward our goal of preventing and curing AIDS.

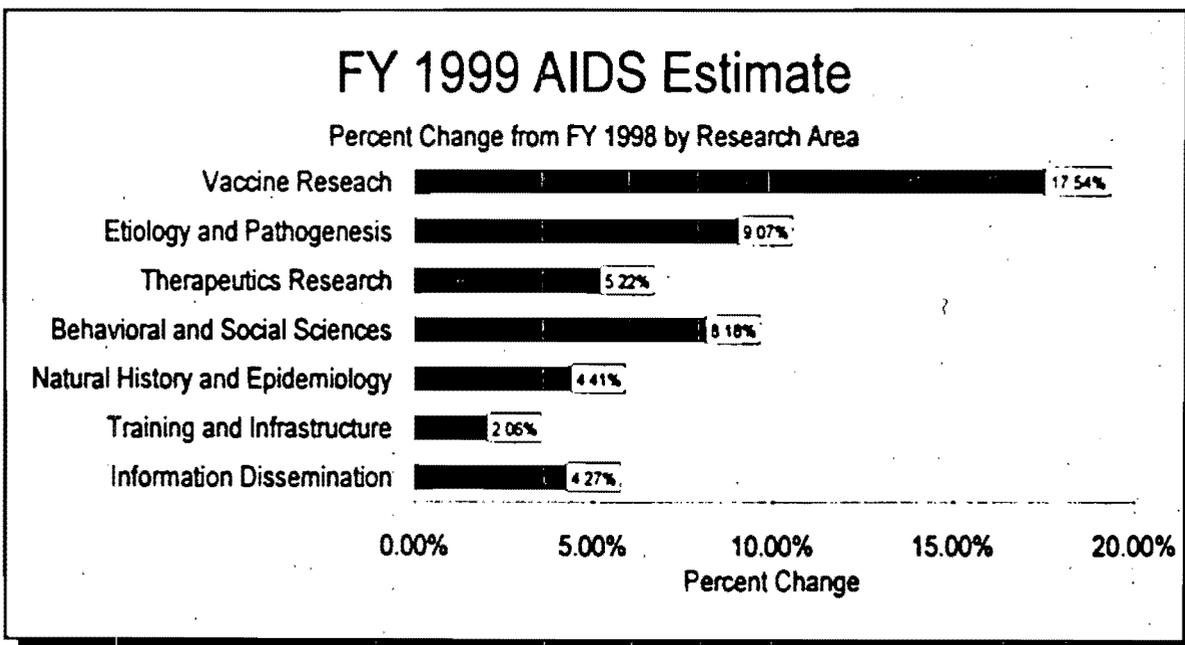
Office of AIDS Research: Rationale for the Budget Request

The President's budget request for the NIH Office of AIDS Research—which includes all AIDS funding for the Institutes and Centers of the NIH—is \$1,730,796,000, a 7.7 percent increase over the FY 1998 Estimate of \$1,607,053,000. This budget will be utilized to intensify AIDS research efforts in priority areas set forth in this budget. This proposed increase will ensure that new scientific opportunities can be exploited and that the development and evaluation of new therapies, vaccines, and behavioral interventions will be enhanced.



Overall Budget Policy

The major priorities of the FY 1999 Plan for HIV/AIDS Research are addressed under each research area: Vaccine Research; Etiology and Pathogenesis Research; Therapeutics Research; Behavioral and Social Sciences Research; and Natural History and Epidemiology Research; Training and Infrastructure; and Information Dissemination. The following chart displays the percent increase of the FY 1999 President's Budget over the FY 1998 Estimate in each of the research areas:



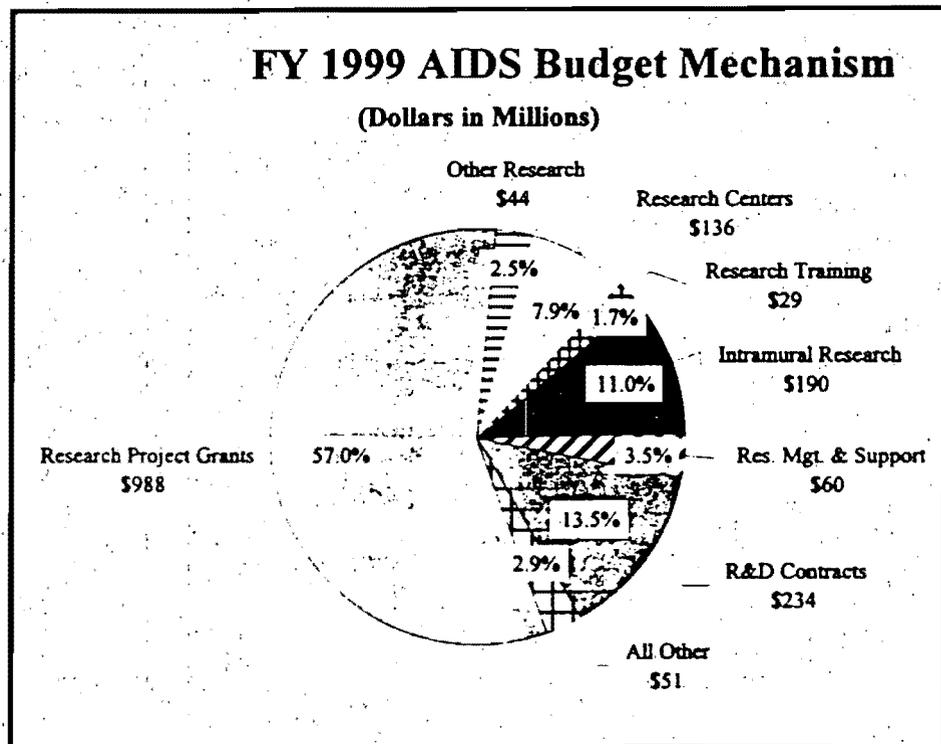
Purpose and Method of Operation

The Office of AIDS Research has continued the practice, started in FY 1994, of increasing the percentage of the budget directed towards investigator initiated research. As seen in the adjacent chart, research project grants constitutes 57 percent of the AIDS budget.

In recent years, the NIH has followed a policy of providing only inflationary increases to the

average cost of competing RPGs. The FY 1999 President's Budget Request provides a significant increase in our investment in medical research, and allows for real expansion in the scope of research undertaken in RPGs by providing competing RPGs an average cost increase of 10 percent over FY 1998 average costs. This increase will enable researchers to explore promising discoveries through investment in instrumentation, animal models, and other high-cost grant components. It will also encourage the most promising new researchers to enter biomedical research by expanding support for new researchers. To attract high quality new researchers and provide effective research support, in FY 1999, NIH will continue the transition begun late in FY 1998, to replace the First Independent Research Support and Transition Award (R29) as the primary mechanism of support for new researchers with the traditional (R01) research grant. New traditional research grants average approximately \$200,000 annually and can compete for renewal, in contrast to FIRST awards, which limit funding to \$75,000 annual direct costs for five years. Support for individual noncompeting RPGs will increase by 3 percent on average over FY 1998 levels.

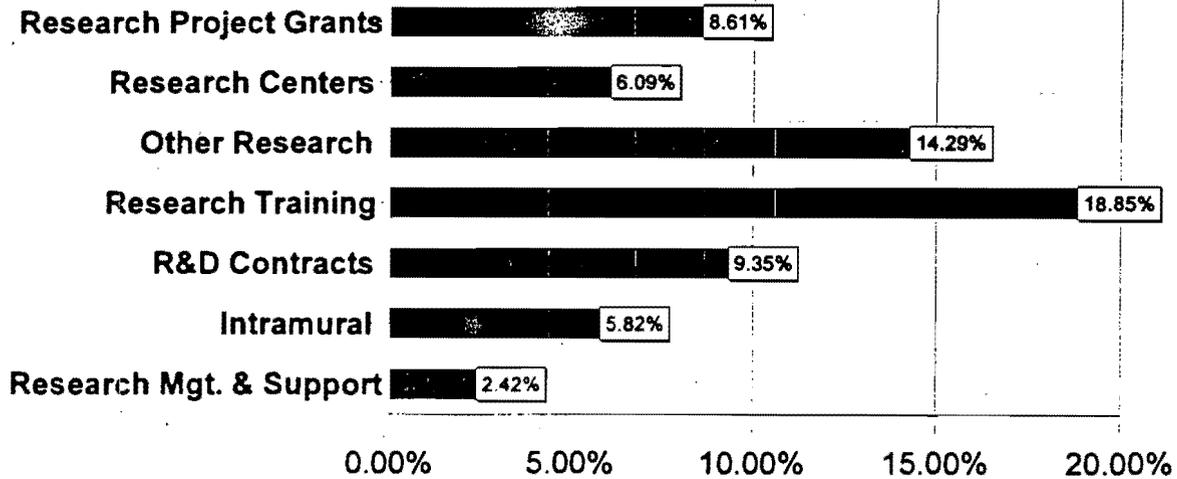
These promises for advancement in medical research are dependent on a continuing supply of new investigators with new ideas. Stipends for young trainees have not kept pace with increases in the cost of living. The FY 1999 President's Budget Request provides a one-time stipend increase of 25 percent for National Research Service Award (NRSA) fellows, to bring NIH



stipends closer to recommendations made by the National Academy of Sciences in their report on training programs: *Meeting the Nation's Needs for Biomedical and Behavioral Scientists*. At the current time, NRSA predoctoral fellows receive an annual stipend of \$11,700 and entry level postdoctoral fellows receive \$21,000. This increase in stipends will provide an annual stipend of \$14,600 for predoctoral fellows and \$26,200 for entry level postdoctoral fellows.

FY 1999 AIDS Estimate

Percent Change from FY 1998 by Mechanism



NATIONAL INSTITUTES OF HEALTH
Office of AIDS Research
Summary by Mechanism

MECHANISM	FY 1997 Budget Authority		FY 1998 Estimate		FY 1999 Estimate	
	No.	Amount	No.	Amount	No.	Amount
Research Grants:						
Research Projects						
Noncompeting	1,644	\$602,168,000	1,760	\$666,985,000	1,840	\$665,173,000
Administrative supplementals	(148)	13,587,000	(75)	7,948,000	(70)	9,505,000
Competing:						
Renewal	196	68,482,000	247	73,252,000	333	105,359,000
New	434	133,718,000	513	139,643,000	614	184,449,000
Supplemental	9	1,371,000	5	564,000	9	745,000
Subtotal, competing	639	203,571,000	765	213,459,000	956	290,553,000
SBIR/STTR	106	19,457,000	117	21,246,000	121	22,708,000
Subtotal, RPGs	2,389	838,783,000	2,642	909,638,000	2,917	987,939,000
Research Centers						
Specialized/comprehensive	29	53,013,000	29	57,066,000	30	61,211,000
Clinical research		35,541,000		36,522,000		37,983,000
Biotechnology		2,296,000		2,555,000		3,055,000
Comparative medicine	10	25,121,000	12	25,949,000	12	26,449,000
Research Centers in Minority Institutions		5,961,000		6,569,000		7,794,000
Subtotal, Centers	39	121,932,000	41	128,661,000	42	136,492,000
Other Research						
Research careers	166	14,522,000	166	15,179,000	164	15,737,000
Cancer education		149,000		323,000		373,000
Cooperative clinical research	3	5,710,000	3	5,631,000	3	8,705,000
Biomedical research support	1	918,000		659,000		659,000
Minority biomedical research support		582,000		631,000		684,000
Other	33	13,320,000	36	15,724,000	38	17,439,000
Subtotal, Other Research	203	35,201,000	205	38,147,000	205	43,597,000
Total Research Grants	2,631	995,916,000	2,888	1,076,446,000	3,164	1,168,028,000
Training	FTTPs		FTTPs		FTTPs	
Individual awards	82	2,097,000	90	2,430,000	90	2,840,000
Institutional awards	729	21,452,000	750	21,737,000	780	25,882,000
Total, Training	811	23,549,000	840	24,167,000	870	28,722,000
Research & development contracts (SBIR/STTR)	216 (2)	219,186,000 (200,000)	216 (5)	213,550,000 (1,450,000)	222 (6)	233,508,000 (1,500,000)
Intramural research		165,921,000		179,197,000		189,618,000
Research management and support		57,575,000		58,186,000		59,596,000
Cancer prevention & control						
Construction						
Library of Medicine		3,365,000		3,371,000		3,472,000
Office of the Director		35,561,000		40,536,000		41,752,000
Subtotal		1,501,073,000		1,595,453,000		1,724,696,000
Buildings and Facilities (CRC Replacement) (Vaccine Facility) (Infrastructure)				11,600,000 (11,600,000)		6,100,000 (6,100,000)
Total, Budget Authority		1,501,073,000		1,607,053,000		1,730,796,000
(Clinical Trials)		(325,904,000)		(340,618,000)		(373,441,000)

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Budget Authority by Activity
(dollars in thousands)

Research Area	FY 1997 Actual	FY 1998 Estimate	FY 1999 Estimate	Change
Natural History and Epidemiology	\$214,861	\$216,798	\$226,367	\$9,569
Etiology and Pathogenesis	438,663	482,385	526,140	43,755
Therapeutics	444,382	457,818	481,722	23,904
Vaccines	130,173	153,042	179,891	26,849
Behavioral and Social Science Research	201,954	215,135	232,737	17,602
Training and Infrastructure	52,059	65,807	66,228	421
Information Dissemination	18,335	16,986	17,711	725
Total obligations	1,500,427	1,607,971	1,730,796	122,825
Unobligated balance, available start of year	(660)	(918)	--	918
Unobligated balance, available end of year	918	--	--	--
Unobligated balance lapsing	388	--	--	--
Total, Budget Authority	1,501,073	1,607,053	1,730,796	123,743

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Summary of Changes

1998 Estimated budget authority		\$1,607,053,000
1999 Estimated budget authority		1,730,796,000
Net change		123,743,000
	1998 Current Estimate Base	Change from Base
	Budget Authority	Budget Authority
Changes:		
A. Built-in:		
1. Intramural research:		
a. Within grade increase	41,599,000	\$611,000
b. Annualization of January 1998 pay increase	41,599,000	259,000
c. January 1999 pay increase	41,599,000	986,000
d. Payment for centrally furnished services	34,334,000	1,032,000
e. Increased cost of laboratory supplies, materials, and other expenses	103,204,000	2,057,000
Subtotal		4,945,000
2. Research Management and Support:		
a. Within grade increase	27,815,000	403,000
b. Annualization of January 1998 pay increase	27,815,000	168,000
c. January 1999 pay increase	27,815,000	647,000
d. Payment for centrally furnished services	6,967,000	210,000
e. Increased cost of laboratory supplies, materials, and other expenses	23,404,000	428,000
Subtotal		1,856,000
Subtotal, Built-in		6,801,000

30 29

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research
Summary of Changes—continued

	1998 Current Estimate Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research projects grants:				
a. Noncompeting	1,760	\$674,933,000	80	(\$255,000)
b. Competing	765	213,459,000	191	77,094,000
c. SBIR/STTR	117	21,246,000	4	1,462,000
Total	2,642	909,638,000	275	78,301,000
2. Centers	41	128,661,000	1	7,831,000
3. Other research	205	33,147,000	—	5,450,000
4. Research training	840	24,167,000	30	4,555,000
5. Research and development contracts	216	213,550,000	6	19,958,000
6. Intramural research		179,197,000		5,476,000
7. Research management and support		58,186,000		(446,000)
8. Office of AIDS Research		40,536,000		1,216,000
9. National Library of Medicine		3,371,000		101,000
10. Buildings and Facilities		11,600,000		(5,500,000)
Subtotal, program				116,942,000
Total changes		1,607,053,000		123,743,000

Note: Includes funds to support personnel included in the individual Institutes and Centers of the NIH.

National Institutes of Health
Office of AIDS Research
HIV/AIDS Funding by Institute and Center

Institute/Center	FY 1997 Actual	FY 1998 Estimate	FY 1999 Estimate
NCI	\$224,733,000	\$226,414,000	\$240,206,000
NHLBI	61,577,000	63,602,000	68,010,000
NIDR	12,932,000	13,493,000	14,898,000
NIDDK	12,718,000	15,382,000	16,843,000
NINDS	24,825,000	26,343,000	28,633,000
NIAID	647,709,000	701,469,000	766,217,000
NIGMS	27,695,000	28,694,000	30,555,000
NICHD	64,369,000	67,485,000	72,260,000
NEI	9,450,000	9,655,000	9,945,000
NIEHS	6,489,000	6,552,000	6,749,000
NIA	1,854,000	1,910,000	1,967,000
NIAMS	4,273,000	4,391,000	4,523,000
NIDCD	1,820,000	1,838,000	1,893,000
NIMH	96,906,000	100,878,000	107,904,000
NIDA	160,832,000	167,398,000	181,170,000
NIAAA	11,051,000	14,453,000	15,487,000
NINR	5,500,000	5,554,000	5,921,000
NHGRI	3,001,000	3,047,000	3,138,000
NCRR	74,101,000	82,377,000	91,848,000
FIC	10,312,000	10,611,000	11,305,000
NLM	3,365,000	3,371,000	3,472,000
OD	35,561,000	40,536,000	41,752,000
B&F	—	11,600,000	6,100,000
TOTAL	1,501,073,000	1,607,053,000	1,730,796,000

NATIONAL INSTITUTES OF HEALTH

OFFICE OF AIDS RESEARCH

BUDGET AUTHORITY BY OBJECT

Object Class	FY 1998 Estimate	FY 1999 Estimate	Increase or Decrease
11.1 Full-Time Permanent	\$45,208,000	\$50,224,000	\$5,016,000
11.3 Other than Full-Time Permanent	8,447,000	9,386,000	939,000
11.5 Other Personnel Compensation	2,523,000	2,814,000	291,000
11.8 Special Personnel Services Payments	4,787,000	5,401,000	614,000
11.9 Total Personnel Compensation	60,965,000	67,825,000	6,860,000
12.0 Civilian Personnel Benefits	13,345,000	15,109,000	1,764,000
13.0 Benefits for Former Personnel	15,000	18,000	3,000
Subtotal, Pay Costs	74,325,000	82,952,000	8,627,000
21.0 Travel & Transportation of Persons	2,986,000	3,085,000	99,000
22.0 Transportation of Things	456,000	480,000	24,000
23.1 Rental Payments to GSA	1,727,000	1,779,000	52,000
23.2 Rental Payments to Others	1,172,000	1,320,000	148,000
23.3 Communications, Utilities & Miscellaneous Charges	3,826,000	3,997,000	171,000
24.0 Printing & Reproduction	885,000	929,000	44,000
25.1 Consulting Services	15,529,000	9,952,000	(5,577,000)
25.2 Other Services	52,181,000	53,946,000	1,765,000
25.3 Purchase of Goods & Services from Government Accounts	97,480,000	99,032,000	1,552,000
25.4 Operation & Maintenance of Facilities	38,842,000	37,384,000	(1,458,000)
25.5 Research & Development Contracts	166,133,000	186,418,000	20,285,000
25.6 Medical Care	863,000	885,000	22,000
25.7 Operation & Maintenance of Equipment	1,631,000	1,660,000	29,000
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal, Other Contractual Services	372,659,000	389,277,000	16,618,000
26.0 Supplies & Materials	24,295,000	25,044,000	749,000
31.0 Equipment	12,780,000	13,422,000	642,000
32.0 Land and Structures	11,000	11,000	0
33.0 Investments & Loans	80,651,000	90,080,000	9,429,000
41.0 Grants, Subsidies & Contributions	1,031,072,000	1,118,202,000	87,130,000
42.0 Insurance Claims & Indemnities	200,000	210,000	10,000
43.0 Interest & Dividends	8,000	8,000	0
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	1,532,728,000	1,647,844,000	115,116,000
Total Budget Authority	1,607,053,000	1,730,796,000	123,743,000

Note Includes funds to support personnel included in the Institutes and Centers of the NIH.

NATIONAL INSTITUTES OF HEALTH

OFFICE OF AIDS RESEARCH

ADMINISTRATIVE COSTS

	FY 1998 Estimate	FY 1999 Estimate	Change
Personnel Compensation:			
Full-Time Permanent (11.1)	\$45,208,000	\$50,224,000	\$5,016,000
Other Than Full-Time Permanent (11.3)	8,447,000	9,386,000	939,000
Other Personnel Compensation (11.5)	2,523,000	2,814,000	291,000
Special Personnel Services Payments (11.8)	4,787,000	5,401,000	614,000
Total Personnel Compensation (11.9)	60,965,000	67,825,000	6,860,000
Civilian Personnel Benefits (12.0)	13,345,000	15,109,000	1,764,000
Benefits to Former Personnel (13.0)	15,000	18,000	3,000
Subtotal, Pay Costs	74,325,000	82,952,000	8,627,000
Travel (21.0)	2,986,000	3,085,000	99,000
Transportation of Things (22.0)	456,000	480,000	24,000
Rental Payments to Others (23.2)	1,172,000	1,320,000	148,000
Communications, Utilities and Miscellaneous Charges (23.3)	3,826,000	3,997,000	171,000
Printing and Reproduction (24.0)	885,000	929,000	44,000
Other Contractual Services:			
Advisory and Assistance Services (25.1)	15,529,000	9,952,000	(5,577,000)
Other Services (25.2)	52,181,000	53,946,000	1,765,000
Purchases from Govt. Accounts (25.3)	65,782,000	65,047,000	(735,000)
Operation & Maintenance of Facilities (25.4)	2,064,000	2,131,000	67,000
Operation & Maintenance of Equipment (25.7)	1,631,000	1,660,000	29,000
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal, Other Contractual Services	137,187,000	132,736,000	(4,451,000)
Supplies and Materials (26.0)	24,210,000	24,953,000	743,000
Subtotal, Non-Pay Costs	170,722,000	167,500,000	(3,222,000)
Total, Administrative Costs	245,047,000	250,452,000	5,405,000

Note: Includes funds to support personnel included in the Institutes and Centers of the NIH.

NATIONAL INSTITUTES OF HEALTH**Office of AIDS Research****SIGNIFICANT ITEMS IN HOUSE APPROPRIATIONS COMMITTEE REPORT****FY 1998 House Appropriations Committee Report Language (H. Rpt.105-205)****Item**

AIDS Funding- Consistent with the philosophy outlined above, the Committee has again chosen not to earmark a specific dollar amount for AIDS research and has not provided a single appropriation for the Office of AIDS Research. In relying on NIH's recommendations for the allocation of the total funding provided by the Committee, the Committee understands that it would be NIH's intent to allocate approximately \$1,574 million to AIDS-related research. The Committee intends that the funds allocated for AIDS should be spent in a manner fully consistent with the AIDS research plan developed by the Office of AIDS Research and expects the Director of NIH to use the full authority of his office to ensure that this occurs. The Committee has provided the Director of the Office of AIDS Research, jointly with the Director of NIH, transfer authority to reallocate up to three percent of funds designated for AIDS research among Institutes, subject to normal reprogramming procedures. The Committee encourages NIH to use this authority whenever it believes that an adjustment in the allocation of AIDS funding between Institutes is appropriate to achieve scientific objectives or to facilitate promising research efforts. The Committee wants to make clear that it continues to support the Office of AIDS Research (OAR), its leadership, and its coordinated budget planning process and that it expects the individual institutes, centers and divisions to fully cooperate with OAR's work. The Committee has provided funding for the OAR within the Office of the Director and intends that the OAR will maintain its current structure and responsibilities, including the allocation of an emergency discretionary fund. (p. 61)

Action taken or to be taken

The OAR has allocated all monies for AIDS-related research to the Institutes and Centers in accordance with the scientific priorities and objectives of the FY 1998 NIH Plan for HIV-Related Research.

Item

Office of AIDS Research- The Committee further commends NIH for establishing the intramural Vaccine Research Center (VRC) dedicated to the discovery and development of an AIDS vaccine. The immunological methodologies required in this effort have the potential to advance the development of vaccines against other new or re-emerging infectious diseases. The Committee looks forward to hearing of progress made in this area. Should additional funds be

required for the VRC in fiscal year 1998, the Committee encourages OAR to identify funds for this purpose, either through the OAR Discretionary Fund or through the use of the three percent transfer authority. (p. 96)

Action taken or to be taken

The OAR has identified \$11,600,000 of AIDS funds for the Vaccine Research Facility, the Non-AIDS budget contains \$5,357,000 for this facility, providing a total of \$16,957,000 in FY 1998. The FY 1999 request contains \$6,100,000 in the OAR appropriation that will be transferred to the Buildings and Facilities account for the Vaccine Research Facility. The Non-AIDS budget contains \$3,043,000 for this facility, providing a total of \$9,143,000 in FY 1999. The NIH does not anticipate the need for additional funds at this time.

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	1998 Amount Authorized	1998 Estimate	1999 Amount Authorized	1999 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	---	Indefinite	\$1,692,074,000
Office of AIDS Research	Title XXIII Section 2353 (d) (1)	42§300cc-40b(d)	a/	---	b/	
Discretionary Fund	Title XXIII Section 2356 (g)	42§300cc-43(g)	a/	---	b/	10,000,000
National Research Service Awards	Section 487(d)	42§288(d)	a/	---	b/	28,722,000
Total, Budget Authority			---	---		1,730,796,000

a/ Funding provided under Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, 1998 (P.L. 105-78).

b/ Reauthorizing legislation will be submitted

33

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Appropriation History

Fiscal Year	Budget Estimate to Congress 1/	House Allowance	Senate Allowance	Appropriation
1995	\$1,379,052,000	\$1,337,606,000	\$1,337,606,000	\$1,335,421,000 2/
1995 Rescission				(1,851,000)
1996	1,407,824,000	3/	1,382,861,000	4/
1997	1,431,908,000	3/	1,460,312,000	4/
1998	1,540,765,000	3/	5/	4/
1999	1,730,796,000			

1/ Includes all amounts associated with the National Institutes of Health AIDS Research Program.

2/ Excludes procurement reform, rent, and salary and expense reductions of \$2,185,000.

3/ The House did not provide separate funding for HIV/AIDS activities. The funds to support these activities are included in the appropriations of the Institutes and Centers.

4/ The Conferees did not provide separate funding for HIV/AIDS activities. The funds to support these activities are included in the appropriations of the Institutes and Centers.

5/ The Senate did not provide separate funding for HIV/AIDS activities. The funds to support these activities are included in the appropriations of the Institutes and Centers.

File AIDS

July 12, 1996



Health Division



Office of Management and Budget
Executive Office of the President
Washington, DC 20503

Please route to:

Nancy-Ann Min

Decision needed _____
Please sign _____
Per your request _____
Please comment _____
For your information _____

Subject: Shalala Announcement of \$100 million for AIDS Protection

With informational copies for:
BC, RT, GA, HPS Chron

From: Vikki Wachino *VAW*

Ph: 202/395-4926
Fax: 202/395-3910
Room: #7026

On Tuesday, Secretary Shalala announced at the AIDS conference in Vancouver that NIH and CDC would spend \$100 million over four years to develop topical microbicide creams to protect women from HIV.

We called ASMB staff to ask what prompted this announcement. They told us that Patsy Fleming had initially contacted a division of the National Institute of Allergy and Infectious Diseases (NIAID) and suggested spending an additional \$10 million above the approximately \$23 million NIH spends annually on topical microbicides. ASMB staff were not clear on how the issue developed after Patsy contacted NIAID, but believe that at some point the Secretary's office got involved and the end result is that NIH spending on topical microbicides will remain relatively unchanged from the \$23 million figure, or about \$100 million over four years.

The news wire story and HHS press release announcing the \$100 million are attached.

Date: 07/09/96 Time: 16:49

A.U.S. Pledges \$100 Million to Find HIV-Killing Creams

VANCOUVER, British Columbia (AP) The U.S. government pledged \$100 million Tuesday to help develop virus-killing creams that would let women protect themselves from AIDS without relying on their partners.

The goal is to create alternatives to condoms that women can use without men's permission especially creams that protect against HIV but would still allow them to get pregnant.

Donna E. Shalala, U.S. secretary of health and human services, said the National Institutes of Health and the Centers for Disease Control and Prevention will spend the \$100 million over the next four years to speed development of such products.

"Today, too often, women must rely solely on their male partner for protection from HIV. And in too many cases, that means no protection at all," she said at the 11th International Conference on AIDS.

The CDC's Dr. Bruce Weniger said such strategies are especially needed in Asia, where men often become infected by prostitutes and then bring the virus home to their wives. These women are often unable or unwilling to insist that their husbands use condoms.

"Women need some product they can use that will protect them without their sex partner's knowledge or consent," he said.

Worldwide, 40 percent of the 21 million people infected with HIV are women. Most of them caught the virus through heterosexual intercourse.

Dr. Christopher Elias of the Population Council, based in Bangkok, Thailand, said that even if new HIV-killing products are developed, condoms will remain the cornerstone of AIDS prevention, since they are highly effective.

"Negotiating consistent condom use, however, is not always feasible for many women," he said.

He also said the new products might provide alternatives to condoms for oral and anal sex for both heterosexual and homosexual couples, although they have not been tested for those purposes.

Because of the time needed to check the safety and effectiveness of vaginal chemicals, Elias said it is unlikely any new products will reach the market before the end of the decade.

Several major studies are under way in Africa of nonoxynol-9, the familiar over-the-counter spermicide, to see if it also stops HIV, as many believe.

But because nonoxynol-9 irritates the vaginal lining, some worry that it might actually increase the risk of AIDS, especially if used several times a day by those who have frequent sex, such as prostitutes.

Reformulated versions of other proven sperm killers, such as the antiseptic chlorhexidine, are also being considered, in part because they are less irritating.

Elias said other possible products being developed include:

C31G, a mixture of two surfactants a type of detergent by disrupting cell membranes, appears to be better than nonoxynol-9 against the bacteria chlamydia. Early safety testing is under way.

Buffering agents that keep acid levels in the vagina high may

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 minority communities, and increases in research investments. However, the Council has been publicly critical of the Administration in some areas, particularly the Administration's commitment to HIV prevention. This meeting provides an opportunity for you to personally reaffirm your commitment to the Council and your seriousness about 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 section 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 passage of 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]

- **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 has taken so far 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]
- **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]
- **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 ensuring 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, you can also announce the release of \$479 million in Ryan White Title I grants (FY1999) to 50 metropolitan areas that are 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 presenters: Regina Aragón and Mike Isbell]

In your closing remarks, 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.
- Other initiatives 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

- 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 (in order)

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.

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.

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.

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.

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.

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.

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 Altagracia 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. Rev. Perez gave an opening prayer at the 1996 Democratic National Convention.

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. Ms. Runions spoke as a person living with HIV at the 1996 Democratic National Convention.

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.

- Long-term Care

Memo

Problem

Policy / Cost / Impact

likely reaction by groups

Alternatives to ~~the~~ Policy

- 5-yr window

- Count savings (US\$ / US\$)

- VP drug cost / price reductions

= Prevention: Needle exchange. Provide ^{HIV} summary of scientific info

Voluntary HIV testing -- national campaign.

Round table & good ideas.

I like it.

Want many

- Vaccine effort w/ international & private entities

About to be appointed.

BTU - export office

- FY 2000 Budget →

• Fall funding CBC - (same as previous years)

↑ International funding increases - make it permanent

Infection decrease ↑ USAID & CDC.

AIDS FILE

**PRESIDENT CLINTON UNVEILS \$479 MILLION IN NEW AIDS GRANTS,
MEETS WITH PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS**
December 18, 1998

Today, President Clinton announced the release of \$479 million in new Ryan White funding to improve primary health care and supportive services for people with HIV/AIDS. The President unveiled these grants in a meeting with his Advisory Council on HIV/AIDS to hear a report on their work and to seek their advice on ways to improve the Nation's response to the HIV/AIDS epidemic. Today the President is:

✓ **Announcing new Title I grants for Ryan White.** The President announced that \$479 million in grants are being released today under Title I of the Ryan White CARE Act to fund primary health care and supportive services for people living with HIV/AIDS. These grants serve low-income individuals and families in 50 eligible metropolitan areas hardest hit by the AIDS epidemic. These grants include special funds targeting African Americans and other racial and ethnic minorities.

✓ **Working with the community to improve the Nation's response to HIV/AIDS.** The President, accompanied by Sandra Thurman, Director of the Office of National AIDS Policy, met with his Advisory Council on HIV/AIDS to hear a report on their work and their advice on ways to improve the Nation's response to the HIV/AIDS epidemic. The President urged the Council to work with Congress to take new steps in the fight against HIV/AIDS, including passing a strong enforceable patients' bill of rights, passing legislation, such as that proposed by Senators Jeffords and Kennedy that helps people with disabilities access affordable health care coverage so they can return to work, and enhancing efforts to find an AIDS vaccine.

The President's Advisory Council on HIV/AIDS was created by the President in 1995 to provide guidance on the Nation's efforts to care for those living with HIV/AIDS, to stop the spread of the disease, and to improve vaccine and treatment research. It is chaired by Dr. Scott Hitt, a physician from Los Angeles specializing in AIDS care. The Council has 35 members, 13 of which are HIV-positive and 13 of which are persons of color. They come from around the country, sharing a broad range of perspectives that reflect the diversity of the epidemic.

✓ **Building on recent efforts to address the HIV/AIDS epidemic.** Today's activities build on a deep ongoing commitment by the Clinton/Gore Administration to respond to the AIDS crisis both in the United States and across the world. The Administration has fought for other critical investments in HIV/AIDS. In the last few months alone, the President:

- **Unveiled new initiative on World AIDS Day 1998 to address crisis of AIDS orphans and international HIV/AIDS.** The President joined Secretary Albright and USAID Administrator Atwood to unveil a new initiative including: a 12 percent increase in NIH AIDS research funding, \$200 million (a 33 percent increase) in HIV vaccine research, a \$10 million effort to address the growing crisis of AIDS orphans in developing nations, and a fact-finding delegation to Africa by Sandra Thurman, Director of the Office of National AIDS Policy.

- **Declared HIV/AIDS in racial and ethnic minority communities to be a severe and ongoing health care crisis and unveiled a new \$156 million initiative to address this problem**, including crisis response teams, enhanced prevention efforts, and assistance in accessing state-of-the-art therapies all targeted toward ethnic and racial minorities in communities across the country;
- **Worked with Congress to secure historic increases in a wide range of effective HIV/AIDS programs.** Increases this year alone include: a \$262 million increase in the Ryan White CARE Act; a 12 percent increase in AIDS research funding at the NIH, a \$32 million increase in HIV prevention programs at the CDC; and a \$21 million increase in the Housing Opportunities for People With AIDS program at HUD.

✓ **A solid record of progress in HIV/AIDS.** The Clinton/Gore Administration has a proud record of accomplishment in its response to HIV/AIDS, including:

- **Increasing funding for major HIV/AIDS programs by over 100 percent:**
 - a 266 percent increase in the Ryan White CARE Act
 - a 67 percent increase in AIDS research at the National Institutes of Health
 - a 125 percent increase in the Housing Opportunities for People With AIDS (HOPWA) program at HUD
 - a 64 percent increase in international AIDS funding at the U.S. Agency for International Development (USAID), and
 - a 34 percent increase in HIV prevention at the Centers for Disease Control and Prevention (CDC)
- **Protecting Medicaid and Social Security.** The President fought to preserve the guarantee of coverage under Medicaid, which serves more than 50 percent of people living with AIDS -- and 92 percent of children with AIDS -- who rely on Medicaid for health coverage. He also revised eligibility rules for Social Security Disability Insurance to increase the number of HIV-positive persons who qualify for benefits.
- **Focusing National Efforts on an AIDS Vaccine.** In May of 1997, the President challenged the nation to develop an AIDS vaccine within the next ten years. He announced a number of initiatives to help fulfill this goal, including: dedicating an AIDS vaccine research center at the National Institutes of Health and encouraging domestic and international collaboration among governments, medical communities and service organizations. On World AIDS Day 1998, the President announced \$200 million in funding for vaccine research at the NIH, a \$47 million (33 percent) increase over the previous fiscal year.

Vaccine / International File

AIDS VACCINE.

January 7, 2000
1:30 p.m.

TO:

Ambassador Dick Holbrooke - USUN
Gene Sperling - White House
→ Steve Riccetti - White House
Jim Steinberg - NSC
Linda Ricci - OMB Communications
John Hamre/Jim Bodner - OSD
Tim Geithener - Treasury
White House AIDS Policy Office
Ken Bernard - NSC
Gayle Smith - NSC
Joe Papovich - USTR
Susan Rice - DOS/AF
Dave Beier - OVP

FROM: RICK SAUNDERS, OVP/NSA

SUBJECT: Draft of the Vice President's Remarks to the UNSC
On HIV/AIDS in Africa

The Vice President will be making two sets of remarks at the UN Security Council on Monday, January 10. The first will be an overview of emerging security challenges confronting the world community in the new century. The second will address the particular problem of HIV/AIDS in Africa.

Attached is a draft of the second speech. Please review it for substance and relay any comments you may have to the Office of the Vice President by 5:00 p.m. today. Phone comments to Jim Babbitt (456-9513) or send written comments via fax to 456-9500.

The first speech is still being written. It will be coordinated separately.

Attachment:

Draft speech text

DRAFT

As of 1:00 p.m.
January 7, 2000

Vice President Al Gore
U.N. Security Council
Statement on AIDS in Africa
January 10, 2000

Mr. Secretary General, Members of the Security Council, Distinguished Guests, and, in particular, Honored Delegates from the Nations of Africa:

“HIV/AIDS is not someone else's problem. It is my problem. It is your problem. By allowing it to spread, we face the danger that ... our youth will not reach adulthood. Their education will be wasted. The economy will shrink. There will be a large number of sick people whom the healthy will not be able to maintain.”

Mr. Secretary and Members of the Council: These are not my words. They were not uttered in the United States or the United Nations. They were spoken by my friend, President Thabo Mbeki of South Africa, as he declared South Africa's Partnership Against AIDS more than a year ago.

Mr. Secretary: those are President Mbeki's words; but they could be mine, yours or any of ours. Indeed they should be. And they should be spoken not only in South Africa, not only in Africa, but all across the earth. In Africa, the scale of the crisis may be greater, the infrastructure weaker, and the people poorer than in countries like my own, but the threat is real for all of us. AIDS cuts across the lines that divide us, and we owe each other the commitment to join together and intensify our battle all around the world – especially where the scourge is greatest.

More than twelve million Africans have already died – one quarter of them children. Twenty million more men, women, and children are now infected. Each day, 11,000 more mothers, fathers, and children become HIV positive – more than half of them under the age of 25.

AIDS has crossed beyond the borders of a humanitarian crisis to become a security crisis for nations of sub-Saharan Africa – because it threatens not just the citizens of those nations, it threatens the very institutions that define and defend those nations.

This disease strikes at the workforce, undercutting the economic strength nations need to fight the crisis. It strikes at parents – undercutting the unifying force of family. It strikes at teachers, undercutting efforts to educate the younger generation and help them lift themselves out of poverty. It strikes at the military, undercutting the means of maintaining order and keeping peace.

The United States is profoundly concerned by the threat AIDS poses to Africa. Of course, I must painfully admit that we have not progressed as much as we would like fighting our own battle against AIDS in the United States. Our most recent Surgeon General's report tells us we have not overcome the ignorance and indifference that lead to

the spread of AIDS. So we continue to study the success of others to add to our experience, just as we seek to share our own knowledge with others.

As Vice President, I have traveled four times to sub-Saharan Africa. I have taken with me top U.S. Health officials, AIDS specialists, corporate leaders, physicians – to help share America's best ideas on fighting this disease. We have met with African leaders and heard their ideas, their concerns, and their difficulties in facing the raging crisis of AIDS.

I have found it inspiring to see so many leaders, health care workers, mothers and fathers bringing fresh energy and attention to this fight. The scale of the crisis is great, but so is Africa's determination. All across the continent there are people in high places and low taking the initiative to fight for the lives of people they love. Ten years ago, Uganda suffered what was believed to be the world's highest infection rates. Today – because the whole society has mobilized to end the stigma, urge prevention, and change behavior -- they are now recording dramatic drops in infection rates. Here is the proof. Working together, we can save millions of lives and turn back the tide of this disease.

We know that the most powerful line of defense against this disease is prevention. That is why the United States commits a substantial share of our AIDS funding to education and prevention efforts worldwide – to help break down the barriers against discussing this disease. And that is why this Security Council meeting is so important; because today we are putting the AIDS crisis at the very top of the world's agenda. Addressing the disease here, before the eyes and ears of the world, sends an unmistakable message that we must end the stigma of AIDS. We must discuss AIDS not in whispers, in private meetings, in tones of secrecy and shame, but right here in one of the great forums of the world, loudly and boldly, with a sense of urgency and concern and compassion. Until we end the stigma, our efforts to end the disease are doomed at the start.

We also need to do more to provide effective treatment when prevention is no longer an option. This means not only medicine; it means better health care delivery systems to monitor and manage treatment. The United States is especially committed to breaking the cycle of infection at one critical point – perhaps its most heartbreaking point -- at the moment of mother and child transmission.

Our ultimate hope is to prevent this disease by vaccination, and we continue to invest billions in research. But we need to do more to harness the power of the private sector. Last September, in his speech to the UN General Assembly, President Clinton noted that only two percent of all biomedical research is devoted to the major killers in the developing world. He committed America to an effort to accelerate the development and delivery of vaccines for malaria, TB, AIDS and other diseases disproportionately affecting the developing world. I will have more to say about that in a moment.

We believe this three-part strategy of prevention, treatment, and search for a vaccine is the right approach to take against this disease, and we have contributed more

than a billion dollars to fund these initiatives worldwide – more than half earmarked for sub-Saharan Africa. But the crisis is growing, and so must our commitment.

Last year, I was privileged to announce a broad new initiative to increase the U.S. commitment to international AIDS programs by \$100 million. This largest-ever increase in U.S. resources doubled our commitment to fight AIDS in Africa. Today, I am honored to announce an American effort to take the fight further. The budget we will send to Congress next month will include an additional increase of \$100 million for an annual total of \$325 million to fund our worldwide fight against AIDS.

This new funding will:

- finance programs to reduce the stigma and prevent the spread of AIDS;
- reduce mother and child transmission;
- support home and community based care for people with AIDS;
- provide community-based care for children orphaned by AIDS;
- and strengthen prevention and treatment infrastructure

[At the same time, I would also like to announce that the budget we will send to Congress next month will also include \$50 million as a U.S. contribution to the Purchase Fund of the Global Alliance for Vaccines and Immunizations. This contribution – a fulfillment of President Clinton's promise last September – will help fund research, production, and distribution of vaccines for the whole range of diseases that especially afflict developing nations.]

I would also like to announce today an initiative to promote an expanded public private partnership in the battle against AIDS. In the next few months, I will convene a meeting of US business leaders active in Africa to develop a set of voluntary principles for corporate conduct in the age of AIDS. This effort has the potential to establish the workplace as a venue for promoting the education and prevention of AIDS. Clearly the corporate sector has an economic interest in fighting the spread of AIDS in their own workforces and in the markets for their goods and services. I look forward to working with them to forge the public-private partnership so vital for fighting this disease.

I would also like to add that in America's effort to address the AIDS crisis, we found it was essential to confront it in the rank and file of our Armed Forces. Secretary of Defense Cohen and General Shelton are eager to share our experience and join in the fight against AIDS in America's military contacts with our African counterparts.

We are also working to help poor countries gain access to affordable medicines, including those for HIV/AIDS treatment. Last month, the President announced a new approach that will ensure that we take public health crises into account when applying U.S. trade policy. [placeholder for USTR language].

These initiatives are part of America's ongoing effort to intensify our global battle against AIDS, but no nation can win this war on its own. Last June, in Cologne, we

joined our G-7 partners in endorsing the Cologne Debt Initiative, a landmark decision dedicating faster and deeper debt relief for heavily indebted poor countries, with the savings to be tied to poverty reduction – specifically including the battle against AIDS.

Any serious effort to fight AIDS must also help fight the poverty that speeds the spread of AIDS. The United States will continue to work with our G-7 partners to make sure greater attention and resources are brought to bear in this fight. I challenge all those nations who enjoy wealth and health in the world to match America's increasing commitment to those nations in greater need of both – particularly those nations struggling under a staggering AIDS burden.

As we work to increase the funds available to fight AIDS, we also have to work to increase the impact of those funds. In July of this year, the global community will gather in Durban, South Africa to participate in the XIII International AIDS Conference. We know hundreds of examples of inspiring efforts to fight AIDS all around the world. But right now, they amount to isolated efforts, not a focused assault. We need every separate initiative by local, national, regional, and global organizations, to be knitted together in a way that takes maximum advantage of their synergy and success. The mission of the Durban Conference is every bit as vital as increasing funding, because it will decide how many lives we can save with our funding. [Before the conference, the United States will conduct a senior internal review of our own worldwide response to AIDS, and engage in discussions with Africa's leaders, to ensure that our approach makes the greatest possible impact in advancing our common efforts to overcome the scourge of AIDS.]

The AIDS crisis is one of the most devastating challenges ever to confront the world community. Archbishop Desmond Tutu -- who joined us in Washington last summer as we announced our AIDS funding increase -- has called this a holy war. For all our friends here and around the world willing to wage and to win this war -- let us take heart from the words of South African poet, Mongane Wally Serote:

*"remember
the passion of our hearts
the blinding ache and pain
when we heard the hysterical sobs
of our little children crying against fate*

*we heard these, we knew them, we absorbed them
but we surged forward
knowing that life is a promise, and that that promise is us"*

That promise is us. We here in this room – representing billions around the world -- we are the promise of hope and of change. We have the knowledge, the compassion, the means, and the moral duty to make a difference.

We must make the promise and keep the promise to wage a wider war against this disease -- so that when the story of the AIDS crisis is told to future generations, the moral

DRAFT

of that story will be the power of the human spirit to unite behind a common cause, defeat a common foe, and advance the health, the happiness, and the harmony of all humankind.

May God bless all the families who have suffered from this disease. May God bless our united efforts to end it forever.

July 15, 1997

Chris Jennings

Deputy Assistant To The President For Health Policy
The White House, 1600 Pennsylvania Ave.
Washington, D. C. 20500

Dear Mr. Jennings:

I have spent hundreds of hours researching AIDS vaccines and I thought that you might be interested to learn that it may be a small, biotech company, CEL-SCI Corporation located in Alexandria, VA, that actually may have the best AIDS vaccine candidate and may be first to test their vaccine in a phase III preventive AIDS vaccine trial. It is possible that a preventive AIDS vaccine may be developed long before President Clinton's ten year deadline. I'll give you a call sometime next week so we can talk about this.

In late May President Clinton made a commitment that the US would develop a **PREVENTIVE AIDS VACCINE** within ten years. One of the basic problems to overcome in developing a successful preventive AIDS vaccine is that the human immunodeficiency virus (HIV) and especially the viruses' surface proteins have a very high mutation rate. Since almost all of the present AIDS vaccine candidates are designed to "recognize" surface protein targets, their high mutation rate unfortunately makes these vaccine targets rapidly "unrecognizable". Clinical trial results to date on preventive AIDS vaccines have been so discouraging that most of the companies now developing AIDS vaccines have switched focus hoping to gain some success by testing their vaccine candidates as a therapeutic treatment for HIV or AIDS patients.

Another basic problem to overcome in developing a successful preventive AIDS vaccine is HIV's great variability. There are nine (9) different HIV-1 subtypes for which collectively well over 100 different HIV strains have now been characterized. The surface protein variability between different subtype strains can be 50% or greater. Therefore HIV variability greatly compounds the "recognition" problem making the development of a broad effective preventive AIDS vaccine even more difficult. Almost all preventative AIDS vaccine candidates to date have shown very minimal, if any, protection when tested against a different strain (from which the AIDS vaccine candidate is derived) of the HIV-1 subtype B (the predominant subtype in the US and Western Europe).

The purpose for this letter is to inform you that a company that I follow as a stock analyst (one of the few companies still working on a preventive AIDS vaccine), recently announced what I believe may be "breakthrough" results. Their vaccine candidate has shown the ability to recognize the "consensus sequence" of four of the nine major HIV-1 subtypes: A, B, C, and E. As noted above, subtype B is predominant in the US and Western Europe and is also found in parts of Thailand and Brazil. Subtype C is predominant in Africa and India and is also found in parts of Asia and Brazil.

This is one of the few preventive AIDS vaccine candidates that is not based on HIV surface protein target identification. Instead "HGP-30", this vaccine candidate, is based on a well conserved protein sequence (peptide) from the INTERNAL p17 HIV-1 CORE PROTEIN. HIV-1 core proteins have a lower mutation rate

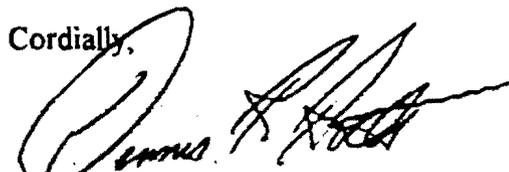
than the virus's surface proteins and there are fewer identified different HIV-1 core protein strains (than surface protein strains) for the nine different HIV-1 subtypes.

CEL-SCI Corporation, the company testing HGP-30, is located Alexandria VA. Items number 5 - 7 (on pages 2 - 4) of the enclosed June 4th six page CEL-SCI update report provide more information on this promising HIV-1 preventive AIDS vaccine candidate.

CEL-SCI should begin a phase II preventive AIDS vaccine clinical trial during Q4 in Africa. The Company could be in a position to know whether they will commence a much larger phase III clinical trial by July or August of next year. This could put them ahead of Pasteur-Merieux-Connaught, the wholly owned vaccine unit of Rhone-Poulenc Inc., a multibillion dollar French pharmaceutical company, which in early June, announced the beginning of a phase II preventive AIDS vaccine trial here in the US which is scheduled to last for two years.

If you would like further details, please contact CEL-SCI directly at (703) 549-5293. Mr. Geert Kersten is the CEO.

Cordially,



Dennis R. Roth

P6/b(6)

Enclosure: Six page update report on CEL-SCI Corporation dated June 4, 1997



CONTINUED STRONG BUY RECOMMENDATION - CEL-SCI CORPORATION

Suitable For Risk Oriented Investors Able To Tolerate Substantial Price Volatility

Closing Price \$4.25 June 4, 1997

Dennis R. Roth (703) 893-8080: Home (703) 759-7873

AMEX:	HIV	NYSE	Sales MM	RPS
52 Week Range	\$2.75 - 14.375	1995A	\$0.424	(\$0.89)
12 Month Target Price	\$10 - \$15	1996A	\$0.322	(\$0.98)
Shares Outd. PD/Float	10.2Mil/7.5Mil			
Daily T/Vol. 30 days	141,300	No Financial Projections Have yet Been Made		
Institutions/Mgmt. Own	1%/5%			
Cash & Inv./Ann. burn rate	\$6.8mil/\$5 Mil(3/31)			
Market Cap	\$43.35 Million			
Cash/share	\$0.67			
Long Term Debt	\$ -0-			

CEL-SCI HAS MADE ENCOURAGING PROGRESS ON MANY FRONTS SINCE OUR FEBRUARY '97 BUY RECOMMENDATION. WE EXPECT THE STOCK'S PRICE TO BEGIN APPRECIATING AS CLINICAL TRIAL RESULTS BEGIN TO COME IN OVER THE NEXT 6 MONTHS FROM THE NEW MULTIKINE HEAD AND NECK CANCER CLINICAL TRIAL PROTOCOL RECENTLY INITIATED IN ISRAEL AND FROM THE HIV MULTIKINE CLINICAL TRIAL NOW ENROLLING IN CALIFORNIA AT THE AIDS RESEARCH ALLIANCE.

1. Phase I/II Clinical Trial Protocol Recently Begun In Israel.

Results from this head and neck cancer protocol should be quickly assessable. It should only take about four weeks per patient to assess tumor response to Multikine treatment. Other advantages of this protocol are: (1) patient acquisition should be easier because it addresses a much broader patient population (approximately 80% of all patients diagnosed with head and neck cancer have either stage 2, 3, or 4 tumors), (2) the protocol stipulates that these patients must not have had any prior treatment (radiation, chemotherapy or surgery) for their cancer so their immune systems are much more intact than is the case for the advanced cancer patients enrolled in the Canadian U. S head and neck cancer trial (begun Q3 '96). Ten patients will be enrolled at this center.

Approximately TWO THIRDS of the world's malignant tumors are TOO BIG to be surgically removed. In a prior pilot phase I/II Florida intrastate head and neck cancer trial in four advanced head and neck cancer patients, three of four patients experienced significant tumor shrinkage in the first few weeks. Patients 1 and 2, after 63 days or 3 cycles of Multikine treatment, experienced maximum tumor regression of respectively 82% and 94%. The endpoints for this recently begun phase I/II clinical trial is to demonstrate drug safety and tumor response to Multikine treatment. To date, Multikine has been very well tolerated in the advanced head and neck cancer patients treated. Head and neck cancer is the fifth most prevalent form of cancer with 500,000 new annual cases worldwide.

2. Enrollment Is Under way At AIDS RESEARCH ALLIANCE In California For HIV Patients Who Want To Add Multikine's Immune Boosting Therapy To Their Present Combination Anti-Viral HIV Drug Regimens.

The AIDS RESEARCH ALLIANCE has received a significant number of responses from HIV patients now on combination anti-viral HIV drug therapy. This study will enroll 10 patients who must have stabilized CD4 cell counts of over 400. The endpoints of this trial are twofold. To see if Multikine:

- Is well tolerated in HIV patients,
- Can stimulate an increase in CD4 cell count (a surrogate marker for overall immune system strength) and/or beneficial increases in other immune cell types.

3. The 24 HIV Patient Phase I/II HGP-30 Therapeutic Clinical Trial That Will Be Shortly Completed Will Be Extended With Some Of These Patients Receiving An Additional Booster Injection Of HGP-30 Supplemented With A New Cytokine Adjuvant, GM-CSF (granulocyte/macrophage colony stimulating factor called "Leukine™"), contributed By Immunex Corporation.

There have been a number of studies that have demonstrated the synergy of GM-CSF with vaccines. In addition, according to the AIDS ReSEARCH ALLIANCE in their Winter/Spring '97 edition of Searchlight, page 23, "recent studies have demonstrated the ability of recombinant (synthetically produced) GM-CSF to increase the efficacy of peptide-based tumor vaccines." GM-CSF primes dendritic cells, which are the most efficient antigen presenting cells (APCs), to better recognize foreign antigen and, at the same time, GM-CSF also increases the number of APCs. Therefore, it is hoped that this novel vaccine adjuvant will increase the immunogenicity of HGP-30 stimulating an immune response that is better able to recognize the human immunodeficiency virus (HIV). Majority owned by American Home Products, Immunex (IMNX-\$35.25) is a Seattle, WA based biotech company with estimated fiscal '97 sales of approximately \$160 million. This trial should commence shortly. Each patient will receive 1 booster shot of HGP-30 along with GM-CSF. The study is expected to be completed during the fall of '97.

4. Phase I Prostate Cancer Clinical Trial Continues With The Possibility That A Phase II Prostate Cancer Study Will Begin During Q4 '97.

The phase I trial scheduled to enroll up to 15 prostate cancer patients who had failed hormonal therapy continues. We believe that a phase II prostate cancer trial may be commenced during Q4 '97. The current trial is being conducted at the Thomas Jefferson Medical Center in Philadelphia. Prostate cancer is the second most prevalent cancer in men.

5. HGP-30 AIDS Vaccine Candidate Produces Antibodies That Recognize Four Major HIV Subtypes

On May 4, at the 9th Annual Meeting of the National Cooperative Vaccine Development Groups held at NIH, CEL-SCI presented evidence that its HGP-30 vaccine candidate induced antibodies in humans and in mice that recognized the corresponding regions of four different major HIV-1 subtypes or class 1 A, B, C and E. All HIV-1 isolates belong to one of two groups. The "M" group has eight HIV-1 subtypes and the "O" group has only one "outlier" subtype. Each of these major HIV-1 subtypes has a number of different "strains" (the number of strains indicated below as of 1994 are those strains for which protein sequences have been analyzed).

The Nine Major HIV-1 Subtypes, Strains Per Subtype And The Countries In Which These Subtypes Predominate

SUBTYPE	STRAINS	COUNTRIES IN WHICH SUBTYPES PREDOMINATE
A	31	Parts of Africa
B	26	Dominant in the US, Western Europe and found in parts of Thailand and Brazil
C	7	Dominant in Africa and India and found in parts of Asia and Brazil
D	10	Parts of Africa
E	31	Parts of Africa and Thailand (subtypes A and E have the same gag p17 consensus sequence)
F	4	Parts of Africa
G	3	Parts of Africa
H	2	Parts of Africa
O	3	Parts of Africa (the "outlier" subtype)

CEL-SCI's HGP-30 AIDS vaccine candidate is a synthetic copy of a 30 amino acid sequence or peptide which is a portion of the p17 HIV-1 core protein from subtype B, SF2 strain (one of 10 strains in subtype B).

CEL SCI last year announced that HGP-30 produced a 78% spontaneous protection rate in a hu-PBL-SCID mouse model versus a 13% spontaneous protection rate against challenge by a different strain of subtype B (the LAI strain) than the SF2 strain from which the HGP-30 amino acid sequence is derived. No other strain of the candidate has shown protection against a

different HIV strain, let alone a 78% protection rate. It is especially encouraging to see a strong antibody response generated by CEL-SCI's HGP-30 subunit synthetic vaccine candidate that is cross reactive (antibodies produced bind well) with other major HIV subtypes or clades which predominate in other countries on other continents. This is an indication that CEL-SCI's HGP-30 vaccine candidate may confer very broad protection as an HIV preventive vaccine. There is no risk of contracting HIV from an HGP-30 immunization.

The above discussed antibody cross reactivity against the different HIV-1 A, B, C and E subtypes was accomplished against these subtypes' "consensus" sequences. The consensus sequence for each of these subtypes corresponds to the same 30 amino acid sequence of the HIV-1 p-17 core protein represented by HGP-30 (for subtype B, strain SF2). The consensus sequence for each major subtype is constructed by using the amino acids (represented by each of the 30 capital letters) that appear most frequently (for each of the 30 positions) considering all the existing strains under each subtype. Note that the individual amino acids of the different HIV subtype consensus sequences that are underlined indicates a variance in that subtype's consensus sequence from the specific amino acid found at the same location in HGP-30. The percentage variation ranged from 10% to 33% for this sequence in these other subtypes. HIV surface protein amino acid (aa) sequences have been shown to vary by as much as 50% or higher. Therefore, we believe that HGP-30, based on a conserved sequence of the p17 core protein, has a better chance of protecting against many HIV-1 subtypes than other AIDS vaccine candidates based on HIV surface protein sequences.

HGP-30's p17 Amino Acid Sequence Similarity To The Consensus Sequences For The HIV-1 A, B, C & E Subtypes

	86	90	95	100	103	110	115																									
HGP-30	Y	S	V	H	Q	R	I	D	V	K	D	T	K	E	A	L	E	K	I	E	T	Q	N	E	S	K	K	K	A	% Variation		
Subtype B	Y	C	V	H	Q	K	I	E	V	K	D	T	K	E	A	L	E	K	I	E	T	Q	N	E	S	K	K	K	A	10		
Subtype C	Y	C	V	H	K	G	I	E	V	R	D	T	K	E	A	L	D	K	I	E	T	Q	N	E	I	Q	Q	K	T	33		
Subtypes A & E	W	C	V	H	Q	R	I	E	V	K	D	T	K	E	A	L	D	K	I	E	T	Q	N	E	S	K	S	O	Q	K	T	27

The other important consideration, in addition to similarity of amino acid sequence, is obviously the immunogenicity of the particular amino acid sequence selected. What immune responses does a particular peptide sequence generate in humans? HGP-30 contains two cytotoxic T cell areas or epitopes (one includes "aa" 93-101 and aa 86-92 with the latter being identified as common to HIV sero positive long term non-progressors) as well as T4 (CD4) helper T cell and B cell (antibody) epitopes. HGP-30 was the first AIDS vaccine candidate to document the production of CD8+ (targeted) cytotoxic killer T cells (Proc. of the Nat. Academy of Sciences, 87:1111). It also has been shown to induce antibodies which recognize HGP-30 and HIV-1 p17 in ELISA assays. Continuing research from different sources indicates that of the two primary possible immune responses:

1. An antibody or humoral response,
2. A cell mediated response,

ONLY ONE, at any given time, is the DOMINANT immune response. Once the HIV successfully invades the host's cells, it is beyond the reach of almost all antibody defenses. Only with a killer T cell or an antibody dependent cell mediated cytotoxicity (ADCC) response can the HIV infected cells that are a continuing source of new HIV virions be targeted and destroyed so that the host's immune system can once again gain the upper hand. Most AIDS researchers believe that a killer T cell response is necessary for long term survival for HIV patients. Therefore HGP-30 is an excellent PREVENTIVE AIDS VACCINE candidate because it:

- Has two KILLER T CELL epitopes and generates antibody responses indicative of an ADCC response,
- Has a "LIMITED" mutation rate giving it the ability to cross react with a number of different HIV subtypes.

6. Crossreactivity Between HGP-30 Immunized Animal And Human Serum And The four HIV A, B, C, and E Subtypes Was Time Dependent And Reactivity Was Increased In The Animal Models By The Use Of Other Newer Vaccine Adjuvants That Are Currently Being Tested As Part Of Other Vaccine Formulations To Prevent Other Diseases

HGP-30, to increase its size and immunogenicity, uses a carrier (Keyhole Limpet Hemocyanin "KLH") and Alum, currently the only FDA approved adjuvant. After receiving two HGP-30 immunizations on days 0 and 14, mice generated cross reactive antibodies in a time dependent manner with the highest response rates for some HIV subtypes or clades being better at 42 days than at 28. With HGP-30, the highest levels of antibody cross reactivity compared to controls were for:

- Human sera (4 subjects): HIV subtypes A, B and E and to a somewhat lower degree to C
- Mouse sera (27 mice, 6-7 per subgroup): HIV subtypes B, C with lower but significant responses to A and B

HGP-30's ability to specifically generate antibody isotypes IgG2a (mouse antibodies) and IgG3 (human antibodies) indicates that this vaccine candidate will induce a desired cell mediated immune response. HGP-30's ability to cross react with serum containing the different HIV-1 subtypes A, B, C, and E indicates that HGP-30 will induce a desired cell mediated immune response with at least four of HIV-1's most significant subtypes. Two of these four subtypes B and C predominate respectively in the US and Western Europe (subtype B) and Africa (subtype C). Subtypes A, B and E are found in parts of Africa, Asia, Thailand and Brazil.

Newer and more immunogenic (but not yet approved) adjuvants have been tested in a number of vaccine clinical trials over the last five years. These new vaccine adjuvants may be approved by the FDA and could be used with vaccine booster injections. CEL-SCI tested two of the newer adjuvants (instead of alum) in mice that had received two or more HGP-30/KLH immunizations with the vaccine constructs:

- Monophosphate lipid MPL[®](S/E) by Ribi Immunochem Research Inc. and
- Novosomes[®] Nonphospholipid liposome by Novavax or supplemented with lipid A or Vitamin E,

Isotype antibody analysis showed that Ribi's MPL[®] (SE) generated a much higher IgG2a response for HIV subtypes A, B, C and E than alum. Novosomes, supplemented with Vitamin E, produced by far the best results with antibody isotype IgG2a cross reacting with subtypes B and C and to a lower degree for subtype A and E compared to alum. Alum, used as the adjuvant for HGP-30, did best at generating both IgG2a in mice and IgG3 in humans with HIV subtype B.

To summarize, CEL-SCI's HGP-30 HIV vaccine candidate (a synthetic peptide copy of amino acids 86 - 115 of the p17 core protein from subtype B; strain SF2) appears capable of generating an antibody response which broadly cross reacts (successfully binds) with corresponding "consensus" sequences of the p17 core protein derived from the HIV-1 subtypes A, B, C and E that vary from HGP-30 by up to 32%. According to the human serum tests, HLA antigen distribution apparently did not play a factor in subtype antibody cross reactivity.

7. CEL-SCI Is Planning To Start A Foreign Phase II 50 - 70 Patient HGP-30 HIV Vaccine Clinical Trial During Q4 '97 And Assuming That The Enrollment Rates And Initial Response In The HGP-30 Vaccine Candidate Are As Expected, A 2,500 Patient Phase III HGP-30 Preventive Vaccine Clinical Trial Would Be Initiated Sometime During Q4 '98.

HGP-30's safety must again be established in a new, different "other country" population that might have different HLA antigen distribution than the population previously tested with HGP-30. Assuming all goes well in the foreign phase II trial, it is likely that CEL-SCI could become THE FIRST COMPANY EVER TO CONDUCT AN HIV PHASE III PREVENTIVE AIDS vaccine clinical trial (presently projected to start during Q4 '98). This would have to be viewed as a rather extraordinary accomplishment and would be a big surprise to the pharmaceutical community considering CEL-SCI's size and resources compared to the size and resources of the competition which include very large pharmaceutical companies in the vaccine development business such as Merck, SmithKline Beecham, Schering-Plough, and Sanofi-Sintelabo, to name a few.

8. A Summary of CEL-SCI's Products And Scheduled Clinical Trials

CEL-SCI's three technologies help the immune system fight disease more effectively:

MULTIKINE: Is a mixture of naturally produced cytokines and therefore more closely resembles the cytokine mix (in terms of types and proportion) generally produced by a healthy person's immune response.

HGP-30 AIDS VACCINE CANDIDATE: Is a potential preventive vaccine/therapeutic treatment against HIV. HGP-30 has been tested in over 60 patients. It also is the only AIDS vaccine to ever have shown protection against a challenge by a different strain of HIV and the level of protection (78%) it achieved is the highest protection level ever published in the hu-PBL-SCID mice model.

L. E. A. P. S.™ (Ligand Epitope Antigen Presentation System) HETEROCONJUGATES: Is a "Platform Technology" that COMBINES a synthetic antigenic peptide (that is a copy of a disease epitope which triggers a specific disease immunogenic response) with a synthetic Ligand (binding peptide) which will **SELECTIVELY STIMULATE** a TH1 cell mediated, a TH2 humoral antibody or a mixed TH1/TH2 immune response. Administered infrequently, like vaccines, L.E.A.P.S. Heteroconjugates may provide a new class of products to treat and/or prevent a variety of difficult to treat or drug resistant diseases such as HIV/AIDS, herpes simplex, malaria, and tuberculosis.

Table Summarizing Multikine™ And HGP-30 Clinical Trials In Progress Or Planned

Product/ Disease	Vaccine or Therapeutic	Clinical Trial Classification	# of Patients # of Centers	Start Or Estimated Start Date*	Projected Comp. Date	Location
Multikine™** Head & neck cancer	Therapeutic	Phase I/II failed chemoth. radiatn. surgery	up to 30 at up to 5 center	Q3 '96 - Q1 '97	'98	Canada/U. S.
Head & neck cancer	Therapeutic	Phase I/II no prior treatmt	ten patients	Q1 '97	Q4 '97	israel
HIV	Therapeutic	Phase I used in combinatn. with anti-viral drugs	14 -AIDS Res. Allian.	Q3 '97	Q4 '97	U. S.
Prostate Canc.	Therapeutic	Phase I	up to 15 one center	Q3 '96	Q4 '97	U. S.
HGP-30*** HIV	Vac. Booster GM/CSF	Phase I Booster Extensn	6 - 9 patients	Q3 '97*	Q4 '97	U. S.
HIV/AIDS	Vaccine	Phase II	50 - 70 One center	Q4 '97*	Q2 '99	Africa

* Estimated start date

** Granted Canadian HPB approval 3/95 and U. S. FDA IND status for the head & neck and prostate cancer study;

*** Clinical trials have been conducted under a California Food and Drug Board intrastate approval

In addition to the above clinical trials, CEL-SCI will complete the 24 patient HGP-30 HIV/AIDS phase I/II therapeutic clinical trial that tested the safety and immune boosting effects of HGP-30 in HIV infected individuals. Results should be reported sometime during the next 60 - 90 days.

On June 5th CEL-SCI Began Trading On The American Stock Exchange Under The New Symbol "MNY"

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File

MEMORANDUM FOR THE PRESIDENT

FROM: Donna E. Shalala
SUBJECT: AIDS Vaccine Development

DRAFT

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

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

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

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

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

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

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

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

JOINT UNITED NATIONS PROGRAM ON HIV/AIDS (UNAIDS) Fact Sheet

The Eight, recognizing the global severity of HIV/AIDS, committed to work together and with others to assure that the Joint United Nations Program on HIV/AIDS (UNAIDS) has the resources necessary to enable it to fulfill its mandate. UNAIDS is responsible within the United Nations system for leading a global effort to expand the scale and quality of the response to HIV/AIDS.

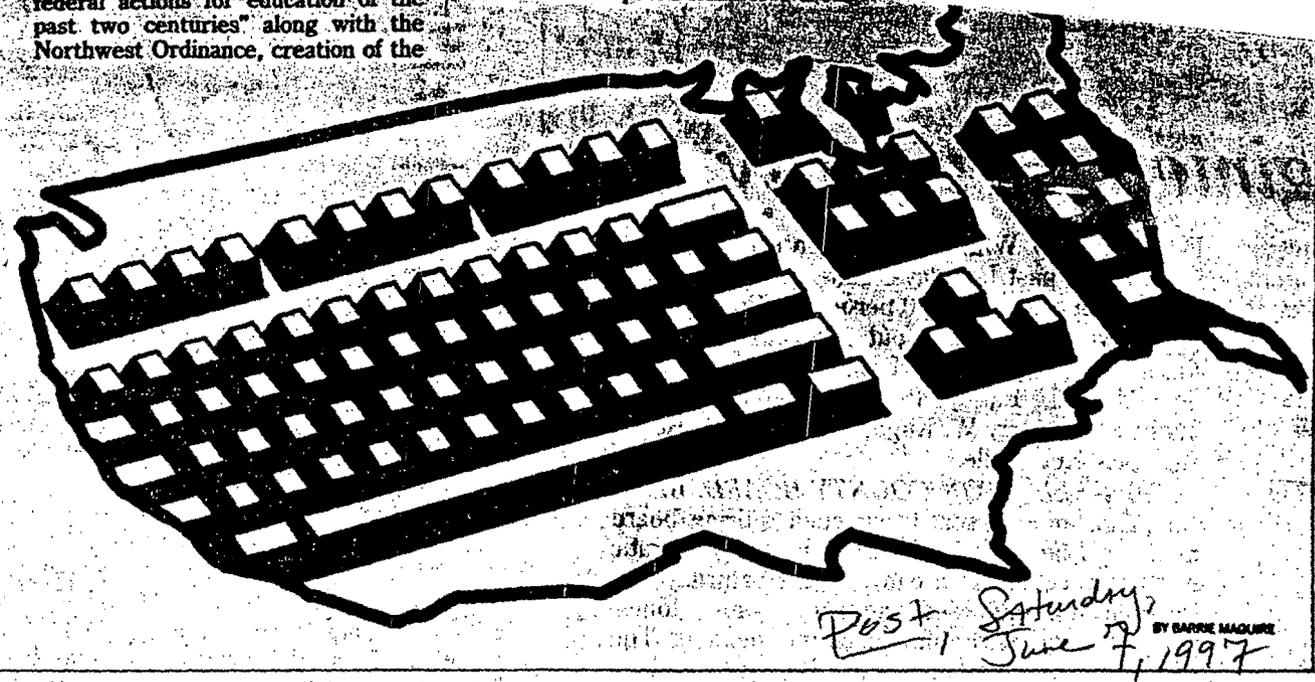
UNAIDS, which came into formal existence in January 1996, is jointly sponsored by the World Health Organization, the United Nations Children's Fund, the UN Population Fund, UNESCO, the United Nations Development Program, and the World Bank, each of which provides some support to the organization. The principle behind the creation of UNAIDS was, and continues to be, that HIV/AIDS is not just a health issue, but rather an issue involving economics and development, education, and other sectors of society and government. The Eight were major advocates for the creation of UNAIDS whose principal functions are to :

- Provide global leadership in the response to HIV/AIDS, promoting a global consensus on policy and programmatic approaches;
- Strengthen the capacity of the UN to monitor trends and the capacity of national governments to develop comprehensive strategies and implement effective HIV/AIDS activities at the country level;
- Promote broad-based political and social mobilization to prevent and respond to the HIV/AIDS epidemic within countries, ensuring that national responses involve a wide range of sectors and institutions and that adequate resources for HIV/AIDS-related activities are mobilized and allocated; and
- Design and implement, in collaboration with its partners, a vaccine development strategy appropriate for developing countries.

Activities of UNAIDS are carried out at both the global and country level. Funding for UNAIDS is provided by voluntary contributions from a variety of donors, largely UN member states. The United States is the largest donor to UNAIDS. It will provide \$15 million in 1997 toward UNAIDS' 1998-99 biennial budget of \$120 million.

establishment of four new Hepatitis C Cooperative Research Centers, and three new Emerging Virus Groups to study Hanta viruses and other emerging viral threats. NIH co-sponsorship of a major international conference on malaria in Africa resulted in a blueprint for malaria research. Separately, a \$15 million program to connect 20 African countries to the Internet through USAID's Leland Initiative will help provide the communication links critical to an electronic disease surveillance network.

placed on a pedestal with other major federal actions for education of the past two centuries" along with the Northwest Ordinance, creation of the more than computer skills to go



The Drive for an AIDS Vaccine

President Clinton's call for the development of an AIDS vaccine within 10 years deserves to be cheered. Instead, it was jeered by Charles Krauthammer [op-ed, May 30]. Rather than prevent AIDS through immunization, Krauthammer suggests that we can end its transmission with traditional public health measures. "Why embark on a huge national venture to create a vaccine for a disease that is already extraordinarily preventable?" Krauthammer asked. It is a question based on a mistaken premise.

Krauthammer is right, up to a point. We should deploy against AIDS more of the public health methods, such as routine testing, that have reduced the incidence of other diseases. But his argument is callous or, at best, myopic.

AIDS is *not* extraordinarily preventable in the Third World, where 93 percent of HIV cases occur. Krauthammer asserts, "To get AIDS you must, in all but the rarest cases, engage in very complicated consensual social behavior, namely unsafe sex or intravenous drug abuse." The AIDS death rate in the United States has leveled off, thanks to the introduction last year of effective combination drug treatments and to educational efforts. But the worldwide death rate continues to rise.

In many parts of the world, people do not know that certain "consensual social

behaviors" put them at risk of infection or they falsely believe they are protecting themselves with ineffective methods. Heterosexual HIV transmission represents just 10 percent of U.S. infections but 90 percent of worldwide infections. A growing number of AIDS victims—especially children—acquire the fatal disease without engaging in any irresponsible behavior whatsoever. Babies whose mothers are infected are themselves born with HIV. In Thailand, children make up approximately 10 percent of new HIV infections. Projections for Zambia and Zimbabwe indicate that AIDS may increase child mortality rates nearly threefold by the year 2010.

Many developing countries have neither the educational nor public health infrastructures to stop the spread of AIDS through behavior modification, as Krauthammer recommends. Max Essex, Chairman of the Harvard AIDS Institute, puts it bluntly: "A vaccine is the only long-term solution for the epidemic."

Although the vast majority of AIDS cases are in the Third World, the pandemic is not just a Third World problem. The United States has a direct national interest in eradicating the disease worldwide. Even if AIDS were eliminated in the U.S., Americans still could not afford to delay development of an AIDS vaccine. The ease with which people move

about the globe is a major reason to jump into the race.

Vaccines are the most cost-effective form of medical intervention. The United States spends \$227 million on polio vaccinations each year. But by preventing the disease, we save \$1 billion in treatment costs and an additional \$2 billion in indirect costs, such as lost wages, annually. The annual cost of medical treatment for AIDS—\$10,000 to \$16,000 per patient—puts it out of reach for all but a small fraction of the people who are infected. The lifetime cost of treating someone with HIV/AIDS in the United States is \$119,000 and climbing. The cost of a preventive vaccine would likely be \$50 to \$150 per person.

We need more public health measures and a vaccine. In fact, President Clinton should accelerate AIDS vaccine research and shorten his timetable from 10 years to five. The five-year reduction would save tens of billions of dollars in treatment costs and, more important, 15 million lives.

Development of an AIDS vaccine is a moral and economic imperative.

—H.R. Shepherd

The writer is chairman of the Albert B. Sabin Vaccine Foundation in New Canaan, Conn.

Don't Call Us ...

Your articles on telemarketing [Style, May 26] brought back to mind an incident I had several years ago. I answered the phone, and the man on the

tell the caller I'm sorry but our household rule prevents me from accepting any offer over the phone.

If the caller has something that may interest me, I suggest he or she drop

were more civil times in many re most particularly in telephone m. One evening the gentleman w swered my call was polite and cc tional. He informed me that he need for additional bonds at tl

File 5 "AIDS Vaccine"

Varmus Meeting With NIH Advisory Council to Discuss AIDS Vaccine Status

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

Background

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

Other Initiatives on the Vaccine

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