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4/11/97

Question: **This week, the Vice President announced that the Health Care Financing Administration (HCFA) is going to extend Medicaid coverage to all people with HIV. Can you explain?**

Answer: The Vice President did announce that we are directing HCFA to determine the feasibility of establishing a demonstration to permit earlier Medicaid coverage of people with HIV/AIDS in the next thirty days. This demonstration would enable people with HIV/AIDS to access coverage of new drug interventions, including protease inhibitors, which often delay the onset of symptoms that are much more expensive and difficult to treat. The demonstration is being designed to determine if earlier access to Medicaid coverage not only improves the health and well being of people with AIDS, but also reduces long-term health care costs.

Today, HIV/AIDS patients have to wait until they become sick enough to qualify for Medicaid through a disability determination. As a result, they often cannot afford our newest and most effective drug therapies. The action by the Vice President clears the way to a more compassionate and potentially cost-effective Medicaid program for people with HIV/AIDS.

Question: **Isn't this eligibility expansion going to be extremely expensive?**

Answer: We actually believe that this expansion has the potential to be cost-effective Under this demonstration, we would begin to treat people at the point when their HIV is detected, rather then waiting until they are extremely sick. This could improve the likelihood that these new drug therapies will help maintain the health and well-being of people with HIV/AIDS, reducing the need for costly long-term health care services.

Chris Jennings, DPC

4.7.97

Press Guidance
April 7, 1997

Question and Answer on Needle Exchange

Background: There is a statutory prohibition on federal funding for needle distribution unless the Secretary of HHS can determine 1.) That needle exchange programs reduce HIV transmission and 2.) That they do not encourage the use of illegal drugs. To answer Congress' call for a study of the needle exchange programs federal funding has been used to conduct research.

Q: Will You work to lift the ban on federal funding of needle exchange programs?

A: Not at this time. As you know, the congressional ban remains in effect until the Secretary of HHS can certify that needle programs reduce the transmission of AIDS and that such programs do not encourage illicit drug use. The scientific studies done so far provide strong evidence that needle exchange programs reduce HIV transmission, but they don't yet offer sufficient evidence of the effect of these programs on illicit drug use. We strongly support continued study of this question so we can know whether needle exchange programs in fact encourage drug use. In the meantime, local communities remain free, as they should, to establish and support needle exchange programs if they choose to do so.

JSilverman
Per conversation with Elena Kagan/OPD

4.8.97

THE WHITE HOUSE

Office of the Press Secretary

DRAFT For immediate release **April 7, 1997**

PRESIDENT NAMES SANDRA L. THURMAN AS DIRECTOR OF THE OFFICE OF NATIONAL AIDS POLICY

The President today announced his intention to appoint Sandra L. Thurman as Director of the Office of National AIDS Policy.

For more than a decade, Ms. Thurman has been a leader and advocate for people with AIDS at the local, state, and federal levels.

From 1988 to 1993, Sandra L. Thurman, of Atlanta, Georgia, served as the Executive Director of AID Atlanta, a community based organization which provides health and support services to people with HIV/AIDS and offers an array of HIV prevention programs. Under her leadership, AID Atlanta, the largest and oldest AIDS service organization in the south, tripled in size and became a multi-million dollar, direct-service agency with 90 staff members and over 1000 volunteers.

From 1993 to 1996, Ms. Thurman was the Director of Advocacy Programs at The Task Force for Child Survival and Development at The Carter Center in Atlanta, Georgia. As Director, she focused on the global health concerns of children, including immunization and the eradication of polio. She is currently Director of Citizen Exchanges at the United States Information Agency.

Ms. Thurman is a Member of the Presidential Advisory Council on HIV/AIDS and of the Georgia State AIDS Task Force, the Fulton County HIV Planning Council and the Executive Committee of Cities Advocating Emergency AIDS Relief (CAEAR). She has served on the Board of Directors of the National Episcopal AIDS Coalition, AID Atlanta, Sisterlove, Inc., and the Atlanta AIDS Interfaith Network, among others. She is a recognized expert on AIDS issues and has provided testimony before the United States Senate, the White House Conference on HIV/AIDS and the National Commission on AIDS. Ms. Thurman earned a Bachelor's degree from Mercer University.

The Office of National AIDS Policy is responsible for coordinating federal policy and programs on HIV/AIDS, and with building partnerships between Federal agencies, the AIDS community, AIDS service providers, state and local officials, and major business leaders. The objective of the ONAP is to increase the rate of progress in treatment and education, and to maintain the focus on science and scientific research.

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THE CLINTON ADMINISTRATION
ON HIV/AIDS

"Our common goal must ultimately be a cure, a cure for all those who are living with HIV, and a vaccine to protect all the rest of us from the virus. A cure and a vaccine, that must be our first and top priority."

President Clinton
White House Conference on HIV/AIDS

In his four years in office, President Clinton has sharply increased the Federal government's commitment to ending the epidemic of HIV/AIDS that has already taken the lives of more than 300,000 Americans. He has done that by:

- Increasing overall AIDS funding by more than 56% in four years.
- Creating a White House Office of National AIDS Policy to bring greater direction and visibility to the war on AIDS.
- Convening the first-ever White House Conference on HIV/AIDS and appointing the Presidential Advisory Council on HIV and AIDS.
- Increasing funding for the Ryan White CARE Act 186% in four years to nearly $1 billion.
- Tripling federal funding for the AIDS Drug Assistance Program to help those without insurance coverage obtain prescription drugs.
- Strengthening the Office of AIDS Research at NIH and vesting it with new authority to plan and carry out the AIDS research agenda.
- Accelerating AIDS drug approval to record times. In four years, FDA has approved 16 new AIDS drugs and 3 new diagnostic tests.
- Doubling funding for Housing Opportunities for People with AIDS.
- Winning the fight to preserve the Medicaid guarantee of coverage for the more than 50% of people living with AIDS who rely on Medicaid for health coverage.
- Revising eligibility rules for Social Security Disability Insurance to make it easier for people living with HIV to qualify for benefits.
- Signing the Kennedy-Kassebaum Health Insurance Portability and Accountability Act, which bans insurance discrimination against people with pre-existing medical conditions including HIV/AIDS.
- Launching a four-year $100 million effort to develop topical microbicides to allow people to protect themselves from HIV.
- Establishing the HIV prevention community planning partnership, which empowers local communities to make decisions about the direction of AIDS preventior programs.
- Launching the Prevention Marketing Initiative, focusing on the risk to young adults (18-25) with frank public service announcements recommending sexual abstinence and, for those who are sexually active, the correct and consistent use of latex condoms.
- Vigorously enforcing the Americans with Disabilities Act, which prohibits discrimination against people with HIV/AIDS. More than 800 charges of AIDS-related discrimination have been settled in four years.
- Leading the fight to repeal the discriminatory "Dornar Amendment," which would have discharged all HIV-positive military personnel.
- Creating the Forum for Collaborative HIV Research t improve knowledge of HIV treatment methods.
- Working with AIDS activists to protect the rights of immigrants with HIV and PLWA's enrolled in managed care plans.
- Creating the Advisory Commission on Consumer Protection and Quality in the Health Care Industry to increase consumers' rights.

THE CLINTON ADMINISTRATION
Meeting America's Challenges and Protecting Our Values
Paid for by Clinton/Gore '96

Questions and Answers on Needle Exchange
- Background - For Internal Use Only -

cc: Shalala
partial endorsement

On the New Report:

Q. Why did you do this report on needle exchange?

A. The report is in accordance with the September 12, 1996 request of the Senate Committee on Appropriations for the Departments of Labor, Health and Human Services, Education, and Related Agencies.

Q. Based on this report, are you lifting the ban on the use of Federal funds for needle exchange programs?

A. No, we are not. In its request for this report (Senate Report 104-368, p.68), the Committee specifically asked us to report on the effect of clean needle exchange programs on reducing HIV transmission, and on whether such programs encourage illicit drug use.

Based on the studies conducted to date, as the report says, "needle exchange programs can be an effective component of a strategy to prevent HIV and other blood borne infectious diseases in communities that choose to include them." However, the studies in the report do not indicate a similar degree of evidence on the question of whether such programs encourage drug use. Therefore, the prohibition remains in effect. However, local communities remain free to use non-Federal funds to support such programs if they so choose.

Q. Why does the report draw conclusions about the efficacy of needle exchange programs in HIV reduction and not about their effects on drug abuse?

A. Because the scientific evidence is strong enough on the first question, and not on the second. As the report says, the existing body of research suggests that "needle exchange programs can be an effective component of a strategy to prevent HIV and other blood borne infectious diseases in communities that choose to include them." That statement is backed up by empirical evidence (i.e., measurable differences in HIV transmission rates) in several studies, including reviews by the GAO and the IOM.

Similar scientific evidence does not exist to meet the congressional test that needle exchange programs also reduce drug use.

Q. Are you saying needle exchange programs encourage illegal drug use?

A. No, we are not saying that at all. What we are saying is that the evidence gathered to date does not provide us with conclusive evidence that needle exchange programs do not encourage drug use – the standard set by Congress. We will continue to support research into this question.

On Views on Needle Exchange:

Q. Do you think communities should fund needle exchange programs?

A. It is up to each community to decide if they want to fund needle exchange programs. It's important to note that dozens of locally and privately funded needle exchange programs are underway around the country. We are interested in reviewing their research, but it is appropriate for local communities to take the lead.

Q. If you think the research shows this is a good policy, why not fund it?

A. Congress has set very high thresholds for funding such programs. Those hurdles have not been met yet.

Q. Why not ask Congress to lift the ban or change the standards so that federal funds can be used for needle exchange?

A. Congress has made clear its intent that both of the standards be met. We share Congress's concern about making sure that our efforts do not encourage illegal drug use. We will continue to work with Congress on this important matter.

Q. If you say needle exchange programs are effective in reducing HIV transmission, isn't it unnecessary to fund the Alaska needle exchange demonstration?

A. The Alaska program looks at a very specific question – whether over the counter sales of needles is more or less effective than a needle exchange program. These are two kinds of interventions and they need to be evaluated. We have built in specific safeguards to make sure this demonstration is conducted in an ethical manner.

Q. Isn't there $17 million in new federal funds for other programs designed to prevent HIV/AIDS transmission among intravenous drug users? Are you going to use that money for needle exchange programs - or for something else?

A. CDC plans to use those funds for other programs designed to prevent HIV/AIDS transmission in this group - for education and treatment, for example. The goal of any intervention with this group is to provide an entry into treatment programs and to reduce the transmission of hepatitis and HIV.

On Needle Exchange and Drugs:

Q. Why give needles to drug addicts at all? Why not just throw them in jail?

A. The intravenous use of illegal drugs is clearly a major law enforcement concern, and it is also an urgent public health problem. We are extremely concerned with preventing the spread of HIV, which is the leading cause of death among adults age 25-44, and the seventh leading cause of death among all Americans. The goal of needle exchange programs is to provide an entry into treatment programs and to reduce the transmission of hepatitis and HIV. To realize our goal of effective HIV prevention, it is vital that we identify and evaluate sound public health strategies to address the twin epidemics of HIV and substance abuse.

Researching NEPs is just one part of the Clinton Administration's intensive strategy of AIDS research, prevention and treatment. We also have a comprehensive drug strategy to prevent the use of illicit drugs, reduce drug-related crime and violence, reduce the number of chronic drug users, and increase drug treatment capacity, outreach, and effectiveness.

Q. But doesn't NIDA grow marijuana, and doesn't FDA provide it to some seriously ill patients?

A. NIDA grows marijuana for research purposes only. We stopped adding people to the FDA's "compassionate use" program in 1992, and that policy was reexamined and reaffirmed in 1994, based on a medical review by PHS.

Q. How can the Secretary say that the Clinton Administration wants to send "clear, consistent no-use messages" about drugs, but still condone giving needles to drug addicts? Isn't that inconsistent?

A. There is no inconsistency - we believe that any use of drugs is illegal, unhealthy and wrong. We have also said consistently that illegal use of intravenous drugs can cause HIV and AIDS.

The Clinton Administration has a comprehensive strategy of AIDS research, prevention and treatment. We also have a comprehensive drug strategy to prevent the use of illicit drugs, prosecute drug pushers, reduce the number of hard-core drug users, and increase drug treatment options.

On Background:

Q. What criteria has Congress required us to meet regarding federal funding for needle exchange programs?

A. In its request for this report (Senate Report 104-368, p.68), the Committee specifically asked us to report on the effect of clean needle exchange programs on reducing HIV transmission, and on whether such programs encourage illicit drug use.

In addition, there are two public laws restricting the use of federal funding for needle exchange programs until certain criteria are met, specifically:

Our appropriation, Public law 104-208, requires the Secretary to certify that such programs reduce the spread of HIV and do not encourage drug abuse.

The second standard, in the Substance Abuse block grant, is even tougher. It requires certification that such programs both reduce the spread of HIV and reduce drug abuse.

Needle Exchange/AIDS Policy Office Director
February 12, 1997

There are several AIDS and needle exchange related events coming together at the end of this week.

FYI BACKGROUND --

- Tomorrow, the NIH concludes a three day conference addressing "at risk" behaviors associated with AIDS, mostly centering on education, condom use, etc. The conference was partly funded by NIH and outside groups. There is a final press conference tomorrow, but it will be handled by NIH and shouldn't come to our press corps.

- Saturday 2/15 is the deadline for the NIH to deliver a report to Congress on the status of current research on needle exchange programs. (The report is actually expected to be delivered to Congress on Tuesday. Folks here will be briefed later this week.) The report is an examination of current research on needle exchange programs and does not make recommendations pro or con. This will likely upset AIDS groups, which think enough research has been done to lift the current federal ban on federal funding for needle distribution.

- Friday is Patsy Fleming's last day as Director of the Office of National AIDS Policy. We are actively reviewing candidates to replace her, but have not yet made a final selection.

POINTS:

Q: <u>What is your position on needle exchange programs?</u>

A: There is a statutory prohibition on federal funding for needle distribution unless the Secretary of Health and Human Services can determine 1.) That needle exchange programs reduce HIV transmissions and 2.) That they do not encourage the use of illegal drugs. Up until now HHS has not been able to determine that we can meet those standards, so federal funding has not been available. To answer Congress' call for a study of needle exchange programs, federal funding has been used to conduct research into whether such programs can work. Dozens of local communities around the country have needle exchange programs which are privately funded.

Q: <u>When will you have a new AIDS Czar?</u>

A: We are actively reviewing candidates and moving forward to find the best peson for the job. (<u>Off-the-record</u> -- we will not let the position go vacant and will likely name someone in an acting capacity Friday while the search goes forward.)

KMcKiernan per conversation with Melissa Skolfield, HHS, 690-7850 and Richard Sorien, AIDS Policy Office

10-18-96
aids

Additional points re:

Illegal immigrants and AIDS care

• The provision in the immigration bill that the Administration fought successfully to remove would have permitted testing and treatment for communicable diseases, except for HIV or AIDS. [Draft conference report, HR 2022, September 10, 1996]

• This was described by the President of the American Public Health Association as "an outrage against the public health." He said this would make it "much harder to control the spread of HIV and AIDS." [Newsday, September 25, 1996]

• Some are saying AIDS care costs $119,000 a year. The most recent estimate of the *lifetime* (not annual) cost of AIDS treatment is $119,000 [Journal of the American Medical Association, July 28, 1993]. *

Per Patsy Flemming, 632-1090

10-18-96
aids

Note to White House Press Office (Mike, Mary Ellen, Kathy, April, et al)
From Victor Zonana, HHS

Alaska Needle Exchange Study Controversy
Background and TPs, and Q's & A's

Background: The public-interest group Public Citizen has asked the National Institutes of Health to cancel a $2.4 million research project into the effectiveness of needle-exchange programs in Anchorage, Alaska. The group charges that the study is ethically flawed for a number of reasons, and goes so far as to compare the Alaska experiment to the infamous Tuskegree Syphillis Study. In response to Public Citizen's letter, NIH director Dr. Harold Varmus has agreed to review the study, which was not scheduled to enroll participants until December.

All inquiries should be referred to NIH chief spokesperson Anne Thomas at 301-496-5787. Here, however, are some TP's and Q's and A's.

- NIH Director Dr. Harold Varmus has decided to review the study.
- The fact that NIH is reviewing the Alaska study should **not** be construed as a change in the federal government's policy on needle exchange. [The federal government, by Congressional stricture, does not fund needle exchange programs, but can fund research to determine whether such programs are effective in slowing the spread of HIV and drug abuse.]
- The study was not scheduled to begin enrolling participants until December.
- The needles that would have been distributed in the study would not have been paid for with federal funds, but by a private foundation.

Questions and answers:

Q: What is the purpose of the study?

A: To examine the relative efficacy of pharmacy sales versus a needle exchange program on reducing risk behaviors and the transmission of Hepatitis B and HIV in injection drug users.

Q: What is Dr. Varmus' response to the Public Citizen letter?

A: Although he agrees with the need to conduct further research into the effectiveness of needle exchange programs in reducing risky behavior, he has asked for a review of the ethical issues and other questions that have been raised.

Q: Does this mean that Dr. Varmus agrees with Public Citizen's assertion that "almost all scientists who have conducted research in this area believe that NEP's can reduce the risk of transmission of HIV and do not lead to increases in drug use?"

A: No. He has questions about spending $2.4 million for a study in Alaska, where there are so few people infected with HIV. He's also concerned about a number of ethical issues, including the potential for drug users in both research groups to contract Hepatitis B when an effective vaccine for this disease exists.

Q: Is the government re-assessing it's position on NEPs?

A: No. We're simply looking at the ethical and other questions that have been raised in connection with this specific study.

Q: Is the federal government paying for the needles?

A: No. They are being paid for from local community funds from the Alaska Science and Technology Foundation?

Q: Why was the Alaska study funded in the first place?

The study has been through multiple reviews. It was reviewed and approved by the University of Alaska's Institutional Review Board. It was also approved by the NIH's Office for the Protection of Research Risks. A Data and Safety Monitoring Board will oversee this study and will have an oversight role over the ethical issues involved.

Still, given the questions that have been raised, Dr. Varmus thought it was appropriate to take another look.

Basic HHS Needle Exchange Talking Points:
(Zonana/HHS)

-- We're deeply concerned about the spread of HIV.

--The issue of whether to provide federal funding for needle exchange programs is complex and difficult.

-- As you know, Congress has set very high thresholds for funding such programs and they would need to be proven to reduce both HIV transmission and drug use. That hurdle has not been met. However, we are financing research into such programs.

-- It's also important to note that dozens of locally and privately-funded needle exchange programs are underway around the country. As our review of the research continues, it's appropriate for local communities to take the lead.

Follow -up question: What are the Congressional restrictions?

There are two: Our appropriation requires the Secretary to certify that such programs reduce the spread of HIV and do not encourage drug abuse.

The second standard, in the Substance Abuse block grant, is even tougher. It requires certification that such programs both reduce the spread of HIV and reduce drug abuse.

AIDS

"Progress Report" by the President's Advisory Council on HIV and AIDS

Background

President Clinton created the President's Advisory Council on HIV and AIDS in June 1995 to provide him and his Administration with an independent external group to advise them on key policy issues related to the AIDS epidemic. The Council has issued three reports. The Progress Report being released today assesses the Administration's response to the first two sets of recommendations issued in July 1995 and December 1995.

Key Points

- The President has not yet seen the report. He is receiving it today.

- We welcome the report as clear evidence that the President is responding aggressively to the very real needs of the AIDS epidemic.

  The report says, and I quote: "The President's personal leadership and commitment in the battle against AIDs is clearly unmatched by his predecessors." *

  "This Administration has clearly made an unprecedented and laudable investment of funding, human resources, and genuine personal commitment."

As the report points out:

- The President has increased funding for AIDS by 43 percent in the four budgets he has presented to the Congress.

- The President has used his personal leadership to rally the nation to respond to the epidemic, including holding the first-ever White House Conference on HIV and AIDS on Dec. 6, 1995.

- The President has exhibited "consistent leadership" in defending Medicaid.

- The President has more than doubled funding for the Ryan White CARE Act.

- The Administration has strongly enforced the Americans with Disabilities Act and its protections against discrimination against people with AIDS.

- The President has made a "strong commitment" to AIDS research and strengthening the Office of AIDS Research at NIH.

Areas of Criticism

The report notes several areas where the Council would like to see further progress. They include:

1. **A National AIDS Plan.** The Office of National AIDS Policy has drafted a national AIDS strategic plan and it is in final review. It will be released next month.

2. **Housing for People with AIDS.** In the first two years of the Clinton Administration, funding for housing for people with AIDS increased by 43 percent. One of the first votes of the Republican Congress was to eliminate funding for this program. The President has successfully defended the program and continued its funding. Secretary Cisneros is examining ways to further increase funding for this program.

3. **AIDS Prevention.** The President has consistently requested additional funds for AIDS prevention and the Congress has, so far, refused to approve those funds. Despite that fact, we have launched innovative education programs recommending abstinence and greater condom use. CDC has empowered local communities to decide how to spend prevention dollars.

4. **Needle Exchange.** In 1988 and again in 1990, the Congress restricted use of federal funds for needle exchange programs. State and local funds are used for such programs when local government deems it necessary. Federal funds are used to evaluate the effectiveness of those programs.

Richard Sorian 632-1090

5.19.97

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 is he 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 inhabit the reproduction of the AIDS virus.

There are many credible scientists and medical researchers who are 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.

12-17-96
aids
Health

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release **December 17, 1996**

Statement by the President

I am pleased today to receive the first-ever National AIDS Strategy. In the fifteen years of this epidemic, we have never had such a unified strategy. This strategy represents an important milestone in the history of the fight to defeat this epidemic.

The National Strategy reiterates our administration's and our nation's commitment to winning the battle against AIDS. It establishes six major goals for our national efforts: to find a cure and a vaccine; to reduce new HIV infections; to assure people living with HIV and AIDS access to high-quality care; to fight AIDS-related discrimination at every turn; to lead the global fight to end AIDS; and to translate our research advances into treatment as quickly as possible.

These goals will help to guide our work in the coming term, and more specifically in the coming year. We have made significant progress in the last four years. Researchers working toward a cure and a vaccine are reporting encouraging news and giving us hope. New treatments, approved by the FDA in record time, are producing some very encouraging results in terms of the quality of people's lives and the potential for extending the length of life.

This progress results from more than a decade of investment in AIDS research, prevention, and care. I am very proud that in the four budgets my Administration has produced, funding for AIDS programs has increased by 55 percent. We have also strengthened the Office of AIDS Research at NIH and tripled funding for AIDS drug assistance programs.

Despite this progress, we must recognize that the AIDS epidemic is not over. Far too many of our sons and daughters are still losing their lives to this epidemic every day. Far too many are still becoming infected. We will win the battle against HIV, but to do so we must stand shoulder to shoulder in the fight and we must build on the strides we have made. I am confident that my Administration will do its part and that we have taken yet another step forward in that battle today.

-30-30-30-

National AIDS Strategy
Talking Points

What is the National AIDS Strategy?
This is a time of extraordinary change in the AIDS epidemic and it is essential that the government have its act together so that we can take advantage of these opportunities. The Strategy does three things: First, it establishes six long-term goals for the President's second term. Second, it establishes short-term opportunities for progress in the next 12 months to move us toward these goals. Third, it lays out dollar-for-dollar what the government is spending NOW on AIDS programs across the government.

What are some of those opportunities for progress?
One example is the new coordinated AIDS vaccine initiative at NIH headed by Nobel Laureate Dr. David Baltimore. A second example is the recent progress in reducing the number of infants born with HIV in this country. That number has declined by 27 percent since the President took office and we want to make further progress in the year ahead. Finally, a third area is the development of better information for patients and their doctors on the best use of the new combination drug therapies.

How is this different from the myriad of other plans that have been issued in the past?
This is the first time the Federal government -- and the President of the United States -- has put together a comprehensive planning document. All of the commissions established in the past have called for the development of such a strategy. This is not a report to be studied, it is a plan that will guide this Administration's activities for the next four years.

Critics say the Strategy doesn't go far enough, that it's too vague, and that it dodges all the controversial issues. Your response?
The Strategy is a far-reaching document that covers every Department of the Federal government involved with AIDS. It lists specific opportunities for progress in the year ahead and provides a framework our efforts to combat the epidemic. The implementation of this Strategy will involve the relevant Federal Agencies, the private sector, community-based organizations, the Presidential Advisory Council on HIV/AIDS, and people who are living with HIV and AIDS. It will be directed by the Office of National AIDS Policy.

What about needle exchange programs?
The report clearly identifies drugs users and their sexual partners as a population that requires priority attention. The question of how to specifically address those issues is part of the implementation process. The Congress has asked the Department of Health and Human Services to prepare a report on this issue that is due in mid-February. It would be inappropriate for this Strategy to interfere with or pre-empt that process.

Why did it take so long?
The development of this Strategy began a little more than a year ago. It required the involvement of all relevant Federal Agencies. But more importantly it also required outreach to those who are on the front lines of the epidemic. The Office of National AIDS Policy conducted 13 town hall meetings around the country to ask the affected communities what they would like to see in a National AIDS Strategy and what kind of goals the President should set. This input was extremely valuable to the creation of this document. We also sought the advice of the Presidential Advisory Council on HIV/AIDS and national AIDS organizations.

What difference with this Strategy make in the lives of people with AIDS?
It is our hope that it will make a significant difference in terms of better treatments for people living with AIDS not only in this country but for people around the world. They will have better information about the way those treatments should be used and better prevention programs to protect people from infection.

How will the departure of Patsy Fleming as National AIDS Policy Director affect this Strategy?
Ms. Fleming has indicated her intention to step down in mid-February and the process of choosing a new director is already underway. We fully expect the new director to be on board when Ms. Fleming leaves. The new director will be an important player in the implementation process.

AIDS REPORT

Q: Why unveil an AIDS strategy?

There has been a significant increase in spending in the area of AIDS and many agencies are involved. Today's report establishes unified strategy to make the most new resources and ensure that research advances translate into clinical practice.

Q: Does the Administration have a strategy to combat any other major diseases

The Department of Health and Human Services has a strategy to fight breast cancer, the National Cancer Institute obviously has a plan for fighting cancer more broadly, and on any disease the Department of Health and Human Services coordinates with the National Institutes of Health and the Center for Disease Control among others.

While AIDS is not the only disease with a plan, it is one in which there has been amazing breakthroughs recently (i.e. protease inhibitors). AIDS remains an infectious disease which continues to spread without a cure.

Per JBen-Ami, Mskofield, VZonana

Recent AIDS statements

1. On December 3rd 1996, the President met with Secretary Shalala, research leaders from NIH, and prevention leaders from CDC for a briefing on the progress in AIDS research. (pool coverage)

2. In October, the President and Mrs. Clinton visited the Names Project Quilt. He was the first President to visit the Quilt. The Vice President and Mrs. Gore also read names at the Quilt. (pool coverage)

3. On May 20, 1996 -- the President signed the Ryan White Care Act in a public ceremony in the Roosevelt Room (pool coverage)

4. In his State of the Union Address, the President made reference to AIDS and cited the disease as one of the reasons to preserve Medicaid eligibility.

6. December 5, 1995 - the President convened the first ever White House Conference on AIDS at which he delivered a major address. (pool coverage)
(Later that day, when he vetoed the Republican budget, he cited its impact on AIDS (through Medicaid) as one of the reasons he took such action)

Additional dates of significance:

July of 1995, he met with his presidential advisory council on AIDS

November 10, 1994, the President announced Patsy Fleming as Director of the Office of AIDS Policy

June 1993, he announced the creation of a National AIDS Policy Office and named Kristine Gebbie

December 1, 1993, the President delivered a major policy address at Georgetown (World AIDS Day)

Per Richard Sorian

4-23-97

GUIDANCE ON HIV EXPERIMENTS IN AFRICA
APRIL 23, 1997

(Post piece today (attached) suggests that HHS-sponsored AIDS-related experiments in Africa are giving placebos to people inappropriately, thus denying them the benefits of AIDS drugs, leading to comparisons to Tuskegee.)

* A variety of different trials are planned to help find treatments that can prevent mother-to-child transmission of HIV in developing countries.

* **The full AZT regimen, which is the standard of care in this country, is not economically feasible for these countries. In cooperation with international health agencies and the host governments, we are seeking treatments that will be effective, affordable, and practical in those countries.**

* **I want to point out that the Department of Health and Human Services has worked with the World Health Organization, UNAIDS, and the host governments to design these trials, and they are fully supported by the international bodies and the host governments.** Likewise the trials have been reviewed from an ethical standpoint by the CDC and NIH institutional review boards and by the host countries.

* Nevertheless, the Public Citizen letter makes some serious charges, and HHS is reviewing those charges. They will certainly be prepared to say more when they have had an opportunity to do that.

TOIV
Based on guidance from HHS

Medical Group Condemns U.S. AIDS Drug Tests in Africa for Using Placebo

The Washington Post
WEDNESDAY, APRIL 23, 1997

By David Brown
Washington Post

A [illegible]al watchdog organization yesterday charged that the U.S. government was sponsoring nine medical studies in the developing world that are unethical because they fail to provide all pregnant women with a drug that could protect their infants from acquiring the AIDS virus during childbirth.

The studies seek to learn whether brief use of AZT, or other drugs, will decrease the mother-to-child transmission of human immunodeficiency virus (HIV). A complicated, three-part treatment with the antiviral drug AZT reduces that transmission by two-thirds, but is viewed by governments and AIDS researchers as far too expensive and cumbersome for the developing world.

The key criticism voiced yesterday was that the studies included some HIV-infected women who are being randomly assigned to receive no AZT or other "active" drug anytime during the experiment. In the countries where the studies are being carried out—mostly nations of West and Central Africa—AZT is largely unavailable.

"These are as unethical as any experiments we have ever seen since the end of the Second World War," said Sidney Wolfe, director of the Public Citizen Health Research Group, an organization that analyzes research, treatment and public health policy.

"What has happened here is Tuskeegee, part two . . . in which even more people will die," said Peter Lurie, an AIDS researcher who assisted Wolfe in analyzing the studies. Lurie's reference was to the infamous four-decade study in which black Alabama sharecroppers with syphilis were observed and not offered treatment until long after it was widely available.

In a letter distributed to reporters at a news conference here, Wolfe asked Donna E. Shalala, secretary of health and human services, to order researchers to provide all women in the studies with at least some AZT, since that drug has been shown to be more effective than nothing.

Seven of the studies are being funded by the National Institutes of Health (NIH), and two by the Centers for Disease Control and Prevention (CDC).

Various scientists and officials overseeing the experiments, however, said they reached consensus years ago that the experiments criticized by Wolfe were ethical and well-designed. They said it is essential to compare "short-course" AZT treatment to what infected pregnant women in the study countries now are getting—which is nothing. All of the studies in question have been approved by research review boards in the United States and the host countries.

"All this debate came up in 1994, and it was felt that the best way to go, and the best interest of the developing world, was to have placebo-controlled trials, where you get accurate data quickly," said Joseph Saba, a research official of UNAIDS, the new AIDS program run by the United Nations, World Health Organization, World Bank, and several other international agencies.

"These studies are attempting to define regimens of treatment that are actually usable in most of the world. They have been put together with extraordinary support and consensus on an international level," said Jack Killen, director of the division of AIDS at the NIH's National Institute of Allergy and Infectious Diseases.

A landmark study, published in 1994, found that the mother-to-child rate of transmission of HIV could by cut from 23 percent to 8 percent if the pregnant woman was given AZT tablets for the last one-third of her pregnancy, intravenous AZT during labor, and if the newborn got the drug for the first six weeks of life. In a more recent study, the transmission rate with treatment dropped to 4.8 percent. The cost of that preventive treatment ranges from $400 to $900.

Because many countries with high prevalence of AIDS are unable to afford that regimen or, in many places, deliver the intravenous medicine even if it were available, many AIDS researchers wondered if a simpler, cheaper, but still effective alternative existed.

The countries include Ivory Coast, Uganda, Tanzania, South Africa, Ethiopia, Burkina Faso, Malawi, and Zimbabwe. In all, more than 12,000 women are involved in the U.S.-funded studies. All participation is voluntary, and the women are counseled on the infection and the details of the study.

In most of the studies, the length of time women take AZT before delivery, as well as the length of time their babies take it after birth, has been shortened. Pills have been substituted for the intravenous dose given during labor. In some of those three treatment intervals, a placebo is given instead of AZT. In most of them, there is one "arm" of the study in which women and babies get only placebo.

At the news conference, Wolfe and Lurie said that about 1,000 babies are likely to become infected with the AIDS virus because their mothers are randomly assigned to these all-placebo options. While they said they do not object to studies that give women placebo for some of the intervals, the all-placebo arms are unethical because they, in effect, knowingly give experimental subjects substandard care.

However, Timothy Dondero, of the CDC, said the sort of studies Wolfe and Lurie advocate would not answer the fundamental question: Is any drug treatment better than the treatment women are getting now?

Both Dondero and Saba said that in order to marshal international support and money for HIV testing, counseling and treatment for millions of pregnant women in poor countries, scientists must present unassailable proof of AZT's effectiveness—which requires trials that include all-placebo arms.

Further, Saba said, doing studies without all-placebo arms would take far longer, delaying implementation of potentially effective treatment and resulting in far more HIV deaths.