

PHOTOCOPY
PRESERVATION

AIDS BACKGROUND

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File
ALPs

**The Elizabeth Glaser
Pediatric AIDS
Foundation**

Fax

To: Phillip Deform From: Kate Carr
Fax: 456-2480 Date: 8/31/99
Phone: _____ Pages: _____
Re: _____ CC: _____

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•Comments:

Hi Phillip -

Thanks so much for calling. We are making an announcement tomorrow in Montreal (see attached statement) and so many of our board members have mentioned the importance of briefing the Vice President on this matter. We have been unable to connect with Sarah. Any help passing this along is appreciated.

Hope all is well. Long time no see.

Kate



ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION

For Immediate Release

Contact: Kelli O'Reilly
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The Elizabeth Glaser Pediatric AIDS Foundation Endorses "Call to Action" to Prevent HIV Infection in Newborns Worldwide

\$1 Million Donation Made to Initiate Action

September 1, 1999 (Los Angeles, CA) - The Elizabeth Glaser Pediatric AIDS Foundation has signed on to the "Call to Action" issued today at the Montreal meeting "Global Strategies for the Prevention of HIV Transmission from Mothers to Infants." To demonstrate its support, the Foundation pledged \$1 million to aid the effort.

"We cannot allow babies to continue to die from a disease that is highly preventable," said Paul Glaser, Chairman of the Board of the Foundation. "There is no excuse for delaying action and we hope our pledge of \$1 million will inspire other groups to do their part."

The "Call to Action" is directed at the governments of all-industrial and developing nations, pharmaceutical companies, multinational corporations, charities, foundations, religious groups, non-governmental organizations, scientists and individuals to come together and take immediate action to prevent babies from becoming infected with HIV.

This "Call to Action" follows the recent results from a joint Uganda/US study that demonstrated the drug Nevirapine could reduce perinatal transmission of HIV by 47%. Nevirapine is administered in a single dose to the mother at the onset of labor and in a single dose to the baby in its first three days of life. The entire course costs less than \$4 at Western list prices. Acting now to initiate implementation could begin to make an impact on the estimated 600,000 HIV infections in children each year. The drug AZT, which has been very successful at reducing the rate of mother to infant transmission of HIV in this country, is not a treatment option for most people in developing nations because of its cost.

"There are many questions yet to be answered," said Glaser. "But the need for these answers should not delay a response now."

- more -

Elizabeth Glaser Pediatric AIDS Foundation
"Call to Action" con't

The global HIV epidemic has reached staggering proportions and, at current rates, threatens to transcend all other health problems in the world. It is estimated that:

- More than 33 million people are HIV-infected and 95% of these people live in developing nations
- 6 million people are infected each year or about 16,000 per day
- Half of new infections are young (age 15-24) and 40% are women
- 600,000 of these newly infected people are newborns
- Over half a million children die annually from HIV

"We believe that no HIV prevention agenda is complete without programs to enable a mother to prevent infection of her baby," said Susie Zeegen, co-founder of the Elizabeth Glaser Pediatric AIDS Foundation. "We have been presented with a promising chance to save children's lives, it is our greatest hope that other organizations will join us in giving this gift to the world's children."

The text of the "Call to Action" can be read on the Foundation's website at www.pedaids.org.

The Elizabeth Glaser Pediatric AIDS Foundation is the leading national non-profit organization dedicated to funding and conducting research focused on pediatric HIV/AIDS. Over the past ten years, the Foundation has raised more than \$80 million and maintained an administrative overhead of less than 6%.

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A Call to Action to Prevent HIV Infection in Newborns

Background

We believe that no HIV prevention agenda is complete without programs to enable a mother to prevent perinatal infection of her child. The most effective means of doing so today is anti-HIV drugs for pregnant women and newborns.

The original AZT regimen tested in the U.S. and the shorter-course variants later tested in Thailand and southern Africa are, unfortunately, well beyond the means of most developing countries to implement. Trade and other legal issues cloud the picture further as poor countries consider how they may reduce cost and increase the distribution of anti-HIV drugs in this global economy. It has been four years since the original data were announced, and nothing has been happening very easily.

But now, everything is beginning to change.

Results from a joint Uganda/U.S. study recently demonstrated that the drug Nevirapine can reduce perinatal transmission of HIV by 47 percent. It is administered in a single dose to the mother at the onset of labor and in a single dose to the baby in its first three days of life. The entire course costs less than \$4 at Western list prices, without taking into account the reductions that may be possible with bulk purchase and negotiated pricing.

These research findings raise new questions, but the need for additional answers cannot be an excuse to delay a response now. These findings—and better ones as they emerge—must be turned into clinical practice.

Call to Action to Prevent Perinatal HIV Infection

We call for immediate action worldwide to prevent babies from becoming infected with HIV.

This action must include:

- The creation of information programs to raise public awareness of the issue of perinatal transmission and the possibility of reducing it;
- The establishment and enhancement of programs to deliver perinatal care and medications to pregnant women and babies;
- The purchase or acquisition of drugs to prevent perinatal transmission for countries that cannot afford them;
- The delivery of drugs to pregnant women and babies to prevent perinatal transmission; and
- Continuing research for additional interventions that might further reduce transmission and expanded efforts to prevent infection of all people.

We explicitly call for this action to be in addition to—not in lieu of—prevention programs for adolescents and adults.

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: JAM DATE: 5/16/13
2013-0512-5

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This call is directed at the governments of all industrial nations. We call on them for immediate support and assistance. We also call on them to negotiate for donations and dramatic discounts from pharmaceutical companies who make the needed drugs and diagnostics and for contributions from all pharmaceutical companies.

This call is directed at governments of developing nations. We call on them to create public information and education campaigns to make all potential parents aware of this step toward a healthy baby. We also call on them to strengthen their systems of perinatal care and programs for families.

This call is directed at pharmaceutical companies. We call on them to assist directly and indirectly with the cost of implementing programs to reduce infection of babies. We also call on them to donate, discount, and negotiate. Noting that several drug companies have received worldwide acclaim for donations of drugs to cure other diseases in poor nations, we call on all companies to respond to the human need in the HIV epidemic.

This call is directed at multinational corporations. We call on them to assist in setting up public information and education programs and in the delivery of drugs. Having proven themselves able to promote and distribute such discretionary products as soft drinks, music recordings, and athletic shoes, they can help spread both the knowledge and the simple means to save babies' lives. We also call on them to contribute, both for the good of their future markets and for the good of the world.

We call on religious groups, charities, foundations, and nongovernmental organizations. We call on them to take the lead in all areas. Partnerships between public and private sectors can expedite all actions.

We call on ourselves as well. We must set up a structure, we must plan, we must call out for funding in all venues, we must work on delivery systems, and we must continue research. We must work with all people affected by HIV to create and mobilize a comprehensive response to the epidemic.

Our call for action is immediate. A new baby is infected every minute of every day. Half of those infections can be prevented. All delays should be measured in those terms. With an investment of \$12 million now, we can begin to prevent the estimated 600,000 HIV infections in children each year. We will seek to raise at least that much as soon as possible.

- "I'll get back to you in a couple of days" means 2,400 babies infected who need not have been.
- "When the review committee meets in a month" means 35,000 babies infected who need not have been.
- "When the U.S. Congress returns in January" means 112,000 babies infected who need not have been.
- "Not until the patent expires," means millions of babies infected who need not have been.

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Conclusion

We call for the world to recognize its obligation to prevent needless HIV infection of babies and to do so today.

We will continue to work on research, on prevention programs for adults and adolescents, and on treatment for those people who are already infected. These are all part of the obligation of the world.

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Attachment to Call for Action

The global HIV epidemic has reached staggering proportions and, at current rates, threatens to transcend all other health problems in the world. It is estimated that

- More than 33 million people are HIV-infected,
- 95% of these people live in developing nations;
- 6 million people are infected each year (or about 16,000 per day);
- Half of these newly infected people are young (age 15-24) and 40% are women;
- 600,000 of these newly infected people are newborns; and
- Over half a million children die annually from HIV.

In some countries, the HIV epidemic is erasing the gains in overall life expectancy that have been achieved in the last 25 years. In many countries, the HIV epidemic is erasing all progress in reducing infant mortality and child mortality.

Prevention of HIV infection among adolescents and adults is clearly necessary. Programs to prevent HIV infection associated with sexual relations or drug use should be undertaken and redoubled by all governments, nongovernmental organizations, and the private sector. Some such programs are underway and have shown early success. However, we believe that much more must be done in primary prevention. Such prevention programs will also reduce the number of infected babies, since uninfected parents will have uninfected babies.

However, while working to prevent infection among adolescents and adults, it is necessary to recognize that there are many women of childbearing age who are already infected. With no intervention, many of these women will transmit the infection to their babies.

**Testimony of
Timothy Dondero, M.D.
Chief
International Activities Branch
Division of HIV/AIDS Prevention
National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention**

**Before the
U.S. House of Representatives
Committee on Government Reform
Subcommittee on Criminal Justice,
Drug Policy, and Human Resources**

JULY 22, 1999

I am Dr. Timothy Dondero, Chief of the International Activities Branch, Division of HIV/AIDS Prevention of the National Center for HIV, STD, and TB Prevention at the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to testify today about the magnitude of the global HIV/AIDS epidemic and CDC's international HIV/AIDS activities.

I will provide an overview summarizing the magnitude of HIV/AIDS epidemic and the closely intertwined tuberculosis (TB) and sexually transmitted diseases (STDs) epidemics worldwide. I will also highlight a few of CDC's international activities and discuss prevention approaches to reduce the impact of HIV/AIDS globally.

Background: Magnitude of Global HIV/AIDS, STDs and TB Epidemics

The HIV/AIDS epidemic continues to progress. More than 33.4 million people are estimated to be infected with HIV worldwide. Nearly 16,000 new infections occur each day, over 600 new infections every hour. Ninety-five percent of HIV-infected people live in the developing world -- and 95% of the deaths caused by HIV have occurred in developing countries. Unlike in the United States, most infections in the developing world are transmitted through heterosexual intercourse; the second most common route of transmission is from infected mothers to their children. In some areas, especially in Asia, HIV transmission through injection drug use is locally important; but for the world as a whole, drug-related HIV is responsible for only a modest part of the epidemic.

The most heavily impacted area of the world is sub-Saharan Africa, with over two-thirds of the world's infections and nearly 85% of the world's AIDS deaths. The next most affected region is south Asia and southeast Asia, with nearly 10% of the world's infections. These areas, and

especially sub-Saharan Africa, are still experiencing explosive HIV epidemics that are taking an enormous toll in human life and having a profound economic and social impact.

Currently it is estimated that there are 22 million adults and 1 million children living with HIV infection in sub-Saharan Africa and over six million infected persons in Asia. By comparison, the U.S. has an estimated three quarters of a million persons living with HIV infection. An estimated four million new infections occur in sub-Saharan Africa each year, over six million throughout the world. The AIDS death toll is rapidly rising with an estimated 5,500 deaths from the disease occurring each day in Africa. Without rapid implementation of large scale effective interventions most, if not all, of these national epidemics will continue to grow. There are many potential national and international consequences to this critical situation, including effects on political and economic stability and other factors that could adversely affect U.S. national interests.

I would like to turn your attention to a figure that graphically illustrates the extremes which the HIV epidemic has reached in the populations of the developing world. This figure shows the most recently available data (1996-98) for HIV infection in pregnant women from capital cities or major urban centers in Latin America, Asia, and Africa. HIV infection in pregnant women is a reasonable indicator of the levels in young adults in those countries generally and a direct indicator of the risk of mother to child infection.

Figure 1: Percent of Pregnant Women with HIV Infection

Source: Health Studies Branch, International Programs Center, U.S. Bureau of the Census; Research Note No. 26, February 1999.

In the southern-most African countries, HIV has reached epidemic proportions only relatively recently. Botswana now has one of the highest documented rates of HIV infection in the world, with over 40% of child bearing women living in cities infected with HIV. Recent reports from four southern African countries, Botswana, Namibia, Swaziland, and Zimbabwe, indicate that a fifth to a quarter of their entire adult populations aged 19-49 are now HIV-infected. The infection is wiping out recent gains in life expectancy. By the year 2010, for example, demographers project that life expectancy will have fallen from 66 to 33 years in Zambia and

from 70 to 40 years in Zimbabwe.

While African countries have been severely affected by HIV disease, other countries including Thailand, Cambodia, and India, have also been impacted by the disease. India has perhaps the largest number of infections of any single country in the world, estimated between 3 and 5 million HIV infected individuals.

Global trends in HIV disease indicate that women are at greater risk than men from heterosexual transmission, and as the HIV epidemic matures in a region, individuals become infected at younger ages and the epidemic moves from high-risk groups to the general population. And infected women are the source of infection for their babies. Without interventions, roughly one quarter of the babies will become infected by the time of birth and an additional 5 to 15% will get infection through breast feeding.

When describing the global magnitude of HIV/AIDS, it is also important to note the interaction between HIV and other diseases, specifically tuberculosis (TB) and sexually transmitted diseases (STDs). The interactions are significant to the control of the HIV epidemic.

Worldwide, 8 million cases of tuberculosis and 3 million deaths occur annually, and 95% of these cases and 98% of the deaths occur in low income countries. Tuberculosis kills more adolescents and adults than any other single infectious disease. The spread of the HIV epidemic has significantly increased the TB epidemic. While some increase in TB is due to demographic shifts in the population, much of the additional TB burden over the last 5 years, especially in Africa, can be attributed to the HIV epidemic. People who have latent, or inactive, TB infection from exposure earlier in their lives run a high risk of developing active TB if they become infected with HIV, a risk 100 times greater than for someone without HIV infection. This enhancement in TB cases seriously increases the burden on the health care system and

specifically on TB control services, already struggling to function in most developing countries, as well as increasing the reservoir of tuberculous infection to be spread to other people. More ominous still is that increased TB in AIDS patients enhances the potential for the spread of multi-drug resistant TB organisms, with negative consequences not only for the geographic areas heavily affected by HIV but for the U.S. and the world generally.

Evidence from epidemiologic studies on four continents has repeatedly linked the presence of sexually transmitted diseases with a two-to-five-fold increased risk for HIV transmission. In 1995, an estimated 333 million cases of four curable STDs (syphilis, gonorrhea, chlamydia, and trichomonas infection) were acquired worldwide, an increase from an estimated 298 million cases in 1990. STDs facilitate HIV transmission by increasing shedding of HIV and also enhance susceptibility to HIV through increasing the likelihood of HIV infection. HIV may also prolong the duration and infectiousness of some STDs, which increases the prevalence of these infections.

But as grim as this HIV, TB and STD situation is, there are actually some glimmers of hope. One example is Uganda, though there are some similar if less extensive signs of success in Tanzania, also in east Africa; and, in Cote d'Ivoire and Senegal, both in West Africa. Thailand has also seen improvements in some of its hardest hit regions.

Over the past 4 to 5 years, Uganda, one of the sub-Saharan countries initially most heavily affected by the HIV/AIDS epidemic, has seen significant and encouraging reductions in the incidence and prevalence of HIV infection in its population. Young women attending antenatal clinics have had a one-third reduction in HIV prevalence between the early 1990's and 1997 (from 32% infected in one area down to 22%), with continuing downward trends. Behavioral studies have shown a two or more year increase in age at first sexual intercourse in youths, a 9% reduction in casual sex, and a 30%-40% increase in condom use. These beneficial trends are attributed to a number of factors simultaneously occurring in Ugandan society.

There has been strong political leadership in efforts to increase AIDS awareness and prevention. The President and the First Lady themselves frequently address HIV-related issues, making them acceptable for public discussion. The Ugandan public is generally aware of HIV, including prevention needs and methods. In addition, Ugandan institutions, including religious groups, help provide a supportive and de-stigmatizing environment. Strong programs also exist for condom social marketing and for screening of transfused blood.

In addition, a very intensive HIV counseling and testing program, technically and fiscally supported by both CDC and USAID, has reached upwards of one-half million persons since 1990 through AIC (AIDS Information Center), a major non-government organization. This internationally acclaimed program, active in urban and rural areas, has functioned as an integral component of national programs for AIDS education and information and has contributed to AIDS surveillance.

Given the magnitude of the epidemic and the continuing explosive risk, and considering the economic and infrastructure realities of the regions of the world most affected, the most critical public health approach is prevention. Providing HIV treatment to the huge numbers of the world's HIV-infected poor people will be difficult in the near future for several reasons. Most people with HIV infections are not aware that they are infected, and counseling and testing facilities are rare in the most affected developing countries. Most antiretroviral medications are very expensive, even with the reduced prices that UNAIDS has been able to negotiate with the drug manufacturers, and way beyond the \$5 to \$15 dollar per person annual expenditure on all of health services typical in these countries. Even if the drugs were available, the hospitals and clinical infrastructure are not currently equipped for the diagnostic work and laboratory monitoring most patients would need to really benefit from the treatment. TB screening of HIV-infected people and offering the low cost preventive medications for the other common opportunistic infections is more feasible than the expensive therapy aimed at the HIV virus itself.

CDC's Role in International HIV Activities

CDC focuses its international efforts by offering assistance to countries with the greatest public health need; conducting collaborative research and training on preventive interventions; serving as partners in global initiatives; and responding to national U.S. interests. We apply U.S. scientific advances in other countries, such as rapid HIV testing, prevention of mother-to-infant HIV transmission, refinement and installation of HIV diagnostic and research techniques, assisting in technical aspects of HIV surveillance, testing and counseling, applications of simple prevention of opportunistic infections, computerization of prevention and service providing groups, and studying the interactions of HIV and TB. Some of these activities involve a partnership with USAID. We also apply lessons learned in other countries to domestic disease control efforts.

CDC has a strong international field station structure in Cote d'Ivoire, Uganda, Kenya, and Botswana in Africa and Thailand in Asia, as well as a long history of providing technical assistance to these and many other countries. In addition to these sites, we have resident advisors relating to HIV and its associated diseases stationed in several places, including India, Bolivia, Indonesia, Vietnam, South Africa, and Mali (a number of these through USAID), and offer many short-term consultations on issues including surveillance, epidemiological assistance, training, program management, laboratory capacity building, and prevention efforts.

At the global level, CDC assists by enhancing the capacity of the UN agencies committed to combating the epidemic through making technical experts available to UNAIDS, UNICEF, and WHO on both a long-term and a short basis. CDC also collaborates extensively with the US Agency for International Development (USAID), the World Health Organization (WHO), the Joint UN Programme on HIV/AIDS (UNAIDS), the United Nations Children's Fund (UNICEF) and the World Bank, as well as ministries of health around the world to provide both long and short term technical assistance and expertise.

Approach to the Epidemic: Prevention

One of the most critical needs in effective HIV/AIDS prevention is political will and political leadership within the country addressing, acknowledging, and focusing resources on HIV/AIDS prevention and control efforts. This key element of effective prevention can be provided only by the leadership in the country itself, though international partners and diplomatic missions can help to encourage and support this effort.

Critical to effective prevention is a well operating surveillance system. This is important so that the extent and trends of the epidemic can be monitored, prevention programs can be targeted and evaluated, priorities can be determined rationally, and the reality and extent of the epidemic can be acknowledged.

Sexual risk and transmission is addressed through behavior modification through the influence of culturally appropriate information and education, HIV counseling and testing, condom availability and social marketing, counseling and peer outreach to those at increased risk, and treatment of sexually transmitted infections. USAID and CDC, as well as other international agencies, provide technical assistance in these areas, but much more is needed. The cost of HIV prevention is less expensive than treating the infection afterwards.

Prevention of mother-to-child transmission is now possible with the recent discoveries through the work of CDC and others that short-course administration of the antiretroviral drug AZT to pregnant women can provide a 50% reduction in transmission. Recent findings of an NIH-supported study of an even shorter and less expensive drug regimen -- one dose of the antiretroviral nevirapine to the mother in labor and one to the baby shortly thereafter -- offer even greater opportunities for mother-infant prevention. Even with the cost of HIV testing and counseling and administration of antiretroviral drugs, such prevention is highly cost effective. However, establishing prevention programs in settings where antenatal services may be weak is

an operational challenge. CDC is providing technical assistance to UNICEF pilot projects of mother-to-child HIV prevention in a number of sub-Saharan African countries.

Treating opportunistic infections of AIDS patients, such as TB, is relatively inexpensive, dramatically lessens the impact of HIV and can improve quality of life. Approximately 2 billion people (one-third of the world's population) are infected with *Mycobacterium tuberculosis*, the cause of TB. TB is the cause of death for one out of every three people with AIDS worldwide. The high level of risk for dual HIV and TB infections underscores the critical need for targeted TB screening and preventive treatment programs for HIV-infected people and those at greatest risk for HIV infection.

However, basic HIV counseling and testing services are generally not yet available for the tens of millions of persons living with HIV in Africa, who could benefit from these inexpensive and effective treatments.

One of the most important prevention methods will be an effective vaccine. Unfortunately, no vaccine is yet available. A number of research groups are working on vaccine development including, prominently, the National Institutes of Health. Two field trials are currently underway, one of these in a developing country -- Thailand, and more are anticipated soon. Developing an effective and affordable vaccine is an extremely high priority, but for the time being the other approaches to HIV prevention are all that we have. These approaches will remain essential even when a vaccine becomes available.

Antiretroviral therapies are a major piece of the prevention puzzle because they offer not only the possibility of prolonged life for an HIV-infected individual but because they also prevent mother-to-child HIV transmission and may reduce transmission of the virus from an infected person through sexual contact. However, as I previously mentioned, antiretroviral drugs are not widely available in developing countries, and their cost, unfortunately, competes for the limited resources available for other health services including HIV prevention. There are numerous

current barriers to use of antiretroviral therapy of HIV/AIDS in developing countries, aside from the cost of the drugs themselves. These include lack of adequate health services and laboratory capability. Another serious consideration regarding extended therapy with antiretroviral drugs is that inappropriate treatment predisposes patients to development of drug resistant HIV. The appearance of drug resistance has already been found in Uganda after relatively few months of antiretroviral drug use. Since antiretroviral therapy is likely to be needed for a lifetime, the risk of developing of resistant HIV strains through inconsistent or partial treatment becomes a public health concern.

Antiretroviral therapy may become more affordable as partnerships are established among international agencies, governments and drug companies. Other cost reducing factors may include reduced drug dosages and reduction in drug prices.

In conclusion, unless a concerted effort is undertaken to bring forth the political will, resources and expertise to implement effective prevention and treatment programs, the outlook for the global AIDS epidemic is bleak.

Thank you for allowing me the opportunity to appear before this Subcommittee.

GOAL 5 - Eliminate disparities in HIV Infection/AIDS.

HIV infection/AIDS is a leading cause of death for all persons 25 to 44 years of age. Between 650,000 and 900,000 Americans are estimated to be living with HIV infection. Approximately 62 percent (375,000) of the 604,200 adults and adolescents reported with AIDS in the United States have died from the disease.

AIDS has disproportionately affected minority populations. Racial and ethnic minorities constitute approximately 25 percent of the total U.S. population, yet they account for nearly 54 percent of all AIDS cases. While the epidemic is decreasing in some populations, the *number* of new AIDS cases among blacks is now greater than the number of new AIDS cases among whites.

There are several different HIV epidemics occurring simultaneously in the United States, each of which must address the specific population affected and their associated risk factors. For example, although the number of AIDS diagnoses among gay and bisexual men has decreased dramatically among white men since 1989, the number of AIDS diagnoses among black men who have sex with men have increased. In addition, AIDS cases and new infections related to injecting drug use appear to be increasingly concentrated in minorities; of these cases, almost 75 percent were among minority populations (56 percent black and 20 percent Hispanic). Of cases reported among women and children, more than 75 percent are among racial and ethnic minorities.

During 1995 and 1996, AIDS death rates declined 23 percent for the total U.S. population while declining only 13 percent for blacks and 20 percent for Hispanics. Contributing factors for these mortality disparities include late identification of disease and lack of health insurance to pay for drug therapies. The cost of efficacious treatment, between \$10,000 and \$12,000 per patient per year, is a major hurdle in the effort to ensure equitable access to available drug therapies.

Inadequate recognition of risk, detection of infection, and referral to follow-up care are major issues for high-risk populations. About one-third of persons who are at risk of HIV/AIDS have never been tested. Better prevention strategies are needed that are acceptable to the target community (i.e., they must be culturally and linguistically appropriate), and the capability of organizations serving at-risk populations to develop, implement, evaluate, and fund prevention and treatment programs must be improved. Efforts should include risk reduction counseling, street and community outreach, prevention case management services, and help for individuals at risk in gaining access to HIV testing, treatment, and related services.

At this moment, there are many causes for optimism in the fight against HIV/AIDS. HIV prevention efforts have contributed to slowing the spread of the disease. For the first 6 months of 1996, there was an overall decrease in deaths among persons with AIDS, attributed primarily to the effect of antiretroviral therapies on the survival of persons with HIV infection. The decrease in the growth of AIDS cases in minority populations, however, has not been so strong.

To enable HIV-infected persons to benefit from treatment advances, HIV counseling and testing programs in screening and health care settings must better facilitate early diagnosis of HIV infection and ensure that HIV-infected persons have access to care and treatment services. Continued emphasis on behavioral risk reduction and other prevention strategies targeted to these populations is still the most effective way to reduce HIV infections.

Although advances in prevention and treatment are improving the quality of life for individuals living with HIV/AIDS, not everyone is benefiting equally from this progress. Concerns regarding education about the benefits of knowing one's serostatus, access to counseling and testing, and referral and access to medical services, including efficacious therapies, will continue to guide the development and administration of Federal initiatives to prevent HIV transmission and improve access to care for individuals living with HIV/AIDS.

Our goal is to continue progress in increasing the overall availability of early diagnosis of HIV infection and ensuring access to appropriate health services for all and to eventually eliminate disparities among groups. By the year 2000, the combined efforts of Medicaid, Medicare, and HRSA's Ryan White CARE

Act will ensure early and equal access to life-enhancing health care and appropriate drug therapies for at least 75 percent of low-income persons living with HIV/AIDS. We will establish educational outreach to all major medical providers to promote the current standard of clinical care for all persons living with HIV/AIDS, including Medicaid-eligible women and children with HIV infection.

Near-Term Goal

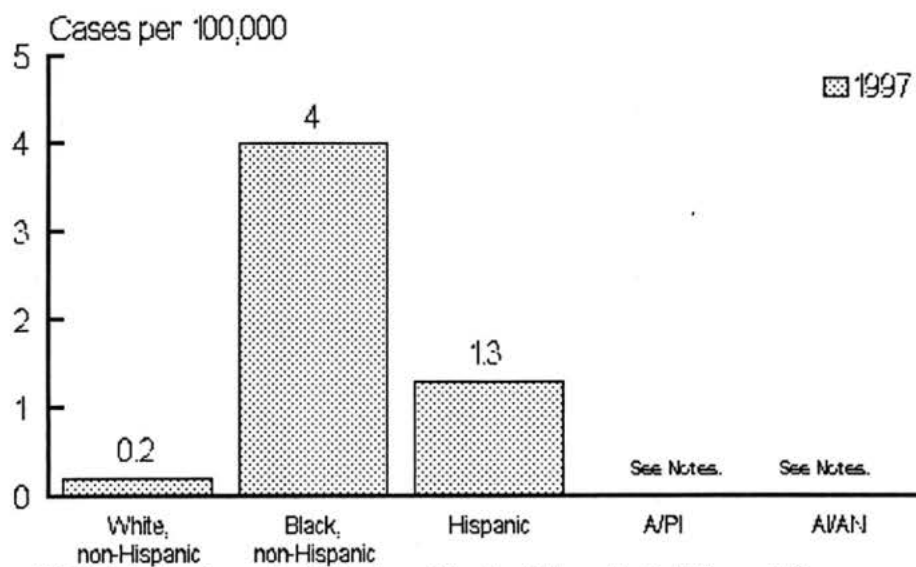
Ensure early and equal access to life-enhancing health care and appropriate drug therapies for at least 75 percent of low-income persons living with HIV/AIDS.

Link to Related Charts

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Please send comments or suggestions to:
HealthDisparities@osaspe.dhhs.gov

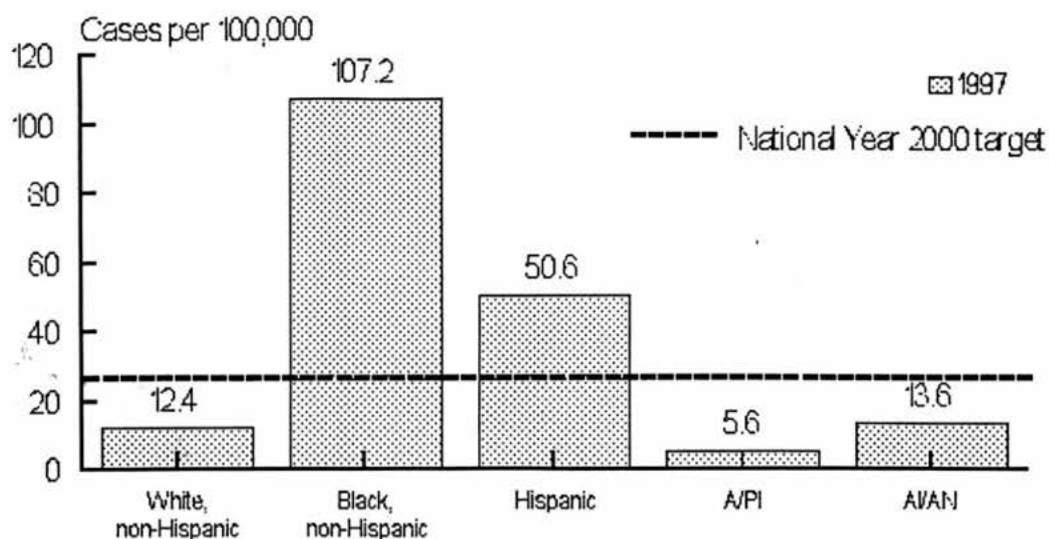
AIDS Case Rates in Children under 13 years by Race and Hispanic Ethnicity, United States, 1997



NOTES: Asian American or Pacific Islander and American Indian or Alaska Native populations have fewer than 10 cases. SOURCE: Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Pediatric AIDS Case Reporting System.

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AIDS Case Rates in Persons 13 years and over by Race and Hispanic Ethnicity, United States, 1997



NOTES: A/PI is Asian American or Pacific Islander; AI/AN is American Indian or Alaska Native.
SOURCE: Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Adult/Adolescent AIDS Reporting System.

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Office of National AIDS Policy
Analysis of FY99 Budget

Review of initial budget proposal from HHS to OMB

PROGRAM	FY97 Enacted	FY98 President's Budget	FY98 House	FY98 Senate	FY99 Proposal	+/- over President's FY98 Budget		+/- over Congress' FY98 Highest	
HRSA									
Ryan White CARE Act									
<i>Emergency Relief</i>	449,943	454,943	471,663	457,943	466,686	11,743	3%	(4,977)	-1%
<i>Block Grants</i>	249,954	264,954	261,994	252,954	279,954	15,000	6%	17,960	7%
<i>ADAP</i>	167,000	167,000	299,000	217,000	299,000	132,000	79%	0	0%
<i>Early Intervention</i>	69,568	84,568	72,928	79,568	99,568	15,000	18%	20,000	25%
<i>Women, Children, Youth</i>	36,000	40,000	37,720	45,000	40,000	0	0%	(5,000)	-11%
<i>Special Projects</i>									
<i>AIDS Educ. & Training Centers</i>	16,287	17,287	17,087	17,287	17,287	0	0%	0	0%
<i>Dental Reimbursement</i>	7,500	7,500	7,860	7,500	7,500	0	0%	(360)	-5%
Subtotal	\$996,252	\$1,036,252	\$1,168,252	\$1,077,252	\$1,209,995	\$173,743	17%	\$27,623	2%
CDC	\$616,790	\$634,266	\$621,790	\$646,790	\$647,090	\$12,824	2%	\$300	0%
SAMSHA									
Knowledge Devt. and Application									
<i>Mental Health</i>	5,270	4,904	4,904	4,904	6,000	1,096	22%	1,096	22%
<i>Substance Abuse Prevention</i>	0	0	0	0	5,000	5,000	0%	5,000	0%
<i>Substance Abuse Treatment</i>	5,000	9,000	9,000	9,000	9,300	300	3%	300	3%
Targeted Capacity Expansion									
<i>Substance Abuse Prevention</i>	0	0	0	0	1,000	1,000	0%	1,000	0%
Substance Abuse Block Grant	55,122	52,920	52,920	52,920	55,122	2,202	4%	2,202	4%
Program Management	500	580	580	580	580	0	0%	0	0%
Subtotal	\$65,892	\$67,404	\$67,404	\$67,404	\$77,002	\$9,598	14%	\$9,598	14%
TOTAL	\$1,678,934	\$1,737,922	\$1,857,446	\$1,791,446	\$1,934,087	\$196,165	11%	\$37,521	2%

AIDS INITIATIVES

- **Funding for AIDS prevention and treatment has been increased to historic levels.** Support for AIDS prevention programs has increased by 19 percent, and support for treatment programs, primarily through the Ryan White Care Act has increased by an extraordinary 95 percent. In addition, earlier this year, Congress responded to the President's request to increase the Federal commitment to State AIDS Drug Assistance Programs (ADAP) by \$52 million. This drug will be used to help AIDS patients buy the expensive new protease inhibitor drugs. Combined with the increase in our AIDS research investment, total funding for HIV/AIDS programs in fiscal year 1996 was \$2.86 billion; this represents a nearly 40 percent increase since the President took office.
- **AIDS is becoming a chronic manageable illness.** Once thought to be invariably fatal, the epidemic of HIV/AIDS is yielding to medical interventions. NIH-funded basic research on the structure of the virus led to a new class of anti-viral agents that, in combination with older drugs, reduce the amount of virus in the blood to detectable levels. Clinical research is restoring patients' damaged immune systems. Patients are living twice as long and all signs point to continued improvements.
- **Preventing HIV transmission to newborn infants.** NIH-funded research demonstrated that the use of AZT in HIV-infected pregnant women reduced by nearly three-quarters the number of infected babies.
- **Accelerated AIDS drug approval to record time.** Since 1993, the Food and Drug Administration has approved 12 new AIDS drugs and two diagnostic tests.
- **Fought to preserve Medicaid guarantee of coverage for people living with AIDS.** Nearly 50 percent of people with AIDS and 92 percent of children with AIDS rely on Medicaid for their health care coverage.
- **Helping protect women from HIV.** Launching a four-year \$100 million effort to develop topical smicrobides to allow women to protect themselves from HIV.

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Divider Title: AIDS Vaccine

Clinton Presidential Records Digital Records Marker

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Divider Title: AIDS Funding



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

March 5, 1997

NOTE TO SYLVIA MATTHEWS

From: Nancy-Ann Min *NEU*

RE: Your Meeting with National Organizations Responding to AIDS (NORA)

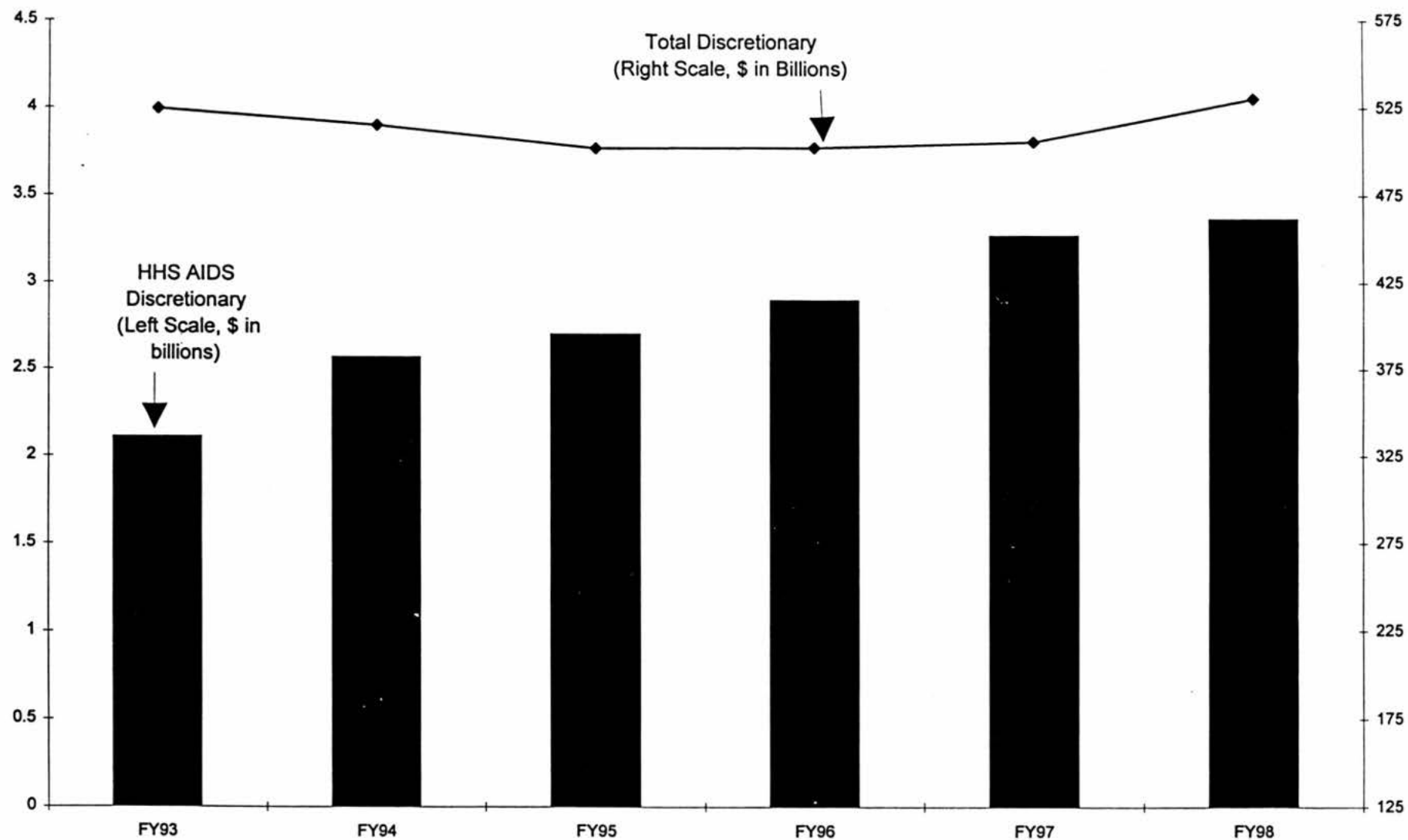
cc: Richard Socarides

Attached is some information that may be useful background for your meeting with NORA. The first five charts show increases in spending during the Clinton Administration. I have already shared these charts with members of NORA when I met with them right after the release of the budget, and, as you can see, not all programs receive increases.

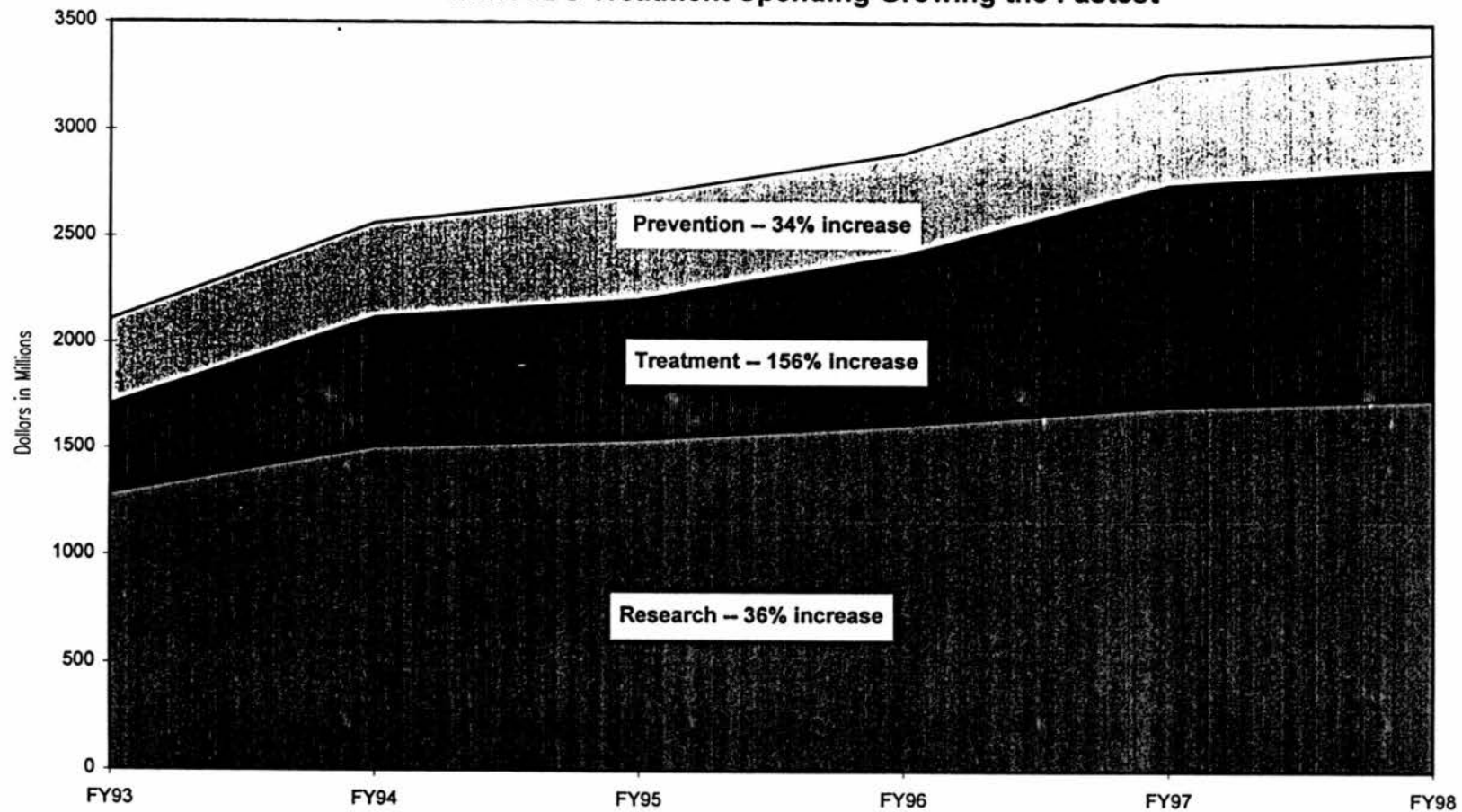
I have also attached other charts which give more detail on increases as well as cuts that have been enacted in AIDS programs. However, I am not sure that this level of detail is necessary for your meeting.

I hope this information is helpful. Please let me know if you have further questions.

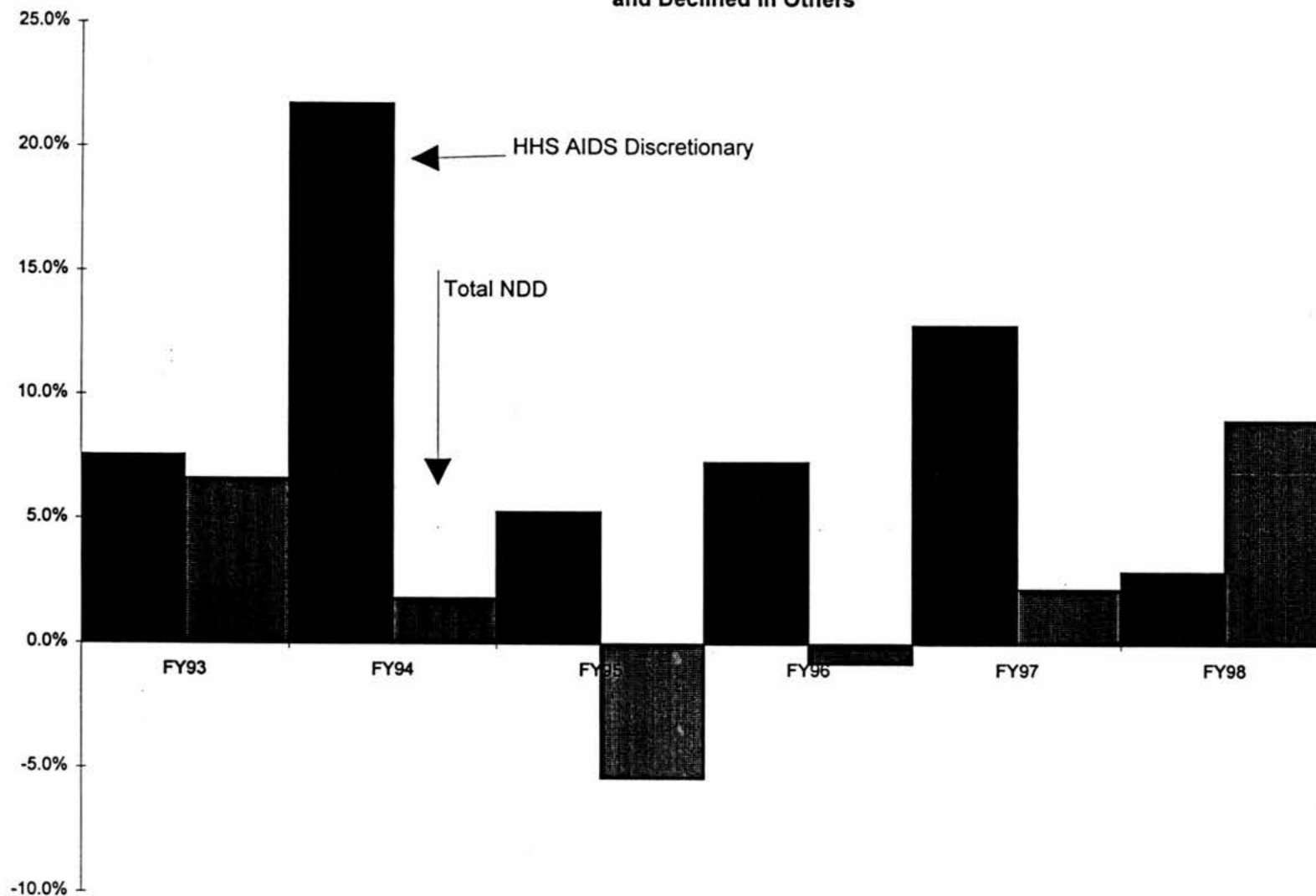
HHS Discretionary AIDS Spending Increases by 60% (from \$2.1 Billion to \$3.4 Billion) over FY 1993-98. Total Discretionary Funding Increases by 1% from \$524.5 Billion to \$530.5 Billion Over the Same Period.



**Overall Discretionary AIDS Funding at HHS Grew 60% (to \$3.4 billion) between 1993 and 1998,
with AIDS Treatment Spending Growing the Fastest**



**Comparing Annual Growth Rates in Discretionary Spending:
HHS AIDS Funding Has Grown Every Year, While Non-Defense Discretionary (NDD) Has Grown in Some Years
and Declined in Others**



FY 1998 Budget Funding for Selected HIV/AIDS Activities (BA – \$ in Millions)					
	FY 1993	FY 1997	FY 1998	% +/- FY 1998	% +/- FY 1998
	<u>Act.</u>	<u>Enacted</u>	<u>Budget</u>	<u>vs. FY 1997</u>	<u>vs. FY 1993</u>
Ryan White	386	996	1,036	4%	168%
NIH AIDS Research	1074	1,501	1,541	3%	43%
CDC HIV Prevention	498	617	634	3%	27%
HUD HOPWA	100	196	204	4%	104%

FY 1998 BUDGET DISTRIBUTION OF RYAN WHITE FUNDS (BA -- \$ in Millions)						
Title	FY 1993	FY 1996	FY 1997	FY 1998	% Increase FY98 over FY97	% Increase FY98 over FY93
	Enacted*	Enacted	Enacted	Total FY98 Budget		
I (Cities)	184.757	391.700	449.943	454.943	+1.11%	+146.2%
II (States)						
Regular Grant	115.288	208.847	249.954	264.954	+6.00%	+129.8%
ADAP Set-Aside	0.000	52.000	167.000	167.000	+0.00%	NA
Total Title II	115.000	260.847	416.954	431.954	+3.60%	+275.6%
IIIb (Clinics')	47.968	56.918	69.568	84.568	+21.56%	+76.3%
IV (Pediatric)	20.897	29.000	36.000	40.000	+11.11%	+91.4%
V (Dental)	0.000	6.937	7.500	7.500	+0.00%	NA
VI (AIDS ETCs)	16.975	12.000	16.287	17.287	+6.14%	+1.8%
TOTAL	385.597	757.402	996.252	1036.252	+4.02%	+168.7%
*Displayed comparably to current law. In FY 1993, Titles IV,V and VI were not authorized or funded under the Ryan White CARE Act.						

FEDERAL HIV FUNDING BY AGENCY

(Obligations in \$ millions)

	FY93	FY96	FY97	FY98	\$ FY98 Budget	% FY98 Budget	\$ FY98 Budget	% FY98 Budget
	<u>Actual</u>	<u>Actual</u>	<u>Enacted</u>	<u>Budget</u>	<u>+/- FY97</u>	<u>+/- FY97</u>	<u>+/- FY93</u>	<u>+/- FY93</u>
Health and Human Services								
HHS Discretionary	2,108	2,898	3,270	3,365	+95	+3%	+1,257	+60%
Medicaid (Federal Share)	1,000	1,600	1,800	1,900	+100	+6%	+900	+90%
Medicare	600	1,100	1,300	1,400	+100	+8%	+800	+133%
Social Security	670	976	1,070	1,163	+93	+9%	+493	+74%
Veterans	299	331	350	358	+8	+2%	+59	+20%
Defense	155	98	98	100	2	+2%	-55	-35%
HUD (HOPWA)**	100	171	196	204	+8	+4%	+104	+104%
OPM-FEHB	175	226	241	253	+12	+5%	+78	+45%
Other***	124	122	126	127	+1	+1%	+3	+2.4%
Total HIV Funding	5,231	7,522	8,451	8,870	+419	+5%	+3,639	+70%

Federal HIV Funding Breakdown By Category

Category	FY 1996 Actual		FY 1997 Enacted		FY 1998 Budget		\$ +/- FY 1998	% +/- FY 1998
	<u>BA</u>	<u>% of Total</u>	<u>BA</u>	<u>% of Total</u>	<u>BA</u>	<u>% of Total</u>	<u>vs. FY 1997</u>	<u>vs. FY 1997</u>
(Research)	1,653	22%	1,738	21%	1,774	20%	+36	+2%
(Prevention)	635	8%	678	8%	697	8%	+19	+3%
(Medical Care)	4,087	54%	4,769	56%	5,032	57%	+263	+6%
(Income Maintenance)	1,147	15%	1,266	15%	1,367	15%	+101	+8%

*HCFA has developed a new method for estimating AIDS costs to Medicaid and Medicare. They have only done estimates of these new methods for 1994-2002.

**The FY97 Enacted level for HOPWA assumes that \$25 million of Section 8 Rental Assistance is recaptured and transferred to HOPWA as provided in section 214(b) (2) of the VA/HUD/Independent Agencies Appropriation Act of 1997.

***Includes USAID, Bureau of Prisons, State, and Labor.

Discretionary HHS HIV/AIDS Funding in The FY 1998 Budget (Dollars in Millions)								
	<u>FY93</u> <u>Actual</u> 73	<u>FY96</u> <u>Actual</u> 73	<u>FY97</u> <u>Enacted</u> 73	<u>FY98</u> <u>Budget</u> 73	<u>FY98 \$ +/-</u> <u>FY97 Enacted</u> 0	<u>FY98 % +/-</u> <u>FY97 Enacted</u> 0%	<u>FY98 \$ +/-</u> <u>FY93 Enacted</u> 0	<u>FY98 % +/-</u> <u>FY93 Enacted</u> 0%
FDA								
HRSA								
Ryan White	386	757	996	1,036	+40	+4%	+650	+168%
Other HRSA	4	5	5	5	0	0%	+1	+25%
TOTAL HRSA	390	762	1,001	1,041	+40	+4%	+651	+167%
IHS	3	3	4	4	+0.1	+4%	+0	+14%
CDC	498	584	617	634	+17	+3%	+136	+27%
NIH	1,071	1,411	1,501	1,541	+40	+3%	+469	+44%
SAMHSA	55	54	66	67	+2	+2%	+12	+23%
AHCPR	10	6	4	1	-3	-73%	-8	-88%
OS								
National AIDS Program Office	2.9	0.5	0.6	0.6	0.0	+3%	-2	-80%
Office of Minority Health	2.4	2.3	2.3	2.3	0.0	+0%	-0	-5%
Office of Civil Rights	2.6	1.0	1.0	1.0	0.1	+5%	-2	-60%
Total OS	7.9	3.8	3.8	3.9	0.1	+2%	-4	-51%
Total HHS Discretionary	2,108	2,898	3,270	3,365	+95	+3%	1,257	+60%

**HIV/AIDS Funding
Government Wide Crosscut
(Obligations in \$ millions)**

AGENCY	Obs	FY85 Act.	FY86 Act.	FY87 Act.	FY88 Act.	FY89 Act.	FY90 Act.	FY91 Act.	FY92 Act.	FY93 Act.	FY94 Act.	FY95 Act.	FY96 Act.	FY97 Enacted	FY98 Budget
HHS Discretionary	Obs	109	234	502	962	1301	1590	1888	1960	2108	2567	2701	2898	3270	3365
Research	Obs	—	—	—	—	940	1116	1230	1259	1285	1508	1545	1619	1707	1743
Prevention	Obs	—	—	—	—	306	366	400	378	398	445	492	476	516	534
Treatment	Obs	—	—	—	—	55	108	258	323	425	613	664	803	1047	1088
Medicaid (Fed. Share)*	Obs	70	130	200	330	490	670	870	1080	1000	1200	1400	1600	1800	1900
Medicare	Obs	5	5	15	30	55	110	180	280	600	800	1000	1100	1300	1400
Social Security	Obs	17	29	60	99	158	234	354	512	670	804	902	976	1070	1163
DI	Obs	12	24	45	79	123	179	259	362	470	564	637	696	760	843
SSI	Obs	5	5	15	20	35	55	95	150	200	240	265	280	310	320
Veterans	Obs	8	20	51	78	136	220	258	279	299	312	317	331	350	358
Research	Obs	—	—	2	3	5	6	7	7	7	6	5	6	6	6
Prevention	Obs	—	—	1	1	28	29	29	30	31	31	31	31	31	31
Medical Care	Obs	8	20	48	74	103	185	222	242	261	275	281	294	313	321
Income Maintenance	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—

AGENCY	Obs	FY85 Act.	FY86 Act.	FY87 Act.	FY88 Act.	FY89 Act.	FY90 Act.	FY91 Act.	FY92 Act.	FY93 Act.	FY94 Act.	FY95 Act.	FY96 Act.	FY97 Enacted*	FY98 Budget
Department of Defense	Obs	0	75	70	44	86	124	127	125	155	127	110	98	98	100
Research	Obs	—	34	18	9	27	33	44	40	66	45	38	28	25	25
Prevention	Obs	—	18	25	26	26	28	19	22	27	22	12	11	11	12
Medical Care	Obs	—	23	27	9	33	63	64	63	62	60	60	59	62	63
Income Maintenance	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
AID	Obs	0	0	0	30	40	71	78	94	117	115	120	115	117	117
Research	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Prevention	Obs	—	—	—	30	40	71	78	94	117	115	120	115	117	117
Medical Care	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Income Maintenance	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Bureau of Prisons	Obs	0	0	1	1	2	4	5	5	5	6	6	6	7	8
Research	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Prevention	Obs	—	—	—	—	—	1	1	1	1	1	1	1	1	1
Medical Care	Obs	—	—	1	1	2	4	4	4	4	5	5	5	6	7
Income Maintenance	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
State Department	Obs	0	0	0	0	1	1	1	1	1	1	1	0	0	0
Research	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Prevention	Obs	—	—	—	—	1	1	1	1	1	1	1	0	0	0
Medical Care	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Income Maintenance	Obs	—	—	—	—	—	—	—	—	—	—	—	—	—	—

AGENCY		FY85	FY86	FY87	FY88	FY89	FY90	FY91	FY92	FY93	FY94	FY95	FY96	FY97	FY98
		Act.	Act.	Act.	Act.	Act.	Act.	Act.	Act.	Act.	Act.	Act.	Est.	Enacted	Budget
Labor	Obs	0	0	1	1	1	1	1	1	1	1	1	1	2	2
Research	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Prevention	Obs	-	-	1	1	1	1	1	1	1	1	1	1	2	2
Medical Care	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Income Maintenance	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Education	Obs	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Research	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Prevention	Obs	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Medical Care	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Income Maintenance	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Housing	Obs	0	0	0	1	0	0	0	48	100	156	171	171	196	204
Research	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Prevention	Obs	-	-	-	1	-	-	-	-	-	-	-	-	-	-
Medical Care	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Income Maintenance	Obs	-	-	-	-	-	-	-	48	100	156	171	171	196	204
OPM -- FEHB	Obs	0	5	8	13	22	37	61	103	175	193	212	226	241	253
Research	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Prevention	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Medical Care	Obs	-	5	8	13	22	37	61	103	175	193	212	226	241	253
Income Maintenance	Obs	-	-	-	-	-	-	-	-	-	-	-	-	-	-
TOTAL	Obs	####	498	908	1590	2292	3062	3823	4488	5231	6282	6941	7522	8451	8870

		FY85	FY86	FY87	FY88	FY89	FY90	FY91	FY92	FY93	FY94	FY95	FY96	FY97	FY98
		Act.	Act.	Act.	Act.	Act.	Act.	Act.	Act.	Act.	Act.	Enacted	Estimate	Enacted	Budget
Total															
Research	Obs					972	1155	1281	1306	1358	1559	1588	1653	1738	1774
Prevention	Obs					402	497	529	527	576	616	658	635	678	697
Medical Care	Obs					760	1177	1659	2095	2527	3146	3622	4087	4769	5032
Income Maintenance	Obs					158	234	354	560	770	960	1073	1147	1266	1367
						2292	3063	3823	4488	5231	6281	6941	7522	8451	8870

*Medicaid estimates do not reflect the effect of protease inhibitors on AIDS costs. HCFA advises that it can not make reliable estimates of the costs of these drugs at this time.

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. *FY 1997 - \$131 million*

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 and the President's FY 1998 budget proposes a ~~\$12 million~~ increase.

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.



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

October 15, 1996

NOTE FOR THE DIRECTOR

FROM: Nancy-Ann Min *NAM*
RE: Highlights of Federal HIV/AIDS Funding and Initiatives during Clinton Administration

The attached table and bullets provide information about our record with respect to funding for AIDS research, prevention, treatment, and services. (This does not include a few relatively small items such as AIDS research at DOD, because we do not have updated numbers for these initiatives).

I thought you might find this background to be useful:

cc: Jack Lew
John Koskinen
Larry Haas
Barry Clendenin

Carol Rasco
George Stephanopoulos
Don Baer
Alexis Herman
Patsy Fleming
Jeremy Ben-Ami
Chris Jennings

**OFFICE OF NATIONAL AIDS POLICY
EXECUTIVE OFFICE OF THE PRESIDENT**

750 17th Street, N.W.
Washington, DC 20503

Phone: 202-632-1090
Fax: 202-632-1096

FACSIMILE COVER SHEET

TO: CHRIS JENNINGS

FAX NUMBER: 456 - 5542

FROM: JANE SANVILLE

DATE: 8.14.96

PAGES INCLUDING COVER SHEET: 5

COMMENTS:

FYI - Raw budget numbers.
Also sent to OMB.

Increases in AIDS-related Spending: FY 1993 v. FY 1997

(in thousands)

Program	FY93 Budget (Bush Administration)	FY97 Clinton Budget	% change compared to FY93
HRSA	\$390,341	\$900,685*	+131%
Ryan White CARE	(\$348,013)	(\$872,465)*	+151%
Title I	(\$184,757)	(\$423,943)	+129%
Title II	(\$115,288)	(\$349,954)*	+204%
Title IIIB	(\$47,968)	(\$64,568)	+35%
Title IV ^a		(\$34,000)	+55%
IHS	\$3,303	\$3,847	+16%
CDC	\$498,263	\$616,981	+24%
NIH	\$1,071,457	\$1,431,908	+34%
Total, HHS, Discretionary	\$2,079,191	\$3,047,592	+47%

*This reflects a budget amendment of \$65 million for the AIDS Drug Assistance Program.

^aThe HRSA pediatric demonstration projects were not incorporated into Title IV until FY94 at \$22 million.

AIDS Spending: Health and Human Services Discretionary Programs
(in thousands)

Program	FY93	FY94	FY95	FY96	FY97 Pres. Budget	Change compared to FY96
FDA	\$72,628	\$72,399	\$72,745	\$72,745	\$72,745	...
HRSA	\$390,341	\$607,796	\$661,185	\$763,526	\$900,685*	+18%
Ryan White CARE	(\$348,013)	(\$579,365)	(\$632,965)	(\$738,465)	(\$872,465)*	+18%
Title I	(\$184,757)	(\$325,500)	(\$356,500)	(\$391,700)	(\$423,943)	+8%
Title II	(\$115,288)	(\$183,897)	(\$198,147)	(\$260,847)	(\$349,954)*	+34%
Title IIIB	(\$47,968)	(\$47,968)	(\$52,318)	(\$56,568)	(\$64,568)	+14%
Title IV ^a		(\$22,000)	(\$26,000)	(\$29,000)	(\$34,000)	+17%
Other HRSA AIDS	(\$42,328)	(\$28,431)	(\$28,220)	(\$25,061)	(\$28,220)	+13%
IHS	\$3,303	\$3,556	\$3,637	\$3,660	\$3,847	+5%
CDC	\$498,263	\$543,253	\$588,731	\$583,433	\$616,981	+6%
NIH	\$1,071,457	\$1,296,471	\$1,333,875	\$1,407,824	\$1,431,908	+2%
SAMHSA ^b	\$25,656	\$27,320	\$24,095	\$14,300	\$11,939	-17%
AHCPR	\$9,824	\$10,624	\$9,084	\$6,634	\$4,755	-28%
OHAP/OMH/OCR	\$7,930	\$7,503	\$6,046	\$4,523	\$4,732	+5%
Total, HHS	\$2,079,191	\$2,568,922	\$2,699,398	\$2,856,645	\$3,047,592	+7%

*This reflects a \$65 million budget amendment for the AIDS Drug Assistance Program

^aThe HRSA pediatric demonstration projects were not incorporated into Title IV until FY94 at \$22 million.

^bThe FY97 request for substance abuse and treatment overall at SAMHSA is \$1.6 billion, an increase of \$207 million over FY96.

AIDS Spending
Other Departments & Agencies
(in thousands)

Department/Agency	FY93	FY94	FY95	FY96	FY97 President's Budget
AID	\$117,000	\$115,000	\$121,000	\$111,000	\$97,000
Defense	\$159,000	\$129,000	\$112,000	\$103,000	\$85,000
HUD/HOPWA	\$100,000	\$156,000	\$171,000	\$171,000	\$196,000*
Justice/Prisons	\$5,000	\$6,000	\$6,000	\$6,000	\$7,000
Labor	\$1,000	\$1,000	\$1,000	\$1,000	\$2,000
OPM	\$175,000	\$193,000	\$212,000	\$226,000	\$241,000
Veterans	\$299,000	\$312,000	\$317,000	\$337,000	\$347,000

*This reflects a budget amendment sent by the President to increase the request for the Housing Opportunities for People with AIDS Program

AIDS Spending Entitlement Spending (in thousands)

Program	FY93	FY94	FY95	FY96	FY97 President's Budget	% change compared to FY96
Medicaid (Federal Share)	\$1,290,000	\$1,490,000	\$1,640,000	\$1,800,000	\$1,970,000	9
Medicare	\$386,000	\$500,000	\$600,000	\$690,000	\$780,000	13
Social Security (SSI)	\$200,000	\$240,000	\$300,000	\$370,000	\$450,000	22
Social Security (DI)	\$515,000	\$600,000	\$705,000	\$710,000	\$795,000	12
Total	\$2,391,000	\$2,830,000	\$3,245,000	\$3,570,000	\$3,995,000	8

October 11, 1996



Health Division



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

Please route to:

Richard Turman
Barry Clendenin
Nancy-Ann Min

RT
BC

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

Subject: **Federal HIV/AIDS
Highlights since FY 1993**

With informational copies for
HPS and HD Chrons, *mm, TR, HPS*

From: Greg White

Phone: 202/395-7791
Fax: 202/395-3910
Room: #7026

Per your request, we have attached a table and some bullets that summarizes highlights of Federal HIV/AIDS funding and initiatives since FY 1993. We consulted with HHS staff, the Health Financing Branch and the OMB Housing Branch on this information.

Please let us know if you have any questions.

Attachment

Highlights of Federal HIV/AIDS Funding and Initiatives: FY 1993- FY 1997

Funding History of Selected HIV/AIDS Activities: FY 1993-97				
(BA -- \$ in Millions)				
	<u>FY 1993</u>	<u>FY 1997</u>	<u>\$ Increase over FY93</u>	<u>% Increase Over FY93</u>
NIH AIDS Research	1,071	1,502	+431	+40%
HRSA Ryan White AIDS Treatment Grants	386*	996	+610	+158%
CDC HIV Prevention	498	617	+119	+24%
Other HHS Discretionary	124	100	-24	-19%
TOTAL HHS Discretionary HIV/AIDS Funds	2,079	3,215	1,136	+55%
Medicaid Federal Share (Mandatory)	1,290	1,970	+680	+53%
Medicare (Mandatory)	385	780	+395	+102%
TOTAL HHS	3,754	5,965	2,211	+59%
HUD Housing Opportunities for People with AIDS	100	196 **	+96	+96%

*Comparable estimate to grants currently authorized under Ryan White. Two grants that are currently authorized under the Ryan White CARE Act 1996 -- Pediatric AIDS Demonstration Grants and AIDS Education and Training Centers, were not funded through Ryan White in FY93. The FY93 estimate includes \$21 million for Title IV Pediatric AIDS and \$16 million for AIDS Education and Training Centers. Both of these grants are now authorized as part of the current Ryan White CARE Act of 1996.

**Assumes \$25 million of Section 8 Rental Assistance is recaptured and transferred to HOPWA, as provided in Section 214 (b) (2) of the VA/HUD/Independent Agencies Appropriation Act of 1997 (P.L. 104-204).

- **HHS Discretionary Funding for HIV/AIDS:** In FY 1997, funding for overall discretionary HIV/AIDS activities administered by HHS has increased by 55% since FY 1993. Highlights of this increase include a 40% increase in NIH AIDS research, a 158% increase in Ryan White AIDS treatment grants and a 24% increase in CDC HIV prevention activities.
- **Support for State AIDS Drug Assistance Programs (ADAP) --** Soon after the Food and Drug Administration (FDA) began approving an expensive new class of AIDS therapies called "Protease Inhibitors" in early 1996, the Administration proposed Budget Amendments of \$52 million and \$65 million in FY 1996 and FY 1997 respectively to increase specific funding for AIDS Drug Assistance Programs (ADAP) through Ryan White. (ADAPs provide access to medications for people with HIV disease who are not covered by Medicaid or do not receive prescription drug coverage through private sources.) Between March 1st and October 1st, 1996, funds appropriated to ADAP increased by at least \$167 million.
- **Medicaid Coverage of Protease Inhibitors --** On June 19, 1996 HCFA sent a letter advising States that they are required to cover protease inhibitors and encouraging them to ensure that appropriate nutritional services are provided to persons living with

HIV/AIDS. HCFA estimates that at least 50% of people with AIDS and more than 90% of children with AIDS are covered under Medicaid.

- **Housing Assistance for People with AIDS** -- Funding for HUD's Housing Opportunities for People with AIDS (HOPWA) has increased by 96% since FY 1993. AIDS housing assistance is also available through some Ryan White CARE Act grants.

October 11, 1996

Clinton Presidential Records Digital Records Marker

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

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: AIDs + Medicaid

395-7840

06-19-96 10:08AM FROM Medicaid Bureau

TO 912026907159

P002/003

*askley-
per your
request.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

JUN 19 1996

Dear State Medicaid Director:

The purpose of this letter is to advise States about the appropriate coverage of drugs for Medicaid eligible persons living with HIV/AIDS, and to encourage States to ensure that appropriate nutritional services are provided to those individuals. This letter specifically addresses the three protease inhibitors recently approved by the Food and Drug Administration (FDA).

Generally, States are required to cover medically accepted indications of FDA-approved drugs and off-label uses accepted by one or more of the compendia listed at section 1927(g)(1)(B)(i) of the Social Security Act. As such, States are required to cover the recently FDA-approved protease inhibitors.

In general, these drugs are approved for use in combination therapy with AZT, 3TC or other nucleoside analogs. Hoffmann-LaRoche's Invirase (saquinavir mesylate) was approved by the FDA in December 1995 for treatment of advanced HIV/AIDS. Merck's Crixivan (indinavir) was approved in March 1996. Crixivan was recommended for approval following the presentation of studies which found that 40 percent of the patients who took the drug alone, and 90 percent of the patients who took the drug in combination with AZT and 3TC (lamivudine), had their HIV viral load fall below detectable levels. The FDA also approved Abbott Laboratories' protease inhibitor, Norvir (zidovudine) in March 1996. Studies have shown that HIV patients' use of Norvir prolongs survival and delays progression to AIDS. In addition, Norvir is being used for patients in the advanced stages of AIDS.

The average wholesale price of the protease inhibitors varies. Norvir, for instance, is listed at \$8,103 plus dispensing fees per patient per year. Crixivan is listed at approximately \$5,400 plus dispensing fees per patient per year, and Invirase is listed at approximately \$6,865 plus dispensing fees per patient per year. While States have discretion to establish certain limitations on the provision of drugs, the effect of such limitations on Medicaid HIV/AIDS-infected patients can have serious ramifications, including the emergence of resistance if such drugs are discontinued. States should examine their drug benefits to ensure that limitations do not excessively or unreasonably restrict coverage of effective treatments (including FDA-approved combination therapy) for HIV/AIDS-infected individuals.

-06-19-96 10:08AM FROM Medicaid Bureau

TO 912026907159

P003/003

Page 2 - State Medicaid Director

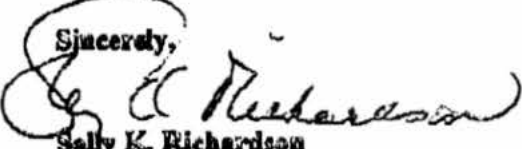
States vary as to whether and how prescription drugs are included in their contracts with, and payments to, managed care plans. If your State includes drugs and covers the HIV population in managed care, these drugs must be available in managed care formularies. If your State excludes prescription drugs from managed care contractual requirements and capitation rates, the requirements of the drug rebate program are then applicable. States should examine their existing contracts to determine if prescription drugs are covered through managed care plans, what (if any) benefit restrictions may apply, and whether the capitation rates should be adjusted to account for the introduction of new drugs such as the protease inhibitors.

The above considerations may not be broadly applicable if people with HIV/AIDS are specifically excluded from managed care (even on a voluntary basis), or the enrollment of HIV/AIDS-infected beneficiaries is small, or not widely distributed among plans. Under these circumstances, States may "carve out" the prescription of, and payment for, drugs used in the treatment of HIV/AIDS (including protease inhibitors) from managed care contracts and capitation rates.

In addition to the above information, we would also like to stress the importance of maintaining adequate nutritional status for those living with HIV/AIDS. Therefore, we encourage States to examine nutritional services benefits to ensure that they are appropriate for the effective care of Medicaid-eligible HIV/AIDS-infected individuals.

One of HCFA's objectives is to assure that Medicaid eligible individuals living with HIV infection or AIDS have access to appropriate benefits under the program. In partnership with you, the States, I feel assured that the objective can be met.

Sincerely,


Sally K. Richardson
Director
Medicaid Bureau

cc:

All Regional Administrators
All Associate Regional Administrators
Division of Medicaid
Director, Health Policy Unit
American Public Welfare Association
Director, Health Committee
National Conference of State Legislatures
Senior Policy Analyst, Human Resources Group
National Governors' Association

AIDS Groups' Concerns about the Medicaid Per Capita Cap

Q: Won't the Medicaid policy proposed by the President make States reduce coverage for people with AIDS?

A: AIDS is a priority. The President has made addressing the needs of people with AIDS a priority; his Medicaid policy is no exception. *(If you want to expand, I have lots of facts on what POTUS has done w/ regard to Rs.)*
Plan strengthens the Medicaid guarantee. The President's Medicaid policy reaffirms his commitment to ensure that all people eligible for Medicaid are guaranteed basic health insurance coverage, regardless of their health. His policy would not alter this guarantee.

Medicaid savings are modest and needed to prevent future attacks. The President is asking Medicaid to make a contribution to deficit reduction, but it is small. The budget saves \$9 billion for the 1998 to 2002 period. Only about one-third of the savings comes from a per capita cap. And, given today's trends, the per capita cap may not be needed. However, it will protect against excessive growth in future, which could trigger another entitlement reform debate and the desire to end the Medicaid guarantee through block grants.

Per capita cap is flexible enough to protect people with AIDS. The President's per capita cap is flexible enough to maintain Medicaid's important role for people with AIDS.

The per capita cap is not imposed at the individual beneficiary level, but is, in fact, one annual limit for each State. States experiencing sudden increases in AIDS spending may use savings from another part of the program to offset this increase.

The limit adjusts for casemix. If the number of people with AIDS on Medicaid increases, the Federal spending limit will increase as well.

A significant amount of AIDS spending is included in the policy's base year. By 1994, Medicaid was already funding nearly \$3 billion in care for people with AIDS. In 1996, the base year for the per capita cap, the amount of Medicaid spending on AIDS was even higher.

The limit will also adjust for different benefits and costs across States. There is a justifiable concern that the limit will not allow states to accommodate costly advances in the treatment of AIDS. To address this concern, the President proposes a commission to look into allowing variable growth rates.

Plan allows States to innovate with home and community care. The budget also gives States the option of developing home and community-based care programs without a Federal waiver. Many States use these programs for people with AIDS.

The President's plan maintains all optional and mandatory eligibility categories and all optional and mandatory benefits. The disabled population who qualify through the Supplemental Security Income (SSI) program are a mandatory eligibility category. Even if a state spends more than its aggregate limit, they cannot eliminate the SSI population from eligibility. Likewise, other mandatory groups such as children under six with income less than 133% of poverty, children from 6-14 with incomes less than 100%, and pregnant women with incomes less than 133% cannot be eliminated from eligibility. The welfare reform law included language requiring states to provide Medicaid to families which would have been eligible for Medicaid via AFDC in July of 1996, even if they no longer are eligible for TANF.

Definition of Disability -- Last year the National Governors' Association proposed to allow states to define disability for Medicaid eligibility purposes. The President's proposal maintains the federal definition of disability. Thus, eligibility for the SSI program will not change under the Presidents plan.

Cost per Beneficiary -- In the President's proposal last year, the base year for per capita spending for each subgroup upon which the growth limits would have been applied was FY 1995. In the new proposal, it may be per capita spending in FY 1996. This would include spending on the new protease inhibitor drugs which began in 1996. Thus the base year is likely to reflect the additional costs for AIDS treatment, while much of the savings (if they exist) are likely to be accrued in future years.

Coverage of Protease Inhibitors -- Some states have complained about the cost of covering the new protease inhibitor drugs. Even if the per capita spending on the disabled is growing faster than the cap, states are unlikely to eliminate coverage for these drugs. Drugs are an optional benefits, but states must cover all drugs if they want to participate in the drug rebate program. Thus, a state could not drop just protease inhibitors from their formulary without dropping all drugs. Currently, all states cover drugs for at least their mandatory population.

Managed Care Quality -- The President's plan last year required states to develop a quality improvement strategy and provided authority to establish solvency standards for Medicaid managed care plans. Other legislative proposals introduced last year included statutorily-defined standards for quality. Currently, we are considering modifying the President's plan to include better-defined quality, access and financial solvency standards for Medicaid managed care organizations.

General AIDS information -- Following is a table which includes our PB 98 estimates of AIDS spending in Medicare and Medicaid, as well as Ryan White and HHS research programs.

Federal Spending on AIDS/HIV						
------------------------------------	--	--	--	--	--	--

	Medicaid		Medicare		Ryan White Care Act	H Rese
	Expenditures \$ Millions	Covered Lives	Expenditures \$ Million	Covered Lives	Expenditures \$ Millions	Expen \$ Mi
FY 96 Actual	\$1,600	99,000	\$1,100	35,000	\$757	\$1,619
FY 97 Enacted	\$1,800	104,000	\$1,300	36,000	\$996	\$1,707
FY 98 PB 98	\$1,900	108,000	\$1,400	37,000	\$1,036	\$1,743

Other materials -- We have also included a background memo written last summer on Medicaid and AIDS.

Draft # 2

Dear Senator Kerry:

Dear Congressman Markey: 2 letters

President Clinton asked me to thank you for sharing your ^{views} ~~opinions~~ on the Medicaid per capita cap proposal included in the Fiscal Year 1998 President's Budget. This proposal is designed to stabilize the growth of Medicaid as a share of economic growth while protecting beneficiaries. The per capita cap protects States facing population growth or economic downturns because it ensures that dollars follow people, allowing Medicaid spending to respond to changes in caseload and the economy.

In so doing, the budget preserves the federal guarantee of health care coverage for the 37 million Americans on Medicaid and protects the federal budget. Despite the reductions in the baseline, Medicaid is expected grow more rapidly starting in FY 1998. The Administration firmly believes that, as part of a balanced budget strategy, we must have a method to curb the future growth in Medicaid expenditures.

The President's plan also includes increased flexibility for states. The proposal includes converting the managed care §1915(b) waivers to state plan amendments, eliminating the current enrollment composition rule (the so-called 75/25 requirement) with a new quality data monitoring system, and raising the threshold for federal review of managed care contracts from the current \$100,000 level to a \$1 million contract amount.

To allow for a change in the mix of Medicaid beneficiaries over time and case-mix differences between states, the plan would calculate the cap for each state by using the specific spending per beneficiary in a base year and the number of beneficiaries in four subgroups (e.g. the aged, individuals with disabilities, non-disabled adults and non-disabled children). Although each of the four eligibility subgroups does have a limit on its level of growth, each state's actual dollar cap is calculated by combining all four subgroups. Therefore, if per capita costs for the disabled population, including persons with AIDS, were growing faster than the cap, the state could offset these costs with savings in the other three groups.

The President's plan maintains all optional and mandatory eligibility categories and all optional and mandatory benefits. Persons with AIDS who qualify through the Supplemental Security Income (SSI) program are part of a mandatory eligibility category. Even if a state spends more than its aggregate limit, ~~they~~ ^{it} cannot eliminate eligibility for the SSI population. The President's proposal also maintains the federal definition of disability. Thus, eligibility for the SSI program will not change under the President's plan.

Thank you for sharing your concerns with ^{us} ~~me~~.

Kaine

for disproportionate share hospitals (DSH). As you know, the DSH program is essential to the stability of the public hospital system in California. If it were not for the DSH program, many of our county health care systems are in danger of collapse. How does HCFA intend to "tighten" the DSH program? And what impact is projected on the public hospital system?

Mr. Vladeck: Most States have come to rely on Disproportionate Share Hospital payments to help defray costs of hospitals serving high numbers of low income and uninsured patients. HCFA continues to support the philosophy of the DSH program, and is ~~proposing to tighten up the definition of what a DSH hospital is in terms of the low income and Medicaid utilization rates to support those hospitals who are serving a disproportionate share of low-income and Medicaid patients.~~ *proposing to gradually reduce federal DSH funding without undermining the important role these funds play for providers that serve a disproportionate number of low-income and Medicaid beneficiaries.* The States would receive approximately \$15 billion less over five years in terms of DSH allotments. Reductions would be phased-in over time, although States would continue to maintain considerable flexibility over how payments would be allocated among providers.

MEDICAID AND AIDS

Ms. Pelosi: (Pol 2) Approximately a third of the projected savings in Medicaid come from a proposed per-capita cap. What would be the impact on AIDS care and the allocation to states with the highest prevalence of AIDS cases?

Mr. Vladeck: It's hard to believe that the per capita cap would have any effect on AIDS care. Since the cap would be set using spending per beneficiary in a base year--increased by an annual growth rate--States with high AIDS ~~costs~~ *costs* ~~populations~~ would be protected with existing State funding.

*Delete
see
Insert A*

Each State will receive a single limit for Federal matching payments based on the total spending in that State in 1996--excluding spending items such as payments for Medicare premiums and cost-sharing and DSH payments--by each of four specific groups: disabled, elderly, children, and adults. The State limit will be grown by an "index." This indexed spending per beneficiary would then be multiplied by the number of beneficiaries in each category in a given year. The category-specific limits would be added together to yield the maximum spending that the Federal government would match.

A

The President's plan maintains all optional and mandatory eligibility categories and all optional and mandatory benefits. Persons with AIDS who qualify through the Supplemental Security Income (SSI) program are part of a mandatory eligibility category. Even if a state spends more than its aggregate limit, they cannot eliminate eligibility for the SSI population. The President's proposal also maintains the federal definition of disability. Thus, eligibility for the SSI program will not change under the President's plan.

Attachment B

No state has requested such a waiver. On June 19, 1996, however, HCFA released a letter to all State Medicaid Directors alerting them that they are required to cover the protease inhibitor drugs for Medicaid eligibles living with HIV/AIDS. In a survey of state programs, HCFA ascertained that all states report covering the drugs, as well as the combination therapy drugs. Most of the states also cover the viral load testing which helps physicians determine the correct dosages of the drugs.

Any low-income person who meets the federal definition of disability is entitled to coverage under the Supplemental Security Income program, as well as Medicaid. Non-disabled persons who are HIV positive can also qualify for Medicaid under the other eligible categories for children, pregnant women and families receiving cash assistance. Under the §1115 waivers, several states have expanded coverage to people with higher incomes than would normally qualify for Medicaid. All new eligibles, whether disabled or not, would also be entitled to coverage for the protease inhibitors.

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Divider Title: ADAP



F A C T S H E E T

BUREAU OF HEALTH RESOURCES DEVELOPMENT

JULY 1997

The Ryan White CARE Act AIDS Drug Assistance Programs (ADAPs) Eligibility Criteria

What is ADAP?

AIDS Drug Assistance Programs (ADAPs) are authorized under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which was enacted in 1990 and reauthorized in May 1996. CARE Act programs, including ADAPs, are administered by the Health Resources and Services Administration (HRSA), an agency of the Department of Health and Human Services.

CARE Act-funded programs and ADAPs are the largest source of Federal funding specifically directed to provide primary care, treatment, and support services for persons living with HIV disease. States are required to use a portion of their funds to provide medications to treat HIV disease, including measures for the prevention and treatment of opportunistic disease.

In 1996, ADAPs nationwide served almost 83,000 low-income persons with HIV who had limited or no coverage from private insurance or Medicaid. During any given month, ADAPs serve an estimated 40,000 individuals.

The CARE Act gives States the authority to determine financial and medical eligibility criteria for participation in ADAPs. Individuals with HIV disease who do not have another source of payment must demonstrate financial need, which States typically define using a multiple of the Federal Poverty Level (FPL).

For help in determining the size and content of ADAP formularies, most (41) States have established Advisory Groups to assist with decision-making on these and other difficult issues. These groups include expert clinicians, public health officials and planners, medical ethicists, and representatives of consumers and service providers.

All States require documentation of HIV status for ADAP enrollment. At present, 14 States also require individuals to demonstrate disease progression, e.g. a lab test showing a CD4 count of 500 or less. In addition, 16 ADAPs have specific criteria for accessing protease inhibitors and/or antiretrovirals, and 3 ADAPs require a diagnosis of AIDS.

The table below summarizes financial eligibility criteria. Twenty-four States have established income eligibility at 200 percent or less of FPL (annual gross income of \$7,860 for an individual, and \$10,610 for a family of two in 1997). In States with higher income eligibility criteria, 80 percent of clients have incomes at 200 percent or less of the FPL. (See page 3 for a State-by-State description of criteria.)

In the past 2 years, rapid growth in client enrollment, utilization, and expenditures has resulted in major challenges to States as they try to promote access to treatment while ensuring that ADAPs remain fiscally sound. State responses include maximizing resources through different cost-saving strategies; establishing representative advisory bodies to help with difficult program decisions, including defining eligibility criteria; and seeking additional funds from State legislatures or other resources.

Financial Eligibility Criteria

Income Threshold as % of Federal Poverty Level (FPL)	Number of State ADAPs
100% or below FPL	1 ADAP
100-200% of FPL	20 ADAPs
200-300% of FPL	17 ADAPs
Over 300% of FPL	10 ADAPs



ADAP in Context

A number of factors affect key State decisions regarding ADAPs. It is important to keep in mind that ADAP is just one of multiple sources of public and private funding for HIV treatment. Medicaid is by far the largest payer, providing treatment to an estimated 60 percent of persons with AIDS nationwide.

However, State Medicaid plans vary widely in terms of eligibility and covered services. States with more restrictive Medicaid eligibility, limited prescription

benefits, and/or no optional coverage for medically needy populations place special pressures on ADAPs. Too often, however, these are also States with limited or no State contributions to the program. These constraints are most often reflected in restrictive financial eligibility criteria and limited formularies. Other factors include the availability of affordable private insurance, insurance risk pools, and whether or not the State limits the extent to which private insurers may cap prescription benefits.

ADAP Eligibility Criteria, FY 1997

STATE	HIV+ DIAGNOSIS	CD4 COUNT <500	SPECIFIC CRITERIA FOR PIs	FINANCIAL ELIGIBILITY (% of FPL)
Alabama	no	yes	no	250*
Alaska	yes	no	no	200
Arizona	yes	no	no	200
Arkansas	yes	no	no	100
California	yes	no	no	400*
Colorado	yes	no	no	200
Connecticut	yes	no	no	300*
Delaware	yes	no	no	300*
District of Columbia	yes	no	no	300*
Florida	no	yes	yes	200
Georgia	no	yes	yes	300*
Hawaii	no	yes	yes	400*
Idaho	no	yes	yes	400*
Illinois	yes	no	no	200
Indiana	yes	no	yes	300*
Iowa	yes	no	no	200
Kansas	yes	no	no	300*
Kentucky	no	yes	yes	300*
Louisiana	yes	no	yes	200
Maine	no	yes	no	200
Maryland	yes	no	no	400*
Massachusetts	yes	no	no	400*
Michigan	no	yes	yes	200
Minnesota	yes	no	no	300*
Mississippi	no	yes	yes	200
Missouri	yes	no	yes	185
Montana	yes	no	no	clients must demonstrate severe financial burden
Nebraska	yes	no	no	200
Nevada	no	yes	yes	200
New Hampshire	yes	no	no	300
New Jersey	yes	no	yes	400*
New Mexico	yes	no	no	300*
New York	yes	no	no	558*
North Carolina	yes	no	no	150
North Dakota	yes	no	no	150
Ohio	yes	no	yes	250*
Oklahoma	yes	no	no	150
Oregon	yes	no	no	250*
Pennsylvania	yes	no	no	400
Puerto Rico	no	yes	no	clients must be certified as indigent
Rhode Island	yes	no	no	400*
South Carolina	no	yes	no	300*
South Dakota	yes	no	no	300*
Tennessee	yes	no	yes	300*
Texas	yes	no	yes	200
Utah	yes	no	no	sliding fee scale for incomes above 101
Vermont	yes	no	no	200
Virginia	no	yes	yes	200
Washington	yes	no	no	400*
West Virginia	yes	no	no	300*
Wisconsin	yes	no	no	200
Wyoming	yes	no	no	300*
Virgin Islands	yes	no	no	
Guam	yes	no	no	

* Among these States, an average of 80 % of enrollees have incomes below 200 %.

ADAP Program Overview

**Table 1: AIDS Drug Assistance Program (ADAP) Funding Sources
FY 1995 - FY 1997**

FUNDING SOURCES	Amount/Percent for Each Fiscal Year (in millions)		
	1995 ¹	1996 ²	1997 ³
TOTAL TITLE II FUNDS	\$47 (45%)	\$119.84(55.7%)	\$220.07(58.5%)
a) TITLE II Base Award	\$47 (45%)	\$57.71 (26.8%)	\$63.20 (16.79%)
b) ADAP Earmark⁴	0.00	\$62.13 (28.9%)	\$156.87(41.68%)
STATE FUNDS	\$28.9 (27%)	\$53.06 (24.7%)	\$91.3 ⁶ (24.26%)
TITLE I CONTRIBUTIONS	\$23.8 (23%)	\$25.84 (12.0%)	\$39.89 ⁵ (10.6.3%)
OTHER RESOURCES	\$5.4 (5%)	\$16.45 (7.6%)	\$25.1 (6.67%)
TOTAL FUNDING RESOURCES	\$105.1	\$ 215.19	\$376.36

Sources:

¹ Expenditure data for the calendar year ported to HRSA by Title II grantees in their 1995 Annual Aggregate Administrative Reports.

² Projected expenditures through FY 1996 (4/1/96-3/31/97) reported to HRSA by grantees in their FY 1997 Title II applications, with updates from selected States through 5/1/97: AZ, CA, FL, GA, IL, IN, MD, MI, NJ, NY, PA, ND, RI, TX, UT.

³ Based on planned allocations reported to HRSA by grantees in their FY 1997 Title II grant applications on ADAP budget and funding sources.

⁴ Congressional appropriations for Title II included \$52 million in supplemental funds for ADAPs in FY 1996, and \$162 million earmarked for ADAP in FY 1997; however, these figures have been adjusted to reflect a total of \$10.1 million in FY 1997 ADAP funds awarded in advance to two States for use in the 4th quarter of FY 1996 to address critical ADAP shortages in those two States.

⁵ Includes information reported by Title I grantees to HRSA on planned Title I CARE Act allocations to State ADAPs, as of June, 1997.

⁶ Negotiations for FY 1997 State appropriations are not yet finalized in several States.

Table 2: Clients Served by ADAPs Nationwide, FY 1994 - FY 1995

Fiscal Year			
FY 1994¹	FY 1995¹	FY 1996²	FY 1997²
49,990 Clients	70,030 Clients	80,000 estimated	86,000 Clients projected

Sources:

¹ Based on data for the calendar year reported to HRSA by Title II grantees in their Annual Aggregate Administrative Reports

² Annualized estimate based on data reported to HRSA by grantees through the third quarter of FY 1996

AIDS Drug Assistance Programs

Table 3.a. Program Characteristics: State and U.S. Totals

Source: Annual Administrative Report, Reporting Period January 1 to December 31, 1995

State	Number of Reports	Administering Agency					Medical Eligibility Criteria					Processing Period				Recertification Frequency					Waiting List	
		HIV/AIDS Unit of Health Department	Health Department (not HIV/AIDS unit)	Welfare or Income Maintenance Dep.	Other Public or Private Agency	AIDS Diagnosis	CD4 Cell Count	HIV-related Symptoms	CD4 Count and HIV-related Symptoms	Other	Less than 10 Days	10 to 30 Days	31 to 60 Days	More than 60 Days	Quarterly	Semiannual	Annual	Other	None	Missing / Unknown	Waiting List this Reporting Period?	Number on Waiting List at End of Period
Alabama	1	1					1			1								1			Yes	150
Arizona	1	1							1	1					1						No	NA
California	1	1							1	1						1					No	NA
Colorado	2				2			2		2						2					No	NA
Connecticut	1			1					1		1				1		2				No	NA
Delaware	2	1			1			1	1	2				1	1						Yes	122
District of Columbia	1	1							1	1					1						No	NA
Florida	1	1					1				1				1						No	NA
Georgia	1				1		1			1					1						No	NA
Hawaii	1	1						1		1					1						No	NA
Idaho	1		1				1			1									1		No	NA
Illinois	1	1						1		1						1					No	NA
Indiana	1				1			1			1			1							Yes	45
Iowa	6	1	1		4	1		5		5	1				1	2			3		No	NA
Kansas	1	1						1		1									1		No	NA
Kentucky	1	1					1			1					1						No	NA
Maryland	1	1						1		1					1						No	NA
Massachusetts	1				1				1	1						1					No	NA
Michigan	1	1					1			1						1					No	NA
Minnesota	1			1					1	1						1					No	NA
Mississippi	1	1					1			1						1					No	NA
Missouri	3	3				1			2		3					2	1				No	NA
Montana	1	1							1	1									1		No	NA
Nebraska	1				1			1		1					1						No	NA
Nevada	1	1							1		1					1					No	NA
New Hampshire	1	1							1	1						1					No	NA
New Jersey	1	1							1		1					1					No	NA
New York	1	1							1	1									1		No	NA
North Dakota	1	1						1		1									1		No	NA
Ohio	1	1							1	1				1							No	NA
Oklahoma	1		1				1			1						1					Yes	.
Puerto Rico	3	1	1		1			1	1	2			1		1				2		Yes	.
Rhode Island	1	1						1		1									1		No	NA
South Carolina	1	1							1	1									1		Yes	250
South Dakota	1		1						1	1									1		No	NA
Tennessee	1	1							1	1						1					No	NA
Texas	1	1							1	1							1				No	NA
Utah	1	1						1		1							1				No	NA
Virginia	1	1						1		1						1					No	NA
Washington State	1	1						1		1					1						No	NA
West Virginia	1	1							1		1								1		No	NA
Wisconsin	1	1								1									1		No	NA
Total	53	34	5	2	12	2	8	18	9	42	10	0	1	3	13	18	4	0	15		567	
% of Total	100%	64%	9%	4%	23%	4%	15%	34%	17%	79%	19%	0%	2%	6%	25%	34%	8%	0%	28%			

Number of States = 42

AIDS Drug Assistance Programs

Table 3.b. Annual Funding and Expenditures: State and U.S. Totals
Source: Annual Administrative Report, Reporting Period January 1 to December 31, 1995

State	Annual Program Expenditures	Annual Program Funding by Source								Percent of Program Funds from CARE Act Titles I and II			
		Title I CARE Act	Title II CARE Act	Title III CARE Act	Other Federal (Incl. Medicaid)	State or Local Public (not Medicaid)	Other Sources	Total	Percent of Total Funds From CARE Act Titles I and II	At Least 50%	25% to 49%	10% to 24%	Less Than 10%
Alabama	\$ 870,369	\$ -	\$ 820,369	\$ -	\$ -	\$ 50,000	\$ -	\$ 870,369	94%	x			
Arizona	\$ 609,578	\$ -	\$ 609,578	\$ -	\$ -	\$ -	\$ -	\$ 609,578	100%	x			
California	\$ 22,702,057	\$ -	\$ 9,804,406	\$ -	\$ -	\$ 12,070,230	\$ -	\$ 21,874,636	45%		x		
Colorado	\$ 569,740	\$ 226,873	\$ 109,539	\$ -	\$ -	\$ 219,409	\$ -	\$ 555,821	61%	x			
Connecticut	\$ 1,067,462	\$ 209,500	\$ 446,323	\$ -	\$ -	\$ 411,639	\$ 187,531	\$ 1,254,993	52%	x			
Delaware	\$ 105,000	\$ -	\$ 105,000	\$ -	\$ -	\$ -	\$ -	\$ 105,000	100%	x			
District of Columbia	\$ 526,530	\$ 74,801	\$ 541,405	\$ -	\$ -	\$ -	\$ -	\$ 616,206	100%	x			
Florida	\$ 7,068,028	\$ -	\$ 7,026,028	\$ -	\$ -	\$ 42,000	\$ -	\$ 7,068,028	99%	x			
Georgia	\$ 1,108,178	\$ 365,420	\$ 1,000,000	\$ -	\$ -	\$ 315,000	\$ -	\$ 1,680,420	81%	x			
Hawaii	\$ 270,049	\$ -	\$ 146,451	\$ -	\$ -	\$ 265,000	\$ -	\$ 411,451	36%		x		
Idaho	\$ 64,344	\$ -	\$ 64,344	\$ -	\$ -	\$ -	\$ -	\$ 64,344	100%	x			
Illinois	\$ 3,562,143	\$ -	\$ 1,892,143	\$ -	\$ -	\$ 1,517,874	\$ 152,126	\$ 3,562,143	53%	x			
Indiana	\$ 882,539	\$ -	\$ 637,610	\$ -	\$ -	\$ 199,537	\$ -	\$ 837,147	76%	x			
Iowa	\$ 74,169	\$ -	\$ 63,698	\$ -	\$ -	\$ -	\$ -	\$ 63,698	100%	x			
Kansas	\$ 326,554	\$ -	\$ 326,554	\$ -	\$ -	\$ -	\$ -	\$ 326,554	100%	x			
Kentucky	\$ 483,829	\$ -	\$ 338,575	\$ -	\$ -	\$ 149,976	\$ -	\$ 488,551	69%	x			
Maryland	\$ 982,332	\$ 171,047	\$ 961,167	\$ -	\$ -	\$ -	\$ -	\$ 1,132,214	100%	x			
Massachusetts	\$ 1,284,169	\$ 328,921	\$ 955,248	\$ -	\$ -	\$ -	\$ -	\$ 1,284,169	100%	x			
Michigan	\$ 646,241	\$ 242,395	\$ 321,734	\$ -	\$ -	\$ -	\$ 58,750	\$ 622,879	91%	x			
Minnesota	\$ 172,278	\$ -	\$ 172,278	\$ -	\$ -	\$ -	\$ -	\$ 172,278	100%	x			
Mississippi	\$ 825,188	\$ -	\$ 825,188	\$ -	\$ -	\$ -	\$ -	\$ 825,188	100%	x			
Missouri	\$ 1,114,597	\$ 331,725	\$ 831,345	\$ -	\$ -	\$ -	\$ -	\$ 1,163,070	100%	x			
Montana	\$ 44,000	\$ -	\$ 44,000	\$ -	\$ -	\$ -	\$ -	\$ 44,000	100%	x			
Nebraska	\$ 100,000	\$ -	\$ 100,000	\$ -	\$ -	\$ -	\$ -	\$ 100,000	100%	x			
Nevada	\$ 594,957	\$ -	\$ 261,609	\$ -	\$ -	\$ -	\$ -	\$ 261,609	100%	x			
New Hampshire	\$ 159,490	\$ -	\$ 128,905	\$ -	\$ 30,585	\$ -	\$ -	\$ 159,490	81%	x			
New Jersey	\$ 3,095,271	\$ 516,250	\$ 2,579,021	\$ -	\$ -	\$ -	\$ -	\$ 3,095,271	100%	x			
New York	\$ 31,854,725	\$ 18,487,842	\$ 8,309,344	\$ -	\$ -	\$ 495,120	\$ 4,562,419	\$ 31,854,725	84%	x			
North Dakota	\$ 17,077	\$ -	\$ 55,000	\$ -	\$ -	\$ -	\$ -	\$ 55,000	100%	x			
Ohio	\$ 1,008,229	\$ -	\$ 1,152,434	\$ -	\$ -	\$ 200,500	\$ -	\$ 1,352,934	85%	x			
Oklahoma	\$ 713,253	\$ -	\$ 507,253	\$ -	\$ -	\$ 206,000	\$ -	\$ 713,253	71%	x			
Puerto Rico	\$ 6,218,013	\$ 2,819,058	\$ 2,781,000	\$ 80,000	\$ -	\$ 7,157,051	\$ -	\$ 12,837,109	44%		x		
Rhode Island	\$ 89,003	\$ -	\$ 89,003	\$ -	\$ -	\$ -	\$ -	\$ 89,003	100%	x			
South Carolina	\$ 533,131	\$ -	\$ 447,500	\$ -	\$ 100,000	\$ -	\$ -	\$ 547,500	82%	x			
South Dakota	\$ 70,693	\$ -	\$ 70,000	\$ -	\$ -	\$ -	\$ -	\$ 70,000	100%	x			
Tennessee	\$ 198,304	\$ -	\$ 287,500	\$ -	\$ -	\$ -	\$ -	\$ 287,500	100%	x			
Texas	\$ 5,277,652	\$ -	\$ 2,058,216	\$ -	\$ -	\$ 3,109,427	\$ -	\$ 5,167,643	40%		x		
Utah	\$ 106,002	\$ -	\$ 95,000	\$ -	\$ -	\$ 114,000	\$ -	\$ 209,000	45%		x		
Virginia	\$ 1,638,008	\$ -	\$ 626,466	\$ -	\$ -	\$ 687,200	\$ -	\$ 1,313,666	48%		x		
Washington State	\$ 540,751	\$ 58,654	\$ 216,019	\$ -	\$ -	\$ 266,078	\$ -	\$ 540,751	51%	x			
West Virginia	\$ 50,296	\$ -	\$ 77,947	\$ -	\$ -	\$ -	\$ -	\$ 77,947	100%	x			
Wisconsin	\$ 232,800	\$ -	\$ 31,301	\$ -	\$ -	\$ 433,600	\$ -	\$ 464,901	7%				x
U.S. Total	\$ 97,857,029	\$ 23,832,486	\$ 47,916,501	\$ 80,000	\$ 130,585	\$ 27,909,641	\$ 4,960,826	\$ 104,830,039		35	6	0	1
% of Total		22.7%	45.7%	0.1%	0.1%	26.6%	4.7%	100%	68.4%	83%	14%	0%	2%

Number of States = 42

AIDS Drug Assistance Programs

Table 3.c. Clients Served (Unduplicated): State and U.S. Totals

Source: Annual Administrative Report, Reporting Period January 1 to December 31, 1995

State	Reporting Period, Months	Clients Served		Gender			Race/Ethnicity						Age			
		Total Clients	New Clients	Male	Female	Missing / Unknown	White	Black	Hispanic	Asian / Pacific Isl.	American Indian	Missing / Unknown	Under 13 Years	13-19 Years	Age 20 and Over	Missing / Unknown
Alabama	12	1,060	290	890	170	#	490	560	#	#	#	10	#	10	1,050	#
Arizona	12	640	410	580	60	#	460	40	130	#	#	#	#	#	630	#
California	12	13,380	6,410	12,190	1,150	50	6,350	2,210	3,970	240	80	530	10	30	13,220	120
Colorado	12	710	370	640	60	#	450	80	120	#	#	60	#	#	710	#
Connecticut	12	1,450	880	1,100	350	#	470	490	350	#	10	120	10	#	1,430	#
Delaware	12	110	40	80	30	#	60	50	10	#	#	#	#	#	110	#
District of Columbia	12	390	390	300	90	#	70	270	40	#	#	#	#	#	390	#
Florida	12	9,060	4,090	6,720	2,300	40	3,030	4,340	1,480	20	20	170	80	100	8,880	#
Georgia	12	1,280	530	1,010	270	#	400	860	20	#	#	#	#	10	1,270	#
Hawaii	12	140	50	130	10	#	80	#	10	40	#	#	#	#	140	#
Idaho	12	60	10	50	10	#	50	#	10	#	#	#	#	#	60	#
Illinois	12	2,050	1,450	1,860	180	#	1,020	610	290	60	60	#	#	#	2,040	#
Indiana	12	470	160	420	40	#	380	70	10	#	#	#	#	#	410	60
Iowa	12	140	70	120	20	#	110	10	#	#	#	#	#	#	130	#
Kansas	12	220	30	190	30	#	180	30	10	#	#	10	#	#	220	#
Kentucky	12	330	190	290	40	#	200	80	10	#	#	40	#	#	300	30
Maryland	12	420	170	330	100	#	150	230	30	#	#	10	#	#	420	#
Massachusetts	12	1,020	660	860	160	#	400	100	220	#	10	290	10	#	1,010	#
Michigan	12	320	130	280	30	#	190	110	20	#	#	#	#	#	320	#
Minnesota	12	450	0	410	30	#	370	40	20	#	10	10	#	#	450	#
Mississippi	12	840	290	650	190	#	330	500	#	#	#	#	10	#	820	#
Missouri	12	1,420	660	1,270	150	#	950	400	20	#	#	50	10	10	1,400	#
Montana	12	30	10	20	#	#	20	#	#	#	#	10	#	#	30	#
Nebraska	12	180	90	160	20	#	130	40	10	#	#	#	#	#	170	#
Nevada	12	260	80	230	40	#	180	30	40	#	#	#	#	#	250	#
New Hampshire	12	110	50	90	10	#	50	#	#	#	#	40	#	#	110	#
New Jersey	12	2,300	950	1,600	700	#	850	850	530	#	#	70	40	10	2,240	#
New York	12	17,140	5,280	13,130	3,410	600	5,950	5,610	5,390	160	40	#	150	70	16,920	#
North Dakota	12	20	10	10	#	#	10	#	#	#	#	#	#	#	20	#
Ohio	12	590	210	520	70	#	430	120	20	#	10	20	#	#	580	#
Oklahoma	12	450	130	380	70	#	360	60	20	#	20	#	#	#	450	#
Puerto Rico	12	5,550	2,530	3,520	1,400	630	#	#	4,960	#	#	590	40	40	4,880	590
Rhode Island	12	130	50	110	20	#	70	10	20	#	#	30	#	#	130	#
South Carolina	12	480	250	350	140	#	130	330	10	#	#	10	10	#	460	#
South Dakota	12	40	20	30	#	#	30	#	#	#	#	#	#	#	40	#
Tennessee	12	180	110	150	30	#	100	80	#	#	#	#	#	#	180	#
Texas	12	4,710	1,500	4,030	680	#	2,380	1,150	1,030	10	10	120	20	10	4,680	#
Utah	12	120	60	110	10	#	100	#	10	#	#	#	#	#	120	#
Virginia	12	850	490	660	160	30	290	470	30	#	#	60	10	#	840	#
Washington State	12	720	290	660	60	#	550	50	80	10	20	10	#	#	720	#
West Virginia	12	60	20	60	#	#	60	10	#	#	#	#	#	#	60	#
Wisconsin	12	270	90	250	20	#	190	60	20	#	#	#	#	#	270	#
U.S. Total		70,090	29,490	56,440	12,290	1,360	28,060	19,950	18,940	580	320	2,250	440	320	68,530	810
% of Total		100%	42.1%	80.5%	17.5%	1.9%	40.0%	28.5%	27.0%	0.8%	0.5%	3.2%	0.6%	0.5%	97.8%	1.2%

Number of States = 42

Counts are rounded to nearest 10 (to 10 if between 1 and 14), except that # replaces demographic values less than 6. U.S. totals are calculated on unrounded data.



FACT SHEET

BUREAU OF HEALTH RESOURCES DEVELOPMENT

JULY 1997

The Ryan White CARE Act AIDS Drug Assistance Programs

The Health Resources and Services Administration (HRSA), an agency of the Department of Health and Human Services, administers the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Enacted in 1990 and reauthorized in May 1996, the CARE Act is the largest source of Federal funding specifically directed to provide primary care and support services for persons living with HIV disease.

Under Title II of the CARE Act, formula grants are awarded to the States and other eligible areas to improve the quality, availability, and organization of HIV health care and support services. In addition to other specific service programs, Title II funds AIDS Drug Assistance Programs (ADAPs). ADAPs provide medications to low-income individuals with HIV disease, who have limited or no coverage from private insurance or Medicaid, in all 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, and Guam.

In 1996, ADAPs served almost 83,000 persons with HIV disease who had limited or no coverage from private insurance or Medicaid. At any one time, ADAPs were serving about 40,000 individuals.

Title II requires that: "A State shall use a portion of the amounts provided to establish a program... to provide therapeutics to treat HIV disease or prevent serious deterioration of health arising from HIV disease in eligible individuals, including measures for the prevention and treatment of opportunistic infections."

ADAPs have served clients since 1987 (see box), but recent treatment advances have focused increasing attention on the program. The newest class of HIV drugs, protease inhibitors (PIs), have proven to be very effective when used in combination with two or three other medications. As a result, demand for the promising new combination therapy has grown rapidly—not only among individuals already in care but also among those who had not previously sought treatment. Because the cost of combination therapy with PIs is very high—between \$10,000 and \$12,000 a year per person—ADAPs are

greatly challenged in responding to the increased client demand.

Even before the expensive new drugs became available, many ADAPs were experiencing strains. The rapid growth of the HIV epidemic among poor and historically underserved populations, and evolving treatment standards which involve more than one antiviral drug, contributed to these strains. In addition, the number of people seeking and receiving treatment for HIV and AIDS continues to increase on a monthly basis.

ADAP funding has increased dramatically in recent years. In fiscal year (FY) 1996, \$52 million in Title II CARE Act supplemental funds was appropriated specifically for ADAPs. This was in addition to the \$53 million that States had already committed from their base Title II awards. In FY 1997, \$167 million was earmarked for ADAPs. Fiscal year 1998 appropriations have not yet been finalized.

State Roles In Managing ADAPs

States have the authority to establish income and medical eligibility criteria and to determine how drugs will be purchased and distributed to clients. States also determine which drugs to include on their formularies. States covering 25 or more drugs.

The ADAP began 10 years ago. In March 1987, zidovudine — better known as AZT— became the first drug approved by the Food and Drug Administration (FDA) to treat HIV disease. However, the annual cost of AZT per person, about \$10,000, placed it out of reach for many people. Congress responded (a month later) in April 1987, by approving \$30 million in funding under a public health emergency provision, and later enacted Public Law 100-71 authorizing the establishment of an ADAP program nationwide.

As HIV treatment advances occurred and as resources permitted, States expanded the program to cover drugs in addition to AZT. In 1990, when ADAP became part of the newly enacted CARE Act, States had the option to cover any FDA-approved drug that could prolong life or prevent deterioration of health.



Covered Drugs

As the number of FDA-approved HIV treatments has increased, States added some or all of the newer drugs within the limits of available resources. The availability of new, effective drugs, combined with the greatly increased cost of new medications, has affected the expansion of formularies. Today, there is considerable variation in the number of drugs on ADAP formularies, ranging from 5 to more than 100, with one-half of the States covering 25 or more drugs.

Purchase and Distribution of Pharmaceuticals

Most ADAPs were established to operate under a pharmacy reimbursement model similar to Medicaid. This allows patients to go to a participating pharmacy, show their ADAP cards and have their prescriptions filled. The pharmacy then bills ADAP.

A few States with a system of pharmacies attached to a network of public health clinics have opted to use that system to purchase and distribute drugs for ADAP clients. Only a few ADAPs directly purchase drugs and mail them to clients.

Cost-Containment Measures

With the significant growth in clients seeking treatment, dramatic increases in the cost of new treatments, and rapidly changing standards of care, ADAPs are challenged to contain costs at the same time they are asked to expand access. As a result, ADAPs have taken a number of steps to stretch dollars. These include changing the system used to purchase/distribute drugs; seeking larger price discounts (e.g., by participating in the Office of Drug Pricing Program administered by HRSA, or negotiating voluntary manufacturers' rebates); tightening income eligibility criteria; deleting some drugs from State formularies; setting caps on ADAP benefits; and/or establishing guidelines for prescribing drugs.

Income Eligibility

Because Title II gives States the authority to set income and medical eligibility criteria for ADAPs, there is wide variation among States. The table below summarizes income eligibility criteria.

The variation in eligibility generally reflects the type and availability of other health care resources for low-

Criteria as Percent of Federal Poverty Level (FPL)	Number of States/Grantees
100% or below FPL	1 ADAP
100 to 200% FPL	20 ADAPs
200 to 300% FPL	18 ADAPs
Over 300% FPL	10 ADAPs
Three States use some other criteria not related to Federal Poverty Level.	

1997 Federal Poverty Level is \$7,890/year per individual.

income individuals with HIV disease. It must be noted that even in States with more generous income eligibility standards, the overwhelming majority of enrolled individuals have incomes below 200 percent of FPL.

Medical Eligibility

All States require individuals who meet income threshold criteria simply to provide proof of their HIV status. Fourteen States also require a laboratory test showing a CD4 count of 500 or less (indicating significant damage to the immune system). For individuals to obtain access to protease inhibitors and/or antiretrovirals, 17 States have additional specific criteria.

ADAPs In Context

A number of factors affect key State decisions regarding ADAPs. The ADAP is just one of multiple important sources of public and private funding for HIV treatment. Medicaid is by far the largest payer, providing treatment to an estimated 60 percent of persons with AIDS nationwide.

However, State Medicaid plans vary widely, in terms of eligibility and covered services. States with more restrictive Medicaid eligibility, limited prescription benefits, and/or no optional coverage for medically needy populations, place special challenges on ADAPs. Too often, however, these are also States with limited or no State contributions to the program. Those constraints are most often reflected in restrictive financial eligibility criteria and limited formularies. Other factors include the availability of affordable private insurance, insurance risk pools, and whether or not the State limits the extent to which private insurers may cap prescription benefits.



F A C T S H E E T

BUREAU OF HEALTH RESOURCES DEVELOPMENT

JULY 1997

The Ryan White CARE Act AIDS Drug Assistance Program Funding Overview

The Health Resources and Services Administration (HRSA), an agency of the Department of Health and Human Services, administers the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. Enacted in 1990 and reauthorized in May 1996, the CARE Act is the largest source of Federal funding specifically directed to provide primary care and support services for persons living with HIV disease.

Title II of the CARE Act mandates that States, the District of Columbia, Puerto Rico, and eligible territories receive formula grants to improve the quality, availability and organization of HIV health care and support services. In addition to other specific service programs, Title II grants support State-administered AIDS Drug Assistance Programs (ADAPs). ADAPs provide medications to low-income individuals with HIV disease who have limited or no coverage from private insurance or Medicaid.¹

Increased Demand for ADAP

The last several years have seen an unprecedented growth in client demand and program costs for the ADAPs. These are due to:

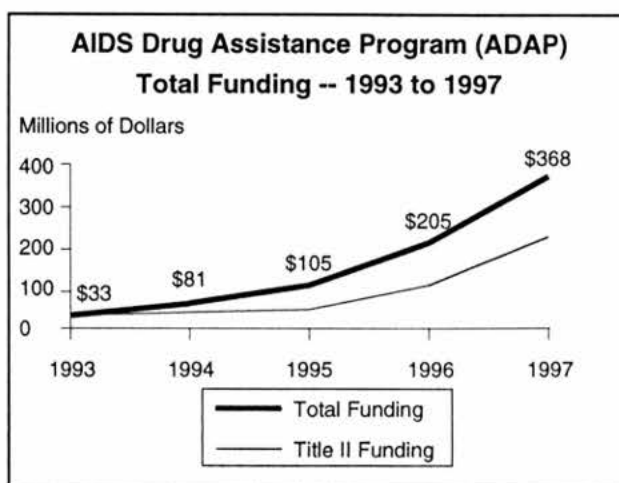
- the rapid expansion of the HIV/AIDS epidemic among low-income and uninsured populations;
- the high cost of newly approved drugs (protease inhibitors) that must be used in multiple-drug regimens; and
- the increasing numbers of people with HIV/AIDS now seeking combination therapy as a result of widely publicized research that supports new pharmaceutical therapies for improving their health status and quality of life.

Future demand on ADAP resources is expected to escalate as the standard of care shifts toward earlier treatment for people with HIV/AIDS, and as patients continue to respond positively to the new drug therapies.

Overview of Funding

In response to the increased demand, both Federal and State funding of ADAPs has grown significantly since 1985 (see chart). Federal sources of ADAP funding include:

- Title II grants — awarded to States based on formula; States have limited discretion in using these funds, but must direct some portion of the grant to the provision of therapeutics or to support ADAPs;
- Title II-earmarked ADAP funds — awarded to States based on formula, but all such funds must be used for ADAP;
- Title I grants to Eligible Metropolitan Areas (EMAs; areas disproportionately affected by the HIV epidemic) — awarded based on formula and need; these grants are used by EMAs to meet needs identified and prioritized by their HIV Services Planning Councils. Funded priorities may include ADAPs.



¹ All 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, and Guam have Title II-supported ADAPs.



States also allocate general revenue or other State funds to support their ADAPs, and by June 1997, 31 States had appropriated funds for ADAPs.

In addition, ADAPs use various cost containment strategies (discussed later) that maximize funds, allowing ADAPs to serve more people living with HIV/AIDS.

Federal Support

Title II: Over the past 3 years, Title II base allocations to ADAPs have risen from \$47 million for FY 1995 to \$63 million for FY 1997. In 1996, an additional \$52 million was specifically earmarked by Congress for ADAPs. This figure increased to \$167 million for FY 1997. Total Title II funds have increased 368 percent, and currently represent 61.5 percent of all available funds for ADAPs.

Title I EMA Support: Some ADAPs rely on allocations from Title I EMAs to help fill service gaps and ensure a continuum of care. In FY 1996, EMAs in 13 of the 23 States with EMAs contributed \$26 million to ADAPs. However, more than 80 percent of these contributions went to the New York State ADAP from the New York City EMA. In FY 1997, 12 States projected receipt of \$23 million from their Title I EMAs, though this amount may well increase during the remainder of the year.

State General Support

During FY 1996, 35 States contributed \$53 million to fund ADAPs. In the current fiscal year, 30 States have thus far allocated a total of \$90 million, a 70 percent increase over last year's total. States' contributions during FY 97 have ranged from a low of \$40,000 to a high of \$27.3 million.

Cost Containment Strategies

Most States participate in multiple cost recovery strategies designed to maximize available ADAP funds and assist the greatest number of people living with

HIV/AIDS. Generally, these strategies result in savings that revert directly back into the State's ADAP budget. Examples of cost-cutting methods include voluntary manufacturer's rebates, purchasing discounts with wholesalers or pharmacies, and insurance recovery mechanisms for clients who have partial drug benefit coverage through Medicaid or a private insurer. For clients in the latter category, ADAPs in some States work to close gaps left by Medicaid and insurance programs. For example, an ADAP might supplement a State Medicaid or insurance program that limits the number of prescriptions that can be filled per month.

During FY 1996, 22 States received \$16 million as a result of these cost-saving mechanisms, funds which were then used to purchase additional pharmaceuticals. In FY 1997, 10 States estimate they will be able to add \$25 million in savings from these mechanisms to their ADAPs. Savings among these 10 States range from \$25,000 to \$15.7 million. Significant additional savings in these and other States are anticipated before the end of the fiscal year.

Current and Emerging Issues

As new and rapidly changing treatments enhance individuals' overall health status and improve their quality of life, ADAPs will continue to face fiscal challenges. Most ADAPs project program growth, with increasing enrollment and utilization of multi-drug combinations. Recent release of the new HIV Clinical Treatment Guidelines that emphasize early and multi-drug treatment that includes protease inhibitors, will also likely increase enrollments. The advent of these new and effective therapeutics require that care providers, ADAPs, and patients view HIV as a treatable and chronic disease, factors that will affect ADAP policies. ADAPs also will need to reexamine their roles as more and more Medicaid enrollees are served through managed care. Finally, future budget constraints and the need for sufficient numbers of HIV-trained and qualified primary health care providers must be anticipated.



FACT SHEET

BUREAU OF HEALTH RESOURCES DEVELOPMENT

JULY 1997

The Ryan White CARE Act AIDS Drug Assistance Programs (ADAPs) Cost-Containment Strategies

What is ADAP?

AIDS Drug Assistance Programs (ADAPs) are authorized under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which was enacted in 1990 and reauthorized in May 1996. CARE Act programs, including ADAPs, are administered by the Health Resources and Services Administration (HRSA), an agency of the Department of Health and Human Services.

CARE Act-funded programs and ADAPs are the largest source of Federal funding specifically directed to provide primary care, treatment, and support services for persons living with HIV disease. States are required to use a portion of their funds to provide medications to treat HIV disease, including measures for the prevention and treatment of opportunistic disease.

In 1996, ADAPs nationwide served almost 83,000 low-income persons with HIV who had limited or no coverage from private insurance or Medicaid. During any given month, ADAPs serve an estimated 40,000 individuals.

Since the creation of ADAPs, States have worked hard to maximize resources in order to provide medications to as many low-income and inadequately insured individuals living with HIV/AIDS as possible. Recently however, States have faced enormous challenges as a result of rapid growth in ADAP enrollment, the number of prescriptions per enrollee, and the cost of treatments. This growth has been due primarily to the introduction of new drugs — especially protease inhibitors (PIs).

When used in combination with other anti-retrovirals, PIs have proven to be very effective in

improving health, extending life, and improving the quality of life for people with HIV/AIDS. As a result, the use of combination therapy has emerged as the new "standard of care". However, the high cost of combination treatment with PIs — approximately \$10,000 to \$12,000 per patient per year, not counting other health care costs — has significantly increased the pressure on ADAPs to adopt a wide variety of cost-containment strategies designed to maximize resources. These include restructuring their purchasing and distribution system, "pay-and-chase" strategies to recover insurance benefits for partially insured clients, and the options detailed below.

HRSA's Office of Drug Pricing Program (ODP):

This program is authorized under Section 602 of the Veterans Health Care Act of 1992. Currently, 18 States participate in this drug purchasing program, which calculates a significant discount off the average manufacturers' price of each drug based on a legislatively mandated formula for qualified "covered entities." Eligible entities include Title II funded State ADAPs and other CARE Act funded local pharmacy assistance programs that meet program guidelines. Participation in the ODP Program is easiest for States that centrally purchase and distribute ADAP medications.

Negotiated Pharmacy/Wholesaler Discounts:

States that do not centrally purchase and distribute drugs typically use a network of participating pharmacies. Enrolled clients present their ADAP card or other identification to obtain their prescriptions, and the pharmacy then bills the State ADAP. ADAPs reimburse the pharmacies at a negotiated discounted price which frequently is similar to the amount paid by the State's Medicaid program.



Voluntary Manufacturers' Rebates: Most States that do not participate in ODP and instead reimburse participating pharmacies also obtain voluntary manufacturers' rebates (refunds) on some or all drugs on their ADAP formulary. To obtain these rebates, each State currently must negotiate individually with each manufacturer. States with a high volume of drug purchases are generally in a better position to negotiate larger rebates, either directly or through a contracted agent.

Other Strategies: In some States where demand outstrips resources, further cost-cutting measures have been adopted. These methods include capping client enrollment, instituting waiting lists, eliminating drugs

from formularies, establishing protocols for accessing certain drugs, and limiting per patient expenditures.

Effectiveness of Cost-Saving Strategies: Last year (FY 1996), 22 States that were not participating in the ODP program reported approximately \$16 million in savings obtained through voluntary manufacturers' drug rebates, price discounts, and other cost-saving strategies. In the first 9 months of FY 1997, 10 States estimate a total of \$25 million in savings from these combined methods. Further savings are expected to be reported during the remainder of the fiscal year, but programs are already anticipating a 56 percent increase over 1996.

Cost Saving Plans, AIDS Drug Assistance Program, July 1997

State	Sect 602/ODP Program	Man'fct. Discount	Vol. Man'fct. Rebates	Medicaid Rebates	Pharmacy Discounts	Multiple Strategies	Manuf PAP
Alabama	Yes	No	No	No	No	No	No
Alaska	No	Yes	Yes	No	Yes	Yes	Yes
Arizona	Yes	No	No	No	No	No	No
Arkansas	No	No	Yes	No	Yes	Yes	Yes
California	No	No	Yes	No	Yes	Yes	Yes
Colorado	Yes	Yes	Yes	No	No	Yes	No
Connecticut	No	No	No	Yes	Yes	Yes	No
Delaware	No	Yes	Yes	No	No	Yes	No
D.C.	No	No	No	No	No	No	No
Florida	Yes	No	No	No	No	No	Yes
Georgia	Yes	Yes	No	No	No	Yes	Yes
Hawaii	Yes	No	No	No	No	No	Yes
Idaho	No	No	Yes	No	Yes	Yes	No
Illinois	Yes	No	Yes	No	Yes	Yes	No
Indiana	No	No	Yes	Yes	No	Yes	No
Iowa	No	No	No	Yes	Yes	Yes	Yes
Kansas	No	No	Yes	No	Yes	Yes	No
Kentucky	No	No	Yes	No	Yes	Yes	Yes
Louisiana	Yes	No	No	No	No	Yes	No
Maine	No	Yes	Yes	Yes	Yes	Yes	Yes
Maryland	No	No	Yes	Yes	No	Yes	Yes
Massachusetts	No	Yes	Yes	No	Yes	Yes	Yes
Michigan	No	No	Yes	No	No	No	Yes
Minnesota	No	No	Yes	No	Yes	Yes	No
Mississippi	Yes	Yes	No	No	No	Yes	No
Missouri	No	No	Yes	Yes	Yes	Yes	Yes
Montana	No	No	Yes	No	Yes	Yes	Yes
Nebraska	Yes	No	Yes	No	No	Yes	No
Nevada	Yes	Yes	Yes	No	No	Yes	No
New Hampshire	No	Yes	Yes	Yes	No	Yes	Yes
New Jersey	No	No	Yes	No	Yes	Yes	Yes
New Mexico	Yes	Yes	No	No	No	Yes	No
New York	No	No	Yes	No	Yes	Yes	No
North Carolina	No	No	Yes	No	Yes	Yes	No
North Dakota	No	No	Yes	No	Yes	Yes	No
Ohio	No	No	Yes	No	Yes	Yes	Yes
Oklahoma	No	No	Yes	No	Yes	Yes	Yes
Oregon	Yes	Yes	Yes	No	No	Yes	No
Pennsylvania	No	Yes	Yes	No	Yes	Yes	Yes
Puerto Rico	Yes	Yes	No	No	No	Yes	No
Rhode Island	No	Yes	Yes	Yes	Yes	Yes	Yes
South Carolina	Yes	No	No	No	No	No	No
South Dakota	No	Yes	No	No	No	No	Yes
Tennessee	Yes	No	No	No	No	Yes	No
Texas	Yes	No	No	No	No	No	No
Utah	No	No	Yes	No	Yes	Yes	No
Vermont	No	Yes	Yes	Yes	No	Yes	Yes
Virginia	Yes	Yes	Yes	No	No	Yes	Yes
Washington	No	Yes	Yes	No	Yes	Yes	Yes
West Virginia	No	No	No	No	Yes	No	Yes
Wisconsin	No	No	Yes	No	No	No	Yes
Wyoming	No	No	No	Yes	Yes	Yes	Yes
Virgin Islands	No	Yes	No	No	No	No	Yes
Guam	No	No	No	No	No	No	No
Total	18	19	34	10	26	41	28



FACT SHEET

BUREAU OF HEALTH RESOURCES DEVELOPMENT

JULY 1997

The Ryan White CARE Act AIDS Drug Assistance Programs (ADAPs) Formulary Overview

What is ADAP?

AIDS Drug Assistance Programs (ADAPs) are authorized under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which was enacted in 1990 and reauthorized in May 1996. CARE Act programs, including ADAPs, are administered by the Health Resources and Services Administration (HRSA), an agency of the Department of Health and Human Services.

CARE Act-funded programs and ADAPs are the largest source of Federal funding specifically directed to provide primary care, treatment, and support services for persons living with HIV disease. States are required to use a portion of their funds to provide medications to treat HIV disease, including measures for the prevention and treatment of opportunistic disease.

In 1996, ADAPs nationwide served almost 83,000 low-income persons with HIV who had limited or no coverage from private insurance or Medicaid. During any given month, ADAPs serve an estimated 40,000 individuals.

The CARE Act gives States the authority to determine which medications approved by the Food and Drug Administration to include in the formulary for their AIDS Drug Assistance Program (ADAP). Historically, ADAPs have focused on treatments specifically developed to treat HIV/AIDS. Most ADAPs also provide access to drugs used to treat or prevent opportunistic diseases that develop in later stages of illness, either directly through the ADAP formulary, or in cooperation with Title II funded consortia. More than 70 percent of States include between 10 and 58 drugs on their formularies. (See page 2 for a State-by-State overview of ADAP formularies.)

In the past few years, States have focused increasing attention on their formularies due to the emergence of new and effective — but high cost —

treatments such as the recently approved protease inhibitors (PIs). The PIs, when taken in combination with two or more anti-retroviral drugs, significantly reduce the amount of virus in the body (called the viral load). This has the potential to improve a patient's health status, life expectancy, and quality of life. Treatment with combination therapy has emerged as the new "standard of care" for HIV/AIDS, confirmed in recently released HIV treatment guidelines. However, the cost of providing combination therapy is currently about \$10,000 per person per year, not including other needed medicine or primary care costs.

As a result, ADAPs nationwide have been seriously challenged as they have tried to respond to the rapid increase in the number of people with HIV/AIDS now seeking treatment, and the very high cost of providing such treatment. Nevertheless, as of June 1997, most States had added protease inhibitors to their ADAP formulary. In the four States that have not yet done so, the Title II CARE Act program assists ADAP eligible clients to access PIs through other resources, including other CARE Act funded programs, clinical trials, and manufacturers' patient assistance programs. It must also be noted, however, that inclusion of PIs in the formulary does not guarantee that these drugs are available to all eligible ADAP clients. Because of the high cost and limited resources, some ADAPs have had to restrict access to PIs — particularly where State resources have not yet been allocated to ADAPs.

For help in determining the size and content of ADAP formularies, most (41) States have established Advisory Groups to assist with decision-making on these and other difficult issues. These groups usually include expert clinicians, public health officials and planners, medical ethicists, and representatives of consumers and service providers. Advisory groups may also assist with other key program activities, with members playing an active role in educating clinicians, providers and consumers on treatment issues.

ADAP Formulary Information, FY 1997

GRANTEE	Total # of drugs in Formulary 1996-97	# of Protease Inhibitors	# of NNRTI	# of NRTI	# of All Other Drugs
Alabama	13	3		5	5
Alaska	11	4	1	5	0
Arizona	19	4	1	5	8
Arkansas	11	0		5	6
California	50	4		5	39
Colorado	11	4		5	0
Connecticut	64	4		5	58
Delaware	47	4	1	5	37
District of Columbia	47	4	1	5	40
Florida	19	4	1	5	8
Georgia	8	3		5	0
Hawaii	36	4		5	21
Idaho	10	1		5	4
Illinois	61	4	1	5	24
Indiana	19	4		5	10
Iowa	23	4		5	12
Kansas	32	4		5	22
Kentucky	22	4	1	5	12
Louisiana	3	3		0	0
Maine	14	3		5	6
Maryland	32	4	1	5	22
Massachusetts	85	4	1	5	20
Michigan	21	4	1	5	11
Minnesota	44	4	1	5	33
Mississippi	14	1		4	0
Missouri	76	4	1	5	65
Montana	10	4		5	1
Nebraska	26	4	1	5	18
Nevada	11	0		5	5
New Hampshire	37	4		5	23
New Jersey	41	4		5	30
New Mexico	60	4	1	5	31
New York	206	4	1	5	198
North Carolina	31	4	1	5	17
North Dakota	59	3		5	51
Ohio	22	4	1	5	11
Oklahoma	17	3		5	9
Oregon	7	0		5	2
Pennsylvania	58	3		5	50
Puerto Rico	117	3		5	90
Rhode Island	26	3	1	5	14
South Carolina	22	4		5	12
South Dakota	35	0	1	5	29
Tennessee	19	3		5	11
Texas	27	4		5	20
Utah	11	4	1	5	0
Vermont	38	4	1	5	27
Virginia	17	1		5	9
Washington	65	4	1	5	53
West Virginia	18	4	1	5	7
Wisconsin	20	4	1	5	9
Wyoming	61	4		5	51
Virgin Islands	14	3		2	11
Average	35.23	3.32		4.83	23.62
Median	23.00	4.00		5.00	12.00

1994 and 1995 Drug Formulary data - AAR

1/97 Total # Drugs on Formulary - ADAP Technical Assistance Directory/NASTA
PI data - FY '97 Title 2 Applications & Telephone Consults



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 19, 1996

NOTE FOR THE CHIEF OF STAFF

FROM: Jack Lew *AL*
Carol Rasco *CHC*
RE: Attached Memorandum to the President Requesting
Decision on \$65 Million Budget Amendment for AIDS Drugs

The attached memorandum follows up on the President's request, as noted in his response to a June 24 memorandum from Carol and Patsy Fleming, that we identify additional resources to enable low-income people to obtain the new AIDS drug therapies that have recently been approved by the FDA. In the memorandum, we propose a \$65 million budget amendment that would be paid for by offsets from within HHS, mainly from a less than 1% across-the-board reduction in administrative costs. (The offsets are still under negotiation with Secretary Shalala; as we note in the memorandum, if HHS refuses to accept the administrative cost reduction, we may be forced to make cuts in HHS programs that would be considerably more difficult).

The Senate Labor/HHS/Education appropriations subcommittee is scheduled to begin its markup on Wednesday, July 24. We want to get this budget amendment to the Congress by no later than Tuesday, July 23. Therefore, we will need the President's decision by Tuesday morning if at all possible.

Please let us know if you have any questions.

cc: Todd Stern
Martha Foley



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 19, 1996

MEMORANDUM FOR THE PRESIDENT

FROM: Jacob J. Lew, Acting Director, Office of Management and Budget
Carol H. Rasco, Assistant to the President for Domestic Policy *CHR*
SUBJECT: Budget Amendment for State AIDS Drug Assistance Programs -- DECISION

Decision Requested

This memo seeks your decision on whether to request an additional \$65 million in fiscal year 1997 for State AIDS Drug Assistance Programs (ADAP)¹, that are partially funded by the Ryan White AIDS treatment grant program administered by the Department of Health and Human Services (HHS). You would transmit this request to Congress in the form of a FY 1997 Budget Amendment and recommend commensurate offsets in other HHS spending for FY 1997. Because the Senate Labor/HHS/Education Appropriations subcommittee will be marking up next Wednesday, we hope to transmit the budget amendment on Tuesday, July 23.

You will recall that Carol Rasco and Patsy Fleming sent you a memo on June 24th concerning a new class of AIDS treatments called "protease inhibitors" (PI), which when used in combination with two older AIDS medications, have been shown to suppress the replication of the HIV virus to extremely low or, in some cases, undetectable levels. The recent Eleventh International Conference on AIDS in Vancouver has further confirmed these findings and has brought real hope that this new triple-combination therapy may eventually make AIDS a chronic disease for those who can afford it.

Based on information gathered at the Vancouver conference and the recommendations of HHS Secretary Shalala and AIDS Policy Office Director Fleming, we recommend that you increase by \$65 million your FY 1997 Budget request for Ryan White ADAP grants. This funding would be in addition to the \$52 million that is already earmarked for ADAP activities in the enacted FY

¹State ADAP programs provide access to medications for low-income individuals with HIV disease who are not covered by Medicaid or who do not receive prescription coverage through private health insurance. They are funded through discretionary grants from HHS and State contributions.

1996 Labor/HHS/Education appropriations bill and in your FY 1997 Budget. As a result of this budget amendment, your FY 1997 Budget would now include an estimated total of \$195 million for grants supporting ADAP activities, an increase of \$133 million (over 200%) since FY 1995.

We recommend that this additional funding be offset within HHS by a combination of:

- (1) \$34 million in the amount of appropriated funds we request for health surveys in the Centers for Disease Control and Prevention (CDC). This would not represent an actual reduction in CDC's program level because the authorizing statute allows funds for these surveys to be transferred from other parts of HHS; this budget mechanism has been used in the past and should not be controversial.
- (2) a \$26 million or 0.77% reduction in administrative costs for all HHS agencies, except the Indian Health Service and Food and Drug Administration, which are funded in another appropriations bill.
- (3) a \$5 million reduction in new evaluation and demonstration project grants funded through the Maternal and Child Health (MCH) block grant; approximately \$95 million in current demonstration projects would be continued. We want to emphasize that the portion of the MCH block grant that goes directly to States -- \$570 million in your FY 1997 Budget -- would be maintained.

We have discussed the budget amendment with HHS, and while the department is supportive of additional funding for the new AIDS drug therapies, there is strong concern about offsetting the cost with a reduction in HHS's administrative costs. If HHS is unwilling to accept this offset, we may be forced to consider actual cuts to programs or activities within HHS to pay for the increased funding for the new AIDS drugs. These reductions would be much more difficult and controversial -- e.g., HHS has suggested cutting our budget request for the Indian Health Service or the "Healthy Start" program, which makes grants to reduce infant mortality.

Background on the \$65 Million Budget Amendment

Triple-combination therapy involving PI drugs is currently very expensive -- as much as \$12,000 per year for an individual for the three-drug regimen. As a result of increased demand for these and other drugs, many State ADAP programs have recently faced serious financial difficulties. To assist States in this area, OMB staff worked with HHS experts (and also consulted with outside groups) to estimate a reasonable amount in additional FY 1997 funds to request at this time. This proved to be a difficult task, especially given the number of uncertainties surrounding the potential usage and price of these newly-approved drugs.²

²A key unknown is the extent to which physicians will prescribe this triple-combination therapy. To avoid having the virus develop a resistance to these medications, patients must follow a disciplined dosage schedule of 14 to 20 pills a day, often with strict dietary restrictions. If patients do not correctly follow this regimen, a disease-resistant new strains of AIDS could develop. Given these rigorous requirements and the potential public health consequences of improper usage, it is not clear what percentage of people with HIV actually will be prescribed and use these drugs. There is, likewise, no scientific consensus as to what stage in the HIV disease should patients begin this therapy or for how long they will need to take it. In addition, as the FDA may approve more drug applications it has received for

Based on the best information available at this time, we estimate that an additional \$65 million for ADAP activities in the FY 1997 Budget is necessary. Including the other amounts in the FY 1997 Budget for grants to States for ADAP activities, we estimate that this budget amendment could help over half of the roughly 65,000 people enrolled nationally in ADAP (most of whom already receive the other drugs in the three-drug regimen) to receive PI drugs. As States continue to make contributions of their own to ADAP (they contributed \$31 million in FY 1995), the number of people who would be assisted in purchasing PI drugs would grow even higher.

In addition to these new funds, we recommend that HHS provide guidance to the States on implementing more uniform "sliding" fee-scale requirements based on income for individuals receiving medications through ADAP, so that these funds can go first to those most in need. In the context of announcing this Federal initiative, the Administration would also call upon the States to continue to make a reasonable contribution of their own to ADAP programs.

However, we would not publicly close the door on future Federal initiatives in this area. As the medical experts learn more about how many and for how long people will eventually utilize these therapies, we will continue to work with HHS, the States and the AIDS community to assess the needs in this area.

Recommendation

We therefore recommend a FY 1997 Budget of \$65 million, with the offsets mentioned above, and seek your decision.

Yes ___
No ___
Discuss ___

additional PI drugs, it is possible that their price will fall.

Clinton Presidential Records Digital Records Marker

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

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

Divider Title: Microbides

...for Accelerated Effort on Microbicides

...hs.gov/news/press/1996pres/960709.html

Date: Tuesday, July 9, 1996
FOR IMMEDIATE RELEASE
Contact: HHS Press Office (202) 690-6343

File AIDS

Shalala Announces HIV Prevention Initiative; Calls for Accelerated Effort on Microbicides

VANCOUVER -- Noting the enormous progress made recently in treating HIV disease, U.S. Health and Human Services Secretary Donna E. Shalala today announced a new integrated HIV prevention research strategy including a "focused and forceful global effort" to develop safe and effective topical microbicides to help women protect themselves against HIV infection.

Speaking to the Eleventh International Conference on AIDS, Shalala said that the U.S. will increase its commitment to HIV prevention research. She also noted that in the last three years, the U.S. government has nearly tripled its commitment to research into topical microbicides and pledged to spend a cumulative total of more than \$100 million over the next four years to research and develop topical microbicides for women.

Shalala announced that the National Institutes of Health (NIH) and the U.S. Centers for Disease Control and Prevention (CDC) will each increase its spending on microbicide research in fiscal year 1997 in an effort to accelerate progress in this field. Shalala also called on other developed nations to increase their commitment to microbicide research and asked pharmaceutical manufacturers to make the development of topical microbicides a priority.

"The development of safe and effective topical microbicides will give women around the world the power to protect themselves against HIV without fear of abuse or condemnation," Shalala said.

The microbicide initiative is part of an overall approach to increasing the U.S. investment in HIV prevention at both NIH and CDC. Those elements include:

- ☐ The development of an integrated program of vaccine research at NIH developed in close collaboration with the biotechnology industry and under new leadership from an extramural scientist. Funding for vaccine research at NIH will increase to \$116 million in FY1997 from \$109 million in fiscal year 1996.
- ☐ The development of a prevention sciences initiative at NIH to address both non-vaccine biomedical and behavioral prevention research, including further research into abstinence. Funding for behavioral research at NIH will increase to \$180 million in FY1997 from \$174 million in FY1996.
- ☐ As part of its overall AIDS research budget, NIH will spend \$25 million on research into topical microbicides.
- ☐ A greater focus by the CDC on the prevention needs of women, substance abusers, and young adults. Overall funding for CDC's prevention efforts will increase to \$617 million in FY1997 from \$583 million in FY1996.
- ☐ As part of its prevention budget, CDC will spend approximately \$4 million on research into topical microbicides.

Shalala said the recent approval by the Food and Drug Administration of a new class of AIDS drugs known as protease inhibitors has brought "real reason for hope" to millions of people around the world who are living with HIV or AIDS.

...for Accelerated Effort on Microbicides

...hs.gov/news/press/1996pres/960709.html

But Shalala noted that progress in treatment of HIV disease should not diminish the global dedication to AIDS prevention. "The best way to extend the length and quality of people's lives is to make sure that they do not become infected with HIV in the first place," she said.

Nearly half of the estimated 20 million people around the world who are infected with HIV are women. In the U.S., women are one of the populations experiencing the sharpest increases in infection rates. In addition, maternal transmission is the major factor leading to pediatric AIDS cases.

Topical microbicides could be in gel, foam, or suppository form. They would be used by women to protect against HIV and other sexually transmitted diseases. Unlike latex condoms, which are currently the most frequently used barrier method for HIV prevention, microbicides would be female controlled.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

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NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research
(INCLUDING TRANSFER OF FUNDS)

For carrying out part D of Title XXIII of the Public Health Service Act, \$1,540,765,000.

Provided, That the Director of the Office of AIDS Research shall transfer funds from this appropriation the amounts necessary to carry out subsection 2353 (d) of the Act.

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

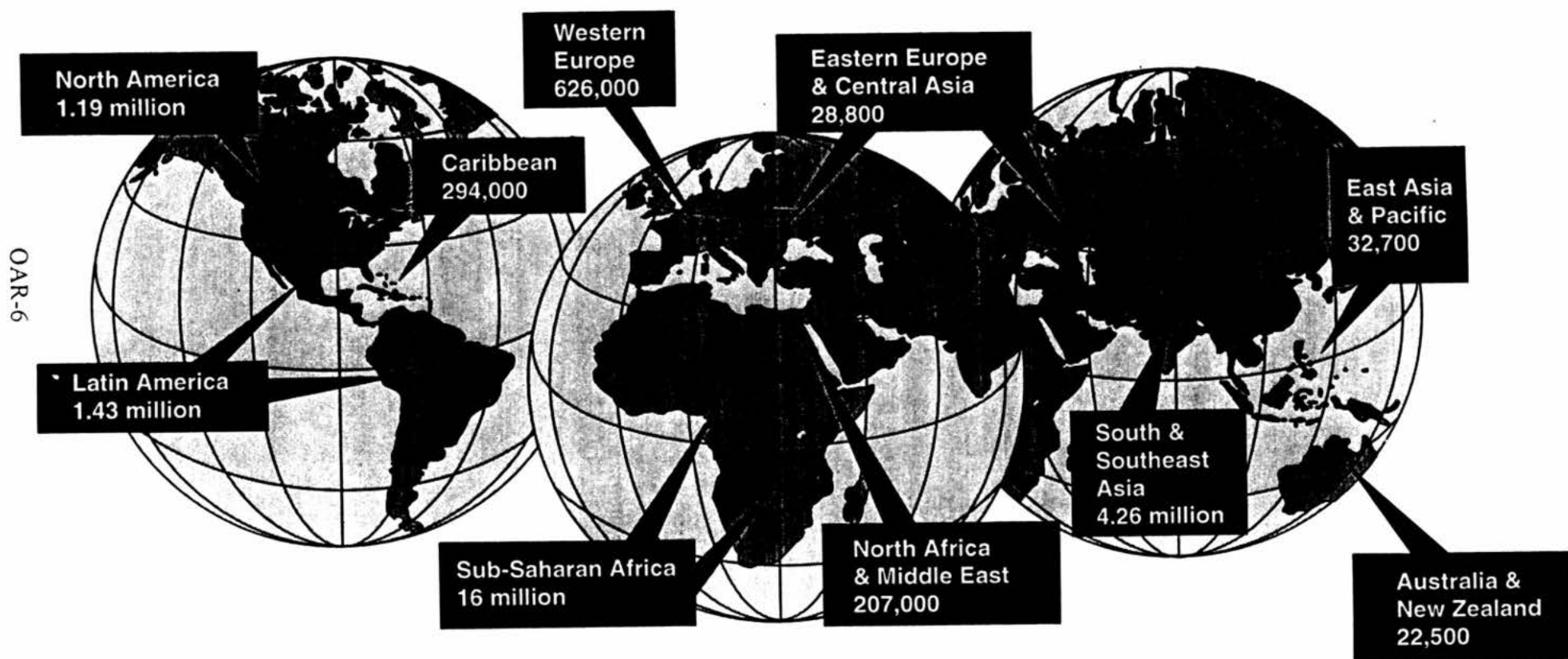
Amounts Available for Obligation

	1996 Actual	1997 Estimate	1998 Estimate
Appropriation	---	---	\$1,540,765,000
Real transfer from: Other NIH Institutes through the NIH Director's one percent transfer authority	\$4,000,000	---	---
Comparative transfer from: National Cancer Institute	225,360,000	\$224,733,000	---
National Heart, Lung and Blood Institute	57,877,000	61,577,000	---
National Institute of Dental Research	12,953,000	12,932,000	---
National Institute of Diabetes and Digestive and Kidney Diseases	11,735,000	12,718,000	---
National Institute of Neurological Disorders and Stroke	23,774,000	24,825,000	---
National Institute of Allergy and Infectious Diseases	595,549,000	647,709,000	---
National Institute of General Medical Sciences	26,135,000	27,695,000	---
National Institute of Child Health and Human Development	60,713,000	64,369,000	---
National Eye Institute	9,075,000	9,450,000	---
National Institute of Environmental Health Sciences	6,051,000	6,489,000	---

Amounts Available for Obligation--Continued

	1996 Actual	1997 Estimate	1998 Estimate
National Institute on Aging	\$1,755,000	\$1,854,000	---
National Institute of Arthritis and Musculoskeletal and Skin Diseases	4,039,000	4,273,000	---
National Institute on Deafness and Other Communication Disorders	1,650,000	1,820,000	---
National Institute of Mental Health	93,483,000	96,906,000	---
National Institute on Drug Abuse	153,233,000	160,832,000	---
National Institute of Alcohol Abuse and Alcoholism	10,124,000	11,051,000	---
National Institute of Nursing Research	4,896,000	5,500,000	---
National Human Genome Research Institute	993,000	3,001,000	---
National Center for Research Resources	68,370,000	74,101,000	---
John E. Fogarty International Center for Advanced Study in the Health Sciences	9,694,000	10,312,000	---
National Library of Medicine	2,916,000	3,365,000	---
Office of the Director	26,550,000	35,561,000	---
Subtotal, adjusted budget authority	1,410,925,000	1,501,073,000	\$1,540,765,000
Unobligated balance, available start of year	18,106,000	17,126,000	---
Unobligated balance, available end of year	(17,126,000)	---	---
Unobligated balance, lapsing	(44,000)	---	---
Total obligations	1,411,861,000	1,518,199,000	1,540,765,000

Estimated Distribution of Cumulative Adult HIV Infections



Global Total: 24.1 million

**as of the end of 1995*

Justification Office of AIDS Research

Authorizing Legislation: Sections 301, 2353, and 2356 of the Public Health Service Act, as amended. Reauthorizing legislation will be submitted.

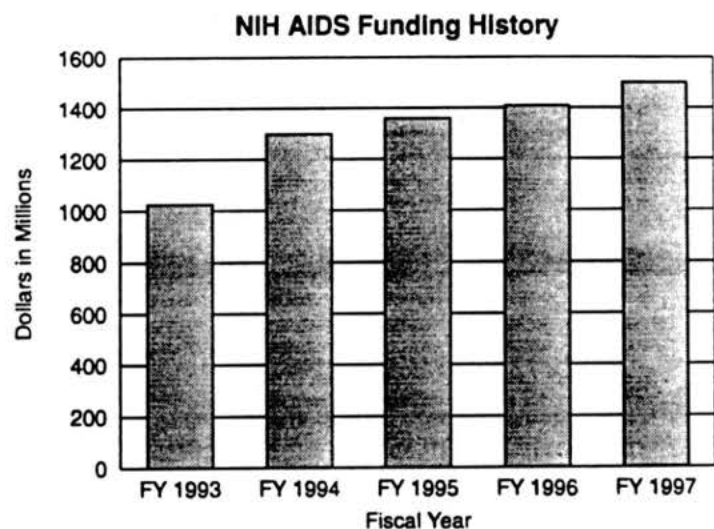
FY 1996 Actual	FY 1997 Estimate	FY 1998 Estimate
\$1,410,925,000	\$1,501,073,000	\$1,540,765,000

General Statement

The FY 1998 budget reflects and addresses the recommendations set forth in the recent comprehensive evaluation of the NIH AIDS research program that was initiated by the Office of AIDS Research Advisory Council. The recommendations from the evaluation report formed the blueprint for the development of the FY 1998 budget.

The FY 1998 budget request for AIDS research at the NIH is \$1,540,765,000. This represents a 2.6 percent increase over the FY 1997 Estimate. This request includes a single consolidated appropriation for all AIDS research provided to the OAR for distribution to the Institutes and Centers of the NIH in accordance with the HIV/AIDS research plan and section 2353(d) of the Public Health Service Act. This consolidated appropriation allows the OAR to effectively manage the research resources on the basis of sound scientific judgment taking advantage of the most promising research opportunities.

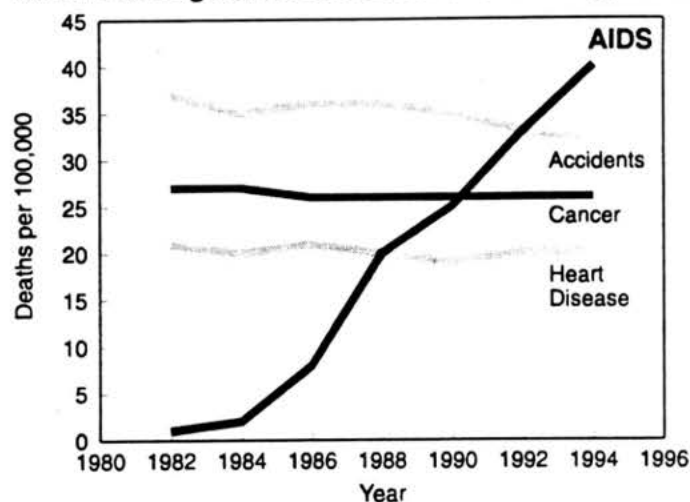
The FY 1998 budget request developed by the OAR represents the resources needed to continue to advance the research efforts in HIV infection and AIDS.



The HIV/AIDS Pandemic

AIDS is the number one cause of death among young adults in the United States today. Rates of increases in AIDS cases are now greatest for women, adolescents, persons infected through heterosexual contact, minorities, and injecting drug users. More than 29 million men, women, and children around the world have been infected with HIV; more than 3 million of those infections occurred in just the past year. Nearly 95% of these infections occur in the poorest parts of the world, without resources or the health care systems to benefit from the dramatic successes in the development of therapeutic agents against HIV. Absent a vaccine, it can be anticipated that AIDS will soon overtake tuberculosis as the leading infectious cause of death in the world.

AIDS: Leading Cause of Death in the 25-44 Age Group



A Year of Scientific Advances

The past year has brought about remarkable progress and dramatic advances in AIDS research. In recognition of this progress, Science Magazine named the "New Weapons Against HIV" as the breakthrough of the year, highlighting the "series of stunning breakthroughs" in the past 12 months in both AIDS treatment and the basic biology of HIV. A new class of drugs, protease inhibitors, used in combination "cocktails" with other antiretroviral therapies, have been shown to dramatically diminish the amount of HIV in the blood of an infected individual. Receptors for molecules called chemokines have been identified as critical co-receptors for HIV, providing another potential target for therapeutic research to block viral replication. Scientists demonstrated that those individuals who have defects in one set of these receptors are protected from HIV-infection despite exposure to the virus, demonstrating the central role of this chemokine receptor in the infectious process.

Progress has been made in the development of effective treatments for HIV-related opportunistic infections (OIs). Such treatments can prolong and improve the quality of life of people with AIDS. More sensitive and reliable measurements of viral load and viral burden have been shown to be accurate indicators of prognosis, of disease progression, and of the antiviral activity of potential therapeutic agents. The impact of these new techniques will permit physicians to better tailor treatments for their patients and allow them to more closely monitor the benefits of therapies.

These critical advances have brought an important sense of hope and renewed vigor to the AIDS research community. But it is essential to point out that these new drugs, while promising, are not a panacea. It is unknown how long the benefits of the drugs will last or whether the virus will become resistant to the drugs. There are many people for whom the new drug regimens have not been effective or for whom the side-effects are intolerable. Access to and affordability of the

therapies is also problematic. In developing countries, where more than 90% of HIV infections occur, these drugs are largely unavailable because of their cost. Thus, the search for better therapies and for a vaccine remain critical priorities.

AIDS Advances Benefit Other Disease Research

The Nation's investment in AIDS research is clearly reaping benefits and opening new and exciting scientific avenues to pursue, not only for AIDS research, but for many other important research areas. AIDS research has accelerated study of the human immune system. This basic immunologic information is being applied to research on many other diseases, such as cancer and autoimmune diseases, including systemic lupus erythematosus, type I diabetes mellitus, rheumatoid arthritis, and multiple sclerosis. AIDS research also contributes to the prevention of other infectious diseases and has provided a new paradigm for treatment of viral diseases.

The great advances made in the treatment and prevention of the opportunistic infections that complicate HIV disease have had an impact on the care of patients with other immunodeficiency states who are susceptible to many of the same pathogens. This research has enhanced the care of cancer patients and patients who have received immunosuppressive therapy for bone marrow or organ transplants or for the treatment of diseases caused by heightened immune responses. HIV research has assisted in identifying new infectious agents that may be responsible for malignancies, such as the recent discovery of a candidate etiologic agent of Kaposi's sarcoma. Such approaches may help to identify other oncogenic agents. HIV research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells gain access to the brain. This research has valuable implications for the study of Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis. Research on HIV-related wasting has provided important information for research on nutritional disorders, metabolic abnormalities, and gastrointestinal dysfunctions.

Efforts to develop drugs for the treatment of HIV has accelerated the development of methods of rational drug design using sophisticated techniques of structural biology and advanced computer imaging methods. These advances will be of great importance in the design of drugs for virtually all disorders. Comparative clinical trials of poxvirus vectors and of vaccine adjuvants in HIV vaccine candidates have supported safety information for cancer vaccine development.

Evaluation Report Frames Scientific Priority Setting

The Office of AIDS Research (OAR) has overall responsibility to plan, coordinate, evaluate, and fund AIDS research carried out in each NIH Institute, Center, and Division (ICD), consistent with its individual mission. As part of the annual planning and budget development process, it became clear that an evaluation of the entire AIDS research program was necessary. A group of scientific experts from outside the government was assembled, chaired by Dr. Arnold Levine of Princeton University. The evaluation group included Nobel laureates, members of the National Academy of Sciences and the Institute of Medicine, internationally recognized scientists, industry leaders, and community representatives. They were asked to evaluate each of the components of the current NIH AIDS research program. The review was unprecedented in its breadth and scope,

cutting across every NIH institute and center. NIH-sponsored AIDS research was evaluated to assure that the most promising areas of science are being supported, that the critical scientific questions are being addressed, and that the most effective use is being made of federal AIDS research resources.

The Report of the NIH AIDS Research Program Evaluation Task Force, often referred to as the "Levine Report," formed the blueprint for the development of the FY 1998 plan, thus continuing the traditional OAR process of involving non-Government experts in the development of the annual AIDS research plan. The planning process established by the OAR also includes the participation of the NIH leadership; NIH Institute and Center Directors; and members of the six OAR scientific Coordinating Committees comprised of NIH intramural and extramural scientists and program managers. These Committees develop plans for specific areas of AIDS/HIV research: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; Behavioral and Social Sciences Research; and Information Dissemination. Each of these groups also address training needs in these areas. The Coordinating Committees developed the first draft of the FY 1998 Plan through a series of meetings, updating the FY 1997 comprehensive Plan and reviewing the recommendations from the Levine Report. The draft plan was then sent to each ICD Director for their review. This process represents the direct interaction between the evaluation and planning processes.

FY 1998 Scientific Priorities

The NIH AIDS research program plan and budget is based on the following scientific priorities, reflecting a broad consensus of the current scientific opportunities and the findings and recommendations of the NIH AIDS Research Program Evaluation Working Group:

- A rededication to fundamental science, emphasizing investigator-initiated research;
- A stronger effort to develop new vaccines and to bring them to clinical trial as soon as possible;
- An augmentation of research efforts to better understand the human immune system;
- An emphasis on prevention science research, including enhanced studies of risk-taking behavior and the development of strategies to avert infection, such as microbicides, female-controlled barriers, and STD treatment and prevention;
- A vigorous therapeutic research program, emphasizing both drug discovery and an efficient clinical trials system, with additional emphasis on increased participation of women, minorities, and other underrepresented populations.

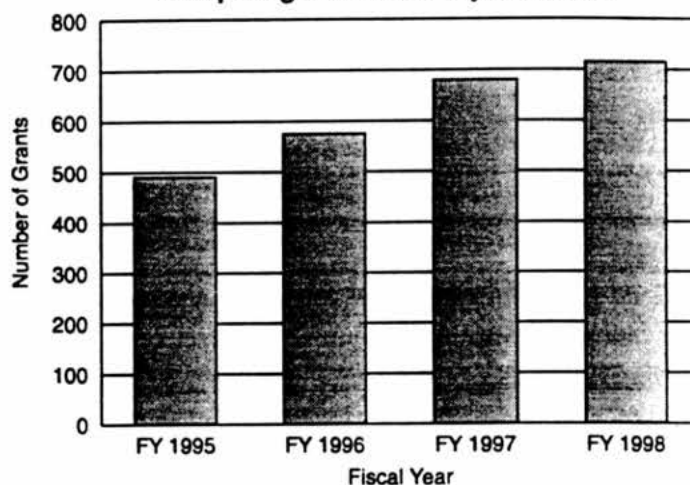
Increased Funding for Investigator-Initiated Research

An OAR review of the total AIDS research portfolio in 1994 revealed that the proportion of the AIDS research budget allocated to unsolicited investigator-initiated research was approximately 24% of the total AIDS research budget. However, for other areas of research across the NIH, the total proportion of the budget allocated for such grants is nearly double that proportion. While

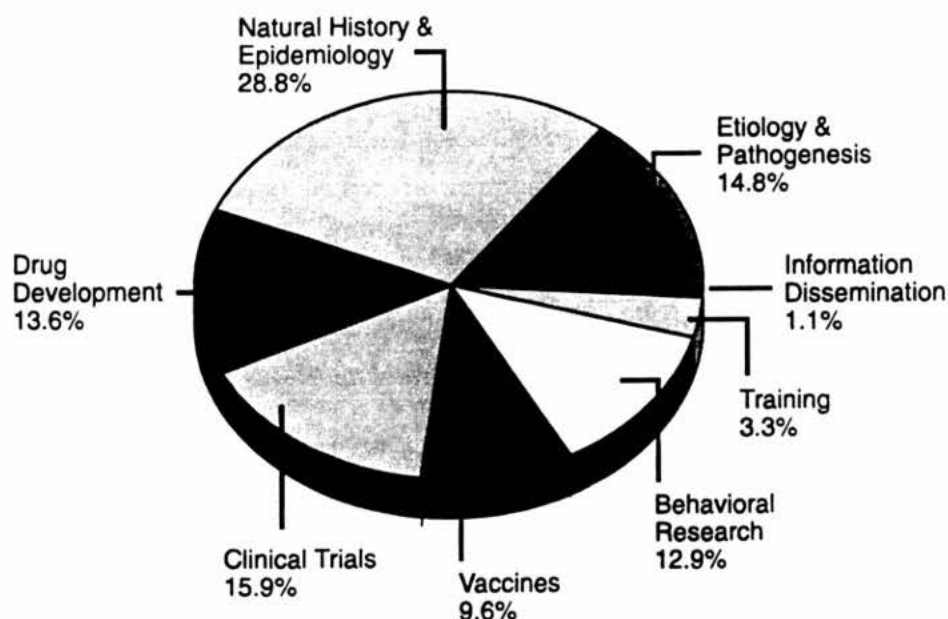
there were valid reasons in the past for this disparity in the funding mechanisms deemed most appropriate at the time, since 1994 the OAR has placed a high priority on increasing the available pool of resources for RO1 grants. In budget discussions each year with the ICDs, the OAR has encouraged the ICDs to increase the RO1 allocation and discouraged whenever possible the use of mechanisms that would unnecessarily target research. As a result of these efforts, it is estimated that the number of new and competing grants in FY 1997

will represent a 40% increase over FY 1995. In FY 1998, the OAR will continue to provide new funds for high-quality peer-reviewed research to nurture novel research approaches, concepts, and directions, as recommended in the Levine Report.

Competing Research Project Grants



FY 1998 AIDS Funding by Area of Emphasis



Area of Emphasis: NATURAL HISTORY AND EPIDEMIOLOGY

Epidemiologic research has shown that the demographics of HIV infection and AIDS in the United States have changed from an illness primarily affecting homosexual and bisexual men to the current epidemic, with increasing rates of infection in heterosexual men and women, adolescents, minorities, and drug users. The NIH conducts studies to examine the transmission of HIV and the progression of HIV-related disease, including opportunistic infections (OIs);

malignancies; neurological, neurobehavioral, and oral manifestations; and other sequelae. Such studies examine the effects of viral factors, host factors, and other factors on the risk of infection and disease progression. Cohorts of HIV-infected individuals and HIV-uninfected individuals at risk of infection are followed in clinical epidemiology studies at domestic and international sites. International epidemiology studies conducted or supported by the NIH contribute significantly to the understanding of HIV transmission, progression of HIV-related disease, risk factors associated with HIV infection and AIDS, and biomedical preventive intervention strategies.

The NIAID-supported National AIDS Specimen Repository contains over one million biological specimens linked to a huge data base from fully characterized and longitudinally followed cohorts. These biomedical samples are available to the scientific community, in collaboration with study investigators. Similarly, the NCI supports a repository of specimens from subjects enrolled in cross-sectional and prospective studies, and the NHLBI supports a serum and cell repository of more than one million specimens from volunteer blood donors and recipients of blood components or plasma derivatives. The NIMH supports the National Neurological Research Specimen Bank, which collects and distributes central nervous system (CNS) specimens from HIV-infected donors and represents a valuable resource for basic science investigations.

Increases in HIV-Related Malignancies and Tuberculosis

The DNA sequences discovered recently in Kaposi's sarcoma (KS) lesions appear to represent a new gamma-herpesvirus, provisionally termed human herpes virus type 8 (HHV8). This may represent the long-sought KS virus that, like Epstein-Barr virus, also may be involved in the etiology of some non-Hodgkin's lymphomas. A thorough understanding of the epidemiology and natural history of HHV8 is needed urgently. It is expected that the number of these malignancies will continue to increase as the life expectancy of HIV-infected patients is prolonged by administration of antiviral therapies and prophylaxis for HIV-related OIs.

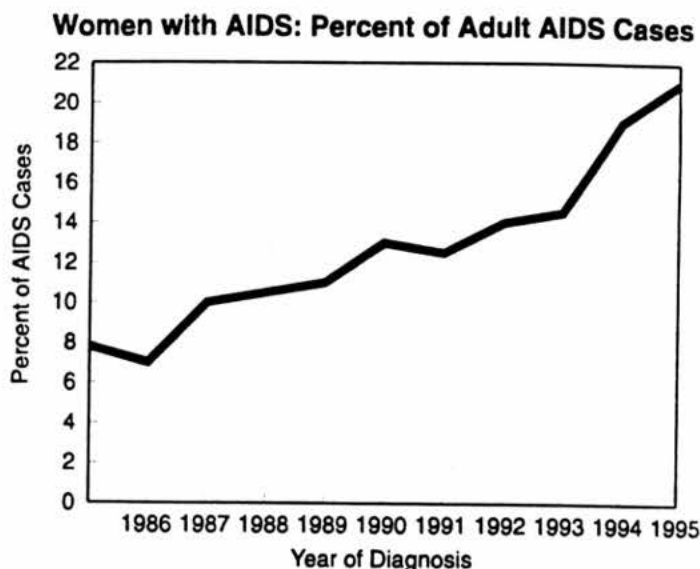
A striking phenomenon has been the increase in tuberculosis (TB), particularly multidrug-resistant TB, related to HIV infection, both globally and in certain populations in the United States. In response to the increasing incidence of TB, programs have been established to focus on the spread of TB among injecting drug users (IDUs), including studies of the incidence and progression of TB in HIV seronegative and seropositive drug users and development of improved screening and adherence strategies. Additional attention will be devoted to study of the possible impact of OIs, such as TB, on influencing the natural history of HIV disease. Ultimately this information could be useful in identifying future opportunities to prevent disease progression, and perhaps HIV transmission as well.

HIV Infection in Women

While many of the clinical manifestations of HIV infection in women are identical to those that occur in men, women also experience some that are unique or more prevalent than in men, such as vaginal and esophageal candidiasis, and chronic herpes simplex infections. The Women's Interagency HIV Study (WIHS), a major study conducted in collaboration with other PHS

agencies, is identifying the nature and rate of HIV disease progression in women, characterizing clinical manifestations of HIV important to women, assessing the effects of therapeutic regimens, and identifying sociocultural and health care access factors that affect disease outcomes in women.

An important concern is the impact of HIV on cervical cancer. Case reports suggest that HIV-associated cases progress more rapidly and are refractory to therapy. The NCI Surveillance, Epidemiology, and End Result (SEER) program has established a Special Surveillance Study to define more closely the incidence and spectrum of the histopathology of cervical cancer in HIV-infected women. The Multistate AIDS Cancer Match Registry is a project aimed at enhancing knowledge about HIV-associated cancer. Coinfection with human papillomavirus (HPV) is common in HIV-infected women. HPV and HIV have been shown to act synergistically to increase expression of individual viral genes. The enhanced expression of viral proteins results in increased viral replication, abrogates host tumor suppressor functions, and further exacerbates cellular immunodeficiency.



Mother-to-Child Transmission

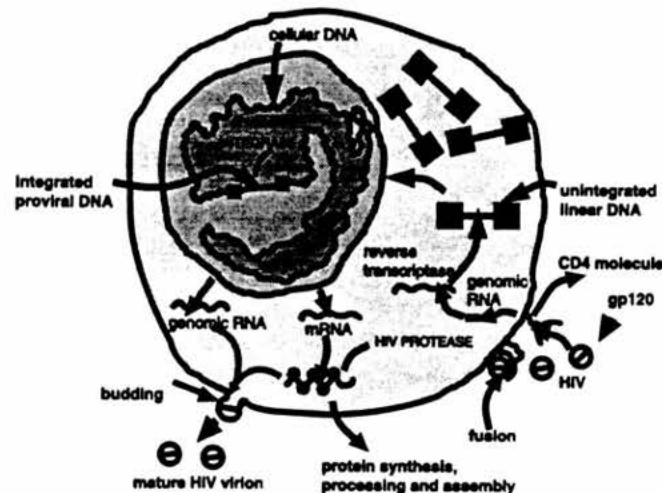
The NIH continues to study the progression of HIV-related disease in infants and pregnant women, including the timing, mechanisms, and risk factors of maternal-fetal transmission. The development of improved diagnostic assays for the early detection of HIV infection among infants, as well as markers predicting rapid versus slower disease progression, form an important part of this effort. In the United States, the NIH is funding a large epidemiologic study evaluating factors associated with risk of perinatal transmission, as well as factors associated with maternal and infant disease progression. This study, the Women and Infants Transmission Study (WITS), collectively funded by NIAID, NICHD, and NIDA, includes extensive laboratory studies as well as a specimen repository. Another pediatric epidemiologic study assessing cardiac and pulmonary complications among HIV-infected children is funded by NHLBI. Perinatal prevention trials in the United States are carried out within the Pediatric AIDS Clinical Trial Group with funding from NIAID and NICHD.

Internationally, a wide variety of perinatal HIV prevention transmission studies are under way. These include antiretroviral and immunotherapy trials in Africa, the Caribbean, and Thailand funded by NIAID and NICHD. In addition, NICHD, NIAID, and FIC are collaborating on several studies in Africa to determine whether micronutrient supplementation can reduce mother-to-child transmission or ameliorate disease progression in HIV-infected children.

Disease Progression

New data have shown that the amount of HIV circulating in the bloodstream is predictive of the rapidity of disease progression. NIH is investigating 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 a stable clinical state even with prolonged immunosuppression (long-term survivors). Special focus is being placed on host genetics and possible states of "resistance" to HIV infection and on characteristics of the viral strain. Information from these cohorts will be crucial in designing and evaluating new therapeutic approaches and vaccines. New reverse transcriptase polymerase chain reaction (PCR) technology has made quantification of HIV in plasma or serum highly reproducible, sensitive, and predictive of AIDS. This technology likely will facilitate the elucidation of the *in vivo* natural history of HIV infection and also sexual and mother-to-child transmission, particularly if the technology can be adapted to the analysis of genital and other body fluids.

Life Cycle of the Human Immunodeficiency Virus (HIV)



Area of Emphasis: ETIOLOGY AND PATHOGENESIS

NIH-sponsored investigations have led to significant advances in the understanding of HIV and how it causes disease. These studies facilitated the identification of HIV as the causative agent of AIDS, the development of a highly sensitive diagnostic test for HIV infection, delineation of some of the mechanisms of immune dysfunction, the elucidation of the role of the structural and regulatory gene products of HIV, and the delineation of the cytopathic effects of HIV infection. Insight gained from these studies is crucial for the development of potential therapeutic agents and vaccines that will result in the control, treatment, and prevention of HIV infection and its sequelae.

By use of sophisticated molecular and cellular biology techniques, scientists are uncovering the detailed processes responsible for virus growth and escape from the immune response. The mechanisms for generation of HIV antigenic variation are being defined, and the role of this variation in disease progression is being identified. Additionally, the cellular factors involved in regulation and expression of viral genes are being delineated. NIH-sponsored research programs focus on mechanisms of viral and immune pathogenesis. The Centers for AIDS Research (CFARs) and investigator-initiated research grants, some of which have been awarded through the Mechanisms of AIDS Pathogenesis initiative, support basic research studies in these areas. Such research provides the knowledge base for drug and vaccine development.

Pathogenic Mechanisms: From Acute Stage HIV Infection Through Clinical Latency to Advanced Disease

Ongoing research at the molecular, cellular, and organ-system levels is elucidating the pathogenic mechanisms of HIV infection. Recent studies have shown that newly infected patients experience a high rate of viral replication and that, in an as yet unpredictable manner, their immune systems undergo changes that continue until the development of AIDS. Studies have shown that HIV infection is active in the lymphoid tissue throughout clinical latency and that accumulation, or trapping, of virus in the lymph nodes may provide a site for transmission of HIV to uninfected immune cells as well as contribute to the destruction of the architecture of the lymphoid tissues. NIH-supported investigators demonstrated that significant levels of virus are present in plasma during all stages of HIV infection, including the clinically asymptomatic phase, and that active virus replication is directly linked to the destruction of T cell populations in infected individuals. This new understanding of the magnitude and kinetics of HIV replication *in vivo* has great implications for understanding and potentially overcoming the obstacle to effective antiviral therapy that is posed by the development of viral variants that are resistant to the inhibitory effects of antiviral drugs. The quantitation of HIV in plasma provides a new, direct virologic end point for monitoring virtually all infected people and may be of particular utility in assessing antiviral efficacy in clinical studies, especially in early-stage disease, where conventional virologic markers are often negative. In addition to measuring viral burden, NIH-sponsored research is demonstrating the breadth and specificity of the anti-HIV immune response as a possible factor in a longer period of clinical latency. This research reinforces the importance of understanding both the generation of HIV genetic variation and the host immune response that struggles to control the infection.

To further the understanding of the interaction between the virus and host immune system response, the NIH is placing particular importance on the study of the *in vivo* effects of HIV infection. NIH-sponsored longitudinal cohort studies constitute a major resource for this type of pathogenesis research. Specific cohorts, such as long-term nonprogressors, HIV-exposed but uninfected individuals, and rapid progressors, will provide clues for treatment and vaccine research by helping to characterize immune response profiles and provide information on correlates of immunity. *In vivo* research into mechanisms of viral immunopathogenesis also utilizes animal models. All the available animal models contribute to our understanding of disease mechanisms.

Factors Affecting Infectiousness and Susceptibility

The biologic determinants of infectiousness and susceptibility are important areas currently under investigation. Specific attention is being given to the possible correlation between the level of cell-free or cell-associated virus in blood, semen, urine, cervical/vaginal secretions, or oral fluids and the probability of transmission. NIH-funded research is studying factors such as the cellular and molecular aspects of mucosal immunity, viral and host genetic factors, and other infectious agents and STDs as cofactors and their impact on HIV susceptibility and transmission.

HIV Pathogenesis Affecting Women and Maternal-Fetal Transmission

In response to the changing demographics of the disease, studies have been designed to elucidate the pathogenic mechanisms more commonly observed in women, children, and adolescents with HIV infection. As part of this effort, the NIH supports a number of epidemiologic cohort studies specifically focused on women and adolescents. The study of patient samples and data generated by these cohorts is providing critical information about the course of the disease in these populations. These NIH-sponsored cohort studies represent an important scientific link between epidemiology and basic research into the pathogenic mechanisms of HIV disease.

Crucial issues associated with maternal-fetal transmission remain, including the specific mechanisms involved and the time distribution at the point at which HIV transmission occurs between mother and infant; whether specific strains (monocytotropic or lymphocytotropic) of the virus are more likely to be transmitted; delineation of the role of maternal immunity in prevention of transmission to the fetus; and the role of cofactors such as substance abuse and other infections.

AIDS-Related Cancers

Since its recognition, AIDS has had a close association with a broad spectrum of cancers, including Kaposi's sarcoma (KS), lymphomas, cervical carcinomas, anogenital carcinomas, and hepatitis B-related hepatocellular carcinomas. The proportions of malignancies and their incidence rates are increasing as the development of effective antiretroviral therapies and prophylaxis against opportunistic infections leads to prolonged survival of HIV-infected patients in the immunodeficient state. NIH-sponsored investigators have demonstrated a striking relationship between profound cellular immunodeficiency, manifested by the depletion of CD4 lymphocytes, and the development of non-Hodgkin's lymphoma (NHL). Studies of AIDS-related KS have uncovered the crucial roles of a cancer-associated herpesvirus, various angiogenic growth factors, and HIV-related factors in disease pathogenesis. The identification of pathogenic factors will also serve as targets for disease prevention and treatment.

Neuropathogenesis

NIH-sponsored studies of the neuropathogenesis of HIV infection are enhancing our understanding of the profound impact of HIV disease on both the central and peripheral nervous systems. New techniques in the molecular detection of HIV, as well as recent research on cellular genes and development of primate models of HIV encephalopathy, have focused on

possible mechanisms of neuronal dysfunction due to toxic cytokines and viral products. These investigations will help provide for a better understanding of the molecular and cellular changes underlying central nervous system (CNS) disease. Studies also will continue to identify the link between HIV-associated neuropathology and neuropsychological impairment. Experimental models of HIV/CNS disease have been established in primates, felines, and rodents. These models can be utilized to investigate various aspects of HIV/CNS disease in humans and are expected to be employed in the future for testing therapies for HIV/CNS disease.

Opportunistic Infections

NIH-sponsored research on the pathogenesis of the opportunistic infections (OIs) involves the study of a diverse group of bacteria, viruses, protozoa, and fungi. Efforts are under way to define the interactions between *Mycobacterium tuberculosis* and HIV at the cellular level and in HIV-infected people. Additional OIs of high priority under study are CMV infection, infectious causes of wasting, *Mycobacterium avium* infection, and infection by pathogenic fungi. Many of these agents also cause disease in non-immunosuppressed individuals. Studies are also examining the OIs that may be the cause of increased morbidity and mortality in women and an overall acceleration of HIV pathogenesis. Since the OIs remain the principal cause of death for HIV-infected people, understanding the mechanisms of pathogenesis of these organisms will contribute to improved quality of life as well as a better understanding of how to treat and prevent these diseases.

Wasting

Wasting contributes significantly to the debilitation, morbidity, and mortality in AIDS. Ongoing studies have shown the etiology of wasting in HIV infection to be complex and multifactorial. Resting energy expenditure is chronically elevated in HIV infection, in part due to disturbances in lipid metabolism. OIs are associated with episodes of rapid weight loss, as appetite is suppressed and caloric intake cannot meet the increased metabolic demands. Elucidation of the factors contributing to wasting will allow effective therapies to be tailored to the specific mechanisms by which wasting occurs, with the potential for prolonging life and enhancing its quality in patients with HIV infection. The mechanisms by which wasting may alter immune function and increase susceptibility to OIs are also under investigation.

Organ System-Specific Complications of HIV Infection

Gastrointestinal dysfunction, particularly diarrhea and malabsorption, is common in HIV infection. Ongoing studies are distinguishing the contributions of opportunistic infections, acquired deficiencies in intestinal enzymes, tumor involvement, and direct intestinal infection with HIV and identifying the specific nature of the resulting enteropathy and malabsorption. HIV-associated heart disease (HIVHD) also represents a cause of morbidity and mortality in seropositive children and adults. Ongoing studies are examining the pulmonary effects of HIV infection, elucidating the basis of HIV-associated nephropathy, and delineating the early cutaneous manifestations of HIV infection.

Area of Emphasis: THERAPEUTICS

NIH Panel to Define Principles of Therapy of HIV Infection

Recent insights into the pathogenesis of HIV disease, coupled with the development of new methods to assess risk of disease progression and efficacy of antiviral therapies, and the advent of potent combination antiviral drug regimens provide great opportunities for prolonging the lives of HIV-infected persons. However, these recent advances in basic and clinical HIV research have occurred at a faster rate than has the understanding of practitioners and patients concerning how to use the newly available therapies and monitoring tools most effectively. The complexity and expense of new combination antiviral drug regimens provide additional challenges to making effective treatments for HIV infection available to all who need them. The OAR has established a panel to define the scientific principles to guide the most effective use of antiviral therapy and viral load testing in clinical practice. The panel is chaired by Dr. Charles Carpenter of Brown University, and panel members include clinicians, basic and clinical researchers, public health officials, and community representatives. The panel's charge is to make recommendations regarding initiation of treatment; suppression of HIV replication; minimizing or preventing emergence of drug-resistant HIV variants; prolonging effectiveness of therapy; and addressing the public health consequences of transmission of multi-drug resistant HIV variants. The panel's recommendations will help health care practitioners and HIV-infected individuals make informed decisions about treatment options.

Therapeutic Discovery and Drug Development

The clinical testing of drugs against HIV, HIV-associated OIs and malignancies, and CNS dysfunctions requires an active preclinical drug discovery and development program. The NIH supports two major approaches in the area of drug development, including screening and rational (targeted) drug programs. The screening approach involves the testing of natural and synthetic compounds for anti-HIV activity. Rational (targeted) drug development involves characterization and delineation of the structural biology of critical HIV molecules for the purpose of developing agents aimed at inhibiting specific steps in the HIV life cycle.

The preclinical AIDS Drug Screening Program has approved six new drugs for Phase I clinical studies. Approximately 218,000 agents have been screened for anti-HIV activity to date through this program. A new panel of cell lines has been developed for testing agents for activity against HIV-related malignancies. Five hundred agents have been tested in the new lymphoma subpanel, and eight of these agents that demonstrated activity are being tested further in the SCID mouse model for efficacy compared with other antilymphoma agents.

NIH-sponsored, investigator-initiated research supports drug discovery efforts. Basic biomedical research on HIV pathogenesis provides crucial information relevant for drug discovery and development efforts. The NIAID-sponsored National Cooperative Drug Discovery Groups (NCDDGs) and the National Cooperative Drug Discovery Groups for the Treatment of the Opportunistic Infections Associated with AIDS (NCDDG-OIs) have expanded collaborative efforts with academia, industry, and government researchers for targeted drug discovery and development of potential treatments for HIV infection and HIV-associated OIs. The NIAID-

sponsored Mycoses Study Group tests agents for improved microbial therapy of systemic mycotic diseases. New standards of care have resulted from these studies. The NIGMS Targeted Antiviral Program provides extramural investigators with access to sophisticated techniques, while a similar program has been established for NIH intramural scientists through the Intramural AIDS Targeted Antiviral Program.

These combined programs have contributed to the discovery and/or development of AZT, ddI, ddC, d4T, recombinant soluble CD4, atovaquone, rifabutin in combination with atovaquone, ofloxacin, paromomycin, *tat* inhibitors, protease inhibitors, and compounds that attack the zinc (Zn) finger and the nucleocapsid. The first generation of protease inhibitors has been approved by the FDA. Although the newly developed drugs show initial promise, the development of resistance over a relatively short period of time may limit the effectiveness of single drug regimens. The use of these drugs in combination is currently being tested to overcome problems of drug resistance.

Program projects and associated R01s organized to develop approaches to structure-based targeted drug design have resulted in progress in determining the structure of several HIV components, such as integrase, RNaseH, p24, reverse transcriptase, and the Zn fingers of the nucleocapsid. Potential inhibitors of these compounds for the treatment of HIV infection and AIDS are currently being tested.

Drug Development and Evaluation of Anti-OI Agents

OIs represent the most common cause of morbidity and mortality of HIV-infected individuals. The NIH, through its intramural and extramural programs, has developed a multifaceted approach to the discovery, development, and preclinical and clinical evaluation of anti-OI agents. Priority is placed on the identification of effective strategies where established therapies do not exist and on the evaluation of new agents with the potential for improving efficacy or reducing toxic effects of existing treatment or prophylactic regimens. Biomedical research on OIs is challenged by the limited understanding of the basic biology and natural history of the causative micro-organisms; the lack of *in vitro* culture systems for susceptibility testing and biochemical studies; the lack of targeted screens or rational design of new agents; the need for optimization of animal models for testing treatment and prophylactic regimens; the need for evaluation of drug combinations for efficacy and safety, drug interactions, pharmacology, and immunotoxicology; and the relatively low level of interest shown by pharmaceutical manufacturers in the development of agents against HIV-associated OIs.

Development of Agents for AIDS-Related Malignancies

The NCI AIDS Lymphoma Network is pursuing innovative therapies for AIDS-related lymphomas including monoclonal antibody conjugates, cytotoxic chemotherapy with antiretroviral agents, hematopoietic simulators, and biologic response modifiers. Collaboration between NCI Clinical Cooperative Groups and the NIAID ACTG will further enhance clinical trials of potential agents against AIDS-related cancers. The Task Force on AIDS Malignancies has been established to coordinate cross-ICD clinical trial efforts in this area.

Clinical Trials

The NIH has the primary responsibility for the federally supported clinical trial efforts in the evaluation of potential therapies for the treatment of HIV infection and its sequelae. More than 45,000 patients have been enrolled to date in NIH-sponsored clinical studies, which have involved the evaluation of nearly 80 agents. Accomplishments in NIH-sponsored clinical trials include demonstration of the efficacy and clinical benefits of AZT for both adults and children with early and asymptomatic infection; the safety and efficacy of ddI and ddC for HIV-infected adults and children; the benefits of ddI and ddC in patients who are intolerant of or who have failed AZT treatment; the antiviral activity of interferon and its benefits for reducing Kaposi's sarcoma lesions; the utility of paclitaxel in advanced KS; the benefits of nimodipine for the treatment of AIDS dementia complex; and the therapeutic benefits of ddC plus AZT combination therapy with FDA approval of the regimen.

Recent accomplishments of NIH-sponsored clinical trials include the completion of two combination nucleoside trials in the adult and one in the pediatric HIV-infected populations which demonstrated clinical superiority of ddI monotherapy and ddI/ZDV combination therapy over ZDV monotherapy; other NIH-sponsored trials have shown clinical benefit of treatment of oral aphthous ulcers with Thalidomide, recombinant human growth hormone for treatment of AIDS-associated Wasting Syndrome (AWS), and megestrol acetate for AWS. NIH trials have contributed to the further understanding of the use of protease inhibitors, such as Saquinavir, Indinavir, and Ritonavir, nucleoside analogs, such as d4T and 3TC, and nonnucleoside reverse transcriptase inhibitors, such as nevirapine and delavirdine, and the impact of these agents on viral load and on clinical outcomes.

Accomplishments in combating HIV-associated OIs include demonstration of the efficacy of TMP-SMX, atovaquone (566C80), dapsone, and aerosolized pentamidine for prevention of *Pneumocystis carinii* pneumonia (PCP) in patients intolerant of TMP-SMX; TMP-SMX for prophylaxis of recurrent PCP; aerosolized pentamidine for prophylaxis and treatment of PCP; fluconazole for the treatment of cryptococcal meningitis and prevention of fungal infections; foscarnet for the treatment of CMV retinitis; IV gamma globulin for reducing OIs in HIV-infected children with CD4+ counts greater than 200/mm³; the combination of pyrimethamine and clindamycin for toxoplasmic encephalitis; and itraconazole for disseminated histoplasmosis (shown to be more effective with fewer side effects than amphotericin B).

Pediatrics

The unique mode of HIV transmission from mother to infant constitutes a major difference between adult and pediatric HIV infection. Interventions to prevent transmission are of high priority, and intervention trials should elucidate important pathogenic factors associated with vertical transmission that apply to other transmission modes. It is especially important to identify the reasons for treatment failures. These intervention trials include evaluating long-term followup of infants (both uninfected and infected) exposed to antiretroviral agents *in utero* for late toxicity. The trials also include evaluating infected women who received prophylactic treatment during pregnancy following treatment discontinuation. There are significant differences between the manifestations of HIV infection in children and those in adults. Also,

the pharmacokinetics, toxicity, and beneficial response profiles of therapeutic agents are often a function of age due to tissue/organ immaturity, requiring specific evaluation of potential agents in children of different ages.

Participation of Underrepresented Populations

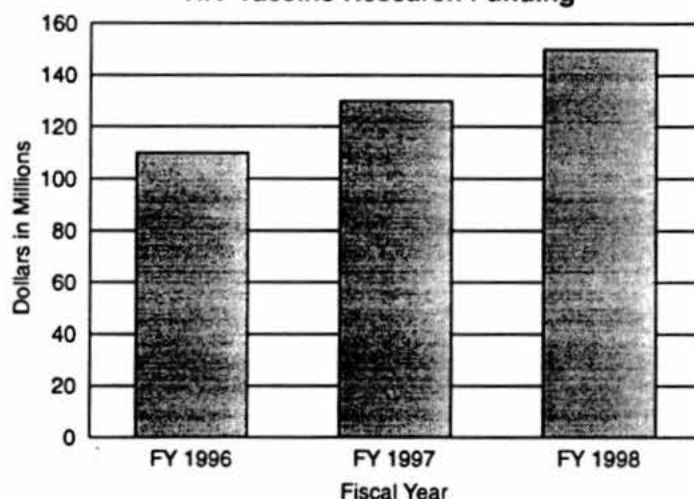
It is critical that the participation of specific populations in NIH-funded clinical trials reflect the changing demographics of HIV infection and AIDS, including women, children, adolescents, IDUs, minorities, the urban poor, and individuals residing in rural areas. Recruitment and enrollment of these underrepresented populations is a high priority in NIH-sponsored studies. In addition, the ACTG supports the AIDS Clinical Trials Infrastructures in Minority Institutions to enhance HIV clinical research performed at minority institutions. This program increases the number of minority staff involved in ACTG research and the number of minority participants in the studies.

Area of Emphasis: VACCINES

Developing vaccines that are safe and effective in preventing HIV infection is a global public health imperative and a top priority for the NIH AIDS research program. One of the key recommendations of the Levine Report called for a restructured, revitalized trans-NIH vaccine research effort with leadership and oversight provided by distinguished, non-Government scientists. The NIH has taken a number of strong steps to address that critical recommendation. To provide adequate funds for this critical area, the OAR

increased funding available for vaccine research by 18% between FY 1996 and 1997. The FY 1998 budget request provides an increase of \$17,445,000 over FY 1997.

HIV Vaccine Research Funding



David Baltimore, Ph.D., Nobel Prize winning scientist and Professor of Molecular Biology and Immunology, Massachusetts Institute of Technology, was selected to serve as a consultant to the NIH to lead this restructured effort to develop a vaccine against HIV. Dr. Baltimore will serve as Chair of the AIDS Vaccine Research Committee, a group of non-government advisors who provide direction and oversight, addressing key scientific questions in vaccine development, including new vaccine designs, efforts to understand the mechanisms of protection in animal models, and potential new targets for vaccines, including co-receptors. These efforts, including scientific workshops bringing together experts, are expected to attract additional scientists into the field of AIDS vaccine research, lead to new avenues of research, and send an important signal to the pharmaceutical industry and the international community of the commitment of NIH to this critical area of research.

The NIH supports a broad program encompassing basic, preclinical, and clinical vaccine research on candidate vaccine products. The goal of preventive vaccines is to slow and eventually end the HIV pandemic, and to protect the individual from HIV infection and/or disease. Protective efficacy against HIV infection can be measured by a range of clinical and virological end points. Desirable goals of vaccination are to induce immune responses that quickly clear or reduce incoming virus and infected cells, or, failing that, control viral replication and maintain a low viral load, thereby preventing disease progression and transmission.

Efficacy of vaccines in preventing infection can be determined relatively early in the conduct of a vaccine trial by viral culture or polymerase chain reaction (PCR). However, assessment of long-term control of viral replication, immunosuppression and disease progression, which may be critical for assessing efficacy, will make the conduct of efficacy trials more complex. This will be particularly true in populations with access to the most effective multiple-drug therapeutic regimens. Vaccine efficacy may also be influenced by the dose of infecting virus and by the site or route of exposure. Vaccine strategies therefore may need to be tailored for route of HIV exposure and may require combination approaches to optimize protection from frequent and/or multiple routes of exposure, especially in individuals whose immune status might be compromised by other factors.

Various strategies for stimulating a protective immune response against HIV infection are being explored through basic research, animal models, and clinical trials. There are many inherent uncertainties, not only in the identification of the immune responses required for protection against HIV infection or disease but also in the vaccine designs and strategies needed to induce such protective responses. Thus, multiple conceptual and practical approaches to development of candidate vaccines are being pursued at the preclinical level, with prioritization into small Phase I trials and additional selection and prioritization of candidates for further clinical study. The conduct of many small trials and the opportunity to return to the laboratory and refine those candidates that prove less than optimally immunogenic permits rapid incorporation of vaccine improvements. Vaccines also may serve as immunomodulators to improve immune function and diminish disease progression in HIV-infected individuals and may potentially prevent transmission from mother to fetus or from one infected adult to another.

Basic Research Relevant to Vaccine Development

Basic research on HIV and the immune system provides crucial information required for the development of vaccine candidates. These efforts, however, are complicated by many unique aspects of HIV infection including an unprecedented degree of antigenic variation. Recent findings indicate that there are at least two major groups of HIV-1 (M and O), with each exhibiting several major genotypic subtypes (clades). To date, virus from one clade (B) predominates in the United States. However, there is extensive variation within a single clade and even in a single individual. Vaccines capable of eliciting an immune response to a broad spectrum of antigenic specificities or to highly conserved epitopes will thus be required to protect against HIV infection. The NIAID-sponsored HIV variation project is investigating the rate and magnitude of both genetic and antigenic variation in HIV and related retroviruses. The findings

from this project will help determine the impact of such variation on strategies for developing potential AIDS vaccines.

Vaccine Strategies

Currently, NIH researchers are pursuing a multipronged approach for the development of HIV vaccines. These include traditional approaches such as the incorporation of killed viruses in known adjuvants and the development of attenuated viruses. There are serious concerns about the safety of these approaches that remain unresolved, but studies in animal models on killed and attenuated virus vaccines may help to reveal the correlates of immune protection and thus determine the requirements for an effective vaccine. However, the unique problems posed by HIV suggest a need for increased efforts to design novel approaches. Several being pursued include the use of synthetic viral peptides, recombinant proteins, and virus-like particles. In addition, live recombinant vectors, vaccines composed of virus genome incorporated into the genomes of highly immunogenic but non-disease-producing carrier viruses such as vaccinia and avipox, are being studied. Other vaccines under evaluation exhibit efficient delivery of antigens to selected compartments of the immune system, such as the mucosal area, where specialized immune responses particularly relevant to preventing entry of HIV are needed. One area of emphasis is the design of synthetic vaccine candidates capable of inducing both cellular and humoral immunity. Another approach is the development of genetically engineered, noninfectious HIV mutants that lack the viral RNA genome or are crippled in such a way that the virus is unable to infect yet contains a full complement of HIV antigenic proteins, which can assemble as virus-like particles, against which a protective response can be generated. The latter vaccine candidates can be produced in genetically engineered cell lines.

Animal Models

Some strains of HIV-1 can infect chimpanzees, thereby establishing an animal model to evaluate vaccines and infection with HIV-1. Infected chimps may provide a valuable resource for studying cross-reactive immune responses. The NIH supports chimpanzee colonies and programs that evaluate vaccine candidates and products for passive immunity in this animal model.

Major developments have resulted from studies using the simian immunodeficiency virus (SIV). The importance of this model rests with both the genetic relatedness of SIV to HIV and the AIDS-like syndromes that develop in several species of infected macaques. These disease end points, which are not demonstrable in the chimpanzee model, are very important for vaccine development. Macaque models permit investigation of vaccine effects that may be more realistic goals for initial human vaccines, protection against disease and vaccine modulation of viral replication. Experimental vaccines analogous to those being developed for clinical trials as well as several other approaches are being evaluated in this model. At the current time, the SIV/ macaque model represents the most complete animal model for the comparative evaluation of AIDS vaccine candidates and adjuvants.

To date, approaches based on live attenuated virus have exhibited the greatest degree of efficacy and provide opportunities for defining correlates of immune protection. Concerns for safety,

particularly in infants, must be resolved before progress can be made with this vaccine approach. However, studies of attenuated AIDS vaccines in animal models may provide constructs with improved safety for development of live vector vaccines or virus-like particles, i.e., genetically "killed" vaccine approaches.

Chimeric viruses (SHIV) made by replacing the envelope gene (and other selected genes) of SIV with any of a variety of HIV-1 envelope genes show increased promise for vaccine evaluation in macaques. SHIV viruses infect and persist in macaques, and recent constructs have induced CD4 cell depletion, AIDS and death. Vaccines containing HIV envelope components, that are intended for human use, can now be tested for immunogenicity and efficacy in macaques in a disease model.

Cooperation with Industry

Industrial partners will play an essential role in development of HIV vaccines and other biomedical interventions to prevent infection. Factors that affect the participation and collaboration of industrial partners need to be addressed. These include not only economic, legal, and regulatory issues but also scientific ones. Vaccines need to prevent HIV infection, not only in the United States but worldwide.

Vaccine Clinical Trials

To date the NIAID-supported AIDS Vaccine Evaluation Group (AVEG) has conducted or initiated 25 Phase I and II trials with 16 different candidates. Significant progress has been made in the evaluation of vaccine candidates developed by manufacturers. For example, all vaccine candidates tested to date in Phase I trials have been shown to be safe and well tolerated. More complex vaccinia and canarypox vectors are now under study. Several peptide vaccine candidates are under study and particulate vaccines are of interest. Additional studies are planned with other vaccine candidates for mucosal administration.

The NIH has performed a Phase II trial with gp120 vaccine candidates that enrolled uninfected at-risk individuals. The study demonstrated that antibody responses did not differ between higher and lower risk populations, and associated studies found that most participants understood the elements of the trial and did not systematically alter their risk behavior as a result of participation in the trial. A second Phase II trial is planned to further explore the combination of recombinant canarypox and envelope subunit boosting.

Preparation for Efficacy Trials of HIV Vaccines and Biomedical Prevention

Research required to prepare for clinical evaluations of potential vaccine candidates in efficacy trials is being performed in several domestic and international areas with populations at risk of HIV infection. As candidate vaccines become ready for efficacy trials, it will be important to have identified populations who remain at risk for HIV infection after counseling and risk-reduction measures have been implemented and who are willing to participate in the trials. Characterizing the circulating viral strains and risk factors, learning how to effectively reduce risk behaviors, and gaining the support of the communities (and, as applicable, governments) will

take considerable time and effort. In preparation for implementation of efficacy trials, investigators participating in the HIV Vaccine Efficacy Trials Network (HIVNET) are determining the incidence of HIV in populations such as injection drug users, gay/bisexual men, and individuals attending sexually transmitted disease clinics, in the United States and several international sites, who may participate in future vaccine trials. The NIH also plans to study innovative strategies for prevention or reduction of sexual and perinatal HIV transmission through the domestic and international epidemiologic and vaccine preparedness cohorts already in place.

Area of Emphasis: BEHAVIORAL AND SOCIAL SCIENCES

At present, the most effective way to prevent or reduce the spread of HIV/AIDS is through behavior change. The primary goal of NIH-sponsored AIDS-related behavioral and social science research is to discover how to change the behaviors that lead to HIV transmission—including preventing their initiation—and how to maintain protective behaviors once they are adopted. An additional goal is to reduce the negative impact of AIDS on HIV-infected individuals, their families, the health care system, and society.

The NIH sponsors research related to: developing, implementing, and evaluating behavioral and social interventions to reduce HIV transmission; strengthening our understanding of the determinants, trends, and processes of HIV-related risk behaviors and the consequences of HIV infection; developing and evaluating behavioral strategies for preventing or ameliorating the negative physical, psychological, and social consequences of HIV infection; and improving the research methodologies employed in behavioral and social science research. Cutting across these areas is a continued commitment to crafting better linkages among researchers, communities most affected by HIV and AIDS, and organizations responsible for providing HIV prevention and health care services.

Interventions To Prevent HIV Transmission

In the past 15 years, much has been learned and accomplished in the area of HIV/AIDS prevention through behavior change interventions. Theory-driven intervention models have been developed and employed by researchers supported by NIH, and have demonstrated that preventive interventions work, even among “hard-to-reach” and socially disenfranchised populations. These interventions have resulted in marked changes in sex and drug-using behaviors most implicated in HIV transmission among such groups as rural gay men, out-of-treatment injection drug users (IDUs), homeless and runaway youth, and the seriously mentally ill.

Delaying the onset of sexual behavior and dissuading youth from engaging in drug use also have been important HIV prevention strategies developed and tested by NIH-supported researchers. To date, most behavior change interventions have been tested in small groups, in a limited number of communities, and over relatively short periods of time. It is now important to replicate and refine the most successful of these interventions to test their effectiveness on a broader scale and over longer periods of time, and to develop new interventions to address

behaviors that have proven most resistant to change. Where appropriate, interventions should be tested in randomized, controlled trials, and when possible, HIV seroincidence should be an additional outcome measure. NIH-supported researchers currently are engaged in multisite investigations to identify the most effective components of behavioral interventions for different populations, including IDUs, crack cocaine users, and STD clinic patients, and to assess their effect on both behavior change and HIV seroincidence in those populations. In addition, determining the cost-effectiveness and cost-utility of such interventions is an area of current exploration by NIH-supported researchers.

Research has shown that successful preventive interventions must be targeted to specific populations and must take into account the cultural and social contexts of different people's lives. NIH-supported projects informed by theoretical models from the behavioral and social sciences are uncovering the specific elements of social and cultural life that contribute to HIV risk and protective behaviors and that must be addressed in interventions.

Community-level interventions may be an important way to effect behavioral change on a broad scale. NIH-supported researchers have investigated the impact of community-level approaches both in the United States and abroad. A study of five cities where HIV had entered a heterosexual IDU community but where HIV seroprevalence remained low and stable, identified three common prevention components: beginning prevention early; community outreach; and access to sterile injection equipment. The researchers concluded that in low seroprevalence areas, such community-level approaches may limit transmission of HIV among populations of IDUs despite continuing risk behavior among a substantial proportion of the population.

Other important areas of intervention research at NIH include the following: the acceptability of both biomedical and behavioral interventions among different individuals and communities; the behavioral aspects of the adoption of new HIV prevention technologies, such as the female condom, microbicides, or the use of zidovudine (AZT) by pregnant women to prevent vertical transmission of HIV; and social and psychological factors influencing participation in study trials and adherence to medical regimens for the treatment of HIV and AIDS-associated disorders.

Understanding HIV Transmission

Ensuring the relevance and effectiveness of behavior change interventions for HIV prevention requires good understanding of the psychological, social, and cultural factors that contribute to HIV risk and protective behavior. Specifically, in the area of HIV and AIDS, NIH-supported researchers are investigating the mechanisms that influence risk behaviors—from neurobiological factors related to sexual drive and drug addiction, to psychological factors related to self-esteem and the ability to negotiate safe sex; to social and cultural factors related to laws, norms, and values about sexuality, drug and alcohol use, and HIV/AIDS itself. This basic research, including the development and testing of theories of behavior change and maintenance in the context of HIV risk, is the essential underpinning of primary prevention and early intervention efforts.

Studies of decision-making processes have identified psychological factors, knowledge, attitudes, and behavioral intentions as important in leading to behavior change among individuals. Most of these approaches focus on the individual at one point in time or at one stage of life. However, HIV risk and behavior change may be experienced differently by people at different stages of development and different points in their lives. This suggests the importance of including a developmental and a life course perspective in HIV prevention and intervention research.

Moreover, it has become apparent that the social nature of HIV risk behavior requires a broader focus than merely on the individual. NIH-supported research has demonstrated the significance of partners, social networks, families, and peer groups in influencing an individual's engagement in or avoidance of risk behavior. For adolescents, research has determined the important role both parents and peers play in decisions to initiate or postpone sexual activity. Among IDUs, personal networks have been determined to be both sources of HIV transmission and potential targets of HIV preventive interventions. In one study, for example, researchers found that higher total personal network density and larger drug network size were positively associated with needle sharing. Understanding the characteristics and dynamics of networks has led to interventions that interrupt such sharing practices.

Another area of particular importance for understanding HIV transmission is the overlap in HIV-related risk behaviors. NIH-supported researchers are investigating the complex interplay of alcohol use, drug use, and risky sexual behavior, including the situational factors that contribute to their mix.

Consequences of HIV Infection and AIDS

NIH-supported researchers are studying the consequences of HIV and AIDS on individuals, their loved ones, and caregivers. These investigations span the sciences from neuroimmunology to social psychology, as they address such issues as the bi-directional relationship between stress, depression, and immune functioning, the psychological costs and benefits of caregiving, and the impact of bereavement on mental health.

As the AIDS epidemic devastates whole communities in some places, it has become increasingly important to investigate its social and cultural consequences. For example, NIH-supported researchers are beginning to examine the implications of the "stigma" of HIV/AIDS -- that is, as a disease that is generally fatal and whose transmission is characterized primarily by socially marginalized activities -- on the care and treatment of infected persons; the social and psychological status of orphaned children whose parents have died from AIDS; and the impact of HIV/AIDS on health care systems and economies of communities that have been most affected by the epidemic.

Research and Evaluation Methodologies

Over the past 15 years, significant improvements have been made in ensuring the validity and reliability of self-report data, the outcome measure of many behavioral and social science-based preventive interventions. In addition to refining computer-assisted technologies that enhance

veracity, some NIH-supported studies are collecting microbiological and disease outcome data (e.g., STD and HIV serological test results) as an additional measure to use in conjunction with self-reports.

The evaluation of HIV prevention strategies and programs is a vital part of the behavioral and social science agenda at NIH. Conducting successful evaluation -- both program evaluation and cost-effectiveness/cost-utility evaluation -- requires well-honed methods, including the identification and implementation of appropriate outcome measures. Further development of methods in this area will allow the determination not only of which interventions are most successful, but also whether particular components of interventions are more effective than others.

Area of Emphasis: TRAINING AND INFRASTRUCTURE

The NIH supports several intramural and extramural research resource programs, including grants for training AIDS researchers, support of animal facilities for animal model research, and constructing or improving existing facilities and equipment for AIDS-related research. Numerous NIH-funded programs have increased the number of training positions in AIDS-related 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 1998 request includes \$1,000,000 for this program. The Fogarty International Center (FIC) sponsors a program for training scientists in developing countries to undertake epidemiologic and postdoctoral research, with the goals of expanding scientific capabilities in the epidemiology, diagnosis, and treatment of HIV/AIDS throughout the world and of facilitating the evaluation of AIDS drugs and vaccines internationally.

The National Center for Research Resources (NCRR) and the National Cancer Institute (NCI) maintain several programs designed to produce primate models for use in the evaluation of potential SIV/HIV vaccines and to ensure adequate supplies of these animals. These programs include the Specific Pathogen Free Rhesus Breeding and Research Program for the SIV/macaque model system and the Chimpanzee Breeding and Research Program (CBRP) for AIDS studies.

The NCRR, through the General Clinical Research Centers (GCRCs), provides research infrastructure for multidisciplinary studies on both children and adults. Specifically, the GCRCs provide patient research facilities, computerized data management and analysis, and specialized laboratories as well as research nurses, dietitians, and biostatisticians for the translation of basic and clinical research into medical practice. These facilities support a variety of studies focused on the area of HIV infection and therapy.

Computers and high-speed computer networks play an increasingly important role in facilitating the understanding of HIV-related pathophysiology at a molecular level and providing rapid communication among basic and clinical investigators. The NCI Biomedical Supercomputer Center facility was a key resource for the prediction of the secondary structure of the entire 9,433 bases of HIV RNA. NCRR-supported supercomputing centers at Pittsburgh, Illinois, Cornell, and Columbia universities provide similar facilities for investigators nationwide.

In addition, the NCRR supports several synchrotron and NMR facilities that provide the technology to determine the structure of candidate HIV-related proteins, and the NIGMS supports a Protein Data Bank located at Brookhaven National Laboratory, which is a repository for the three-dimensional coordinates of all proteins whose structures have been determined. Specific drugs are being developed on the basis of known molecular structures to block virus action and provide new therapies for HIV infection and its consequences. A multiagency High Performance Computing and Communications (HPCC) Initiative includes NIH participation by a number of ICDs. This initiative permits the development of faster computers and better algorithms for predicting molecular structure and function from genetic sequence, which is an important area of research. The HPCC Initiative will establish a National Information Infrastructure (NII) linking academic and commercial research centers. Nearly 10 million users worldwide are connected to the current Internet at this time. NLM provides support for connecting medical centers and community hospitals to the Internet and for developing prototype biomedical digital image libraries that use the Internet as a high-speed distribution channel. The NII will provide an increasingly fast communication line for sharing data among laboratories on an international scale.

Area of Emphasis: INFORMATION DISSEMINATION

The NIH has responsibility for disseminating information to support research, treatment, and prevention related to HIV and AIDS. Since 1991, the NIH has used a dedicated system of electronic and print notification, collectively known as Clinical Alerts, to rapidly disseminate information that critically affects the care of patients, such as results of HIV-related clinical trials to health care professionals, the news media, community service providers, and the general public. NIH also develops and disseminates clinical care guidelines, standards of care, and results of state-of-the-art meetings that redefine clinical care guidelines.

Computerized data bases, including those on the MEDLARS system (AIDSLINE, AIDSTRIALS, AIDSDRUGS, and DIRLINE), as well as the AIDS Clinical Trials Information Service (ACTIS) and the HIV/AIDS Treatment Information Service (ATIS), are vital to information dissemination. They provide the foundation for the global dissemination of information concerning basic research, clinical trials availability and results, and standards of care as well as information of interest to HIV-infected individuals and their advocates. The data bases are available free of charge to users. A new AIDS module has been added to a larger training program on the use of on-line data bases NLM is conducting with the Historically Black Colleges and Universities (HBCUs).

The Internet is an expanding and increasingly important medium for information dissemination. NIH Home Pages for OAR, NIAID and NLM are on-line, providing extensive HIV/AIDS research and programmatic information for the public, patients, health care providers, scientific investigators, and policymakers.

An important challenge to the NIH is to provide accurate and up-to-date HIV/AIDS treatment information to people in underserved communities and communities of color. A key part of this

effort is building trust and strengthening outreach to local and national community organizations. NIAID has developed a kit of English and Spanish language materials to assist health care providers, particularly in community clinics, in educating their patients about HIV and the diseases associated with AIDS and how to find out about clinical trials. The rapidly expanding field of information technology is providing unprecedented opportunities to enhance the flow of information among researchers, health care providers, and the HIV-affected communities.

Conclusion

Three years ago, the OAR brought about a rededication to basic research. The OAR utilized its authority in setting the research agenda to shift the NIH AIDS research emphasis and resources to fundamental science. This rededication to basic research has contributed to the important advances and critical breakthroughs that have been achieved in AIDS research. The priorities of the AIDS research program are the development of a safe and effective preventive vaccine for the millions who are at risk of infection and better therapies for the men, women and children who are already infected.

NATIONAL INSTITUTES OF HEALTH
1998 Congressional Justification
Summary by Mechanism
OFFICE OF AIDS RESEARCH

	FY 1996 Budget Authority		FY 1997 Estimate		FY 1998 Estimate	
	No.	Amount	No.	Amount	No.	Amount
<u>Research Projects</u>						
Noncompeting	1,495	\$511,370,000	1,648	\$591,002,000	1,756	\$626,610,000
Administrative supplementals	(79)	8,781,000	(52)	6,137,000	(52)	6,128,000
Competing	567	201,825,000	680	206,286,000	714	187,533,000
Subtotal, RPGs	2,062	721,976,000	2,328	803,425,000	2,470	820,271,000
SBIR/STTR	90	16,736,000	114	22,216,000	120	23,269,000
Total, RPGs	2,152	738,712,000	2,442	825,641,000	2,590	843,540,000
<u>Research Centers</u>						
Specialized/comprehensive	28	52,953,000	32	58,155,000	32	63,619,000
Clinical research	0	33,683,000	0	35,522,000	0	35,522,000
Biotechnology	0	2,526,000	0	2,555,000	0	2,555,000
Comparative medicine	12	23,211,000	12	24,616,000	12	24,892,000
Research centers in minority institutions	0	5,929,000	0	5,961,000	0	6,006,000
Subtotal, Centers	40	118,302,000	44	126,809,000	44	132,594,000
<u>Other Research</u>						
Research careers	151	13,103,000	155	13,979,000	149	13,612,000
Cancer education	0	0	0	0	0	0
Cooperative clinical research	3	9,949,000	3	10,220,000	4	9,980,000
Biomedical research support	0	479,000	0	659,000	0	659,000
Minority biomedical research support	0	538,000	0	582,000	0	594,000
Other	35	11,957,000	31	12,171,000	31	12,325,000
Subtotal, Other Research	189	36,026,000	189	37,611,000	184	37,170,000
Total, Research Grants	2,381	893,040,000	2,675	990,061,000	2,818	1,013,304,000
<u>Training</u>	<u>FTTPs</u>		<u>FTTPs</u>		<u>FTTPs</u>	
Individual	85	2,057,000	85	2,121,000	88	2,246,000
Institutional	715	19,319,000	704	20,205,000	709	20,827,000
Total, Training	800	21,376,000	789	22,326,000	797	23,073,000
Research & development contracts (SBIR/STTR)	243 (2)	244,778,000 (157,000)	249 (2)	233,739,000 (174,000)	250 (2)	238,210,000 (175,000)
Intramural research		164,530,000		160,391,000		171,357,000
Research management and support		57,735,000		55,630,000		55,630,000
Cancer prevention & control		0		0		0
Construction		0		0		0
Library of Medicine		2,916,000		3,365,000		3,279,000
Office of the Director		26,550,000		35,561,000		35,912,000
Total, OAR		1,410,925,000		1,501,073,000		1,540,765,000
(Clinical Trials)		(341,940,000)		(351,588,000)		(357,544,000)

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NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Budget Authority by Activity (dollars in thousands)

	FY 1996 Actual	FY 1997 Estimate	FY 1998 Estimate	Change
Natural History and Epidemiology	\$215,606	\$228,291	\$227,752	(\$539)
Etiology and Pathogenesis	399,471	430,578	444,260	13,682
Therapeutics	432,350	447,149	453,831	6,682
Vaccines	111,058	130,899	148,344	17,445
Behavioral and Social Science Research	186,301	196,586	199,331	2,745
Training and Infrastructure	50,458	49,968	50,242	274
Information Dissemination	16,617	17,602	17,005	(597)
Total obligations	1,411,861	1,501,073	1,540,765	39,692
Obligations from prior year authority	(980)	--	--	--
Unobligated balance lapsing	44	--	--	--
Total, Budget Authority	1,410,925	1,501,073	1,540,765	39,692

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Summary of Changes

1997 Estimated budget authority	\$1,501,073,000
1998 Estimated budget authority	1,540,765,000
Net change	39,692,000

	1997 Current Estimate Base	Change from Base
	FTEs Budget Authority	FTEs Budget Authority
Changes:		
A. Built-in:		
1. Intramural research:		
a. Within grade increase	\$41,102,000	\$606,000
b. Annualization of January 1997 pay increase	41,102,000	340,000
c. January 1998 pay increase	41,102,000	875,000
d. Legislative proposal, 1.51% increase in the CSRS rate	41,102,000	157,000
e. Service and supply fund	9,692,000	252,000
f. Increased cost of laboratory supplies, materials, and other expenses	71,691,000	1,854,000
Subtotal		4,084,000
2. Research Management and Support:		
a. Within grade increase	25,294,000	379,000
b. Annualization of January 1997 pay increase	25,294,000	209,000
c. January 1998 pay increase	25,294,000	536,000
d. Legislative proposal, 1.51% increase in the CSRS rate	25,294,000	110,000
e. Service and supply fund	3,308,000	86,000
f. Increased cost of laboratory supplies, materials, and other expenses	20,693,000	538,000
Subtotal		1,858,000
Subtotal, Built-in		5,942,000

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research
Summary of Changes--continued

	1997 Current Estimate Base		Change from Base	
	No.	Amount	No.	Amount
B. Program:				
1. Research projects grants:				
a. Noncompeting	1,648	\$597,139,000	108	\$35,599,000
b. Competing	680	206,286,000	34	(18,753,000)
c. SBIR/STTR	114	22,216,000	6	1,053,000
Total	2,442	825,641,000	148	17,899,000
2. Centers	44	126,809,000	0	5,785,000
3. Other research	189	37,611,000	(5)	(441,000)
4. Research training	789	22,326,000	8	747,000
5. Research and development contracts	249	233,739,000	1	4,471,000
6. Intramural research:				
a. Programmatic changes		160,391,000		(3,118,000)
b. Special emphasis areas		---		10,000,000
Subtotal, intramural		160,391,000		6,882,000
7. Research management and support		55,630,000		(1,858,000)
8. Office of AIDS Research		35,561,000		351,000
9. National Library of Medicine		3,365,000		(86,000)
Subtotal, program				33,750,000
Total changes				39,692,000

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

National Institutes of Health

Office of AIDS Research

AIDS Funding by Institute and Center

Institute/Center	FY 1996 Actual	FY 1997 Estimate	FY 1998 Estimate
NCI	\$225,360,000	\$224,733,000	\$224,256,000
NHLBI	57,877,000	61,577,000	62,419,000
NIDR	12,953,000	12,932,000	12,750,000
NIDDK	11,735,000	12,718,000	12,638,000
NINDS	23,774,000	24,825,000	25,116,000
NIAID	599,549,000	647,709,000	678,230,000
NIGMS	26,135,000	27,695,000	28,160,000
NICHD	60,713,000	64,369,000	65,247,000
NEI	9,075,000	9,450,000	9,476,000
NIEHS	6,051,000	6,489,000	6,324,000
NIA	1,755,000	1,854,000	1,874,000
NIAMS	4,039,000	4,273,000	4,310,000
NIDCD	1,650,000	1,820,000	1,774,000
NIMH	93,483,000	96,906,000	98,510,000
NIDA	153,233,000	160,832,000	163,440,000
NIAAA	10,124,000	11,051,000	11,234,000
NINR	4,896,000	5,500,000	5,360,000
NHGRI	993,000	3,001,000	2,990,000
NCRR	68,370,000	74,101,000	77,053,000
FIC	9,694,000	10,312,000	10,413,000
Subtotal, ICs	1,381,459,000	1,462,147,000	1,501,574,000
NLM	2,916,000	3,365,000	3,279,000
OD	26,550,000	35,561,000	35,912,000
TOTAL, NIH	1,410,925,000	1,501,073,000	1,540,765,000

DHHS-National Institutes of Health
AIDS By Functional Category
(dollars in thousands)

<u>Category</u>	<u>FY 1996 Actual</u>	<u>FY 1997 Estimate</u>	<u>FY 1998 Estimate</u>
I. BASIC SCIENCE RESEARCH:			
A. Biomedical Research:			
1. HIV and HIV genome	\$110,026	\$117,821	\$122,326
2. Immunology	197,594	214,134	218,530
3. Blood/Blood products	17,166	18,225	16,007
4. Diagnostic methods/reagents development	11,173	10,770	10,440
5. Animal models and related studies	29,552	30,289	31,133
SUBTOTAL, Biomedical Research	365,511	391,239	398,436
B. Neuroscience and Neuropsychiatric Research	52,870	55,619	56,418
C. Behavioral Research:			
1. Mechanisms of behavior and behavior change	27,065	26,700	26,970
2. Prevention of high-risk behaviors	148,047	158,299	162,269
SUBTOTAL, Behavioral Research	175,112	184,999	189,239
D. Therapeutic Agents:			
1. Development	216,022	220,606	224,462
2. Clinical Trials	265,212	269,281	270,675
SUBTOTAL, Therapeutic Agents	481,234	489,887	495,137
E. Vaccines:			
1. Development	73,441	94,420	108,870
2. Clinical Trials	38,513	45,575	49,040
SUBTOTAL, Vaccines	111,954	139,995	157,910
F. Research Enhancement:			
1. Training	26,338	27,221	27,416
2. Construction (Extramural)	16	220	226
SUBTOTAL, Research Enhancement	26,354	27,441	27,642
TOTAL, BASIC SCIENCE RESEARCH	<u>1,213,035</u>	<u>1,289,180</u>	<u>1,324,782</u>

DHHS-National Institutes of Health
AIDS By Functional Category
(dollars in thousands)

<u>Category</u>	<u>FY 1996 Actual</u>	<u>FY 1997 Estimate</u>	<u>FY 1998 Estimate</u>
II. RISK ASSESSMENT AND PREVENTION:			
A. Surveillance:			
1. Diseases associated with HIV	2,701	2,629	2,650
2. HIV surveys (incidence, prevalence)	237	244	245
3. Knowledge, attitudes, behaviors	786	798	467
SUBTOTAL, Surveillance	3,724	3,671	3,362
B. Population-Based Research: Natural History, Transmission, Risk Factors:			
1. Transmission:			
a. Sexual	25,169	27,636	26,622
b. Intravenous drug abusers	2,886	3,479	4,018
c. Hemophilia populations	974	994	991
d. Blood recipient/donor studies	1,959	4,141	4,939
e. Perinatal infection	28,305	26,919	27,576
f. Occupationally related	0	130	133
g. Other/Miscellaneous	5,343	4,448	4,856
SUBTOTAL, Transmission	64,636	67,747	69,135
2. Natural history and cofactors	117,231	128,616	131,972
SUBTOTAL, Population based research	181,867	196,363	201,107
C. Information and Education/Preventive Services:			
1. High risk or infected persons:			
a. Health education/risk education	417	679	592
b. Counseling, testing, partner notification	235	256	257
c. Perinatal AIDS prevention projects	0	0	0
d. HIV prevention among drug abusers	0	0	0
e. Special projects:			
(1) Conference of Mayors	0	0	0
(2) HIV-related tuberculosis demonstration projects	0	0	0
(3) National Hemophilia AIDS/HIV prevention project	0	0	0
(4) Community-based demonstration projects	0	0	0
SUBTOTAL, Special projects	0	0	0
SUBTOTAL, High-Risk or Infected Persons	652	935	849
2. Special Minority Initiatives	381	401	408

DHHS-National Institutes of Health
AIDS By Functional Category
(dollars in thousands)

<u>Category</u>	<u>FY 1996 Actual</u>	<u>FY 1997 Estimate</u>	<u>FY 1998 Estimate</u>
3. School and college aged youth:			
a. National efforts	0	0	0
b. State and local projects	0	508	518
c. Program development and training	50	0	0
SUBTOTAL, School and college aged youth	50	508	518
4. General Public and Special Programs:			
a. National:			
(1) Clearinghouse	0	0	0
(2) Hotline (general public)	0	0	0
(3) Treatment trials and therapy, information services	4,149	4,012	3,938
SUBTOTAL, National	4,149	4,012	3,938
b. Regional, state, and local	0	0	0
SUBTOTAL, Gen. Pub. and Spec. Prog.	4,149	4,012	3,938
5. Health-Care Workers and Providers:			
a. Education and training centers	639	644	643
b. Other types of training	411	651	660
SUBTOTAL, Health-Care Workers and Providers	1,050	1,295	1,303
6. Prevention Capacity Enhancement	0	0	0
SUBTOTAL, Information and education/preventive services	6,282	7,151	7,016
TOTAL, RISK ASSESSMENT AND PREVENTION	191,873	207,185	211,485
IV. CLINICAL HEALTH SERVICES RESEARCH AND DELIVERY:			
A. Services	0	0	0
B. Health Services Grants	0	0	0
C. Construction	0	0	0
D. Research	6,017	4,708	4,498
TOTAL, CLINICAL HLTH SERV. RESCH AND DE	6,017	4,708	4,498
V. PHS-WIDE ACTIVITIES:			
C. Construction (PHS Facilities)			
TOTAL	1,410,925	1,501,073	1,540,765

NATIONAL INSTITUTES OF HEALTH

OFFICE OF AIDS RESEARCH

BUDGET AUTHORITY BY OBJECT

OBJECT CLASSIFICATION	FY 1997 Estimate	FY 1998 Estimate	Increase or Decrease
Personnel Compensation:			
11.1 Full-Time Permanent	\$43,523,000	\$45,184,000	\$1,661,000
11.3 Other than Full-Time Permanent	8,159,000	8,451,000	292,000
11.5 Other Personnel Compensation	2,233,000	2,316,000	83,000
11.8 Special Personnel Services Payments	4,006,000	4,307,000	301,000
11.9 Total Personnel Compensation	57,921,000	60,258,000	2,337,000
12.0 Civilian Personnel Benefits	13,186,000	13,712,000	526,000
13.0 Benefits for Former Personnel	12,000	12,000	0
Subtotal, Pay Costs	71,119,000	73,982,000	2,863,000
21.0 Travel & Transportation of Persons	2,736,000	2,739,000	3,000
22.0 Transportation of Things	388,000	395,000	7,000
23.1 Rental Payments to GSA	1,174,000	1,233,000	59,000
23.2 Rental Payments to Others	1,417,000	1,445,000	28,000
23.3 Communications, Utilities & Miscellaneous Charges	3,760,000	3,808,000	48,000
24.0 Printing & Reproduction	760,000	766,000	6,000
25.1 Consulting Services	3,803,000	3,782,000	(21,000)
25.2 Other Services	42,147,000	47,452,000	5,305,000
25.3 Purchase of Goods & Services from Government Accounts	99,470,000	102,367,000	2,897,000
25.4 Operation & Maintenance of Facilities	41,103,000	41,303,000	200,000
25.5 Research & Development Contracts	179,934,000	183,860,000	3,926,000
25.6 Medical Care	697,000	731,000	34,000
25.7 Operation & Maintenance of Equipment	1,482,000	1,480,000	(2,000)
25.8 Subsistence & Support of Persons	0	0	0
25.0 Subtotal, Other Contractual Services	368,636,000	380,975,000	12,339,000
26.0 Supplies & Materials	20,679,000	20,850,000	171,000
31.0 Equipment	8,730,000	8,741,000	11,000
32.0 Land and Structures	5,000	5,000	0
33.0 Investments & Loans	0	0	0
41.0 Grants, Subsidies & Contributions	1,021,510,000	1,045,662,000	24,152,000
42.0 Insurance Claims & Indemnities	152,000	157,000	5,000
43.0 Interest & Dividends	7,000	7,000	0
44.0 Refunds	0	0	0
Subtotal, Non-Pay Costs	1,429,954,000	1,466,783,000	36,829,000
			0
Total Budget Authority	1,501,073,000	1,540,765,000	39,692,000

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

NATIONAL INSTITUTES OF HEALTH

OFFICE OF AIDS RESEARCH

ADMINISTRATIVE COSTS

OBJECT CLASSIFICATION	FY 1997 Estimate	FY 1998 Estimate	Change
Personnel Compensation:			
Full-Time Permanent (11.1)	\$43,523,000	\$45,184,000	\$1,661,000
Other Than Full-Time Permanent (11.3)	8,159,000	8,451,000	292,000
Other Personnel Compensation (11.5)	2,233,000	2,316,000	83,000
Special Personnel Services Payments (11.8)	4,006,000	4,307,000	301,000
Total Personnel Compensation (11.9)	57,921,000	60,258,000	2,337,000
Civilian Personnel Benefits (12.0)	13,186,000	13,712,000	526,000
Benefits to Former Personnel (13.0)	12,000	12,000	0
Subtotal, Pay Costs	71,119,000	73,982,000	2,863,000
Travel (21.0)	2,736,000	2,739,000	3,000
Transportation of Things (22.0)	388,000	395,000	7,000
Rental Payments to Others (23.2)	1,417,000	1,445,000	28,000
Total, Budget Authority			
Miscellaneous Charges (23.3)	3,760,000	3,808,000	48,000
Printing and Reproduction (24.0)	760,000	766,000	6,000
Other Contractual Services:			
Advisory and Assistance Services (25.1)	3,803,000	3,782,000	(21,000)
Other Services (25.2)	42,147,000	47,452,000	5,305,000
Purchases from Govt. Accounts (25.3)	70,394,000	72,746,000	2,352,000
Operation & Maintenance of Facilities (25.4)	1,678,000	1,717,000	39,000
Operation & Maintenance of Equipment (25.7)	1,482,000	1,480,000	(2,000)
Subsistence & Support of Persons (25.8)	0	0	0
Subtotal Other Contractual Services	119,504,000	127,177,000	7,673,000
Supplies and Materials (26.0)	20,662,000	20,833,000	171,000
Subtotal, Non-Pay Costs	149,227,000	157,163,000	7,936,000
Total, AIDS	220,346,000	231,145,000	10,799,000

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Significant Items in the House and Conference Appropriations Committee Reports

1997 House Appropriations Committee Report Language

Item

*Office of AIDS Research--...*The Committee commends the NIH for its initiation of a comprehensive external review and evaluation of the entire NIH AIDS research program. The Committee has received the Working Group Report, and urges the Director of NIH, in concert with the Director of OAR, to implement these important recommendations, which set forth a blueprint for the future of AIDS research. The Committee also looks forward to receiving the final reports of the panel's review of individual scientific areas.

Action taken or to be Taken

The Evaluation Group, brought together by the Office of AIDS Research Advisory Council, was charged with reviewing the current NIH AIDS research program. This review was unprecedented in its breadth and scope spanning every Institute and Center. NIH-sponsored AIDS research was evaluated to assure that the most promising areas of science are being supported, that the critical scientific questions are being addressed, and that the most effective use is being made of federal funds designated for AIDS research. The final reports of the panel's review of individual scientific areas will be sent to the Committee under separate cover.

The NIH is currently preparing an implementation plan to respond to the recommendations of the Working Group. This plan is being reviewed by the Institutes and Centers of the NIH and is expected to be provided to the Office of AIDS Research Advisory Council (OARAC) in March.

Item

*Office of AIDS Research--*Last year, the number of AIDS cases passed the 500,00 mark. AIDS is now the leading cause of death for Americans between the ages of 25 and 44. The disease is spreading most rapidly among African American and other at-risk minority populations, adolescents, and women. Therefore, the Committee urges the OAR to carefully monitor these changes and ensure that the research plan includes objectives and strategies to respond to demographic changes in a timely fashion. NIH is also strongly encouraged to strengthen and to include the direct participation of African Americans and other minorities in its AIDS/HIV research, research training, and outreach activities. The Committee expects the NIH to report on its progress in achieving this objective during next year's appropriations hearings.

Action Taken or to be Taken

The NIH has taken a number of steps to improve and/or retain the participation of African Americans and other minorities in its AIDS/HIV research, research training, and outreach activities. The following are a few examples of these efforts:

- The NIH continues to emphasize the enrollment of minority populations in clinical trials; 60 percent of the current enrollment in National Institute of Allergy and Infectious Diseases (NIAID)-supported therapeutic trials are people of minority background.
- A number of NIH Institutes collaborate in supporting the Women's Interagency HIV Study (WIHS). The study is addressing the clinical, immunologic, virologic, and behavioral aspects of HIV disease progression in women. The current participation of the Washington, DC consortium site of Howard University, Whitman-Walker Satellite Clinic and Georgetown University, is 80 percent African American women. This program gives the participants an incentive by providing increased access to gynecological care.
- The National Institute of Mental Health, NIH Office of Research on Minority Health, and the NIAID, awarded 11 collaborative AIDS research projects to foster communication between the investigators participating in the Centers for AIDS Research and the Research Centers in Minority Institutions (RCMI).
- Several of the institutions selected for National Cancer Institute funding to pursue research activities as part of its AIDS malignancy program were specifically considered for their ability to recruit minorities.
- The National Library of Medicine (NLM) has had a long-standing outreach program with Historically Black Colleges and Universities that has been expanded to include HIV/AIDS. This collaboration enables NLM to place important information in the hands of health professionals working closely with those most heavily affected communities.
- National Institute on Alcohol Abuse and Alcoholism (NIAAA) is actively encouraging minority participation in a program that will develop alcohol-related HIV preventive interventions. NIAAA is interested in determining the prevalence and interrelationships of various diagnoses, including alcohol abuse/dependence, in African Americans and other minorities who are diagnosed with AIDS/HIV.
- In FY 1996, 11 of the 18 Research Centers in Minority grantee institutions funded by the National Center for Research Resources participated in AIDS relevant research. These projects focused on many different aspects of AIDS research including transmission of the AIDS virus from mother to child.

- The Fogarty International Center established a minority health initiative within the AIDS International Training and Research Program.

1997 Conference Committee Report Language

Item

Distribution of AIDS funds--The conference agreement includes a general provision not included in either the House or Senate bill which directs that the funding for AIDS research as determined by the Directors of the National Institutes of Health and the Office of AIDS Research (OAR) be allocated directly to the OAR for distribution to the Institutes consistent with the AIDS research plan.

Action Taken or to be Taken

In the FY 1997 Appropriation language for the NIH, Congress provided a significant role to the Office of AIDS Research (OAR) for coordination and managing the NIH efforts to address the HIV/AIDS epidemic in the United States. The NIH was specifically instructed to determine the amount of resources necessary to meet the needs of the HIV/AIDS research portfolio.

The NIH determined that of the total amount of funds available in the appropriation, \$1,501,720,000 should be available for HIV/AIDS research. HIV/AIDS funding at this level provides the NIH the resources necessary to carry out its mandate with respect to HIV/AIDS research, while preserving other prominent NIH research priorities.

Of the total amount available to the OAR, \$1,501,720,000, the distribution by Institute was determined by the priorities set forth in the FY 1997 Plan for HIV/AIDS Research.

NATIONAL INSTITUTES OF HEALTH

Office of AIDS Research

Authorizing Legislation

	PHS Act/ Other Citation	U.S. Code Citation	1997 Amount Authorized	1997 Estimate	1998 Amount Authorized	1998 Budget Estimate
Research and Investigation	Section 301	42§241	Indefinite	---	Indefinite	\$1,507,692,000
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/	23,073,000
Total, Budget Authority			---	---		1,540,765,000

a/ Funding provided under Omnibus Consolidated Appropriations Act, 1997 (P.L. 104-208).

b/ Reauthorizing legislation will be submitted.

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			

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.

Race Initiative
policy -
health



HUMAN
RIGHTS
CAMPAIGN



Chris -
see below.
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AIDS Facts

In the first six months of 1996, AIDS deaths in the United States decreased by 13%, marking the first such decline since the epidemic began in 1981. This decrease is the result of the sustained investment this country has made in HIV/AIDS research, prevention and care. But the need continues to grow. The facts are¹:

- As of February 28, 1997, 581,429 Americans have been diagnosed with AIDS since 1981: 488,300 (84%) men; 85,500 (15%) women; and 7,629 (1%) children
- 365,000 American lives have been lost to AIDS since 1981; an average of 100 Americans are diagnosed with AIDS daily
- An average of 100 to 150 men, women and children become infected with HIV every 24 hours
- HIV infection remains the leading cause of death among 25-44 year olds, accounting for 19% of deaths in this age group
- One-quarter of new HIV infections in the United States occur among young people under age 21
- In the first six months of 1996, women accounted for 20% of newly reported AIDS cases; in the first six months of 1996, there was a 3% increase in AIDS deaths among women
- In 1985, 233 children were left without parents due to AIDS; in 1995, there were 30,000 children orphaned by AIDS; by the year 2000, this figure is expected to exceed 85,000 children²
- Over 76% of women infected with HIV are women of color
- In 1996, people of color accounted for over half (62%) of all adult AIDS cases reported in the United States; African Americans accounted for a larger proportion (41%) of adult AIDS cases than whites (38%) for the first time in the epidemic

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¹Source: Centers for Disease Control and Prevention, 1996

²Source: AIDS Project Los Angeles

CLINTON GORE 96

The Briefing Room Bill Clinton & Al Gore on the Issues

Fighting AIDS—Care, Research, Prevention

“AIDS inflicts tragedy on too many families. But ultimately, it is a disease; one we can defeat just as we have defeated polio, many forms of cancer, and other scourges in the history of our nation. How can we do it? With commitment and courage and constancy, and with vocal and responsible leadership from our nation’s government.”

—President Bill Clinton

HIV/AIDS is a national public-health emergency. Every day, the disease affects more people in more communities. Preventing HIV infection, finding a cure for AIDS, and providing quality care and treatment for those living with the disease are top priorities for President Clinton. He is providing the commitment and leadership that are making the difference by:

- ★ Increasing overall AIDS funding by more than 56 percent in four years.
- ★ Creating the Office of National AIDS Policy at the White House to bring greater direction and visibility to the war on AIDS.
- ★ Convening the first-ever White House Conference on HIV and AIDS and appointing the Presidential Advisory Council on HIV and AIDS, composed of a group of whom 30 percent are HIV-positive and 50 percent are self-identified lesbian or gay.
- ★ Increasing funding for the Ryan White CARE Act 186 percent in four years to nearly \$1 billion. — \$158 b
- ★ 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, the 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 percent of people living with AIDS who rely on Medicaid for health coverage. \$100 over 90% of children
- ★ Revising eligibility rules for Social Security Disability Insurance to make it easier for people with HIV to qualify for benefits.
- ★ Signing the Kassebaum-Kennedy Health Insurance and 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 protection programs.
- ★ Launching the Prevention Marketing Initiative, focusing on the risk to young adults (aged 18 to 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 "Dornan Amendment," which would have discharged all HIV-positive military personnel.
- ★ Creating the Forum for Collaborative HIV Research to improve knowledge of HIV treatment methods.
- ★ Working with AIDS activists to protect the rights of immigrants with HIV and people living with AIDS enrolled in managed care plans.
- ★ Creating the Advisory Commission on Consumer Protection and Quality in the Health Care Industry to increase consumers' rights. ?

Building on Our Progress

To protect our families, President Clinton will continue to fight for funding for AIDS research, prevention, and care.

He will continue to work with business and religious leaders, community organizations, the pharmaceutical industry, and those living with the disease to improve our national response to HIV/AIDS by:

- ★ Eliminating barriers to AIDS vaccine and drug development and their approval. Vice President Gore is leading an effort to increase cooperation between the federal government and the pharmaceutical industry on AIDS research and drug development.
- ★ Protecting the federal guarantee of Medicaid coverage for people living with HIV/AIDS.
- ★ Continuing strong support for the Office of AIDS Research at the National Institutes of Health (NIH) to provide greater focus and direction for our national AIDS research effort.
- ★ Decreasing the number of infants born with HIV by administering AZT to HIV positive women during pregnancy and delivery and to infants after birth.
- ★ Supporting efforts to protect health care professionals in the workplace.
- ★ Establishing a national goal to reduce the number of new HIV infections each year until AIDS is eradicated.
- ★ Working to eliminate AIDS-related discrimination in the workplace, health care institutions, employment, and housing.
- ★ Collaborating with business leaders to increase workplace AIDS education to help reduce the stigma attached to HIV/AIDS.
- ★ Working with parents, schools, clergy, and youth advocates to reduce the number of adolescents and young adults becoming infected with HIV.

Meeting Our Challenges ★ Protecting Our Values

Paid for by Clinton/Gore '96 General Committee, Inc.

NATIONAL INSTITUTES OF HEALTH

AIDS vs. Cancer Research

QUESTION:

In the face of higher rates of incidence and deaths from other diseases such as cancer and heart disease, is NIH's spending on AIDS research out of balance with that for other diseases?

ANSWER:

- ▶ I do not believe that research on AIDS is "out of balance" with other diseases. NIH research funding in 1997 for cancer (\$2.4 B) exceeds research on AIDS (\$1.4 B) and heart disease (\$893 M). However, such comparisons can be a bit misleading.
- The public health impact and the value of dollars spent on any disease must be assessed through a series of measures, including mortality and morbidity; incidence and prevalence rates; cause and mode of transmission; fatality rates, years of potential life lost; demographic factors, and research opportunities. It is inappropriate to use any one of these criteria independent of the others when making resource allocation decisions.
- ▶ What we spend on AIDS research is a vital and necessary investment in the Nation's public health. The following reasons help distinguish AIDS from cancer and heart disease:
 - AIDS is still a growing epidemic and remains one of the most serious threats to the Nation's public health.
 - AIDS is infectious and, because it mutates so quickly, future trends are not entirely predictable.
 - AIDS disproportionately kills younger people during their most productive years.
 - AIDS has a wide impact far beyond the diagnosis of a single disease, as it contributes to other public health crises in tuberculosis, other sexually transmitted diseases, drug abuse, and infant mortality.
 - AIDS is becoming a growing burden on the public sector as the demographics of AIDS and HIV infection are changing more and more to individuals in lower economic brackets.
 - AIDS research spin-offs are benefiting many other areas, such as cancer, lupus, diabetes, rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, dementia, encephalitis, and meningitis.

National Institutes of Health				
	1995	1996	1997	% Chg
Dollars:				
AIDS.....	\$1,333,875,000	\$1,407,824,000	\$1,431,908,000	+1.7%
Cancer.....	\$2,217,000,000	\$2,251,000,000	\$2,392,000,000	+1.8%
Heart Disease....	\$834,000,000	\$877,000,000	\$893,000,000	+1.8%
* Excludes VCT AIDS testing, included in the AIDS figure.				
New Cases per Year:				
AIDS.....	73,000			
Cancer.....	1,252,000			
Heart Disease....	n.a.			
Dollars per Case:				
AIDS.....	\$18,272			
Cancer.....	\$1,770			
Heart Disease....	n.a.			
Deaths per Year:				
AIDS.....	41,930			
Cancer.....	547,000			
Heart Disease....	955,000			
Dollars per Death:				
AIDS.....	\$31,812			
Cancer.....	\$4,053			
Heart Disease....	\$873			

ADDITIONAL INFORMATION:

► Growing Public Health Impact:

- The pandemic of AIDS and HIV infection continues to grow - more persons in every geographic area and age group are becoming infected every day, despite what we have learned about it and its transmission. Unlike cancer or heart disease, AIDS is an expanding public health threat. In 1994, more than 80,000 new AIDS cases were reported to CDC. It is estimated that approximately 40,000 new HIV-infections occur yearly among adults and adolescents.
- Since the disease was identified only 15 years ago, AIDS has killed over a quarter of a million Americans. In the U.S., one person dies from AIDS every 8 minutes.
- Unknown in 1980, AIDS was the 15th leading cause of death overall in the U.S. in 1987. Today, it is the 8th ranked cause of death in the U.S., accounting for over 38,000 deaths per year. AIDS is the leading cause of death among persons between the ages of 25 and 44, representing nearly one in four deaths. During the same time, rates of cancer and heart disease have remained relatively stable.

- The World Health Organization (WHO) estimates that 18.5 million adults and 1.5 million children world-wide already have become HIV-infected and nearly 10,000 new infections occur each day. More than 2.5 million adults, children, and infants have died. Approximately 90% of HIV-infected individuals are in developing countries, with Africa and now Asia bearing the greatest burden of the epidemic.

► AIDS Research Spin-offs:

- AIDS research has accelerated study of the human immune system, contributing to our understanding and treatment of many other diseases, such as cancer and autoimmune diseases, including lupus, diabetes, rheumatoid arthritis, and multiple sclerosis.
- AIDS research has led to a better understanding of the mechanisms by which infectious agents and inflammatory cells gain access to the brain. This research has valuable implications for research on Alzheimer's disease, dementia, multiple sclerosis, neuropsychological disorders, encephalitis, and meningitis.
- AIDS research has enhanced the care of patients with other immunodeficiency states, such as cancer patients and patients who have received immunosuppressive therapy for bone marrow or solid organ transplants, who are susceptible to many of the same opportunistic pathogens.

is widespread agreement that Medicaid's role in HIV funding is likely to grow in the future. In order to understand these predictions, it is necessary to review how persons with HIV disease can become eligible for Medicaid benefits.

III. MEDICAID ELIGIBILITY FOR PERSONS WITH HIV DISEASE

Persons with HIV disease qualify for Medicaid in two basic ways. First, they may become disabled as a result of their illness, deplete their resources, and thus be eligible for SSI payments or qualify as medically needy. Second, they may qualify for reasons unrelated to their illness, by meeting the usual categorical and financial tests for Medicaid eligibility.

A. SSI Disability Coverage

Persons who receive SSI on the basis of disability are generally eligible for Medicaid, with exceptions in certain States discussed in Chapter III, Eligibility. In order to receive SSI, a disabled person must meet income and resource standards, must be determined by a physician to meet medical standards of disability, and must not be engaged in substantial gainful activity (earnings from work may not exceed \$500 per month). As a result of a Social Security Administration (SSA) ruling, persons with a confirmed diagnosis of AIDS are presumed to have met the disability standard. The "presumptive disability" rule does not confer automatic eligibility on persons with AIDS. They must still meet the financial standards and must not be engaged in "substantial gainful activity" (generally, must not have employment earnings over \$500 per month); but they may qualify for benefits more rapidly than other applicants, whose medical disability must be determined on an individual basis.

In applying the presumptive disability rule, the SSA initially used the definition of AIDS established by the CDC. Under this definition, an HIV-positive individual is not considered to have AIDS unless he or she has had certain opportunistic infections or has exhibited other specified symptoms. More recently, SSA has developed a broader listing of HIV-related impairments that can be used to establish presumptive disability for persons who do not have AIDS but are considered equally disabled.

The HIV-infected persons who are not yet symptomatic or who do not have the particular impairments on the SSA list are not presumptively eligible. Some may be ill enough to qualify as disabled for SSI purposes on an individual basis by going through a standard medical review process. Those who are not yet ill may not qualify at all. One consequence is that low-income persons in the early stages of HIV disease may not receive Medicaid coverage for the treatments that could slow the progress of the disease. In addition, the medical review requirement may delay coverage even for persons who are seriously ill.

Table I-2 shows the initial disposition in FY 1986 through FY 1988 of applications for SSI or for Social Security disability insurance (SSDI) on the basis of HIV-related problems. SSDI uses the same disability criteria as SSI, but does not impose income or asset tests. Instead, a disabled person is potentially

eligible if he or she is "insured" under the Social Security system by having paid the Social Security payroll tax for the required number of quarters. Some low-income people with sufficient work history may receive both SSI and SSDI.

TABLE I-2. Disposition of Initial Social Security Decisions for Cases with HIV-Related Impairments, Fiscal Years 1986 to 1988

	Allowed in initial decision			Total allowed	Denied	Percent allowed
	DI only	SSI only	SSI and DI			
Impairment:						
AIDS	2,309	2,819	4,416	10,434	384	96.2%
Symptomatic HIV	406	844	918	2,168	1,568	73.6%
Other AIDS-related	4,686	3,564	5,148	13,396	2,798	98.7%
Total	2,491	7,027	10,482	26,000	4,684	91.7%

NOTE: "Other AIDS-related" includes persons who were recorded as having AIDS or HIV, but for whom other problems were listed as the first and second impairments in Social Security records.

Source: Social Security Administration, Office of the Actuary.

As the table shows, a total of 26,000 applicants with an HIV-related impairment were approved for SSDI, SSI, or both in the initial decision on their applications, while 4,684 were denied benefits. (Some of these were later approved on reconsideration or appeal.) The approval rate was much higher for applicants with AIDS than for those with non-AIDS symptomatic HIV disease. Persons whose primary impairment was some problem other than HIV disease, but who also reported HIV, were more likely to be approved than those whose non-AIDS HIV disease was the primary impairment.

The SSA standards governing presumptive SSI eligibility for persons with HIV disease have been challenged in court in at least one State on the grounds that they discriminate against women. The contention is that the listing of impairments reflects the course of HIV disease in men, while women tend to have different symptoms and are therefore excluded. Others have argued that the CDC definition and the somewhat broader SSA listing have more generally failed to keep pace with changing manifestations of HIV disease. In 1989, for example, one in four deaths among persons with symptomatic HIV disease were of persons who did not meet the CDC AIDS definition.⁹

As was noted earlier, CDC has proposed a revision of the AIDS definition to include certain asymptomatic persons with depleted immune systems. SSA will not be bound by this change, but has published proposed rules that would allow consideration of functional impairment, rather than just a particular list of problems or symptoms, in determining whether an individual's illness is

⁹DIHS, HIV Prevalence Estimates, Nov. 30, 1990.

not all states have medically needy standard. (see next pg)

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sufficiently severe to warrant presumptive disability.¹⁸ While the replacement of simple decision rules with a fuller evaluation may make more people eligible, some advocates have expressed concerns that it will also lengthen the eligibility determination process.

B. Medically Needy Eligibility

As of January 1991, disabled persons could qualify as medically needy in 35 States.¹⁹ Medically needy disabled persons do not meet the income standards for SSI, and therefore do not receive cash assistance, but do meet the other criteria for SSI eligibility. They may receive Medicaid if they meet the State's asset limits and if their net income, after subtracting incurred medical expenses and certain other disregarded amounts, is below a medically needy standard established by the State. Some persons who lack other insurance coverage may "spend down" to Medicaid eligibility by incurring large medical bills.

One group that may be especially likely to qualify as medically needy are those who are receiving SSDI payments but have not yet become eligible for Medicare benefits. Recipients of SSDI benefits must wait 6 months for those benefits and may receive Medicare only after completing an additional 24-month waiting period, for a total delay of 29 months. Because this is longer than the average life span after a formal diagnosis of AIDS, few SSDI recipients with AIDS ever receive Medicare benefits. (Estimates are that Medicare covers no more than 1 to 3 percent of total costs for the treatment of AIDS.)

As was noted earlier, some persons with low enough SSDI benefits may also qualify for SSI and thus receive Medicaid. This was true for about 55 percent of the successful SSDI applicants in FY 1986-FY 1988. For the rest, however, the SSDI benefits raise their incomes above SSI cash assistance standards. Those who are in States with medically needy programs can spend down to Medicaid eligibility; those in States without such programs may be left with no coverage at all. (Applicants for SSI must also apply for, and if eligible accept, SSDI benefits; thus they cannot forgo the SSDI payment in order to qualify for Medicaid.)

C. Low-Income Persons With HIV Disease

Some persons with HIV disease may be eligible for Medicaid for reasons not directly related to their illness. This may be especially true of intravenous (IV) drug users and their sexual partners and children, who are likely to have low incomes and who may have qualified for Medicaid prior to developing HIV disease on a basis other than disability. These include recipients of Aid to Families with Dependent Children (AFDC) and others qualifying through recent expansions of Medicaid eligibility for low-income mothers and children.

¹⁸Federal Register, v. 56, no. 243, Dec. 18, 1991. p. 65702-65714.

¹⁹See Chapter III, Eligibility for a listing of these States.

One recent study of Medicaid enrollees with AIDS in California and New York found that, in an average month in 1986, one third of the beneficiaries in New York had qualified through AFDC or as Ribicoff children, compared to just 4 percent in California.²⁰ This corresponds to the greater prevalence of AIDS among women and children in New York, which in turn reflects the higher proportion of cases related to drug use. A study of Medicaid spending for persons with AIDS in Michigan confirms that women were more likely than men to be eligible for Medicaid before they were diagnosed as having AIDS.²¹

D. Future Trends

Two major trends are likely to affect the role of Medicaid in financing care for persons with HIV disease. The first is a shift in the epidemic towards populations that are more likely to qualify for Medicaid early in the course of the disease. The second is a possible erosion in private insurance coverage.

The HIV disease is now spreading more rapidly among IV drug users and their sexual partners, and less rapidly among gay and bisexual men. This means that an increasing proportion of AIDS cases will be among the low-income persons who are least likely to have other insurance coverage and most likely to qualify for Medicaid. The shift in risk factors is accompanied by a shift in demographic characteristics. HIV infection is increasingly a problem of minorities and women. CDC estimates that new AIDS cases among blacks and Hispanics will grow 30 to 40 percent faster than among whites in the 5 years ended 1993, while cases among women will grow 30 percent faster than among men.

This shift is significant, because of the strong relationship between demographic characteristics and the likelihood that a person with AIDS will qualify for Medicaid. Table I-3 shows the sources of third-party payment for AIDS hospitalizations in greater New York in 1985. Black and Hispanic men were much more likely to rely on Medicaid than were white men, and much less likely to have Blue Cross or commercial insurance. The pattern was even more pronounced for women with AIDS. (The study did not categorize women by race. However, three out of four women with AIDS are black or Hispanic.)

²⁰Ellwood, Marilyn Rymer, Thomas R. Fanning, and Suzanne Dodds. *Medicaid Eligibility Patterns for Persons with AIDS: California and New York, 1983-1987*. Lexington, MA, Systemetrics/McGraw-Hill, 1991. Prepared for Office of Research, Health Care Financing Administration. Ribicoff children meet the financial standards for AFDC but not the categorical standards. They may include children in foster care, in two-parent families, or in other settings.

²¹Solomon, David J., et al. Analysis of Michigan Medicaid Costs to Treat HIV Infection. *Public Health Reports*, v. 104, no. 5, Sept.-Oct. 1989. 424.

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STATEMENT FROM THE DIRECTOR July 14, 1997

State of the HIV Epidemic: Preparing for a New Era in Prevention

*Statement from Helene Gayle, M.D., M.P.H.
Director, National Center for HIV, STD, and TB Prevention, CDC*

We have entered a new era in the HIV epidemic—both in terms of treatment and prevention. Dramatic progress has been made in preventing new infections and in slowing the progression of disease for those infected. From January through September 1996, the estimated number of deaths dropped 19%, from 37,900 to 30,700, versus the comparable 1995 period.

The decline in deaths likely reflects the impact of new combination therapies in lengthening the healthy lifespan of infected individuals and the slowing of the epidemic overall. HIV prevention efforts have contributed to a slowing in the spread of the disease, with annual increases in new AIDS cases in the U.S. dropping from over 85% in the mid-1980's to a current rate of less than 5% each year. In 1995, the increase in AIDS incidence slowed to only 2%. With sustained prevention and continued improvements in treatment for HIV infection, we may soon begin to see measurable declines in AIDS incidence.

The greatest successes have been seen among those at highest risk—gay and bisexual men—particularly those affected by the first wave of HIV infection. We saw signs of behavior change in this group in the late 1980's. Now we are seeing a slowing in the rate of new AIDS cases among gay men overall, and declines in new infections in some areas.

HIV prevention efforts are having an impact in many diverse areas of prevention. Communities across the U.S. are demonstrating success in a number of areas. Condom use is increasing among some sexually-active young people, injecting drug users (IDUs) in some areas are reducing risky behaviors, and we have seen dramatic progress in preventing perinatal transmission.

But at least 40,000 new infections are occurring each year, and much work is left to be done. Nationwide, AIDS cases are now increasing most rapidly among women—particularly minorities. AIDS incidence in women now outpaces men, and heterosexual transmission is the fastest growing mode of transmission. Heterosexual AIDS cases are now growing at 15-20% a year, compared to increases of 5% or less among men-who-have-sex-with-men (MSM) and injecting drug users (IDUs).

HIV increases
to among

Other troubling trends point to the need for increased efforts among young and minority gay and bisexual men—who remain at high risk. Recent studies have found that as many as 5-9% of young gay and bisexual men ages 15-22 may be infected in many areas.

HIV has evolved from a period of explosive growth in a few geographic areas, primarily

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among gay and bisexual men and IDUs, to the development of diverse local subepidemics, where the dynamics of HIV vary by community and region. So, while communities will face many of the same concerns, programs must be locally designed to be relevant and effective. CDC's challenge will be to ensure each community has the tools to address the evolving epidemic and the unique challenges facing the community.

This is a time of renewed optimism in the fight against AIDS. Yet with these prevention and treatment advances, we also face new challenges—challenges that must be met, if we are to preserve the progress made.

First, AIDS prevalence has increased 10% since mid-1995. If the number of new HIV infections each year remains stable or increases, and HIV-related deaths continue to decrease, there will be an increasing number of people living with HIV and AIDS. Consequently, additional resources will be needed to provide these individuals quality services, treatment, and care.

Second, to continue to provide the necessary data to plan, direct, and evaluate HIV prevention efforts, HIV/AIDS surveillance systems must adapt to changes in medical practices which increase survival following diagnosis of HIV or AIDS. If progression to AIDS is successfully delayed for an increasing number of individuals, AIDS case reports may no longer provide a reliable indication of trends in the epidemic and will underrepresent the need for treatment services and care. Surveillance systems will therefore need to improve methods to monitor the number of individuals with living with HIV infection.

And finally, as we continue to work to develop better treatment options, we must not lose sight of the fact that preventing HIV infection is the only way to reduce the burden of this disease. Targeted, sustained prevention reduces the number of people who need to undergo complex, costly treatment regimens.

To this point, as the epidemic has evolved, so must prevention. Prevention in this era of continuous and incremental advances in science will become more complex than ever before. After 15 years of planning, implementing, and evaluating efforts to stem the HIV epidemic, we know that preventing HIV infection depends not only on studying and implementing biomedical interventions to thwart the virus, but even more upon influencing millions of individuals in diverse populations to adopt or maintain safe behaviors. As we move forward scientifically, we must be attuned to how these advances are communicated and influence people's perceptions of risk and their attendant behaviors.

It is essential that individuals at risk for HIV infection continue to protect themselves through safer behaviors. Available therapies are complex, and a great deal of uncertainties remain about long-term effectiveness, safety, and the possibility of resistance. New options offer great hope for those already infected, but HIV remains a life-threatening infection that can and should be prevented.

Progress in both treatment and prevention will be incremental during the next era of this epidemic. While we have made significant progress in fighting this disease, a great deal remains unknown about the specific mechanisms of infection, and disease progression from the time of HIV infection to development of illness. As our understanding advances, the public must receive accurate and timely information. But both scientists and the media must be careful to communicate these advances along with the cautionary notes.

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For example, the next communication challenge in this era of prevention will stem from the possibility of a medical regimen to reduce the chance of HIV infection after a sexual or drug-related exposure to HIV (post-exposure prophylaxis or PEP). While no data currently exist about the effectiveness of PEP for these types of exposures, scientists and medical experts are now discussing the possibilities. At this point, there are more questions than answers. As these discussions evolve, communication must be clear, so that people do not see PEP as a means of primary prevention. While such a therapy may reduce infections in isolated situations, taking a chance on a complex and costly drug regimen after exposure should not take the place of adopting and maintaining behaviors that can prevent HIV exposure in the first place.

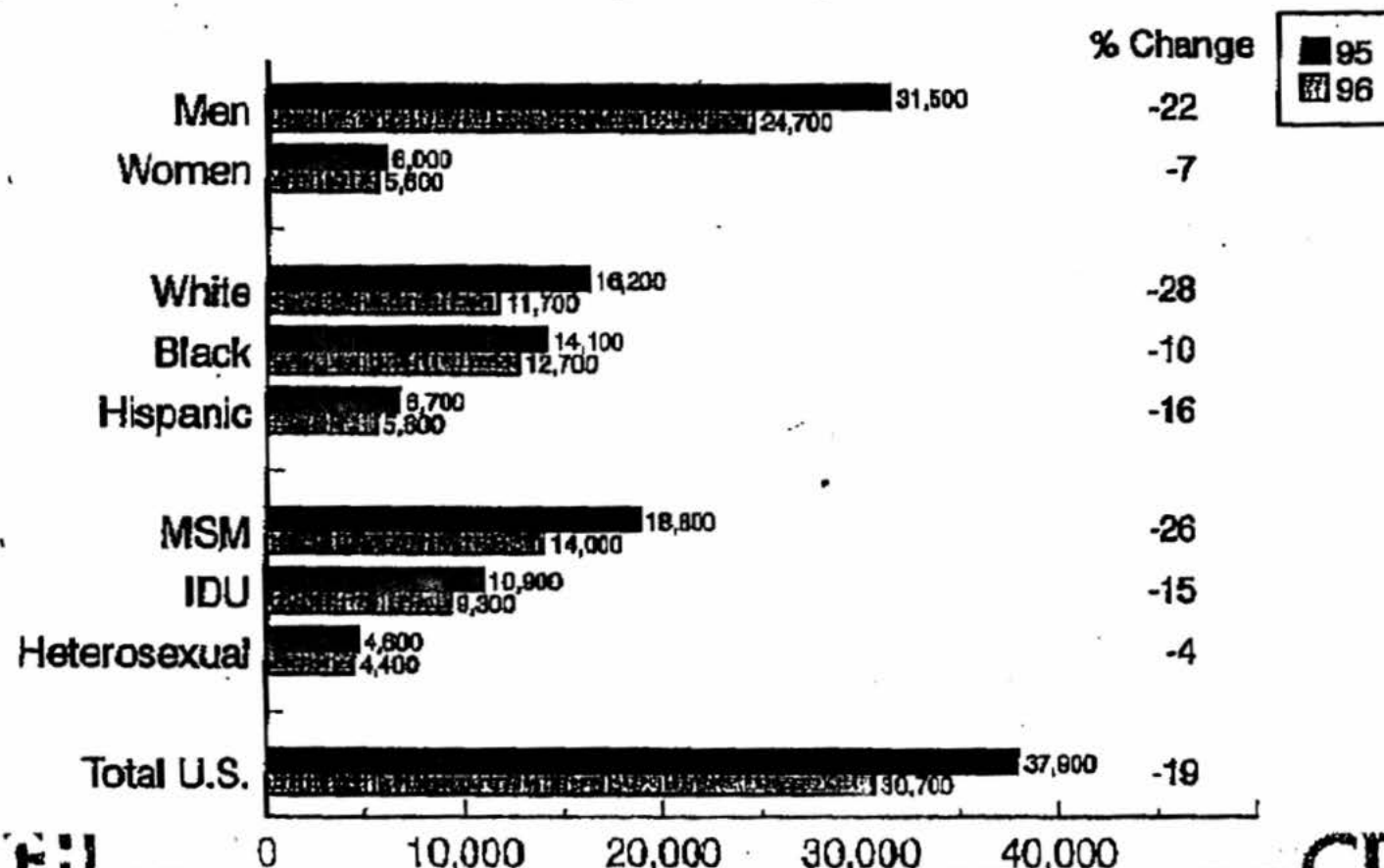
We hope that progress in this and other areas of HIV prevention and treatment over the next decade will be dramatic, and that advances will continue to be made. To meet this challenge, CDC is committed to maintaining a comprehensive approach to HIV prevention, including providing the best available epidemiological and behavioral data, conducting prevention research to develop new tools and methods for prevention, and working with communities to ensure that scientific advances and lessons learned are applied to designing effective prevention programs. And as we enter a new era in combating this epidemic, we must fight the disease on multiple levels—but remember that it is always better to prevent than to treat this disease.

For more information, call Terry Hammond at (404) 639-8895.

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Estimated Number and Percent Change in AIDS-Deaths*

Deaths Occurring Jan-Sept 1995 and 1996



NCSEH

National Center for HIV, STD & TB Prevention

CDC

FOR IMMEDIATE RELEASE
June 20, 1997

Contact: José Zuniga
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STATE OF AIDS FORUM CHALLENGES LEADERS IN FIGHT AGAINST AIDS

Nationally-renowned AIDS experts to outline challenges
posed by AIDS epidemic in 1997 and beyond

WASHINGTON, DC - America's leaders in the fight against AIDS will convene in Washington, D.C., July 14 for a *State of AIDS Forum* that will both define and respond to the political, social and scientific challenges posed by an evolving epidemic. AIDS Action's 1997 *State of AIDS Forum* comes at a time when the AIDS community is grappling with the implications of promising AIDS drug therapies, an historic decline in AIDS deaths, and the need to re-define our national and local response to AIDS.

"Those who define the debate around AIDS will effect the change necessary to find a cure and vaccine, prevent further infections, and care for those already infected. One thing is certain, we are about to leave behind AIDS as we have known it for over 16 years," said Daniel Zingale, AIDS Action's executive director. "We have invited our nation's AIDS leaders and members of the media to participate in what may well define not only this moment in history, but perhaps how the next chapter will read."

The forum will bring together chief executive officers of the nation's leading AIDS service providers, Clinton administration officials, public health and AIDS policy experts, clinicians, and people living with HIV and AIDS. Among some of the confirmed attendees are Dr. Helene Gayle, director of the Centers for Disease Control and Prevention's (CDC) National Center for HIV, STD & TB Prevention, and Sandra Thurman, director of the White House Office of National AIDS Policy.

A two-hour media briefing will open the *State of AIDS Forum*. The briefing begins at 9 a.m. in the Main Ballroom of the National Press Club in Washington, DC. Dr. David Ho, TIME Magazine's "Man of the Year," has been invited to present [confirmation pending]. Gayle will release the CDC's latest AIDS surveillance report, including information on whether or not the decline in AIDS deaths in the United States will continue. Additionally, five other presenters will speak on the clinical, political, and AIDS service implications of HIV disease in 1997 and beyond. A roundtable discussion among the presenters, a panel of AIDS community leaders, and members of the media will immediately follow the presentations. Bentley Health Care, Inc., is generously underwriting the forum.

Media credential forms are available upon request by calling Kurt Schade, communications assistant, at (202) 986-1300, Ext. 3060.

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AIDS Action is the nation's foremost AIDS advocacy organization, representing all Americans affected by HIV and AIDS and over 1,400 community-based organizations that serve them.



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FOR IMMEDIATE RELEASE
July 7, 1997

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MEDIA ADVISORY

CDC to release new AIDS deaths data at first national State of AIDS Forum

Forum to focus on challenges of changing epidemic in context of new AIDS drugs, declining death rates

WASHINGTON, DC - The nation's leading AIDS policy organization will convene the first national forum on the state of the AIDS epidemic in the context of promising new AIDS drug therapies and declining death rates. The AIDS Action State of AIDS Forum, which begins at 9 a.m., July 14, in the National Press Club's Main Ballroom, will open with the release of new figures from the Centers for Disease Control and Prevention (CDC) on AIDS mortality. AIDS experts will announce the results of studies showing that the advent of potentially life-saving drugs poses new challenges for people with AIDS and those who serve them. People with AIDS and AIDS service providers from around the country will discuss the personal and professional challenges they face in the new era of AIDS.

CDC Announces New AIDS Death Rate Statistics, Examines Trend in AIDS Mortality
"AIDS Deaths Drop 13 Percent in U.S." Last year's dramatic announcement by the CDC offered hope that new AIDS drugs were keeping more Americans with HIV/AIDS alive. Dr. Helene Gayle, director of the CDC's National Center for HIV, STD & TB Prevention, announces anxiously-awaited new statistics on AIDS mortality rates that may show whether there is a continued downward trend in the number of AIDS-related deaths.

An L.A. Story: Study Finds That People of Color Lack Access to New Drugs
AIDS-fighting drugs can only save lives if patients have access to them. James Loyce, executive director of AIDS Project Los Angeles (APLA), releases the results of a client survey indicating that, while 75 percent of Caucasian clients have access to protease inhibitors, only 57 percent of African-Americans and 54 percent of Latinos are able to obtain the life-prolonging drugs. Another shocking figure shows that 13 percent of clients indicated they had been prescribed protease inhibitors but could not access them.

It Takes Two to Tango: Why Do Some Doctors Refuse to Prescribe Life-saving Drugs to Some Patients? Why Do Some Patients Fail to Adhere to Medication?
Misconceptions and lack of AIDS-specific training among medical professionals may prevent doctors from prescribing combination drug therapies to patients whose lives could be saved. Meanwhile, some patients fail to adhere to promising AIDS drug therapies because they lack continued access or there are miscommunications in the doctor-client relationship. Dr. Linda Frank, director of the Pennsylvania AIDS Education and Training Center (AETC), addresses the complex issue of "compliance" as a new challenge for the doctor-patient team.

- MORE -

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Outpatient Care Could Squeeze Patients Out If Hospitals Close AIDS Clinics

Hospital-based AIDS programs are increasingly squeezed for funding as patients on protease inhibitors spend less time in the hospital and receive more of their care through outpatient visits, which are not covered by Medicaid to the same extent as inpatient services. A New York study released by Dr. Victoria Sharp, director of St. Luke's-Roosevelt Hospital's AIDS Center, finds hospitals in the state losing up to \$70,000 a day - a trend that could result in the closing of outpatient AIDS clinics and a loss of medical services for people with AIDS.

The Best and Worst of Times: Protease Inhibitors Don't Work For All People

Protease inhibitors have been widely praised for their success in prolonging the lives of people with AIDS. However, the drug therapies do not work for everyone. Gregg Consalves, policy director of the Treatment Action Group (TAG), presents on people with AIDS who either show no improvement after undergoing much-touted combination therapies with protease inhibitors, or who cannot tolerate the therapies' toxic effects.

Fewer AIDS Deaths Mean More Challenges to Local Communities

While the success of protease inhibitors brings new hope to people with HIV/AIDS, declining AIDS death rates are increasing the demand for services from local AIDS service organizations. Douglas Nelson, executive director of the AIDS Resource Center of Wisconsin, discusses new challenges that AIDS service providers face as their caseloads rise and public interest and funding begin to decline.

Agenda for a Changing Epidemic: Public Policy in a New Era of AIDS

The top priority of AIDS public policy is to save lives. AIDS Action Deputy Executive Director Christine Lubinski outlines an agenda for helping people with HIV/AIDS gain access to life-saving drugs - and other services they need to stay alive and healthy - while also preventing the further transmission of HIV.

A roundtable discussion following the formal presentations will include the aforementioned presenters, chief executive officers of AIDS service organizations, National AIDS Policy Director Sandra Thurman, and people with HIV/AIDS from across the country. The people with HIV/AIDS who will share their personal experiences are Michelle Lopez, a mother of two whose daughter Raven is on protease inhibitors; Tracy Nell, who accesses Medicaid-funded AIDS care at Continuum in San Francisco; Denise Stokes, an Atlanta woman who is a member of President Clinton's Advisory Council on HIV/AIDS; Derrill Edwards from Wilmette, Illinois; and Winnie Fairchild, a grandmother who accesses care at the Whitman-Walker Clinic in Washington, D.C.

Bentley Health Care, Inc., which is generously underwriting the forum, is a Beverly Hills-based global health care company that will provide outpatient diagnostic and therapeutic services to patients with catastrophic illnesses requiring sophisticated long-term care in AIDS, cancer, kidney failure and organ transplantation.

"We are pleased to support this important AIDS Action national forum because it reflects our complete commitment to more effective treatments and increased research efforts for all those affected by HIV disease," said Dr. Bernard Salick, Bentley Health Care's Chairman and CEO.

1997 AIDS Action State of AIDS Forum

DATE: Monday, July 14, 1997
TIME: 9 - 11 a.m.
PLACE: National Press Club, Main Ballroom
(14th & F Streets)

Media interested in covering AIDS Action's *State of AIDS Forum* must submit a media credential by Friday, July 11. To obtain a credential form, please call Kurt Schade at (202) 986-1300, Ext. 3060. Media queries should be directed to José Zamiga at (202) 986-1300, Ext. 3042.