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S. Hrg. 109–419

ADDRESSING DISPARITIES IN THE FEDERAL HIV/AIDS CARE PROGRAMS

HEARING

BEFORE THE

FEDERAL FINANCIAL MANAGEMENT, GOVERNMENT INFORMATION, AND INTERNATIONAL SECURITY SUBCOMMITTEE

OF THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

JUNE 23, 2005

Printed for the use of the Committee on Homeland Security and Governmental Affairs

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ADDRESSING DISPARITIES IN THE FEDERAL HIV/AIDS CARE PROGRAMS

THURSDAY, JUNE 23, 2005

U.S. SENATE,
SUBCOMMITTEE ON FEDERAL FINANCIAL MANAGEMENT,
GOVERNMENT INFORMATION, AND INTERNATIONAL SECURITY,
OF THE COMMITTEE ON HOMELAND SECURITY
AND GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:33 p.m., in room SD–562, Dirksen Senate Office Building, Hon. Tom Coburn, Chairman of the Subcommittee, presiding.

Present: Senators Coburn, Carper, and Lautenberg.

OPENING STATEMENT OF SENATOR COBURN

Senator COBURN. The hearing will come to order. Senator Carper is on his way I understand. So we do not delay our panelists and those testifying, we will start.

Today's hearing will examine the financial status of the Ryan White CARE Act, the Nation's largest provider of AIDS-specific services, which Congress is expected to reauthorize later this year.

I had the privilege of authoring the 2000 reauthorization of this important law and, as a practicing physician, I have cared for numerous patients with HIV who relied upon the CARE Act for their medical needs.

Twenty years ago, I delivered a baby girl who would become the first child I ever delivered to die from AIDS. I discovered she was infected with HIV after I diagnosed her mother with full-blown AIDS and a full-blown pneumocystis infection. The mother died 2½ weeks after we learned she had the disease. Her daughter struggled through 7 years of treatment before she succumbed to the same fate as her mother.

Back then, much was still not known about HIV and AIDS. Few medical therapies were available to treat the disease. The epidemic was believed to be almost entirely centered in a few metropolitan areas and among very specific groups of high-risk individuals. Even within the public health community, fear and lack of knowledge about this new disease left many of those living with the virus unable to access the care that did exist and fear of stigmatization kept many others from even seeking testing or treatment.

Today, HIV affects every State in our Nation, and the virus does not discriminate against any particular race, gender, age or sexual behavior. Medical breakthroughs, however, have dramatically

transformed HIV infection for many into a chronic, manageable disease and, thereby, have delayed the onset of AIDS.

In 1990, Congress passed the Ryan White CARE Act to provide for the unmet health needs of persons living with HIV disease. The CARE Act was named after Ryan White, an Indiana teenager whose courageous struggle with HIV/AIDS and against AIDS-related discrimination, helped educate our Nation.

While the face of AIDS has changed, our Federal response has been slow to adapt to those changes. Funding for the CARE Act has increased dramatically from $257 million in 1991 to over $2 billion in 2005. Yet thousands of Americans with HIV are on waiting lists for access to life-saving AIDS medications, and many others face formulary restrictions. And while patients in Kentucky and West Virginia have died while on waiting lists for treatment provided by the AIDS Drug Assistance Program, one of the metropolitan areas is actually receiving CARE Act funds for the deceased.

Furthermore, tens of millions of CARE Act dollars go unspent annually in some jurisdictions, while other States find themselves faced with cutting patients' access to life-saving AIDS drugs. These disparities have been created by a number of factors. First, the CARE Act continues to distribute Federal funds based not upon the number of people with HIV but rather AIDS, the end stage of HIV infection. It often takes up to 10 years for AIDS to develop after HIV infection, and now, thanks to new innovations, even later.

Because AIDS cases comprise only a fraction of the total population of those living with HIV, this misplaced emphasis as a basis for the CARE Act funding ignores the vast majority of those with HIV. These affected communities are being ignored and not receiving a fair share of Federal support.

Studies have shown that those with HIV but not AIDS are much more likely to be women, African-American, Hispanic, and those who live in rural areas.

Incorporating HIV data into funding formulas and prevention strategies will ensure we stay in front of the disease, and that resources are directed towards where the disease is headed rather than where it was a decade ago.

In 2000, Congress sought to eliminate these disparities and treat all people with HIV/AIDS equally under the CARE Act—by incorporating all those living with HIV, rather than just those diagnosed with AIDS, in funding formulas. The law requires that beginning no later than fiscal year 2007, cases of HIV disease reported to and confirmed by the Director of the Center of Disease Control and Prevention as sufficiently accurate and reliable will be the basis for CARE Act funding priorities and formulas.

Funding disparities have also been created by a "hold-harmless" provision in Title I of the CARE Act. This hold-harmless provision was intended to ensure that no eligible metropolitan area (EMA) suffered from dramatic funding decreases from one year to the next. While well intentioned, this hold-harmless provision has ironically caused harm in many areas, and all but one of the 51 EMAs would fare better if the hold-harmless provision was eliminated altogether.

Last year, the San Francisco EMA received 92 percent of all hold-harmless funding. As a result, San Francisco receives twice

the amount per AIDS case as every other EMA, and actually received funding for AIDS patients that have long since passed away. The city finds itself in a unique position where it must find ways to spend excess money on nonessential services while its reported AIDS cases continue to drop.

In sharp contrast, the largest AIDS service provider in the country in Washington, DC, the D.C. EMA, is faced with dire financial problems that have forced the closing of several offices, and massive staff layoffs, despite a growing population affected by HIV/AIDS.

In addition, some States benefit from "double countings"—when AIDS cases are actually counted twice, once for funding under Title I and again under Title II. States that receive Title I funding receive 38 percent more per AIDS case than States without an EMA.

Beyond simply addressing the formulas to ensure funding equity, services provided by the CARE Act must also be updated. When it became law 15 years ago, few medical therapies existed and the CARE Act primarily provided social services and end-of-life care for those with HIV/AIDS. What wonderful progress we have made.

Since that time, medical breakthroughs have contributed to a great transformation in the lives of those with HIV. AIDS deaths have dropped significantly and, for many, HIV has become a chronic rather than a terminal disease.

As a result, more Americans are living with HIV than ever before, and the cost of life-saving drugs is considerable. A drug combination including Fuzeon, for example, can cost between $30,000 and $35,000 a year to treat a single patient. This incredible cost to provide essential treatment underscores the need to prioritize core medical services and effective prevention. Let me say that again, prioritize core medical services and effective prevention.

The U.S. Federal Government is expected to spend nearly $20 billion on HIV/AIDS related programs this year alone, and we as a Nation have committed ourselves to provide billions of dollars worth of medication and care services to those living with HIV in Africa and elsewhere.

Clearly, there is no acceptable reason why with such a large financial investment any American living with HIV can not access medically necessary care.

I look forward to hearing from our witnesses today, who include Dr. Marcia Crosse, Director of the Government Accountability Office's Public Health and Military Health Care Issues; Dr. Deborah Hopson, Associate Administrator of the Health Resources and Services Administration's HIV/AIDS Bureau; Dr. Robert Janssen, Director of the Division of HIV/AIDS Prevention of the National Center for HIV, STD, and TB Prevention at the Centers for Disease Control and Prevention; and Dr. Michael Montgomery, Chief of the Office of AIDS for the California Department of Health Services.

Senator Lautenberg.

OPENING STATEMENT OF SENATOR LAUTENBERG

Senator LAUTENBERG. Thanks, Mr. Chairman. I note with respect your background and your interest and your view on things, but I do appreciate your calling this hearing and giving us an op-

portunity to examine the implementation of the Ryan White CARE Act.

I was proud to be an original cosponsor of this legislation when it was first enacted by Congress in 1990. And as most know, it was named after Ryan White, a young Indiana person whose brave struggle against AIDS-related discrimination helped to educate our Nation.

The good news is—and we heard it from Senator Coburn—is that in the years since this legislation was passed, we have seen dramatic breakthroughs and treatments, and today a diagnosis of AIDS is no longer a death sentence. The bad news is that it is still a very serious problem, and it continues to spread.

More than 30,000 people in my home State of New Jersey are living with HIV or AIDS. The number increased 3.5 percent over a 6-month period last year. Of those 30,000 New Jerseyians with HIV and AIDS, more than one-third are women. New Jersey ranks first in the percentage of women diagnosed with AIDS within the United States and third in the number of pediatric AIDS cases.

I once visited a ward in Jersey City where pediatric AIDS victims were housed, and it was a tragic sight to witness.

Today, Ryan White CARE reaches more than half a million Americans every year, and it is our Nation's largest program specifically targeted to help people living with HIV disease.

The CARE Act was amended and reauthorized in 1996 and once again in 2000. It is due for another reauthorization by September 30 of this year.

When the CARE Act was authorized by the Senate in 1990 no funds were appropriated in the original Labor HHS budget that year. I worked hard, along with Senator Byrd from West Virginia, to find funding for the original CARE Act. I also worked to ensure that smaller cities which had high per capita rates of AIDS were included in the Title I funding formula. By way of example, I worked to include Jersey City as one of the special targeted recipients of aid along with the Newark metropolitan area. Overall, New Jersey has six areas that are eligible to receive funds under Title I of the CARE Act.

I hope this Subcommittee will support the reauthorization of this important program. I also urge my colleagues to oppose any effort to shift funding from areas with the high concentrations of HIV and AIDS cases.

Mr. Chairman, I believe that while the costs have, I think, been effectively put to good use, I think that you have to have some kind of a structure to get things to the patients and the people who ought to be cautious about the fact that AIDS are transmittable and have a violent outcome.

I thank you very much, and look forward to hearing from our witnesses.

Senator COBURN. I am going to ask the witnesses to limit their testimony to 10 minutes, and I am also going to make a comment about availability of your testimony. This is directed toward the Administration and not the individuals sitting here, because I know the vetting process under which your testimony goes.

Three hours before this Subcommittee hearing we received testimony. That is totally unacceptable for us to discuss a subject as se-

rious as this, and the Administration proves itself incapable or incompetent to bring forth testimony on a hearing that they have been aware of for 2 weeks. So I would hope that you would take that message back so that in fact we can do the job. Without timely availability of testimony, which I understand neither Dr. Janssen or Dr. Hopson, is your fault, it is difficult. The fact is that timeliness and availability of testimony allows us to do a better job here, and ultimately fund this program better.

I want to recognize Dr. Robert Janssen, Director of HIV/AIDS Prevention, National Center for Infectious Disease to go first, and Dr. Hopson, Associate Administrator for HIV Health Resources and Services Administration in Department of Health and Human Services to go second, and Dr. Michael Montgomery, Chief of Office of AIDS, Department of Health and Human Services, Sacramento, California, followed by Dr. Crosse, Director, Public Health and Military Health Care Issues.

Dr. Janssen.

TESTIMONY OF ROBERT S. JANSSEN, M.D.,[1] DIRECTOR, DIVISIONS OF HIV/AIDS PREVENTION, NATIONAL CENTER FOR HIV, STD, AND TB PREVENTION, COORDINATING CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. JANSSEN. Thank you, Mr. Chairman. Thank you, Senator Lautenberg. Thank you for the opportunity to discuss trends in HIV and AIDS in the United States and the status of HIV surveillance systems.

At the National HIV/AIDS Prevention Conference held in Atlanta last week, CDC announced that there are now an estimated 1,039,000 to 1,185,000 Americans living with HIV or AIDS. This is an increase from the 850,000 to 950,000 reported 5 years ago.

Due to more effective treatment, people are living longer and healthier lives after a diagnosis of HIV. Despite the growing pool of persons capable of transmitting the virus, we estimate that the number of persons becoming newly infected last year has remained constant over the last 10 years, at approximately 40,000 new infections per year, as you can see in this figure.

CDC's analysis of trends in HIV diagnoses includes all new HIV diagnoses with or without an AIDS diagnosis in the 32 States that have conducted confidential name-based HIV/AIDS case reporting for at least 4 years. Between 2000 and 2003, 125,800 people were diagnosed with HIV infection in these 32 States. During 2000–2003, the overall rate of HIV diagnoses, that is, the number of diagnoses per 100,000 people, remained stable. It was 19.5 in 2000, and 19.7 in 2003. However, sharp racial disparities continue to exist. Rates of HIV diagnoses among African-Americans are significantly higher than among other racial and ethnic groups.

Looking at trends by risk, the annual diagnoses among men who have sex with men, or MSM, increased 11 percent during this 4-year period. MSM accounted for 44 percent of HIV cases in this time period.

[1] The prepared statement of Dr. Janssen appears in the Appendix on page 32.

The annual number of diagnoses associated with high-risk heterosexual contact remained roughly stable from 2000 to 2003, while new diagnoses associated with injection drug use declined slightly.

In 2003, the highest rate of HIV diagnosis was among African-American males, 103 per 100,000 population. That is a rate that is nearly three times the rate among Hispanic males and seven times the rate among white males. The rate of HIV diagnoses among African-American females in 2003 was 53 cases per 100,000. That is almost five times higher than among Hispanic females, and more than 18 times higher than among white females. Among American Indians/Alaska Natives, the rate of HIV diagnosis among males was slightly higher than the rate of white males, and the rate among females was twice that among white females. The lowest rates by gender are among Asian/Pacific Islander males and females.

AIDS cases and deaths reported from all U.S. States and territories continue to provide a valuable measure of the impact of the disease. Data on the number of new AIDS cases provide us with measures of late-state disease, but are not reflective of the entire HIV epidemic. HIV progresses to AIDS in an untreated person in approximately 8 to 10 years, and even longer for persons receiving treatment. The number of persons diagnosed with and dying of AIDS after the introduction of highly active antiretroviral therapy dropped dramatically until 1998, and since then has remained relatively constant.

African-Americans continue to be most severely affected by AIDS. In 2003, rates of AIDS cases were highest among African-Americans, next highest among Hispanics, then American Indian/Alaska Natives, then whites, and lowest among Asian/Pacific Islanders.

From the end of 1999 through the end of 2003, the number of persons in the United States living with AIDS increased 30 percent, from a little over 311,000 to nearly 406,000.

CDC is responsible for ensuring the integrity of the national HIV/AIDS surveillance system to accurately monitor the epidemic in the United States. CDC also provides funding and technical assistance and coordinates activities with States to aggregate data that comprises this national system. As with other diseases, individual State governments have statutory and regulatory authority for HIV/AIDS reporting and data protection, including the decision as to what methods will be used for disease reporting, such as name-based or code-based. Except for HIV, all other reported infectious diseases, including AIDS, are routinely reported to States using name-based reporting systems. States then remove names before submitting the data to CDC.

Since the beginning of the epidemic, AIDS surveillance has been the cornerstone of national, State, and local efforts to monitor the scope and impact of the HIV epidemic. AIDS surveillance data, however, no longer accurately describe the full extent of the epidemic, as effective therapies slow the progression of HIV disease. To more accurately describe the epidemic, in 1999 CDC recommended that all States implement reporting of HIV diagnoses and advised that cases be reported to local and State health departments by name.

To reach the goal of nationwide high-quality HIV data, as of today, CDC is now moving from advising to recommending jurisdictions use name-based HIV reporting, using the same name-based approach currently used for AIDS surveillance nationwide. Currently, 38 States and five territories have adopted name-based HIV reporting, seven States, the City of Philadelphia, and the District of Columbia have code-based reporting, in which a code is reported to the health department. Five States have name-to-code reporting, in which a name is reported to the health department and the health department creates a code.

There are 14 areas that use codes, and in those areas 13 different codes are used. Because all States do not use a uniform name-based approach to HIV reporting, there are limitations to the current national HIV reporting database. These limitations include national data on HIV diagnoses are not representative of some high morbidity areas, for example, California, whose data are not included.

Despite a growing number of States with quality systems, the staggered implementation of HIV reporting means HIV data at the national level are currently less accurate than AIDS data at the national level.

In 1999, CDC published a set of performance standards for HIV reporting systems. CDC reports HIV infection data only from areas conducting confidential name-based reporting because this reporting has been shown to routinely achieve high levels of accuracy and reliability. Confidential name-based surveillance systems have been shown to best meet the necessary performance standards. Studies have also shown that implementing code-based and name-to-code systems are more expensive to implement than confidential name-based systems. Currently, only confidential name-based HIV reporting integrated with AIDS surveillance data can be used by States to identify and remove cases that are counted in more than one State—a process we call de-duplication—before they can be incorporated into CDC's national surveillance database.

The last Ryan White CARE Act reauthorization called for an Institute of Medicine study of States' HIV surveillance systems and their adequacy and reliability for the purpose of using such data as the basis for CARE Act formula grant allocation. The reauthorization also called for the Secretary of the Department of Health and Human Services to make a determination regarding use of HIV data for CARE Act formulas.

The Institute of Medicine issued a report, "Measuring What Matters," on allocation, planning and quality assessment for the CARE Act. Based on the report findings in June 2004, the Secretary determined that HIV data not be used for purposes of making formula grants under Titles I and II of the Ryan White CARE Act and that estimated living AIDS cases continue to be utilized until such time as high-quality HIV data are available nationwide.

We continue to work closely with the States to help them adopt and implement high-quality HIV surveillance systems. Having all States collect HIV information in the same manner will ensure the Nation has reliable and valid data to monitor and describe the scope of the epidemic, to assure equitable distribution of resources to those with greatest need, and to plan for and evaluate preven-

tion, care and treatment programs. A uniform system is needed for measuring HIV incidence. It is also needed for evaluating HIV and AIDS care in the United States.

We have recently launched the Morbidity Monitoring Project, that is a study which, when fully, funded will allow nationwide estimates of the quality of HIV and AIDS care, also reasons why people are not receiving care and information on sexual and drug use risk behavior.

Again, I want to thank you, Mr. Chairman, and the Committee, for this opportunity to talk about HIV and AIDS trends in the United States and HIV surveillance systems.

Thank you.

Senator COBURN. Dr. Hopson.

TESTIMONY OF DEBORAH PARHAM HOPSON, Ph.D.,[1] ASSOCIATE ADMINISTRATOR, HIV/AIDS BUREAU, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ms. HOPSON. Good afternoon. Mr. Chairman, Members of the Subcommittee, thank you for the opportunity to meet with you today on behalf of the Health Resources and Services Administration to discuss the programs of the Ryan White Comprehensive AIDS Resources Emergency Act, also known as the CARE Act.

We certainly appreciate, Dr. Coburn, your continuing support that you and your colleagues have for the CARE Act programs. Your interest in the CARE Act services is certainly welcome, given the state of today's epidemic as just described by the CDC.

The Ryan White CARE Act is the centerpiece of our domestic response to care and treatment needs of low-income people living with HIV and AIDS. Currently funded at $2.1 billion, it provides primary health care, life saving medications and support services to individuals who lack health insurance and financial resources to provide for themselves. On two occasions, including his most recent State of the Union Address, President Bush has addressed the importance of this program and has called for the timely reauthorization of the Ryan White CARE Act.

Since its last reauthorization we have been able to provide antiretroviral treatment, primary care and support services to over half a million people annually in the United States, Puerto Rico, the Virgin Islands and Pacific Basin. Fifty percent of these individuals live below the Federal poverty level, less than 10 percent had any private health insurance, and less than 30 percent were enrolled in Medicaid. In 2003 over half of the Ryan White clients were African-American. The Ryan White CARE Act programs have provided important benefits to these populations. Overall, AIDS mortality is down, and lives have been extended with HIV/AIDS medications purchased through the AIDS Drug Assistance Program, also known as ADAP. Pregnant women have been provided with care that has allowed them to give birth to children free from HIV infection, and thousands have received support services that have allowed them to access and remain in health care.

[1] The prepared statement of Ms. Hopson appears in the Appendix on page 43.

Although we are making progress in providing services to people living with HIV and AIDS, the epidemic is not over and will be in need of our continuing attention for some time to come. The President and the Secretary understand the dynamics and severity of the epidemic, and they are committed to ensuring the Department's HIV/AIDS programs are as effective as possible in preventing infection and treating those who become infected.

During the past 5 years we have recognized that as essential as the CARE Act has been to serve Americans living with HIV and AIDS, it is an imperfect instrument in need of revitalization. Despite record levels of funding, we continue to face waiting lists for life saving drugs through the ADAP, and there are marked disparities in access to quality medical treatment across the country. As minority populations are increasingly and disproportionately impacted by HIV/AIDS, changes to existing systems of care designed for an earlier epidemic are increasingly urgent. We are challenged as never before to make sure that Federal funds are directed where they are most needed and used for the most vital purposes.

President Bush has laid out three principles for the reauthorization of the CARE Act: First, that we should focus Federal resources on life-extending medical care such as antiretroviral drugs, doctor visits, and lab tests, core services that are critical to maintain the health and well-being of people living with HIV and AIDS; second, that we provide greater flexibility so that CARE Act resources can be targeted to areas of greatest need; and third, that we ensure accountability in all that we do.

Based on the new CDC data, it is estimated, as Dr. Janssen has just said, that there are between 1 million and 1.2 million people living with HIV disease in the United States. Approximately 40,000 new HIV infections and over 18,000 AIDS related deaths occur per year. Of those living with HIV disease, 74 percent are male, 47 percent are African-Americans, while 34 percent are white and 17 percent are Hispanic.

In addition to challenges related to poverty and lack of adequate health insurance, individuals living with HIV disease commonly face other problems. About 22 percent of those with HIV/AIDS were infected through injection drug use. An estimated 20 to 50 percent of people living with HIV/AIDS suffer from mental illness, both related and unrelated to their infection, and co-infection with hepatitis B and C is an increasing problem.

As I stated earlier, each year the CARE Act programs, primarily through grants to States, metropolitan areas, providers and educators, reach more than half a million underserved persons, more than half of those living with HIV/AIDS in the United States. Since AIDS was first recognized the pattern and treatment of HIV disease has shifted. Now we can strive to manage HIV/AIDS as a chronic disease.

More than 2,700 providers funded by the CARE Act programs are providing primary care and treatment, and are building networks with other public and private providers to respond the response to the epidemic. Innovative outreach programs and community based points of entry, such as public health, faith-based, social service and substance abuse treatment organizations help to extend CARE Act services to hard-to-reach and at-risk populations.

Since the initiation of the CARE Act programs in 1990, perinatal transmission of HIV has declined dramatically. Less than 2 percent of all CARE Act HIV positive clients are children under 12 or younger, due in large part to the advances in prevention of perinatal transmission. The CDC reports that in 25 States with long-standing confidential name-based HIV reporting, cases of HIV/AIDS and infants born to HIV-infected mothers declined 74 percent over the 10-year period from 1994 until 2003.

Access to antiretroviral therapy for the CARE Act population has been expanded through the cost saving mechanisms being used by individual State ADAPs and other discount programs. Antiretroviral therapy has led to longer, healthier lives for individuals living with HIV and AIDS. As a result, almost one-third of the CARE Act population is age 45 or older.

ADAP, which provides funds to States to purchase life saving medications, is the single largest CARE Act program because of the high cost of medication and the growing number of people living with HIV and AIDS. In fiscal year 2005, HRSA distributed $787.5 million in ADAP funds to States, and the fiscal year 2006 President's Budget request includes a $10 million increase for ADAP. The ADAP program reaches approximately 90,000 people every month. This program is State-defined and thus differs in eligibility criteria and formularies from State to State.

The epidemiology and treatment of HIV has shifted in recent years to a more chronic disease model requiring a changing continuum of services to support this model. This shift and the success of new treatment has resulted in longer life spans and an overall increase in the demand for care and related treatments.

Going forward, the greatest challenge is reaching people who have nowhere else to turn, especially as HIV/AIDS prevalence, health care costs and the burden of HIV among uninsured and underinsured increases. Resources are likely to become more and more strained as the CARE Act's outreach efforts, coupled with CDC's prevention initiatives continue to successfully identify individuals living with HIV disease.

These newly infected individuals are more likely to be low income, to be minority and to have complex co-morbidities, as I mentioned before. Many will live in rural areas. Strengthening health care and community organizations capable of serving these populations will be an increasingly important role in the CARE Act's next decade.

Mechanisms to allocate funds must be cognizant of these changes: "hold-harmless" provisions, formulas based on AIDS rather than HIV, and allowing funds that have not been put to work in a timely manner to roll over or revert to the Treasury rather than giving DHHS the necessary flexibility and authority to reprogram resources to communities in need, must be re-engineered.

We take great pride in the advances in care and support for people living with HIV/AIDS that have been made by the CARE Act program over these last 15 years. We are thankful to you for your help and that of the dedicated providers and communities all over the country. However, we are humbled by the significant challenges that remain to reach people living with HIV/AIDS who have nowhere else to go for care in an age of increasing HIV/AIDS prev-

alence, increasing health care costs, and a growing burden of HIV among the uninsured and underinsured.

We will soon be releasing an expanded set of policy points based upon the President's principles. We intend these to serve as guideposts for discussion and deliberation on the very tough issues we must face together: how we ensure that the most vulnerable and needy in this country receive life saving treatment, how to work more effectively with State and local governments and communities impacted by HIV, how to hold ourselves and our partners more accountable for the use of Federal tax dollars, and importantly, how to advance HIV prevention in this Nation.

We look forward to working with you to revitalize the CARE Act. Thank you.

Senator COBURN. Thank you, Dr. Hopson. Mr. Montgomery.

TESTIMONY OF MICHAEL MONTGOMERY,[1] CHIEF, OFFICE OF AIDS, CALIFORNIA DEPARTMENT OF HEALTH SERVICES, AND CHAIR, NATIONAL ALLIANCE OF STATE AND TERRITORIAL AIDS DIRECTORS

Mr. MONTGOMERY. Good afternoon, Mr. Chairman and distinguished Members of the Subcommittee. My name is Michael Montgomery, Chief of the Office of AIDS for the California Department of Health Services. I am also the Chair of the National Alliance of State and Territorial AIDS Directors, or NASTAD. I want to thank you for inviting me to speak with you today to discuss the importance of the Ryan White CARE Act in helping States provide comprehensive care and treatment services to persons living with HIV and AIDS.

State AIDS Directors appreciate the long-standing support of the U.S. Senate for the Ryan White CARE Act programs. Assuring that all people with HIV and AIDS, regardless of geographic location, have equal access to appropriate and high quality HIV and AIDS services is our highest priority.

I would like to share with you some of the views of my fellow State AIDS Directors in addition to those in the State of California. I have limited my comments to those that address disparities in the CARE Act or are issues covered in the ongoing GAO investigation.

California's Office of AIDS administers California's HIV/AIDS prevention and care programs which are funded by Federal and State funds, including CARE Act Title II funds. HIV infections have penetrated nearly every metropolitan and rural community in our State. California remains an epicenter of the AIDS epidemic with 137,213 cumulative cases, and 57,308 individuals living with AIDS as of May 31, 2005. Today California has 37,531 reported HIV, non-AIDS cases.

In Federal fiscal year 2005, California received $221 million in Ryan White funding for Titles I and II, including $31 million for the Title II base, $90 million for ADAP, and $169,000 for our single emerging community, Bakersfield. California has nine Title I eligible metropolitan areas that are funded at $99 million. Governor Schwarzenegger and the California legislature have demonstrated

[1] The prepared statement of Mr. Montgomery appears in the Appendix on page 49.

their commitment to HIV/AIDS care and treatment by providing $111 million in the State General Fund in spite of California's continuing budget deficit.

For people with HIV the CARE Act is the safety net under other public programs such as Medicaid and Medicare. The Ryan White programs must adapt to fill the gaps particular to each State. ADAPs work closely with their State Medicaid programs to ensure that ADAPs remain the payer of last resort. In particular, State ADAPs will be working to fill gaps in coverage for those enrolled in the new Medicare prescription drug plans, and those who have incomes over 150 percent of the Federal poverty level. As the payer mixes and cost of delivery of care vary across the country, it makes the exercise of comparing CARE Act programs from one State to another exceedingly challenging.

Annually ADAPs serve approximately 136,000 clients or about 30 percent of the people with HIV and AIDS estimated to be receiving care nationally.

In conjunction with my colleagues from New York, I helped establish NASTAD's ADAP Crisis Task Force to negotiate with the pharmaceutical industry on behalf of all ADAPs. Although the larger States have the bargaining power, we feel it is critical that all ADAPs, large and small, have access to the same prices and discounts. The task force began negotiations in March 2003 with eight manufacturers of AIDS drugs. As a result of this highly successful public/private partnership, we received supplemental discounts, rebates and price freezes that achieved an estimated $90 million in savings during fiscal year 2004. ADAPs receive the lowest available prices in the country for antiretroviral therapies.

Understanding that there are disparities between States and what they are able to offer in terms of the level of services, State AIDS Directors recommend keeping the Title II base formula as is. Equity among the States cannot be achieved simply by rearranging the $334 million in the Title II base, and the problem in geographic disparities cannot be solved on the back of Title II alone. The entire CARE Act must have responsibility to achieve equity for persons living with HIV and AIDS.

When looking at per AIDS case funding disparities from State to State, one needs to take into consideration Title III, Title IV and part F in addition to Title I and II. In the reauthorization of the CARE Act in 2000 language was included which directed HRSA to prioritize Title III funding and non-Title I areas. This has been notably successful in moving toward geographic equity in funding, and any analysis of per AIDS expenditures while looking at Titles I and II alone distorts the equation.

Disparities in the availability of resources affect the accessibility and equality of HIV services both within and between States. State AIDS Directors recognize that the multi-Title structure of the Ryan White CARE Act contributes to the challenges faced by some States in effectively addressing the needs of persons living with HIV and AIDS. In many States the current structure is a contributing factor to funding disparities that affects availability, accessibility and quality of services both within and between States, as well as the coordination of HIV care and efficient delivery of essential services.

While the Ryan White CARE Act cannot be viewed as the sole mechanism for equalizing these inherent differences, the current structure of the CARE Act leaves many States struggling with the delivery and coordination of HIV services while trying to meet the legislative mandates to provide for the public health of its citizens.

In recommending retaining the current structure of the CARE Act, State AIDS Directors do so while establishing the following two goals which are reflective of our vision for improved HIV care services in the Nation.

1. To enhance the availability of ADAP resources and services for persons living with HIV and AIDS in need in all areas of the Nation; and

2. To provide additional resources to States with chronically insufficient Title II base funds by strengthening the emerging communities' mechanism.

Time does not permit for me to describe the details of these proposals which are outlined in my submitted testimony, and NASTAD's recommendations to guide the 2005 Reauthorization of the Ryan White CARE Act.

State AIDS Directors believe the current Emerging Communities provision should be modified to address the needs of States with a severe lack of Title II base resources that fund critical primary care and support services. Authorized in 2000 the Title II Emerging Communities Supplemental Grant sought to address the challenges faced by areas with a significant burden of AIDS cases, but that lack the density of cases to be a Title I EMA.

Since its creation, emerging communities have been subject to significant funding fluctuations due in large part to emerging communities not permanently being eligible once they begin receiving funds. The number of areas eligible for these supplemental grants has continued to diminish over the 5-year reauthorization period because of reductions in the number of AIDS cases. In the past 4 years, 14 emerging communities have been eliminated altogether.

We strongly support incorporation of HIV data in CARE Act distribution formulas. We believe the use of HIV cases in addition to AIDS cases in CARE Act allocation formulas is preferable and more closely reflects the epidemic than living AIDS cases.

Forty-three jurisdictions have name-based HIV reporting, with the remaining 13 jurisdictions utilizing a name or a name-to-code system for reporting HIV cases. Several jurisdictions have only recently implemented HIV reporting, both code and name-based, and therefore their HIV data is not yet considered mature enough to use in funding formulas.

To incorporate HIV data in fiscal year 2007, CDC will need to develop a methodology to estimate HIV cases for these States. State AIDS Directors urge that the CDC be required to work with the States when developing this methodology.

California is the only State among the five largest that uses an HIV reporting system different than its AIDS reporting system. The Schwarzenegger administration is concerned that by not converting to a names-based HIV reporting system, California risks losing its fair share of CARE Act funds when the funding formula changes. While legislative attempts were unsuccessful this year to

change from a code to name-based reporting, a spirited dialogue in California continues.

Having said that, State AIDS Directors unanimously agree that our Federal funds should not be withheld in order to force States to switch reporting systems. We believe surveillance is within the domain of the States. The States should determine what methodology best serves the needs of their citizens.

State AIDS Directors unanimously agree that expiring unexpended funds must be put back into the CARE Act rather than return to the Treasury as is currently the case. Our ADAP proposal would redistribute unobligated and expiring funds from all titles back into the ADAP program. Unspent funds typically result from delays in notice of grant awards from the Federal Government, from timing issues related to subcontracting of services, payroll savings due to State hiring delays or freezes, expenditure of other grant funds for similar services, or unanticipated fluctuations in spending at the State level. California currently has $5,319 in carryover.

States with excessive and chronic amounts of unobligated funds need immediate technical assistance from HRSA to address issues that are hindering a State from spending their award. We support providing HRSA the authority to move unobligated funds from States with an identified need lower than the Federal funds appropriated to States with chronic shortages.

State AIDS Directors support the continuation of a hold-harmless provisions for the Title II base at a reduced rate of loss. From California's perspective the hold-harmless provisions is necessary to protect California from under-funding resulting from the estimated living AIDS case formula, which underestimates California's actual living AIDS cases by 30 percent, a $20 million loss to the State in current year's Title II funding.

Experience shows that after the last reauthorization due to the unintended consequences of changes in the law, 30 States were held harmless from significant funding losses. With limited funding, as well as three consecutive years of cuts to the Title II base, these disparities cannot be corrected via major shifts in Title II resources without impacting critical existing services in jurisdictions that would lose funding.

However, we support the removal of the second hold-harmless provision to the overall Title II award that has resulted in the unintended effect of reducing the amount of money available for the ADAP supplemental allocation due to significant fluctuations in the emerging communities funding.

I hope my remarks have illustrated the critical importance of the Ryan White CARE Act to California and the complexities of addressing disparities, and that you will consider the recommendations I have outlined.

Thank you for the opportunity to speak to you today. I look forward to answering any questions you may have.

Senator COBURN. Thank you, Mr. Montgomery. Dr. Crosse.

TESTIMONY OF MARCIA G. CROSSE, Ph.D.,[1] DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Ms. CROSSE. Mr. Chairman and Members of the Subcommittee, I am pleased to be here today to discuss the Ryan White CARE Act. As we have heard, the CARE Act makes funds available to States and localities to provide health care, medications and support services to individuals and families affected by HIV and AIDS.

In fiscal year 2004 over $2 billion in funding was provided through the CARE Act, the majority of which was distributed through Title I grants to eligible metropolitan areas, or EMAs, and Title II grants to States, the District of Columbia, and territories. Metropolitan areas qualify as EMAs if they have a total of 2,000 reported AIDS cases in the previous 5 years. Titles I and II use formulas to distribute grants according to a jurisdiction's reported counts as AIDS cases.

The Care Act reauthorizations in 1996 and 2000 modified the original funding formulas. Prior to 1996 the CARE Act measured a jurisdiction's caseload by its cumulative count of AIDS cases, which is the number of AIDS cases, both living and deceased, recorded since reporting began in 1981. The 1996 reauthorization changed the measurement to an estimation of the number of living AIDS cases. This switch would have resulted in shifts of funding away from jurisdictions with a longer history of the disease and a higher proportion of deceased cases.

To ease these funding shifts, the CARE Act includes hold-harmless provisions under Title I and Title II that protect grantees from decreases in funding from one year to the next. Title I of the CARE Act also includes a grandfather clause for EMAs that guarantees once a metropolitan area has become an EMA, it will continue to receive funding under Title I even if its caseload drops below the threshold for eligibility.

The most recent reauthorization of the CARE Act in 2000 maintained these modifications, and it further specified that HIV cases should be used in funding formulas no later than 2007, as we have heard. HIV case counts have not been used to date to distribute funding under the CARE Act.

To assist the Subcommittee in its consideration of the CARE Act, my testimony provides our preliminary findings on some of the issues we are reviewing for the Chairman and other requesters. My remarks today will focus on selected provisions of the CARE Act. Specifically I will discuss: The impact of CARE Act provisions on the distribution of funds that is based upon the number of AIDS cases in metropolitan areas; the impact of the CARE Act's hold-harmless provisions and a grandfather clause on the distribution of funds; and the potential shifts in funding among grantees if HIV case counts had been incorporated in fiscal year 2004 funding formulas.

Our analysis shows that certain CARE Act Title I and Title II provisions related to the distribution of funds to metropolitan areas result in variability between the amounts of funding per case among grantees. As you will see in the figure, States that have EMAs within their borders receive more funding for estimated liv-

[1] The prepared statement of Ms. Crosse appears in the Appendix on page 59.

ing AIDS cases than those without EMAs because cases within EMAs are counted twice, once to determine Title I funding to EMAs and once again to determine a State's Title II grant. For example, States with no AIDS cases in EMAs receive about $3,600 per AIDS case. States with 75 percent or more of their cases in EMAs received about $5,000 per AIDS case, or as the Chairman noted, 38 percent more funding than States with no EMA.

If the total Title I and Title II funding had been distributed equally per AIDS case among all grantees, each State would have received about $4,800 per AIDS case.

Metropolitan areas that have been affected by the epidemic, but do not have the necessary numbers of AIDS cases to become EMAs, may qualify for funding as emerging communities under Title II. As the figure shows, the allocation of these grants is made by separating eligible jurisdictions into two tiers based on their reported numbers of AIDS cases. Because one-half of the total emerging communities grant award is allocated to each tier regardless of how many cases are in each tier, in fiscal year 2004, jurisdictions in one tier with a total of 15,994 cases received $313 per case, while jurisdictions in the other tier with a total of 4,754 cases received $1,052 per case.

The hold-harmless provisions under Titles I and II, and the grandfather clause for EMAs under Title I sustain the funding and eligibility of CARE Act grantees by guaranteeing either a certain percentage of previous years' funding amounts or an EMA's eligibility to receive funding. These provisions make it more difficult for CARE Act funding to track the most current distribution of the epidemic.

As this figure shows, Title I's hold-harmless provisions for EMAs has primarily benefited the San Francisco EMA, which received over 90 percent of the fiscal year 2004 Title I hold-harmless funding. San Francisco is the only EMA that has deceased cases factored into its allocation because it is the only EMA with hold-harmless funding that dates back to the mid 1990s when funding was based on the cumulative count of AIDS cases, living and dead. In essence, deceased cases are still being used to determine funding for San Francisco, with the result that the city's funding is equivalent to what an EMA with 84 percent more living cases would have received.

As you can see in the next figure, the grandfather clause in Title I maintained the funding for 29 or the 51 EMAs that became eligible for Title I base grants in the past. These EMAs, however, would not have qualified for Title I base grants in fiscal year 2004 based upon their case counts which were below the eligibility threshold of 2,000 reported AIDS cases in the last 5 calendar years. Four of these EMAs had fewer reported cases than any of the cities receiving emerging communities funding.

All States have established HIV case reporting systems, and the 2000 reauthorization of the CARE Act required that HIV cases be used in determining formula funding no later than fiscal year 2007. However, CDC, as we have heard, currently only accepts name-based case counts, the States shown in our figure in blue. Therefore, State reported HIV cases that used codes rather than names

would not be counted in allocating CARE Act funds if HIV case counts were used in funding formulas.

As shown in the figure in orange, 12 States, the District of Columbia and Philadelphia, Pennsylvania have some form of a code-based system rather than a name-based system. CDC does not accept the code-based data principally because methods have not been developed to make certain that a code-reported HIV case does not represent an individual already counted in another jurisdiction.

While we are aware of some of the limitations of HIV data, as an example of what might occur, we used two approaches to examine the potential impact of using HIV cases in addition to AIDS cases on fiscal year 2004 Title II base grant distributions.

The first approach reflects the data that would be used if funding allocations were based on the HIV and AIDS case counts currently received by CDC.

Under the second approach we used the same HIV and AIDS case counts as our first approach for the jurisdictions where CDC accepts HIV data, but supplemented these data with the HIV case counts collected by the other States and the District of Columbia from which CDC did not accept HIV data.

AS shown in this figure, for each approach we estimated the impact if funding was distributed equally per case, both without hold-harmless or minimum grant provisions, shown on the two figures on the left, and with such provisions, shown on the right.

Our analyses indicate that under either approach to including HIV cases, at most 14 percent of CARE Act Title II base funding would have shifted, with southern States being the primary beneficiaries. Some States, however, could have seen large increases or decreases. Changes in funding would be largely offset, at least initially, if the funding formulas included hold-harmless and minimum grant provisions.

In conclusion, the services provided under the CARE Act have filled important gaps in communities throughout the country, but as Congress reviews this Act, we believe it is important to understand how variable this funding can be. Today I have highlighted a few of the issues that are relevant to this review. For each or these issues, we found that the provisions of the CARE Act have impacted the extent to which funds have been distributed in proportion to the incidence of HIV and AIDS. It is clear that the level of funding available per case is quite variable, depending upon where an individual lives.

The way cases from EMAs are counted twice, the tiered allocation of funds to emerging communities, the hold-harmless provisions and the grandfathering of EMAs have all resulted in considerably more funding going to some communities than others with equivalent numbers of cases.

The inclusion of HIV cases in the funding formulas would also result in variable funding depending in part upon the type of reporting system used in each State.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other members of the Subcommittee may have at this time.

Senator COBURN. Thank you, Dr. Crosse.

I am going to recognize my Ranking Member and good friend for an opening statement, and then we will take up the questioning.

OPENING STATEMENT OF SENATOR CARPER

Senator CARPER. I appreciate the opportunity first of all to welcome our witnesses. I apologize for being delayed and missing at least the very beginning of some of the opening statements, and pleased that I had a chance to hear from each of you.

I think Senator Coburn as a physician has probably forgotten more about these issues than I know, so I come to this hearing really as an opportunity to learn. I understand that the Ryan White CARE Act was first enacted, in 1990. And Senator Lautenberg was there as a page. [Laughter.]

Senator CARPER. And he is still with us.

It is named after a very courageous teenager who struggled not only with AIDS but also against discrimination as we all recall, so there is fear and prejudice as well.

These days I think we have made a whole lot of progress. We have lived to see it both in terms of combating this stigma and in combating the disease itself. I think we will all agree that we have a good long ways to go. The CARE Act, nonetheless, has been one of the chief Federal programs in this fight against HIV and AIDS.

I think we can all agree that our goal in examining the Ryan White Act today is to ensure that Americans living with HIV/AIDS can get needed care and services.

The Ryan White program serves an estimated, I am told, 533,000 people each year, and it provides not only vital prescription drugs, but needed support services to help patients stay on those drugs and to adhere to a complex drug regimen.

My own State of Delaware has done, we believe, a good job of providing needed health services to those with HIV and AIDS. We have made quality health care a priority, and are fortunate to be able to offer a generous Medicaid program, a very generous AIDS drug program and a high-quality Ryan White services.

Our witnesses that we have heard from here today have been discussing a number of different issues, largely focusing on the funding of Ryan White. Since I believe this is a jurisdiction of this Subcommittee, and several of these issues that deal with variations in the level of funding and care around our country, we have been hearing, and we are going to hear some more about some of the States getting more funding than others, about some States having ADAP waiting lists while others are unable to serve everyone and so forth. I think it is imperative that we ensure that any living person with HIV or AIDS receives a high standard of care no matter where he or she lives, whether it is New Jersey or Delaware or Oklahoma.

However, I think it is important that we keep in mind several issues when considering the data that we are hearing today. Let me mention a couple of those. First, the Ryan White CARE Act on the whole is working. We have lengthened the time from HIV infection to the onset of AIDS. People are living longer and they are living healthier. We can always strengthen the program but I think we have done a fair job so far.

Second, as we consider whether we are appropriately distributing funding, I think we should ensure that we are looking at the whole picture. GAO has presented some various data today on the per case funding around the country and on ADAP waiting lists. However, we should consider a few issues, namely, whether per case funding is the best way to examine Ryan White funding distribution, and whether we can look at Ryan White funding in a vacuum. In every single State the burden placed on Ryan White depends on what percentage of the HIV/AIDS population is enrolled in Medicaid and how generous that State's Medicaid is. It depends on what percent of people with HIV/AIDS are enrolled in Medicare and what percent have private insurance.

So the needs of different areas of the country, both in terms of funding and needed services, are going to vary. I think it is important that we consider this whole picture finally.

If we determine that there are inequities, then we ought to seek to address them, but we should keep in mind that many of our cities, where over 70 percent of people with HIV/AIDS still do reside, have built up successful public health infrastructures to combat this disease, and we want to be careful not to jeopardize or dismantle those.

I hope the issues that are brought up here today can inform not only me, but the upcoming debate on reauthorization. Ryan White has always been a bipartisan issue, and I hope that this Congress in this year will continue that tradition, and we can work together with our friends in the House of Representatives to produce a bipartisan reauthorization package.

Again to our witness, thanks for coming.

And, Mr. Chairman, thanks for letting me give this belated opening statement.

Senator COBURN. Thank you, Senator Carper.

We have a vote on, and I think I will recess the Subcommittee so that we can go vote and come back. It will take us about 10 minutes, hopefully.

The Subcommittee stand in recess.

Senator LAUTENBERG. Mr. Chairman, may I ask before we go to adjournment, to be able to submit some questions to the witnesses in writing?

Senator COBURN. Absolutely.

Senator LAUTENBERG. And to include a letter written by myself and several other Senators from California and New York to Mr. Walker, who is the Comptroller General of the United States, regarding GAO studies?[1]

Senator COBURN. Without objection.

Senator LAUTENBERG. Thank you.

Senator COBURN. And we will stand in recess until we get back from the vote.

[Recess.]

Senator COBURN. The Subcommittee will come back to order.

I am going to start with some questions, and I think Senator Carper will be returning. We did put into the record questions that Senator Lautenberg wanted to have asked.

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[1] The letter to Mr. Walker appears in the Appendix on page 106.

Dr. Janssen, in your testimony you said CDC is moving from advising to recommending jurisdictions use name-based reporting. What is the practical impact of that change in terminology? Will CDC withhold financial resources, for example, if a jurisdiction does not follow CDC's recommendations?

Dr. JANSSEN. First, we have heard from a number of jurisdictions about CDC recommendations, jurisdictions that would like to move from code-based to name-based systems, and they felt that a stronger recommendation from CDC would help them be able to move through their State legislatures and through their regulatory processes to change their systems.

Senator COBURN. So that might mean if they heard from Congress about that, too, might be beneficial?

Dr. JANSSEN. I can only speak from a CDC perspective about that, but at least that is what we have been told by health departments. So it is a stronger recommendation than we had made in 1999. The reason for it is really several-fold. As many people have mentioned already, we do not currently include code-based data. The reason is that we have not completely even developed methods for evaluating code-based data within a State or even between States. We have completed, and just completed at the end of last year, a pilot evaluation of several code-based systems that gave us mixed results. Based on that, we are attempting to develop a full evaluation system of those code-based systems.

Senator COBURN. Tell me what mixed results means?

Dr. JANSSEN. Some States found that they were having trouble meeting the standards we published in 1999, and at least in one case in the pilot they did meet the standards, in addition which we think that—CDC works with the Council of State and Territorial Epidemiologists who develop lists of reportable diseases, and we felt that HIV should be, like other infectious diseases, reported by name and reported voluntarily by the States.

We do not intend to withhold funds from States that continue to collect data by codes. Even though we do note that in many cases this seems to be a cumbersome process, it also is more expensive, and at this point there are no data to suggest that code-based data collection systems are better than name-based systems.

The reason for code-based systems originally were based on very valid concerns from members of affected communities about potential discrimination and about potential non-public health uses of data.

Senator COBURN. I understand that. I understand the background on it. Well, given the fact that the law says name-based reporting, and they have about 18 months to do it, why would we not send a stronger signal to say: You need to be moving here?

Dr. JANSSEN. Well, I think this is a strong signal. I think the shift from an advisory condition to a recommendation is actually a very large move on the basis for CDC and for the Department, and I think that does signify a major shift, and I think there are a number of jurisdictions right now who are looking at how difficult it is to use code-based systems, and concerned, as Mr. Montgomery noted, about potentially losing Ryan White funds because of the use of code-based systems.

Senator COBURN. That is my whole point. If, in fact, the law says you will use HIV name reporting and, in fact, in his testimony, Mr. Montgomery said that the CDC will need to develop a methodology to establish estimates of HIV cases for these States. That is not what the law says. And I am not sure CDC has the authorization under the Ryan White Act to do that, because of what the law states, as the primary author of that bill in the year 2000. Is it your understanding that the law does not allow for that, and only counted cases of HIV disease reported to and confirmed by CDC? That is what the law says CDC will be acceptable for Federal funding. So is it clear to CDC that is what the law says?

Dr. JANSSEN. Absolutely. What we are doing is working—we feel very strongly that the best data are reported cases. For some purposes we have to use modeled estimates for data, but for this case, we feel very strongly that the best data are case counts of reports.

Senator COBURN. And we know that because that is a public health strategy that has worked in numerous other diseases, correct?

Dr. JANSSEN. Including AIDS.

Senator COBURN. Right. Let me refer to something—I keep wanting to call on you, Dr. Parham. I am sorry. Dr. Hopson talked about the decline in perinatal transmission of HIV. Why did that come about?

Dr. JANSSEN. It has come about because of the effectiveness of any antiretrovirals for preventing mother to child transmission, from the old 076 trial. And now what is happening more recently is that mothers are on HAART, and that even more effectively reduces transmission. AZT by itself cut it in half. HAART now reduces it to less than 2 percent.

Senator COBURN. What about the fact that affected mothers who are pregnant who are tested for HIV so we know their status?

Dr. JANSSEN. Right, that is also part of it. The first thing we have to have is the intervention, and then once we have that, we need to identify the people who benefit from that intervention, and in fact, as you pointed out, that is what getting people tested has done.

Senator COBURN. Actually, I would portend to you that it is reversed. You need to identify. Because what we did know before we had the 076 study and before we had HAART therapy, that if in fact we eliminated breast feeding from women that transmitted—we knew what the percentage was of transmittable disease in terms of pregnancy, and if in fact we eliminated breast feeding, and if we did a caesarian section. And we did some of the other things that lessened the disease.

So that is one of the things that kind of troubles me about this. Knowing the vectors and treating them with respect, but also knowing where the risk factors are has to become a complete part of our model.

The other thing I wanted to talk with you about, on names-based reporting, is that if States are going to be compliant for 2007 funding that would mean they need to start next month. Is that right?

Dr. JANSSEN. They would need to start as soon as possible.

Senator COBURN. How will they meet the requirements under the 2000 CARE Act if they have not started in July?

Dr. JANSSEN. We have been working with, and intend to continue to work with, health departments and provide as much support as we possibly can to enable them to meet the obligations that they have.

Senator COBURN. Is that something different than you told me before in terms of HIV name-reporting under the law?

Dr. JANSSEN. No. I think what we are doing is we are making a recommendation for name-based reporting, and we have been and will continue to work with States to develop the best systems that they can use.

Senator COBURN. All right.

Mr. Montgomery, has California conducted any evaluation of its HIV reporting system for accuracy and reliability?

Mr. MONTGOMERY. We have had insufficient funding to do a complete study of it. We have studied how closely we are adhering to CDC standards, and in most of the measures we are, except for the percentage that report Social Security numbers. But we believe our system is very accurate. It is also, as Dr. Janssen implied, very cumbersome, and it has been in operation for nearly 3 years, and we have only two-thirds of the prevalent cases reported, so it obviously has some challenges.

Senator COBURN. A California performance review recently found the State will risk losing up to $50 million annually in Ryan White CARE Act funds if the CDC does not confirm California's reported HIV cases for fiscal year 2007. California can prevent this loss if it converts its HIV reporting system to names-based AIDS reporting system. You have a names-based AIDS reporting system, correct?

Mr. MONTGOMERY. We do.

Senator COBURN. And are there difficulties with that reporting system?

Mr. MONTGOMERY. There are not.

Senator COBURN. All right.

Dr. Hopson, Mr. Montgomery and NASTAD have proposed requiring unobligated funds be redistributed back into the ADAP fund. This could result in $30 million more for ADAP next year, and most likely much smaller amounts in the years that follow. Can you comment on his proposal?

Ms. HOPSON. I have not see the NASTAD proposal, so, no I cannot comment at this time.

Senator COBURN. Can you provide for us the total amount spent by the CARE Act on planning activities for the past 2 years?

Ms. HOPSON. That I can provide. For the years in question, 2003 and 2004 in the Title I program, we spent $30.3 million for planning council support. This represents 2.4 percent of the Title I appropriation for those years.

In Title II the consortia spent $48.7 million on grantee planning and evaluation, on consortia needs assessment plan and evaluation activities, and that represented 2.3 percent of the Title III appropriation for those years.

And in the Title III program we have a planning grant program. We did not fund any planning grants in 2004, but we did fund five planning grants in 2003, and the amount was for $299,058, which is 0.07 percent of the Title III appropriation for those years.

Senator COBURN. OK, thank you. Do you believe that the priority of the CARE Act should first and foremost be to provide direct medical care and medication to Americans living with HIV/AIDS, regardless of geography, and only after that should other non-essential funds be used?

Ms. HOPSON. Yes, I do, and certainly the first principle that President Bush outlined was that we should focus the Federal resources, meaning the Ryan CARE Act resources, on life extending medical care such as antiretroviral therapy, doctors visits, and lab tests and so forth. These are the core services that many are talking about in terms of the CARE Act, so, yes, that is the first principle that the President has outlined and the way that we should look at prioritizing funding—prioritizing how we fund grantees in the Ryan White CARE Act.

Senator COBURN. Should unspent CARE Act funds then be redistributed to where there is a need?

Ms. HOPSON. That is another one of the President's principles that he has outlined, is that we need to have flexibility so that the Secretary of HHS would have flexibility to redistribute funds to the areas of greatest need or to target those funds, better target those funds.

Senator COBURN. Dr. Crosse, based on the charts that you put up there in terms of the disproportion—and I know there is some question about whether that accurately reflects care given with all the other models of care and organizations that have been there—is there any recommendation that you can make to us that would help us redistribute fairly under Title I, Title II, Title III and Title IV—given the least harm to those in place, organizations that are offering services, but yet create a fairer and more equitable distribution of funds based on care and outcome?

Ms. CROSSE. Well, I do not think that we could give you a simple recommendation on what to do. Among all of the things that we have examined for this testimony, we found all these provisions that are leading to variability in the funding, and that are not necessarily counterbalanced by other provisions that we have not discussed today.

Clearly, some of the provisions I think are more distorting of the funding than others. Things such as minimum grant provisions may be necessary, for example, for States with very small numbers of cases in order to be able to maintain any sort of a program at all. But we certainly have some concerns about some of the hold-harmless funding, whether that should be maintained with as gradual a decline as it has been in the previous reauthorizations, or whether it is essential in all of these programs at all.

As you correctly pointed out, the hold-harmless funding for the EMAs primarily benefits one. If that hold-harmless provision were eliminated, depending upon the assumptions you make, at most we believe three EMAs might lose money. The other 48 of the 51 EMAs would gain money, including 18 of the 21 that are receiving hold-harmless funding. So there clearly are some distortions in the way that the current bill has played out.

It does not take into account necessarily the variability in need across States, which is a much more complex question, but clearly the funding provided by the Federal Government through this pro-

gram is not in proportion to the prevalence of the disease as it currently stands.

Senator COBURN. Dr. Janssen, I am going to enter into the record an article that was place in the Atlanta paper by *Associated Press*,[1] based on the CDC's press release in terms of your new data. And I have one or two questions. Of that number, what percentage are unaware of their HIV status?

Dr. JANSSEN. We estimate that about 25 percent of people living with HIV are unaware of their HIV status.

Senator COBURN. So 250,000 people in this country are unaware of their HIV status.

Dr. JANSSEN. Approximately, yes.

Senator COBURN. Which means they are going to rapidly progress over the next 8 to 10 years. They are also going to infect others. And what is the CDC's position on how we approach that 250,000 people?

Dr. JANSSEN. In April 2003, we launched Advancing HIV Prevention. A large part of that is focusing on increasing testing, availability of testing, and recommending testing. The first part of that is routine offering in medical care settings. We will be coming out with new guidelines at the end of this year based on making recommendations about more routine testing and screening in health care settings. Those should be available by September or October of this year.

We also have been encouraging and stimulating the use of rapid testing for outreach purposes. We have an article that will be published tomorrow in the Morbidity and Mortality Weekly Report, on a model that we are calling Social Networks, where people who are living with HIV recruit friends, sex partners, drug-using network partners to come in and get tested, people who they think may be infected who do not know if they are infected. We are reporting those data tomorrow which showed that about 5.7 percent of people recruited in nine demonstration projects that we funded tended to be new HIV diagnoses. That is about 2½ times what we routinely get out of our counseling-testing system.

Senator COBURN. Is there any concern on your part that this level incidence of HIV may be getting ready to bump up from 40,000 cases?

Dr. JANSSEN. I think that as we look at a variety of different pieces of data to try to triangulate on what that real number is, I think my major concern is that number is not going down. The increase we are seeing in HIV reports among men who have sex with men are of concern. What we do not know is whether they reflect new infections or whether we are seeing more testing.

Because of Advancing HIV Prevention, I am anticipating we may see a bump in HIV reports because of increases in diagnoses, so that is going to be confusing. Our HIV surveillance, incidence surveillance system is being implemented right now. We anticipate having our first national HIV incidence estimate ready by mid fall of 2006.

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[1] Article from the Associated Press appears in the Appendix on page 136.

Senator COBURN. I want you to look at this chart.[1] We drew this chart up just so you can see the disparity that is happening through Ryan White funding now. I think there are six other EMAs in California that suffer directly because of the excess protections that are afforded San Francisco. That is all of the EMAs in the country. And if you look at that, what you can see is a significant disproportion, so it is pretty hard to defend—even though there are wonderful programs in the San Francisco EMA, it is pretty hard to defend this kind disproportion funding. Ideally we would like to see it higher for everybody, but the point is, is the CARE Act going to have to be changed to straighten that out, and in a gentle way that does not disrupt the institutional structures that are there?

In 2003, you launched the new initiative, Dr. Janssen, Advancing HIV Prevention, with four key strategies that emphasized routine HIV testing. How many States have adopted those strategies?

Dr. JANSSEN. We have not done a systematic assessment of the number of States that have adopted strategies. However, in the new Health Department Cooperative Agreement, which the funding began January 2004, we did put some directives into the language in that announcement. The first was that community planning groups would prioritize people living with HIV as the No. 1 priority group for prevention interventions in their jurisdictions. In addition to which we encouraged use of changing testing, looking at where they are getting higher yields, moving money from one place to another in terms of getting better yields in terms of testing.

In 2003 and 2004, we purchased 700,000 rapid tests for use in out of medical care settings. In 2005 we spent $2.3 million on the oral fluid test, again for increasing access to testing away from medical care settings, out in the community.

In addition, for community based organizations we have in the new program announcement that was funded June 1 last year, about two-thirds of the funds—I am sorry—about 60 percent of the funds in that new program announcement were all directed Advancing HIV Prevention activities.

Senator COBURN. So you have markedly increased rapid testing. On the STD clinics that you fund through prevention, are these recommendations in terms of the Advancing HIV Prevention incorporated in those grants, in that money for the CDC funded STD clinics?

Dr. JANSSEN. For HIV testing and activities in those STD clinics, yes.

Senator COBURN. So they are following this advancing program.

Dr. JANSSEN. They are. And what we will be encouraging more this year, some clinics have developed an opt-out approach to testing. There is an example in Texas actually where they have been doing this for a number of years, and we are looking at other STD clinics as demonstration projects later this year to actually implement opt-out testing in those settings.

Senator COBURN. Mr. Montgomery, I want to give you a chance to respond to anything that we might have said about this or any other area. I do not want you to feel cut off as you leave here, and

[1] The chart entitled "EMA Funding Amounts per AIDS Case, fiscal year 2004," submitted by Senator Coburn appears in the Appendix on page 109.

I do look forward to working with you to solve the problems in California because there is a concentration, but just as important is solving the problems here in Washington, DC with the unmet need that is not being met. And if you have anything you would like to say, I would love to hear it.

Mr. MONTGOMERY. Thank you for the opportunity. Yes, I have a couple things I would like to say, and one is I wanted to clarify the earlier discussion about the need for estimated cases to incorporate HIV in 2007. I was talking about both names-based and code-based reporting, but the systems that are immature is really what I was addressing.

I would like to go back to comments I made in my testimony, and say that I think that the discussion of using AIDS cases as a measure of equity is a very complicated issue. I appreciate that in your question to GAO, you included Title III and Title IV and Part F in that formula, and I would really encourage you to ask GAO to look at all titles and how that affects the per-AIDS case formula.

In California's case if you use Title I and Title II, California is above average for the per-AIDS case measure. If you add in Title III, IV and Part F, California is below average in terms of the average expenditure per case.

Senator COBURN. That is a great challenge. We will ask it.

Mr. MONTGOMERY. And I think that is a measure of the reauthorization in 2000 that you worked so hard on, there was language put in there to encourage HRSA to direct Title III funds to non-EMA areas, and that has had an impact, and I congratulate you on putting that in the language.

And I would also encourage you to discuss with GAO looking at the effect of using an estimated living AIDS case formula, which inherently underestimates in some jurisdictions the impact of the epidemic. For California it underestimates our epidemic significantly, and it underestimates our living AIDS cases by 30 percent, which is a profound effect.

Senator COBURN. But that is where we find ourselves in trouble. We are afraid to go out and test.

Look, this is a treatable controllable epidemic. It is controllable. If we will all get tested and all get treated, we can break the back of the AIDS epidemic as you wanted to do, Dr. Janssen. But the fact is, nobody has the courage to stand up and say we need to treat this. We need to go after those people that are going to discriminate on the basis of this disease, and then we need, as a Nation, to stop this. The best HIV prevention is to test everybody and know where they are so that they, first of all, can be treated early with life saving drugs so they do not progress, and so they do not infect anybody else.

Just to give a little history, when I was here in 1996, ACOG refused to recommend prenatal testing of pregnant women for HIV, refused adamantly. Well, you cannot treat pregnant women with HIV if you do not know their status.

Now that we are following a public health strategy on HIV for pregnancy, what have we seen? We have seen a 76 percent reduction in infection. That means people are going to have to get treated, whereas before that, they were not being treated, and their life would be limited.

So my caution is, is for us all to take our biases out of the room and say, "How do we treat this disease as a Nation?" We can make a big difference next year if we all will just say, "Let us do the right thing. Let us test. Let us go after this disease. Let us not let one innocent person, one individual in this country get this disease." We could do that. But it takes all of us walking from all stripes of life, every angle, every philosophy, working together and say the enemy is not each other, the enemy is the disease, and we need to go after the disease.

Anybody else want to offer any comments? Dr. Crosse.

Ms. CROSSE. Yes. I would just, in response to Mr. Montgomery, let him know that as part of the work we are doing for the Chairman and the other requesters, we are examining other portions of the CARE Act.

Senator COBURN. I want to thank each of you. You will be receiving some extra questions from us in written form. We would love to have you send those back to us within 2 weeks.

And I will give Senator Carper an opportunity to ask questions because I was just about ready to dismiss the panel.

Senator CARPER. I am glad you are still here. I have just one question. I think I am going to ask Dr. Janssen, if you would, to respond to this for me, please. I think you spoke to this in your testimony, but I want to come back and revisit it.

It seems that most stakeholders support distributing Ryan White funds based on the number of HIV cases in an area instead of the number of AIDS cases in a particular area, at least that is my sense. However, I am concerned that a number of States, including my own State of Delaware, may be in danger of losing a large portion of our funding because CDC will not accept the type of HIV data that we collect and that some other folks collect. I think your testimony notes that name-based reporting has been shown to—and I think these may be your words in your testimony—achieve high levels of accuracy and reliability. But you do not seem to be saying that code-based reporting cannot be improved or made more accurate.

In fact, the Institute of Medicine did a study, a study I think you reference in your testimony. They recommended that CDC accept HIV data from all States, including those that have code-based systems. The Institute of Medicine has also said that duplicate cases could be estimated and that procedures could be developed to adjust for this.

What I would just ask, is CDC pursuing this option? Should I be worried that in 2007 CDC will not accept my State's data and maybe the data of some other States as well?

Dr. JANSSEN. In terms of coded identifiers, we have conducted an evaluation, a pilot evaluation last year which ended early this year, and which I had told Senator Coburn that showed mixed results in terms of how some of these codes worked. In some areas they worked, in some not, at least in a pilot.

We still are in the process of developing a full evaluation of coded identifiers. So even that effort has not been developed. It is possible to develop it and we are working on it.

A bigger concern, however, is de-duplication across jurisdictions, from one State to another. In an area, such as Maryland, Wash-

ington, DC, and Virginia, up to 20 percent of cases could be reported from more than one jurisdiction. So there is a lot of overlap. Nationwide it is about 2 percent I believe, where——

Senator CARPER. So you could have one person whose case is being reported in the District, and the same person whose case is reported in the State of Maryland?

Dr. JANSSEN. In Maryland, yes.

Senator CARPER. And would you say that is unusual?

Dr. JANSSEN. That is unusual. It is more like 2 percent nationwide. I have to check with Dr. McKenna, who is our surveillance——

Senator CARPER. Where is Dr. McKenna?

Dr. JANSSEN. Right here. So it is 4 percent for AIDS and 9 percent for HIV. So 20 percent is pretty high. The problem is when you have different codes across those boundaries, it is virtually impossible to de-duplicate cases.

We have talked about this a fair amount, and we believe from an academic perspective conceptually one might be able to develop such methods, but practically, we are not convinced it is possible. So that, I think, is probably for us—and was mentioned earlier—the most difficult problem is trying to de-duplicate cases across State boundaries.

There is also a problem within States with codes, and we have not—it is not proven; it is a conceptual problem—and that is in jurisdictions it is not just the HIV test that is reported to the health department. CD–4 counts are reported, viral loads are reported. So someone in care might be reported to the health department 7, 8, or 10 times a year. Over years they could be reported 40 or 50 times to the health department. If they go to different providers and the code is changed in just one way, they would be counted multiple times.

So that becomes a problem where you have people who are in care reported multiple times, and then you have somebody who is just diagnosed and not in care. And so they end up not being represented equally with the people who are in care. So that is a potential problem with codes even within a State.

So your question was, can codes be made to work better than names or even as good as names? At this point we have no evidence that codes are better than names. We have evidence, as Mr. Montgomery mentioned, in California, for example, where actually the system is fairly cumbersome and difficult and expensive.

So those are some of the reasons that we are recommending that States use name-based systems.

Senator CARPER. Anybody else on the panel want to take a shot at what I just asked? Mr. Montgomery, did you?

Mr. MONTGOMERY. We now have 3 years of experience of operating a codes-based system and it is an extremely complicated system. We think it is very accurate. But we think that it is, as Dr. Janssen said, very expensive, and has caused backlogs within the health department, so we are concerned about our ability to carry out a code-based system.

Senator CARPER. OK. A quick follow up, if I could, Dr. Janssen. You mentioned a pilot study that was conducted earlier. When was that, this year, last year?

Dr. JANSSEN. It was finished at the end of last year in terms of data collection. Analysis was done in the spring.

Senator CARPER. And you mentioned that there is a more comprehensive evaluation. Is it under way or planned?

Dr. JANSSEN. Being developed.

Senator CARPER. And when would you expect that to be done?

Dr. JANSSEN. The end of next year, 2006.

Senator CARPER. Our thanks to each of you. Thanks for joining us. And I learned a new word today, de-duplicate. [Laughter.]

This is a good job we have, we learn something every day. That is my new word.

Senator COBURN. I would just like unanimous consent to enter this article into the record.[1] The *Los Angeles Times* reported that county health officials are being allowed to peruse medical records in California, complete with patient names, to ensure the cases are being reported.

If it is true, that would undermine the whole concept of a code-based system. The fact is, as California right now, through your office, is recommending that it is going to have to spend $500,000, I believe, is to formally evaluate the system and determine whether the system meets CDC's minimum guidelines.

We are running short on time, and we know what the law says. The message ought to be, get a names-based system since the names-based system on AIDS is working and not being violated, and we know it works, and we know we are going to have better success. And you are going to save a lot of money, and that money that you save is going to treat a lot of folks.

Thank you each for being here.

[Whereupon, at 4:21 p.m., the Subcommittee was adjourned.]

[1] The article from the *Los Angeles Times* appears in the Appendix on page 231.

APPENDIX

PREPARED STATEMENT OF SENATOR AKAKA

Thank you, Mr. Chairman, for having this hearing today and allowing me to address the Subcommittee regarding the effectiveness of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act.

The Centers for Disease Control and Prevention (CDC) announced that as of the end of 2003, more than a million people in the United States were estimated to be living with HIV. This bleak statistic is a return to levels experienced in the 1980s. The HIV/AIDS epidemic is growing among traditionally under-served and hard-to-reach populations. In my home state of Hawaii, as of December 31, 2004, there were 2,779 people infected with HIV or who have AIDS, as reported by the Department of Health. Of that total, 19 percent were Asian/Pacific Islander, 11 percent were Native Hawaiians, 6 percent were Hispanic and 5 percent were African-Americans. It is estimated by Hawaii's STD/AIDS Prevention Branch that there are an equal number of people infected, but who do not know it. A growing number of these reported cases are among Native Hawaiian and Pacific Islanders.

People are living longer with HIV. However, the rate of infection remains at unacceptable levels. Meanwhile, the President's proposed budget has not adequately funded the CARE Act. While funding may be described as level, the number of people living with the disease is growing. This means fewer dollars are available to help people in need. If this trend continues, we will see more sick people not receiving the care they so desperately need to stay alive, which is why we must increase funding for the CARE Act. It is frustrating to me to see funding remain level, while demand grows for the vital services that the CARE Act provides.

Mr. Chairman, as the number of Americans living with HIV crosses the one million mark, the CARE Act represents yet another vital Federal health care program that is not receiving adequate funding. Increasing funding for the CARE act will expand health care services for HIV positive/AIDS patients, to eliminate wait lists for AIDS drug assistance programs, to provide housing for those in need, and to ensure that women, children and families impacted by HIV/AIDS receive the adequate care and counseling they need. We know that getting people into treatment early slows the decline of their immune systems and saves money by allowing people to continue to work.

At the same time, we must remain diligent in our prevention message. Governments, at all levels, must redouble their prevention efforts, especially in minority communities because the epidemic continues to grow disproportionately among people of color, women and young people. Also, access to quality health care services for all persons with HIV/AIDS, regardless of geographic location, needs to be a priority.

Mr. Chairman, the need to provide health care services for HIV positive and AIDS patients continues to grow. Again, thank you for calling today's hearings. I look forward to our witnesses' testimony.

Testimony

Before the Senate Homeland Security and Governmental Affairs Subcommittee on Federal Financial Management, Government Information, and International Security

United States Senate

Domestic HIV/AIDS Surveillance: Current Trends and Status of HIV Reporting

Statement of
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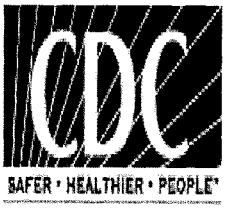
U.S. Department of Health and Human Services



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Introduction

Good afternoon Mr. Chairman and Members of the Subcommittee. My name is Robert Janssen and I am the Director of the Divisions of HIV/AIDS Prevention at the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to discuss current trends in HIV/AIDS in the United States and the status of state HIV surveillance systems.

We are now in the third decade of the HIV/AIDS epidemic. To date, HIV has claimed the lives of more than 22 million people worldwide. In the United States, more than 500,000 people have died of AIDS. The number of new HIV infections annually has declined from more than 150,000 in the late 1980s to an estimated 40,000 a year today. What is more difficult to measure, however, are the countless Americans who have been spared from infection through prevention efforts implemented nationwide. While cases of disease can be counted, it is impossible to count what didn't happen, namely, cases averted.

In addition to the dramatic declines in the occurrence of new cases since the beginning of the epidemic, the HIV/AIDS epidemic has changed in other important ways. Initially, it primarily affected whites, but today the majority of those affected are people of color. Racial and ethnic minorities are disproportionately at risk for and affected by the HIV/AIDS epidemic. The epidemic also continues to have a great impact on men who have sex with men (MSM).

Dramatic decreases in mother to child HIV transmission (perinatal transmission) are one of the great success stories of HIV prevention. Since 2000, CDC estimates that 280-370 HIV-infected infants are born in the United States each year -- a substantial

reduction from the 1,000 to 2,000 perinatal HIV cases estimated to have occurred each year in this country in the early 1990s. These declines are due to multiple interventions, such as routine voluntary HIV testing of pregnant women, including the use of rapid HIV tests at delivery for women of unknown HIV status, and the use of antiretroviral therapy by HIV-infected women during pregnancy and infants after birth. We remain concerned about perinatal HIV transmission and reducing perinatal transmission is one of our key prevention goals. We continue to work to further decrease perinatal transmission by promoting active case management for high risk women, routine opt-out testing, and the use of rapid tests at labor and delivery for mothers whose status is unknown.

We also have seen declines in the number of HIV and AIDS cases attributed to injection drug use. For example, the number of AIDS cases attributed to injection drug use has declined by about 15 percent from 1999 to 2003.

HIV/AIDS Trends

At the National HIV/AIDS Prevention Conference held in Atlanta, Georgia last week, CDC announced that there are now an estimated 1,039,000 to 1,185,000 people living with HIV/AIDS, up from the 850,000 to 950,000 previously reported. Due to more effective treatment, people are living longer and healthier after a diagnosis of HIV. Despite the growing pool of persons capable of transmitting the virus, the number of persons becoming newly infected each year has remained constant over the last 10 years, at approximately 40,000 new infections per year. (See Figure 1, HIV Infection Incidence and Prevalence, by Year, 1977-2003, United States.)

Of great concern to us is that approximately 25 percent of those infected with HIV do not know they are infected. We believe that infections transmitted from this group

account for more than half of new HIV infections each year, underscoring the rationale for our substantially increased efforts to reach at-risk communities with HIV testing services. Knowledge of one's HIV infection can help prevent the spread of HIV to others. When people know their status they are more likely to protect their partners from infection.

Trends in Estimated HIV Diagnoses

CDC's analysis of trends in HIV diagnoses includes all new HIV diagnoses, with or without an AIDS diagnosis, in the 32 states that have conducted confidential, name-based HIV/AIDS case reporting for at least four years. Between 2000 and 2003, 125,800 people were diagnosed with HIV infection in these 32 states. During 2000-2003, the overall rate of HIV diagnoses (i.e. the number of diagnoses per 100,000 population) remained relatively stable (19.5 in 2000 and 19.7 in 2003). However, sharp racial disparities continue to exist. Rates of HIV diagnoses among African Americans are significantly higher than among other racial and ethnic groups.

Looking at trends by risk, the annual diagnoses among MSM increased 11% during this four-year period, with the largest increase occurring between 2001 and 2002. MSM continue to constitute a substantial proportion of HIV cases—44% of cases in the period from 2000 to 2003. The increase in HIV diagnoses among MSM may be linked to a rise in use of crystal methamphetamine (crystal meth) among MSM. Crystal meth, a powerful, illicit drug that can reduce inhibitions, has been associated with high-risk behaviors and sexually transmitted diseases in multiple studies.

The annual number of diagnoses associated with high-risk heterosexual contact remained roughly stable during 2000-2003; new diagnoses associated with injection drug use declined slightly.

In 2003, the highest rate of HIV diagnosis was among African American males (103.4 per 100,000 population), with a rate almost seven times that of white males (15.2) and nearly three times the rate among Hispanic males (40.4) The rate of HIV diagnosis among African American females in 2003 (53 cases per 100,000 population) was more than 18 times higher than among white females (2.9) and almost five times higher than among Hispanic females (10.9). Among American Indians/Alaska Natives, the rate of HIV diagnosis among males (15.6) was slightly higher than the rate among white males; the rate among females (6.4) was twice the rate of white females. But studies show that cultural, socioeconomic, and health-related factors, in addition to barriers to risk reduction, may drive the HIV epidemic in communities of color.

Trends in AIDS Diagnoses and Deaths

AIDS cases and deaths, reported from all U.S. states and territories, continue to provide a valuable measure of the impact of the disease in various areas and populations. Data on the number of new AIDS cases provide us with measures of late stage disease, but are not reflective of the entire HIV epidemic. HIV progresses to AIDS in an untreated person in approximately 8 to 10 years, and even longer for persons receiving treatment. The number of persons developing and dying of AIDS after the introduction of highly active antiretroviral therapy dropped dramatically until 1998. Since then, the number of persons developing and dying from AIDS has remained relatively constant.

African Americans continue to be most severely affected by AIDS. In 2003, rates of AIDS cases were 58.2 per 100,000 among African Americans, 20.0 among Hispanics, 8.1 among American Indian/Alaska Natives, 6.1 among whites, and 4.0 among Asian/Pacific Islanders.

Trends in Persons Living with AIDS

From the end of 1999 through the end of 2003, the number of persons in the United States who were living with AIDS increased from 311,205 to 405,926 – an increase of 30%.

State HIV surveillance systems

CDC is responsible for ensuring the integrity of the national HIV/AIDS surveillance system to accurately monitor the epidemic in the United States. CDC also provides funding, technical assistance, and coordinates activities with states to aggregate data that comprises the national system. As with other diseases, individual state governments have authority for statutory and regulatory issues for HIV/AIDS reporting and data protection, including the decision as to what type of system will be used for disease reporting, such as name-based or code-based. Except for HIV, all other reported infectious diseases, including AIDS, are routinely reported to states using name-based reporting systems. States remove names before submitting the data to CDC.

Since the beginning of the epidemic, AIDS surveillance has been a cornerstone of national, state, and local efforts to monitor the scope and impact of the HIV epidemic. AIDS surveillance data, however, no longer accurately describe the full extent of the epidemic, as effective therapies slow the progression of HIV disease. Since 1999, CDC has advised states to conduct HIV reporting using the same name-based approach currently used for AIDS surveillance nationwide. Currently, 38 states and 5 territories have adopted name-based HIV reporting. Seven states, the city of Philadelphia, and the District of Columbia, have code-based reporting, and 5 states have name-to-code reporting. (See Figure 2, Current Status of Implementation of HIV Infection Surveillance, January 2005.) In the 14 areas using codes, 13 different codes are used.

Except for HIV, all other reported infectious diseases are routinely reported to the states using name-based reporting systems. It is important to note, for confidentiality purposes, that the CDC does not receive the names of individuals. This information resides at the state level.

Because all states do not use a uniform, name-based approach to HIV reporting, there are some limitations of the current, national HIV reporting data. These limitations include:

- National data on HIV diagnoses are not representative of some high morbidity areas, such as California, whose data are not included in the national dataset.
- Despite a growing number of states with quality systems, the staggered implementation of HIV reporting means HIV data at the national level is currently less accurate than AIDS data at the national level.

In 1999, CDC published a set of performance standards for HIV reporting systems. CDC reports HIV infection data only from areas conducting confidential name-based reporting because this reporting has been shown to routinely achieve high levels of accuracy and reliability. Confidential name-based surveillance systems have been shown to best meet the necessary performance standards. Studies have also shown that implementing code-based and name-to-code systems are more expensive to implement than confidential, name-based systems. And currently, only confidential name-based HIV reporting, integrated with AIDS surveillance data, can be used by states to identify and remove cases that are counted in more than one state (a process called de-duplication) before they are reported to CDC's national surveillance database.

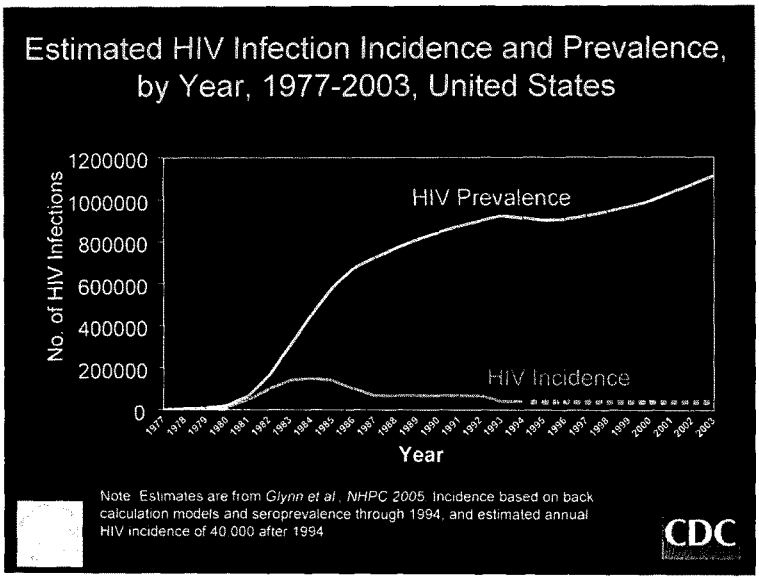
The last Ryan White CARE Act reauthorization called for an Institute of Medicine study of states' HIV surveillance systems and their adequacy and reliability for the purpose of using such data as the basis for CARE Act formula grant allocation. The reauthorization also called for the Secretary to make a determination regarding the use of HIV data for CARE Act formulas. The Institute of Medicine issued a report, *Measuring What Matters*, on allocation, planning and quality assessment for the Ryan White CARE Act. Based on the report findings, in June 2004, the Secretary of HHS determined that "HIV data not be used for purposes of making formula grants under Titles I and II of the Ryan White CARE Act, and that estimated living AIDS cases continue to be utilized until such time as high quality HIV data are available nationwide."

To reach the goal of nationwide, high-quality HIV data, CDC is moving from "advising" to "recommending" jurisdictions use name-based HIV reporting. We

continue to work closely with the states to help them adopt and implement high quality HIV surveillance systems. Having all states collect HIV information in the same manner will ensure that the nation has reliable and valid data to monitor the scope of the epidemic; plan for and evaluate prevention, care, and treatment programs; and focus those programs on persons most at risk.

Thank you again for this opportunity. I will be pleased to answer any questions.

Figure 1


Estimated HIV Infection Incidence and Prevalence, by Year, 1977-2003, United States
No. of HIV Infections
1200000
1000000
800000
600000
400000
200000
0
HIV Prevalence
HIV Incidence
1977
1978
1979
1980
1981
1982
1983
1984
1985
1986
1987
1988
1989
1990
1991
1992
1993
1994
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1998
1999
2000
2001
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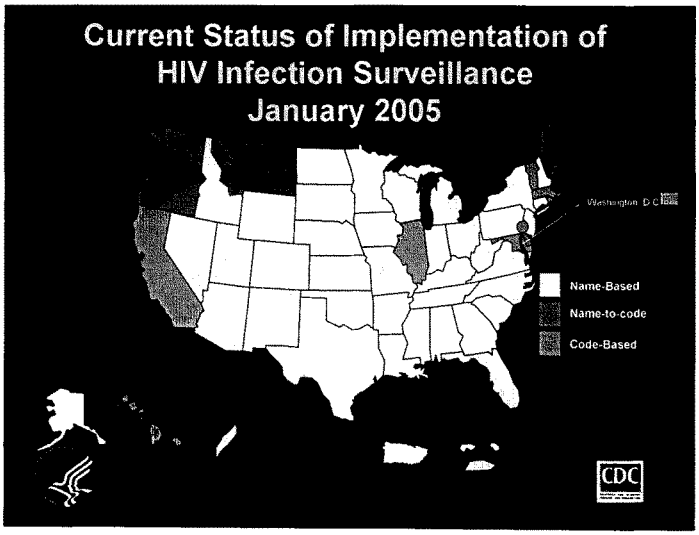
2003
Year
Note Estimates are from Glynn et al, NHPC 2005 Incidence based on back calculation models and seroprevalence through 1994, and estimated annual HIV incidence of 40,000 after 1994
CDC

Figure 2


Current Status of Implementation of
HIV Infection Surveillance
January 2005
Name-Based
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Before the Committee on Homeland Security and Governmental Affairs
Subcommittee on Federal Financial Management, Government Information, and International Security
"Domestic HIV/AIDS Care Programs"
June 23, 2005

Mr. Chairman, Members of the subcommittee, thank you for the opportunity to meet with you today on behalf of the Health Resources and Services Administration (HRSA) to discuss the programs of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act. We appreciate your continuing support, and that of your colleagues, for CARE Act programs. Your interest in CARE Act services is certainly welcome, given the state of today's HIV epidemic as described by the CDC.

The Ryan White CARE Act is the centerpiece of our domestic response to care and treatment needs of low income people living with HIV/AIDS. Currently funded at $2.1 billion, it provides primary health care, life saving medications, and support services to individuals who lack health insurance and financial resources to provide for themselves. On two occasions, including his most recent State of the Union Address, President Bush has addressed the importance of this program and has called for the timely reauthorization of the Ryan White CARE Act.

Since its last reauthorization we have been able to provide anti-retroviral treatment, primary care, and support services to over half a million people annually in the United States, Puerto Rico, the Virgin Islands and pacific basin. Fifty percent of these

individuals lived below the Federal Poverty Level, less than 10% had any private insurance, and less than 30% were enrolled in Medicaid. In 2002 almost half of Ryan White clients were African-American. The Ryan White CARE Act programs have provided important benefits to these populations. Overall AIDS mortality is down and lives have been extended with HIV/AIDS medications purchased through the AIDS Drug Assistance Program (ADAP). Pregnant women have been provided with care that has allowed them to give birth to children free from HIV infection, and thousands have received support services that have allowed them to access and remain in health care.

Although we are making progress in providing services to people living with HIV/AIDS, the epidemic is not over and will be in need of our continuing attention for some time to come. The President and the Secretary understand the dynamics and severity of the epidemic and they are committed to ensuring the Department's HIV/AIDS programs are as effective as possible in preventing infection and treating those who become infected. During the past five years we have recognized that, as essential as the CARE Act has been to serve Americans living with HIV/AIDS, it is an imperfect instrument in need of revitalization. Despite record levels of funding we continue to face waiting lists for life-saving drugs through the ADAP program and there are marked disparities in access to quality medical treatment across the country. As minority populations are increasingly and disproportionately impacted by HIV/AIDS, changes to existing systems of care designed for an earlier epidemic are increasingly urgent. We are challenged as never before to make sure that Federal funds are directed where they are most needed and used for the most vital purposes

President Bush has laid out three principles for the reauthorization of the CARE Act: First, that we should focus Federal resources on life-extending medical care such as anti-retroviral drugs, doctor visits, and lab tests – core services that are critical to maintain the health and well-being of people living with HIV/AIDS; second, that we provide greater flexibility so that CARE Act resources can be targeted to areas of greatest need; and third, that we ensure accountability in all that we do.

Current State of the Disease

Based on new CDC data, it is estimated that there are between 1 million and 1.2 million people living with HIV disease in the United States. Approximately 40,000 new HIV infections and over 18,000 AIDS related deaths occur per year. Of those living with HIV/AIDS disease, 74% are male and 47% are African-Americans while 34% are White and 17% are Hispanic.

In addition to challenges related to poverty and lack of adequate health insurance, individuals living with HIV disease commonly face other problems. About 22% of those with HIV/AIDS were infected through injection drug use. An estimated 20%-50% of people living with HIV/AIDS suffer from severe mental illness both related and unrelated to their infection and co-infection with hepatitis B and C is an increasing problem.

Current State of the CARE Act

The CARE Act, funded at approximately $2.1 billion in FY 2005, funds primary health care and support services for individuals living with HIV disease who lack health

insurance and financial resources for their care. Each year, the CARE Act programs, primarily through grants to States, metropolitan areas, providers and educators, reach more than half a million underserved persons - more than half of those living with HIV/AIDS in the United States. Since AIDS was first recognized, the pattern and treatment of HIV disease have shifted. We now can now strive to manage HIV/AIDS as a chronic disease.

More than 2,700 providers funded by the CARE Act programs are providing primary care and treatment and are building networks with other public and private providers to expand the response to the epidemic. Innovative outreach programs and community-based points of entry, such as public health, faith-based, social service and substance abuse treatment organizations, help to extend CARE Act services to hard-to-reach and at-risk populations.

Since the initiation of the CARE Act programs in 1990, perinatal transmission of HIV has declined dramatically. Less than 2% of all CARE Act HIV-positive clients are children age 12 or younger due, in large part, to the advances in prevention of perinatal transmission. The CDC reports that, in 25 states with long-standing confidential name-based HIV reporting, cases of HIV/AIDS in infants born to HIV-infected mothers have declined 74% over the 10 year period from 1994 to 2003.

Access to antiretroviral therapy for the CARE Act population has been expanded through the cost-saving mechanisms being used by individual State AIDS Drug

Assistance Programs and other discount programs. Antiretroviral therapy has led to longer, healthier lives for individuals living with HIV and AIDS. As a result, almost one third of the CARE Act population is age 45 or older.

ADAP, which provides funds to States to purchase life-saving medications, is the single largest CARE Act program because of the high cost of medication and the growing number of people living with HIV/AIDS. In FY 2005, HRSA distributed in excess of $787.5 million in ADAP funds to States, and the FY 2006 President's budget request includes an increase of $10 million. The ADAP program reaches approximately 90,000 people every month. The program is State-defined and thus differs in eligibility criteria and formularies from State to State.

The epidemiology and treatment of HIV has shifted in recent years to a more chronic disease model requiring a changing continuum of services to support this model. This shift and the success of new treatments has resulted in longer life spans and an overall increase in the demand for care and related drug treatments.

Going Forward

The greatest challenge is reaching people who have nowhere else to turn - especially as HIV/AIDS prevalence, health care costs, and the burden of HIV among the uninsured and underinsured increases. Resources are likely to become more and more strained as the CARE Act's outreach efforts coupled with CDC's prevention initiatives continue to successfully identify individuals living with HIV disease.

These newly infected individuals are more likely to be low-income, to be minority, and to have complex co-morbidities such as mental health and substance abuse problems. Many will live in rural areas. Strengthening health care and community organizations capable of serving these populations will be an increasingly important role in the CARE Act's next decade.

Mechanisms to allocate funds must be cognizant of these changes: "hold harmless" provisions, formulas based on AIDS rather than HIV, and allowing funds that have not been put to work in a timely manner to "roll over" or revert to the Treasury rather than giving DHHS the necessary flexibility and authority to reprogram resources to communities in need, must be re-engineered.

We take great pride in the advances in care and support for people living with HIV/AIDS that have been made by the CARE Act programs over the last 15 years. We are thankful for your help and that of the dedicated providers and communities all over the Country. However, we are humbled by the significant challenges that remain to reach people living with HIV/AIDS who have nowhere else to go for care in an age of increasing HIV/AIDS prevalence, increasing health care costs, and a growing burden of HIV among the uninsured and underinsured. We will soon be releasing an expanded set of policy points based upon President's principles. We intend these to serve as guideposts for discussion and deliberation on the very tough issues we must face together: how to ensure that the most vulnerable and needy in this country receive life saving treatment, how to work more effectively with state and local governments and communities impacted by HIV, how to hold ourselves and our partners more accountable for use of Federal tax dollars and, importantly, how to advance HIV prevention in this Nation. We look forward to working with you to revitalize the CARE Act.

Testimony for Submission by

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Presented to the House Subcommittee on Federal Financial Management, Government Information, and International Security of the Homeland Security and Government Affairs Committee

For the oversight hearing "Addressing Disparities in Federal HIV/AIDS CARE Programs"

Thursday, June 23, 2005, 2:30 p.m.

The California Office of AIDS respectfully submits testimony for the record regarding the importance of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act in helping California provide comprehensive care and treatment services to persons living with HIV/AIDS. I am the Chair of the National Alliance of State and Territorial AIDS Directors (NASTAD) and a founding member of NASTAD's ADAP Crisis Task Force, which negotiates drug prices and supplemental rebates and discounts with the pharmaceutical industry on behalf of all the ADAPs in the country. I am submitting this testimony on behalf of NASTAD as well. State AIDS directors appreciate the longstanding support of the United States Senate for the Ryan White CARE Act programs that are of the utmost importance to Americans living with HIV/AIDS.

As the Chair of NASTAD, I would like to share with you some of the views of my fellow state AIDS directors, in addition to the state of California. I have limited my comments to those that address disparities in the CARE Act or are issues covered in the ongoing GAO investigation.

California's Office of AIDS administers California's HIV/AIDS prevention and care programs, which are funded by federal and state funds, including CARE Act Title II funds. California was and remains an epicenter of the AIDS epidemic. HIV infections have penetrated nearly every metropolitan and rural community in our state. California ranks second in the nation in the number of cumulative AIDS cases as well as those living with AIDS with 137,213 cumulative cases and 57,308 individuals living with AIDS by May 31, 2005. We have had approximately 80,000 Californians die as a result of having AIDS. Of those living with AIDS, half are members of minority groups; 29% Hispanic, 19% Black, 3% Asian American, Pacific Islander or Native American. Women make up 11% compared to 89% for men. In terms of persons with HIV, California has 37,531 reported cases.

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In federal fiscal year 2005, California received $221 million in Ryan White funding for Titles I and II – including $31 million for the Title II base, $90 million for ADAP, and $169,000 for our one emerging community – Bakersfield. California has nine Title I Eligible Metropolitan Areas that are funded at $99 million. Governor Schwarzenegger and the California legislature have demonstrated their commitment to HIV/AIDS care and treatment by providing $111 million in state General Fund in spite of California's budget deficit.

Importance of the Ryan White CARE Act

The CARE Act is a federal-state partnership to provide comprehensive care and treatment to low income, uninsured and underinsured people living with HIV/AIDS. Title II is designed to assure that people living with HIV have access to quality HIV care, regardless of whether they live in rural, suburban or urban areas. $1.1 billion in federal funds were appropriated to Title II in FY2005, including $797 million in dedicated funds for ADAP. In 2004, over 136,000 individuals received ADAP services.

The Ryan White CARE Act has made an enormous difference in the lives of California's men, women and children who are infected with HIV/AIDS. The CARE Act has enabled us to make a broad range of health care and supportive services available through community systems of care provided to increasing numbers of people with HIV/AIDS. For many living with HIV/AIDS, these systems are their only source of care and treatment.

California has worked hard to provide a continuum of care for all residents infected with HIV and to provide equal access to the standard of HIV care. We have taken a leadership role in promoting the coordination amongst all the CARE Act funded entities within the state. The state is committed to coordinating and planning programs that ensure that all persons living with HIV disease in California have access to basic care and support needs. We are also committed to avoiding duplication or overlap of services and obtaining services and products of the highest quality at the lowest possible cost. Through the coordination of CARE Act grantees, state and local partnerships have been established at every level.

Understanding that there are disparities between states in what they are able to offer in terms of level of services, state AIDS directors recommend keeping the Title II base formula as is. Equity among states cannot be achieved simply by rearranging the $334 million in the Title II base. The entire CARE Act has the responsibility to achieve equity for persons living with HIV/AIDS. When looking at per AIDS case funding disparities from state to state one needs to take into consideration Title III, IV and Part F in addition to Titles I and II. In 2000, the CARE Act required that new Title III awards be prioritized to states without EMAs. State AIDS directors recognize the importance of getting additional resources to states that are traditionally under resourced and are proposing to alter the Emerging Communities provision to do so.

As the payer of last resort, the CARE Act is the safety net under other public programs such as Medicaid and Medicare. As Medicaid programs are altered from state to state, the Ryan White programs must adapt to fill the gaps. State ADAPs in particular will be filling in gaps for those enrolled in the new Medicare prescription drug plans with incomes of over 150% of the federal poverty level (FPL). As the payer mixes and cost of delivery of care vary across the country, it

makes the exercise of comparing CARE Act programs from one state to another exceedingly challenging.

The state AIDS Drug Assistance Program is the largest component of the CARE Act. AIDS Drug Assistance Programs (ADAPs) provide HIV/AIDS-related prescription drugs to uninsured and underinsured individuals living with HIV/AIDS in the 50 states, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, the North Marianas and the Marshall Islands. ADAPs began serving clients in 1987, when Congress first appropriated funds to help states purchase AZT—the only approved antiretroviral at the time. In 1990, ADAPs were incorporated under Title II of the newly enacted CARE Act. Federal funding for ADAPs is allocated by formula to states and territories.

Since the advent of highly active antiretroviral therapy (HAART) in 1996, AIDS deaths have declined and the number of people living with HIV/AIDS has increased markedly. ADAPs have played a crucial role in making HAART more widely available. In a given year, ADAPs reach approximately 136,000 clients, or about 30% of people with HIV/AIDS estimated to be receiving care nationally.

The services provided by ADAPs differ from state to state. Eligibility criteria and other services provided such as resistance testing and HCV treatments all differ between states. For example, in FY2004 formularies ranged from 25 FDA approved antiretrovirals (ARVs) to all FDA-approved HIV-related drugs. There is also a tremendous range in eligibility criteria. Eligibility criteria range from 125% of the federal poverty level (FPL) in one state to 500% FPL in several states. The variation between states in the coverage gaps to be filled by ADAPs is further exacerbated by the variation in benefits and eligibility criteria of state Medicaid programs.

Congress and the President have shown strong support for ADAP. On June 23, 2004, President Bush announced immediate availability of $20 million in one-time funding outside of ADAP to provide medications to individuals on ADAP waiting lists in 10 states (registered as of June 21, 2004). Currently 1,438 individuals are enrolled in the program (as of May 12, 2005), which is administered separate from ADAPs in eligible states by BioScrip, Inc.

ADAPs are not entitlement programs; annual federal, and in most cases state, appropriations determine how many clients ADAPs can serve and the level of services they can provide. In fiscal year 2004, overall ADAP budget increases were driven by increased state contribution and increases in pharmaceutical discounts and rebates; not the federal budget. As of May 12, 2005, a total of 1,891 individuals were on ADAP waiting lists in 10 states. As mentioned above, 1,438 of these individuals are currently receiving medications through the President's Initiative, which is set to expire in September 2005. Another 453 individuals on waiting lists in eight states are not covered by the President's Initiative. Eleven ADAPs have instituted capped enrollment and/or other cost-containment measures since April 1, 2004. Eleven ADAPs anticipate the need to implement new or additional cost-containment measures during the current ADAP fiscal year ending March 31, 2006.

California has the largest ADAP in the country serving 28,095 clients in calendar year 2004. Our drug expenditures exceeded $239 million in 2004 with nearly 900,000 prescriptions filled. California is fortunate to have a robust ADAP with a financial eligibility of 400 % of FPL and

152 drugs on our formulary. This is in large part due to the generous contribution from the state of $66 million.

ADAPs receive the lowest prices in the country for antiretroviral therapies. In conjunction with my colleagues from New York, I helped establish NASTAD's ADAP Crisis Task Force to negotiate with the pharmaceutical industry on behalf of all ADAPs. Although the large states had the bargaining power, we felt it was critical that all ADAPs, large and small, had access to the same prices and discounts. The Task Force began negotiations in March 2003 with the eight manufacturers of ARVs (Abbott, Boehringer-Ingelheim, BMS, GSK, Gilead, Merck, Pfizer, and Roche). As a result of this highly successful public-private partnership, we achieved supplemental discounts/rebates and price freezes that achieved an estimated $90 million in savings during fiscal year 2004. California's ADAP would not be as robust as it is without the additional rebate money being pumped into the program. The Task Force has expanded negotiations to makers of therapies to treat opportunistic infections (OIs) and other high cost, highly utilized drugs. A recent study by the University of California, Los Angeles, verified that, as a result of these negotiations, ADAPs were achieving the lowest prices available without a federal mandate.

Accountability

In a June 2004 speech, President Bush discussed for the first time the Administration's priorities for the reauthorization of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act expiring in September 2005. Bush stated, "[w]e must hold accountable organizations that receive federal help to fight AIDS by keeping track of their progress." State AIDS directors support accountability of all CARE Act programs and grantees. Provisions in the CARE Act require a variety of data to be supplied by grantees to the Health Resources and Services Administration (HRSA), the agency that oversees the CARE Act. This data provides HRSA with a detailed account of how grantees are utilizing federal resources. States and territories are monitored in a rigorous manner by HRSA. States and territories are required to provide program budget and fiscal reports and detailed contractor/provider budget packages each year. Grantees must also provide to HRSA a budget package for each Title II subgrantee with whom they contract.

States are mandated to monitor the organizations with which they subcontract to provide services to individuals living with HIV/AIDS. The majority of states have in place systems of accountability that include both fiscal monitoring and program monitoring. States must also ensure that subgrantees have quality management (QM) programs in place, which help the subgrantee and the state identify problems that may impact health status outcomes.

Additionally, since the enactment of CARE Act in 1990, the Office of the Inspector General (OIG) within the Department of Health and Human Services (HHS) has audited HRSA's HIV/AIDS Bureau (HAB) and CARE Act grantees a minimum of 25 times to ensure accountability in the usage of CARE Act resources. The OIG routinely audits states and their subgrantees for compliance with operating procedures, as well as conducting inspections and evaluations of the programs.

In 2004, the OIG performed an audit of California's Title II funds to determine whether the health department met key service-delivery performance goals and complied with program requirements; followed applicable cost requirements in the expenditure of Title II funds; and purchased prescription drugs at the lowest prices available for ADAP. The OIG found that California met its key service-delivery performance goals and complied with program requirements; complied with cost requirements in the expenditure of CARE Act Title II funds; and purchased prescription drugs at discounted prices below those mandated. The sole finding concerned the interval between the collection and expenditure of manufacturer rebates. Corrective action has been taken and rebates have for two years in a row allowed for the expansion of California's ADAP to meet caseload growth.

Recommendations for Reauthorization

The CARE Act has had a tremendous impact on the lives of people with HIV/AIDS throughout the nation, improving the availability and quality of health care services for these individuals and their families. As the largest federal program for people living with HIV/AIDS, the CARE Act is an essential source of support for HIV/AIDS care and treatment services. The number of people living with HIV/AIDS is growing, therefore, increasing the number of individuals expected to be served by CARE Act programs. The epidemic continues to grow disproportionately among people of color, women and young people. Assuring that all persons with HIV/AIDS, regardless of geographic location, have equal access to appropriate and high-quality HIV/AIDS services is our highest priority.

Disparities in the availability of resources affect the accessibility and quality of HIV services, both within and between states. State AIDS directors recognize that the structure of the Ryan White CARE Act contributes to the challenges faced by some states in effectively addressing the needs of persons living with HIV/AIDS. In many states, the current structure is a contributing factor to funding disparities that affects availability, accessibility and quality of services, both within and between states, as well as the coordination of HIV care and the efficient delivery of essential services. While the Ryan White CARE Act cannot be viewed as the sole mechanism for equalizing these inherent differences, the current structure of the CARE Act leaves many states struggling with the delivery and coordination of HIV services, while trying to meet legislative mandates to provide for the public health of citizens within their respective jurisdictions.

We recognize that alternative proposals for serving persons living with HIV/AIDS have been developed, including the Institute of Medicine's report *Securing the Legacy of Ryan White*. This report attempts to respond to these challenges. These proposals are worthy of and warrant further study, consideration and discussion.

State AIDS directors recommend retaining the current structure of the CARE Act. We do so while establishing the following two goals which are reflective of our vision for improved HIV care services in the nation: (1) to enhance the availability of ADAP resources and services for persons living with HIV/AIDS in need in all areas of the nation, and (2) to provide additional resources to states chronically insufficient Title II base funds through the Emerging Communities mechanism.

Increase ADAP Stability

We recommend the establishment of a guaranteed minimum level of new funding to ADAP for use in providing access to HIV/AIDS drugs and care, and to direct a portion of this new funding to states with waiting lists, inadequate formularies and restrictive income eligibility criteria. State AIDS directors recommend that a minimum increase of $60 million be provided annually to support ADAPs. While $60 million does not represent the entire need (ADAPs traditionally require a minimum of $100 million in growth each year in order to meet demands), this guaranteed funding would enable states to provide treatments to low-income individuals, consistent with U.S. Public Health Service guidelines, while enabling them the flexibility to make formulary decisions based on the financial status of their ADAPs.

If the annual appropriation increase for the ADAP earmark is less than $60 million, we recommend that an amount necessary to ensure a minimum increase of $60 million be provided through the following mechanisms:

1. Redirect to the ADAP earmark any unexpended funds from all titles of the CARE Act from all years with the exception of the previous two grant periods (e.g., in year 16, utilize all unexpended funds from year 13 and earlier).
2. Redirect to the ADAP earmark any unexpended funds that exceed HRSA's approved percentage of any CARE Act grantee's award amount (using the FSR submitted 90 days following the conclusion of each grant award) from all titles of the CARE Act. Grantees would be able to spend up to the approved amount of their previous year's award for use during the next grant cycle – the remaining amount of unexpended funds for each grantee for that year would be reserved for this provision during the next award cycle for Title II/ADAP grants.
3. Institute an equal percentage tap on all CARE Act titles, excluding ADAP.

Additional resources to states without EMAs

Authorized in 2000, the Title II Emerging Communities (ECs) Supplemental grants sought to address the challenges faced by areas with a significant burden of AIDS cases but that lacked the density of cases to be a Title I Eligible Metropolitan Area (EMA). The goal of the grants was to provide resources to smaller communities to enhance local health care infrastructure to provide HIV care services. The EC provision, as currently written, places traditionally underserved rural areas at a disadvantage. A significant number of largely rural states are ineligible to receive any of these supplemental funds because they do not have urban areas that meet the EC eligibility criteria.

Since its creation, ECs have been subject to significant funding fluctuations, due in large part to ECs not permanently being eligible once they begin receiving funds. The number of areas eligible for these supplemental grants has continued to diminish over the five-year authorization period because of reductions in the number of AIDS cases. In the past four years, 14 ECs have been eliminated altogether.

State AIDS directors believe the current EC provision should be modified to address the needs of states with a severe lack of Title II base resources that fund critical primary care and support services. States with chronically insufficient Title II base funds have long wait times for primary

care and struggle to meet the needs of persons in rural areas that lack the density to secure Ryan White resources. We are seeking to redistribute EC dollars to provide resources to states with significantly fewer dollars per AIDS case[1] than the national average. States without Title I EMAs comprise the vast majority of states with a per AIDS case funding rate below the national average.

Specifically, we are recommending redefining the current provision to target additional funding to states that have a CARE Act per capita funding level below the national average. Funds should be redirected to states without Title I EMAs that do not receive minimum award funding and to those states with Title I EMAs in which 50% or greater of their state's cases reside outside of their Title I EMA(s). States would use the additional monies for activities allowed under the Title II base authorization and HRSA guidance and direct resources to the communities where cases within their states reside. This proposal maintains the original intent of the EC provision by directing resources to states with epidemics that are not highly concentrated enough to be eligible for Title I funding. NASTAD recommends an authorizing level and funding of $35 million to address disparities through a revised EC provision.

In addition, state AIDS directors recommend reducing Title I eligibility to 1,500 estimated living AIDS cases during the previous five years. There is one EC, Memphis, Tennessee, that is an outlier among ECs having 360 more cases on average over the past five years than the next lowest EC. In FY2005, Memphis has 1,666 cases with the next lowest EC having 1,193. Therefore, NASTAD recommends that Memphis and communities in the future with 1,500 cases or more be deemed a Title I EMA.

Incorporation of HIV into Formula

The CARE Act currently calls for the use of HIV data in distribution formulas in fiscal year 2007. We strongly support this transition which will promote more effective targeting and distribution of CARE Act resources. We believe the use of HIV cases in addition to AIDS cases in CARE Act allocation formulas is preferable and more closely reflects the epidemic than living AIDS cases.

Forty-three jurisdictions have name-based HIV reporting. The remaining 13 jurisdictions utilize a code or name-to-code system for reporting HIV cases. Several jurisdictions have only recently implemented HIV reporting and therefore their HIV data is not yet considered "mature" enough to be reliable. CDC has not accepted HIV case report data from the 13 jurisdictions that collect and report HIV case data using codes or name-to-code systems, determining that these systems do not meet national performance and evaluative standards.

California is the only state among the five largest that uses an HIV reporting system different than its AIDS reporting system. The Schwarzenegger administration is concerned that by not converting to a name-based HIV reporting system, California risks losing its fair share of CARE Act funds when the funding formula changes. While legislative attempts were unsuccessful this year to change from code to name-based reporting, a spirited dialogue in California continues. Having said that, state AIDS directors unanimously agree that our Title II funds should not be

[1] The state per AIDS case rate was determined by totaling a states Title I, II, III IV, and Part F (excluding Emerging Communities and SPNS) and dividing by a state's estimated living AIDS cases.

withheld in order to force states to switch reporting systems. We believe surveillance is within the domain of the states; states should determine what methodology best serves the needs of their citizens.

Regardless of which reporting system is utilized, there are still states with data derived from systems which remain immature. To incorporate HIV data in fiscal year 2007, CDC will need to develop a methodology to estimate HIV cases for these states. State AIDS directors urge that CDC be required work with the states when developing this methodology.

Redirection of Unexpended CARE Act Funds

While administering CARE Act funds, states and Eligible Metropolitan Areas (EMAs) periodically finish fiscal years with small amounts of unspent funds. These amounts, typically ranging from five or ten percent of overall awards, may be requested in the subsequent fiscal year to provide services during that fiscal year. The unspent funds typically result from delays in notice of grant awards from the federal government, timing issues related to subcontracting of services, payroll savings due to state hiring delays or freezes, expenditure of other grant funds for similar services, or other unanticipated fluctuations in spending at the state level. Occasionally, the amount of unexpended funds reaches beyond ten percent of a grantee's overall award for reasons specific to the individual jurisdiction. California currently has $5,319 in carryover, which is significantly less than the $1.7 million figure recently released by HRSA. Some states have reported that the figures do not exclude funds that have been approved for expenditure by states. The accounting of carryover needs to be improved so that it's an accurate reflection of unobligated funds.

State AIDS director unanimously agree that expiring unexpended funds must be put back into the CARE Act rather than being returned to the Treasury as is currently the case. States with excessive and chronic amounts of unobligated funds need immediate technical assistance from HRSA to address issues that are hindering a state from spending their award.

Our ADAP proposal would redistribute unobligated funds from all Titles back into the ADAP program. Although this would be considered one-time-only funding, it would allow states to provide life saving therapy to individuals in need for a year, as well as assist states with transitioning clients currently participating in the President's $20 million waiting list initiative, scheduled to expire September 30, 2005.

Hold Harmless

State AIDS directors support the continuation of a hold harmless provision for Title II at a reduced rate of loss. Experience shows that after the last reauthorization, due to the unintended consequences of changes in the law, 30 states were held harmless from significant funding losses Hold harmless provisions limit shifts in Title II base and ADAP earmark funding that otherwise could help address funding disparities that exist from state to state. However, with limited funding, as well as two consecutive years of cuts to the Title II base, these disparities cannot be corrected via major shifts in Title II resources without impacting critical existing services in jurisdictions that would lose funding.

We do support the removal of one of the two hold harmless provisions under Title II. The first of the two provisions ensures that the amount of a grant awarded to a state or territory for a fiscal year under either the Title II base or the ADAP earmark is not less than a defined percentage of the amount the jurisdiction received in fiscal year 2000. We are requesting a change to this provision to reflect a 1.5% loss each year (based on FY2005 funding levels) with a maximum possible loss of 7.5% over a five-year period, or 92.5%.

We are requesting removal of the second hold harmless to the overall Title II award that includes the Title base, ADAP earmark, ADAP Supplemental Grants, Emerging Communities, and Minority AIDS Initiative funding. The second hold harmless has resulted in the unintended affect of reducing the amount of money available for the ADAP Supplemental due to significant fluctuation in the Emerging Communities funding. The ADAP Supplemental is a 3% set-aside of the ADAP earmark designed to increase access to care in states with ADAP restrictions.

State Match and Maintenance of Effort

The CARE Act contains two provisions designed to assure state funding support for HIV care and treatment programs. To prevent federal funds from offsetting specific HIV-related budget reductions at the state level and to encourage increased state contributions to HIV care services, Title II contains a state funding match and maintenance of funds assurance requirement. It is critically important to continue the state commitment and keep these provisions in law with the exception of the match requirement for the ADAP Supplemental Grants. Because of a 1:4 state match requirement for ADAP Supplemental Grants, some eligible states have been unable to access the funds. This match requirement has resulted in a loss of funds to several state ADAP programs that are in dire need of additional resources. We support the removal of the match requirement for the ADAP Supplemental only, with other state match and maintenance of effort requirements continuing in a reauthorized CARE Act.

Integration of Prevention into Care Setting

Federal agencies, health departments, and communities understand the growing importance of close linkages between HIV prevention and care services to ensure that individuals learn their HIV status and receive referrals to appropriate services. HIV prevention is increasingly seen as a standard of care for persons living with HIV. Studies indicate that HIV-positive individuals take steps to protect their partners from infection, with 70% reporting reductions in risky behaviors even at one year after diagnosis.

Health departments use partner counseling and referral services (PCRS) as one tool to identify HIV-positive individuals and ensure their linkage to medical, support, and prevention services. Research has found PCRS to be a cost effective strategy for identifying HIV infected persons unaware of their serostatus. The CARE Act allows Titles I and II to conduct early intervention services (EIS). Previously, early intervention activities were only allowed among Title III and IV grantees. The 2000 CARE Act amendments also added grants to states for carrying out programs providing PCRS. While the CARE Act called for $30 million to be appropriated in FY2001 for the new PCRS grants, no money has ever been provided to states through this grant mechanism.

Currently, all states and territories conduct PCRS as a requirement of their prevention cooperative agreement through the Centers for Disease Control and Prevention (CDC). PCRS includes three basic elements: 1) Seeking the names of partners who may be at risk for infection (partner elicitation), 2) Locating partners and notifying them of their risk (partner notification), and 3) Providing HIV testing and risk reduction counseling to partners (partner counseling). PCRS is not limited to the time of initial diagnosis but is offered continuously to provide on-going support for positive persons related to serostatus disclosure and to ensure that both positive persons and their partners have access to prevention services. Partner notification, a key public health strategy to fight communicable disease, lies within the authority of health departments as part of their mission to protect public health.

State AIDS directors support the continuation of funding for PCRS through the CDC cooperative agreements with the states and six directly funded cities.

Perinatal Prevention

Perinatally acquired AIDS cases have decreased dramatically due, in large part, to HIV testing among greater numbers of pregnant women and their subsequent treatment. In 2003, the CDC reported only 152 new cases of perinatally transmitted AIDS. This represents an 84% decline from a high of 954 new AIDS cases in 1992. Only three states account for over 50% of all new perinatal cases reported to the CDC. 22 states reported no pediatric AIDS cases. Perinatal initiatives developed by state and local health departments have contributed to the significant decline in perinatally acquired AIDS cases from the peak in the early 1990s.

In 1996, Congress authorized through Section 2625 of the CARE Act $10 million for grants to support counseling, testing, and outreach to pregnant women and infants. Priority in funding was given to states with the highest prevalence of perinatal transmission cases.

California had 14 cases reported in 2003. California has an opt out/opt in process for testing previously untested pregnant women. We treat each case of perinatal transmission as a sentinel event and follow-up to determine where the woman fell through the cracks in the health care system. We still find that access to prenatal care is the largest barrier to reducing the number of perinatally-acquired infections to zero with many of the women knowing their HIV status before delivery. The lack of access to care and fear of seeking care for non-citizens and substance using women remains the primary barrier.

The prevention of mother to child transmission is one of our greatest prevention successes. One way to continue the reduction in cases is to provide hospitals serving the un- and underinsured with HIV rapid tests for use in the labor and delivery setting. This would require resources for the test kits as well as training for hospital staff on counseling and administration of the screening test.

The California Office of AIDS thanks the Chairman, Ranking Member and members of the Subcommittee for their thoughtful consideration of our recommendations to revise the CARE Act to increase equitable access to critical CARE Act funded services.

United States Government Accountability Office

GAO

Testimony

Before the Subcommittee on Federal Financial Management, Government Information, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate

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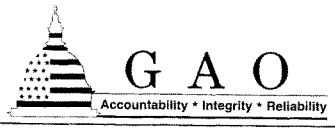
RYAN WHITE CARE ACT

Factors that Impact HIV and AIDS Funding and Client Coverage

Statement of Marcia Crosse
Director, Health Care



GAO-05-841T

June 23, 2005

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Highlights

Highlights of GAO-05-841T, a testimony before the Subcommittee on Federal Financial Management, Government Information, and International Security, Committee on Homeland Security and Governmental Affairs, U.S. Senate

RYAN WHITE CARE ACT

Factors that Impact HIV and AIDS Funding and Client Coverage

Why GAO Did This Study

The Ryan White Comprehensive AIDS Resources Emergency Act (CARE Act) was enacted in 1990 to respond to the needs of individuals and families living with the Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS). In fiscal year 2004, over $2 billion in funding was provided through the CARE Act, the majority of which was distributed through Title I grants to eligible metropolitan areas (EMA) and Title II grants to states, the District of Columbia, and territories. Titles I and II use formulas to distribute grants according to a jurisdiction's reported count of AIDS cases. Title II includes grants for state-administered AIDS Drug Assistance Programs (ADAP), which provide medications to HIV-infected individuals.

GAO was asked to discuss the distribution of funding under the CARE Act. This testimony presents preliminary findings on (1) the impact of CARE Act provisions that distribute funds based upon the number of AIDS cases in metropolitan areas, (2) the impact of CARE Act provisions that limit annual funding decreases, (3) the potential shifts in funding among grantees if HIV case counts were incorporated with the AIDS cases that are currently used in funding formulas, and (4) the variation in eligibility criteria and funding sources among state ADAPs.

www.gao.gov/cgi-bin/getrpt?GAO-05-841T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7118.

What GAO Found

Under the CARE Act, GAO's preliminary findings show that the amount of funding per AIDS case varied among states and metropolitan areas in fiscal year 2004. Some CARE Act provisions that distribute funds based on the AIDS case count within metropolitan areas result in differing amounts of funding per case. In particular, when a state or territory has an EMA within its borders, the cases within that EMA are counted twice during the distribution of CARE Act funds—once to determine the EMA's funding under Title I, and once again to determine a state's Title II grant.

The hold-harmless provisions under Titles I and II guarantee a certain percentage of a previous year's funding amount, thus sustaining the funding levels of CARE Act grantees based upon previous years' measurements of AIDS cases. Title I's hold-harmless provision for EMAs has primarily benefited the San Francisco EMA, which received over 90 percent of the fiscal year 2004 Title I hold-harmless funding. San Francisco alone continues to have deceased cases factored in to its allocation, because it is the only EMA with hold-harmless funding that dates back to the mid-1990s when formula funding was based on the cumulative count of diagnosed AIDS cases.

If HIV case counts had been incorporated with AIDS cases in allocating Title II funding to the states in fiscal year 2004, about half of the states would have received an increase in funding and half of the states would have received less funding. Many of those states receiving increased funding would have been in the South, a region that includes 7 of the 10 states with the highest estimated rates of individuals living with HIV. However, wide variation in the maturity of states' HIV reporting systems could limit the adequacy of their HIV case counts for the distribution of CARE Act funding.

Among state ADAPs, there is wide variation in the criteria used to determine who is eligible for ADAP medications and services, and in the additional funding received beyond the Title II grant for each state ADAP. States have flexibility to determine what drugs they will cover for their ADAP clients and what income level will entitle a person to eligibility, among other criteria, and the resulting variation can contribute to client coverage differences among state ADAPs. There is similar variation in additional funding sources and eligibility criteria among states that have established waiting lists for eligible clients. The Centers for Disease Control and Prevention and the Health Resources and Services Administration provided comments on the facts contained in this testimony and GAO made changes as appropriate.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act).[1] I will specifically address factors that impact CARE Act funding of services for those with the Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Syndrome (AIDS) and program coverage for CARE Act clients. As of December 2003, over 1 million individuals within the United States are estimated to be infected with HIV, including about 406,000 individuals with AIDS. Administered by the Health Resources and Services Administration (HRSA), the CARE Act makes funds available to states and localities to provide health care, medications, and support services to individuals and families affected by HIV and AIDS.

In fiscal year 2004, more than $2 billion was provided through the CARE Act for these health care and support services. The majority of these funds were distributed under Title I and Title II within the CARE Act through formula-derived base grants, which distribute funding to all eligible jurisdictions, and through supplemental grants, which distribute funding to a subset of all eligible jurisdictions. Title I provides funding to all eligible metropolitan areas (EMA) according to an EMA's number of AIDS cases.[2] Title II provides funding to all states, territories, and the District of Columbia. Within both of these titles are formula grants intended to distribute funds proportionally to grantees based upon a measure of each grantee's share of AIDS cases. Grantees' reports of AIDS cases are used in funding formulas because when the CARE Act was enacted in 1990, most jurisdictions tracked and reported AIDS cases instead of HIV cases.

The CARE Act's reauthorizations in 1996 and 2000 modified the original funding formulas. Prior to the 1996 reauthorization, the CARE Act measured a jurisdiction's caseload by its cumulative count of AIDS cases, which is the number of AIDS cases recorded since reporting began in 1981. The 1996 reauthorization changed the measurement of a jurisdiction's

[1]Pub. L. No. 101-381, 104 Stat. 576 (codified as amended at 42 U.S.C. §§ 300ff—300ff-101 (2000). The CARE Act added a new title XXVII to the Public Health Service Act. In general, because Title I of the CARE Act authorized grants to metropolitan areas and Title II authorized grants to states, these programs are referred to as Title I and Title II programs, respectively.

[2]Under Title I, a metropolitan area with a population of at least 500,000 and 2,000 reported AIDS cases in the last 5 calendar years becomes eligible to receive a portion of Title I funding.

caseload to an estimation of the number of living AIDS cases.[3] This switch would have resulted in large shifts of funding away from jurisdictions with a longer history of the disease and a higher proportion of deceased cases than other jurisdictions. The CARE Act includes hold-harmless provisions under Title I and Title II that protect grantees from decreases in funding from one year to the next. Title I of the CARE Act also includes a grandfather clause for EMAs. A type of hold-harmless itself, this grandfather clause guarantees that once a metropolitan area has become an EMA, it will continue to receive funding under Title I, even if its caseload drops below the threshold for eligibility. The most recent reauthorization of the CARE Act in 2000 maintained these modifications, and it further specified that HIV cases should be used in funding formulas no later than fiscal year 2007. As of June 2005, HIV case counts have not been used to distribute funding under the CARE Act.

A portion of Title II funding is for state AIDS Drug Assistance Programs (ADAP), which provide medications to infected individuals. In fiscal year 2004, Title II base ADAP grants—the ADAP grant given to all states—totaled $728 million, accounting for 36 percent of all CARE Act funding. The programs are administered at the state level and each state is allowed flexibility in determining its program eligibility criteria and the drugs it provides. Some ADAPs establish waiting lists for eligible individuals for a period of time when the ADAP cannot provide covered drugs.

To assist the subcommittee in its consideration of the CARE Act, my testimony provides our preliminary findings on some of the issues we are reviewing for the Chairman and other requesters. My remarks today will focus on selected provisions of the CARE Act and ADAP. Specifically, I will discuss

1. the impact of CARE Act provisions on the distribution of funds that is based upon the number of AIDS cases in metropolitan areas,

2. the impact of the CARE Act's hold-harmless provisions and a grandfather clause on the distribution of funds,

[3]HRSA calculates a jurisdiction's estimated living AIDS cases by using data from the Centers for Disease Control and Prevention on the reported AIDS case counts for the last 10 years and weighting those numbers to account for the likelihood of deaths. We used this estimate in our analyses of CARE Act funding formula allocations, and we refer to this measure as the number of AIDS cases in our discussion of these analyses.

3. the potential shifts in funding among grantees if HIV case counts had been incorporated in fiscal year 2004 funding formulas, and

4. the variation in eligibility criteria and funding sources among the state ADAPs.

To address these issues and those within our broader review of the CARE Act, we interviewed officials from HRSA and the Centers for Disease Control and Prevention (CDC). CDC collects HIV and AIDS case counts from states and territories. We also interviewed officials from the National Alliance of State and Territorial AIDS Directors. We obtained and analyzed data from HRSA regarding the distribution of CARE Act funding and from CDC regarding AIDS and HIV case counts.[4] We obtained and analyzed HIV case counts from those states from which CDC does not accept these data because they do not use names to identify the cases. CDC and the states provided us with case counts that were available as of June 30, 2003, the cutoff date for data used to determine fiscal year 2004 funding. HRSA provided us with CARE Act funding distributions for fiscal year 2004.[5] Based on the information HRSA, CDC, and the states provided regarding its verification of the reliability of these data, we determined these data to be sufficiently reliable for the purposes of our analyses. We performed our work from July 2004 through June 2005 according to generally accepted government auditing standards. CDC and HRSA provided comments on the facts contained in this statement, and we made changes as appropriate.

In brief, our analysis shows that certain CARE Act Title I and Title II provisions related to the distribution of funds to metropolitan areas result in variability between the amounts of funding per case among grantees. States and territories that have EMAs within their borders receive more funding per estimated living AIDS case than those without EMAs because cases within EMAs are counted twice—once to determine Title I funding to EMAs, and once again to determine a state's Title II grant. Metropolitan areas that have been affected by the epidemic but do not have the necessary number of AIDS cases to become EMAs and receive Title I funding may qualify for funding as Emerging Communities under Title II.

[4]The HIV case counts were calculated by subtracting the number of reported deaths among HIV cases from the number of reported HIV cases.

[5]Our analyses include CARE Act funding and programs in the 50 states, the District of Columbia, and Puerto Rico.

However, the allocation of these grants is made by separating eligible jurisdictions into two tiers based on their reported number of AIDS cases. Because one half of the total Emerging Communities grant award is allocated to each tier regardless of how many cases are in each tier, in fiscal year 2004 jurisdictions in one tier received $1,052 per case while jurisdictions in the other tier received $313 per case.

The hold-harmless provisions under Titles I and II and the grandfather clause for EMAs under Title I sustain the funding and eligibility of CARE Act grantees on the basis of a previous year's measurements of the number of AIDS cases in these jurisdictions. By guaranteeing either a certain percentage of previous years' funding amounts or an EMA's eligibility to receive funding, these provisions make it more difficult for CARE Act funding to track the most current distribution of the epidemic. The San Francisco EMA has primarily benefited from Title I's hold-harmless provision, receiving over 90 percent ($7,358,239) of the fiscal year 2004 Title I hold-harmless funding. San Francisco's current hold-harmless funding can be traced to its 1995 base grant, which was determined using the cumulative number of AIDS cases, living and dead, reported since 1981. In essence, deceased cases are still being used to determine funding for San Francisco. Hold-harmless provisions under Title II also sustain a state's level of funding based on case counts from previous years. Because funding for one of these Title II hold-harmless provisions is drawn from a set-aside for states with a severe need for drug assistance, this hold-harmless provision could affect the amount of funding received by these severe-need states in the future. The grandfather clause in Title I maintained the funding for 29 of the 51 EMAs that became eligible for Title I base grants in the past. These EMAs, however, would not have qualified for Title I base grants in fiscal year 2004 based upon their case counts, which were below the eligibility threshold of 2,000 reported AIDS cases in the last 5 calendar years.

If the HIV case counts from state reporting systems had been used with estimated living AIDS cases in allocating fiscal year 2004 Title II base funding, about half of the states would have received increased funding and the other half would have received decreased funding. Using two different approaches, we found that at least 11 of the states with increased funding were located in the South, the region with the highest estimated number of people living with HIV or AIDS in 2003. All states have established HIV case reporting systems, and the 2000 reauthorization of the CARE Act required that HIV cases be used in determining formula funding no later than fiscal year 2007. However, wide differences between states' HIV case reporting systems—in their maturity and reporting

methods, for instance—could affect the use of HIV and AIDS case counts to distribute CARE Act funding because an immature reporting system might not capture an accurate count of a state's HIV cases. More mature systems have longer histories of collecting newly diagnosed HIV cases and retroactively reporting HIV cases that had been diagnosed before the reporting system existed. We found that funding would have shifted to jurisdictions with more mature HIV reporting systems, which includes many of the reporting systems in the South. However, changes in funding would be largely offset, at least initially, if the funding formulas included hold-harmless and minimum grant provisions.

There is wide variation among state ADAPs in the eligibility criteria they set for their programs and in the additional funding those programs receive from sources other than their Title II base ADAP grant. States determine what drugs they will cover for their ADAP clients and what income level will make a client eligible for ADAP coverage, among other criteria. States also vary in the amount of funding they receive from other sources in addition to their Title II ADAP base grant. State ADAPs can receive funding from a variety of sources, including transfers from other CARE Act grants and contributions from states, that can lead to a wide range of funding amounts per AIDS case. However, we did not find a relationship between any one factor—a particular income eligibility criterion, for example, or a type of additional funding beyond the base grant—and the existence of a waiting list of ADAP clients that could not be served at a particular time.

Background

Over the course of the last quarter century, the epidemic has spread to every region of the country. HIV and AIDS cases have been reported in all states, the District of Columbia, and U.S. territories, but the impact of the epidemic varies by region and within states. The South is estimated to have the highest cumulative number of diagnosed AIDS cases, people living with AIDS, and deaths from AIDS. In 2003, 7 of the 10 states with the highest estimated rates of individuals living with HIV were located in the South.

The CARE Act was enacted in 1990 to respond to the needs of individuals and families living with HIV or AIDS and to direct federal funding to areas disproportionately affected by the epidemic. Titles I and II of the act provide base funding to affected EMAs and states based on the proportion

of each jurisdiction's caseload of AIDS cases. These titles also establish other types of grants to provide supplemental funding.[6] For example, Title II includes Severe Need grants for states with demonstrated need for supplemental funding to support their ADAPs. Title II also includes funding for emerging communities that are affected by AIDS but do not have the 2,000 AIDS cases reported in the last 5 calendar years in order to be eligible for Title I funding as EMAs. In order to address the impact of the disease on racial and ethnic minorities, Minority AIDS Initiative grants are distributed through both Title I and Title II to EMAs and states.

Metropolitan areas heavily affected by HIV or AIDS have always been recognized within the structure of the CARE Act. We previously found that, with combined funding under Title I and Title II, states with EMAs receive more funding per AIDS case than states without EMAs.[7] To adjust for this situation, the 1996 reauthorization instituted a two-part formula for Title II base funding that takes into account the number of AIDS cases that reside within a state but outside of any EMA's jurisdiction. Under this distribution formula, 80 percent of the Title II base grant is based upon a state's proportion of all AIDS cases, and twenty percent of the allocation is based on the number of AIDS cases within that state's borders but outside of EMAs. A second provision included in 1996 protected the eligibility of EMAs. The 1996 CARE Act amendments provided that once a jurisdiction is designated an EMA, that jurisdiction is "grandfathered" so it will always receive some amount of funding under Title I even if its reported number of AIDS cases drops below the threshold for eligibility. Hold-harmless provisions and the grandfather clause were maintained in the 2000 reauthorization of the CARE Act. Table 1 describes selected CARE Act formula grants for Titles I and II.

[6]There are supplemental grants under Title I that are determined by a competitive application process. For purposes of this testimony, these Title I supplemental grants were not included.

[7]See GAO, *Ryan White CARE Act of 1990: Opportunities Are Available to Improve Funding Equity*, GAO/T-HEHS-95-126 (Washington, D.C.: Apr. 5, 1995). See also related GAO products at the end of this statement.

Table 1: Description of Selected CARE Act Title I and Title II Formula Grants

Formula grant	Eligible grantees	Distribution	Minimum grant	Hold-harmless provision[a]
Title I Base Grant	Jurisdictions with 500,000 or more in population and with 2,000 reported AIDS cases in the most recent 5 calendar years become, and remain, EMAs	Distributed among all EMAs based on proportion of all AIDS cases	No	Grant annually declines to 98%, 95%, 92%, and 89% of the base year grant, respectively.[b] In fifth and all subsequent years, EMA receives 85% of base year grant.
Title II Base Grant	All 50 states, the District of Columbia, and U.S. territories	Eighty percent of base grant divided among states/territories based upon their proportion of all AIDS cases. Twenty percent of base grant is divided among states/territories based upon proportion of all AIDS cases that are located outside the EMAs within the states'/territories' borders.	For states with less than 90 AIDS cases, $200,000; states with 90 or more AIDS cases, $500,000; for territories, $50,000	Base formula grant declines by 1% per year from the fiscal year 2000 award. In fifth and subsequent years of provision, grant remains at 95% of 2000 appropriation.
Title II ADAP Base Grant	All 50 states, the District of Columbia, and U.S. territories	Distributed among all states/territories according to their proportion of all AIDS cases	No	Grant declines by 1% per year from the fiscal year 2000 grant. In fifth and subsequent years of provision, funding remains at 95% of 2000 grant.
Title II ADAP Severe Need Grant[c]	States and territories demonstrating a severe need that prevents them from providing medications to clients in a manner consistent with Public Health Service guidelines	Distributed among all qualifying states/territories based upon their proportion of AIDS cases in all qualifying states/territories; eligible states/territories must also agree to match 25% of their Severe Need grant	No	No
Title II Emerging Communities Grant	Jurisdictions with more than 50,000 in population, not eligible for Title I, and with 500-1,999 reported AIDS cases in the most recent 5 calendar years	Funds are divided into two tiers: 50% distributed among communities with 1,000-1,999 AIDS cases, and 50% distributed among communities with 500-999 AIDS cases, based on their proportion of AIDS cases in Emerging Communities within the tier	Minimum of $5 million for each tier	No

Source: HRSA.

[a]If the distribution formula would otherwise result in decreased funding, a hold-harmless provision may be triggered to mitigate the decrease in funding.

[b]The base year is the fiscal year prior to that in which the provision is triggered.

[c]Funding for Severe Need grants may be reduced to maintain funding for some states under a Title II hold-harmless provision.

The 2000 reauthorization specified that CARE Act Title I and Title II funding formulas should use HIV case counts as early as fiscal year 2005 if such data were available and deemed "sufficiently accurate and reliable" by the Secretary of Health and Human Services (HHS).[8] The 2000 reauthorization also required that HIV data be used no later than the beginning of fiscal year 2007. In June 2004 the Secretary of HHS determined that HIV data were not yet ready to be used for the purposes of allocating formula funding under Title I and Title II of the CARE Act. The Secretary cited a 2004 Institute of Medicine (IOM) report, which identified several limitations in the ability of states to provide adequate and reliable HIV case counts for use in CARE Act formula allocations.[9]

CARE Act Funding Provisions Result in Disproportionate Funding

Some CARE Act provisions have led to jurisdictions receiving different amounts of funding per AIDS cases. The counting of AIDS cases within EMAs once to determine Title I funding and once again to determine Title II funding results in states with EMAs receiving more funding per AIDS case than states without an EMA. In addition, Emerging Communities grants are awarded to eligible communities that are separated into two tiers based on each community's AIDS cases reported in the most recent 5 calendar years. Because one half of the total Emerging Communities grant award is allocated to each tier regardless of the total number of reported AIDS cases in each tier, a disproportionate amount of funding per case was distributed among the grantees in fiscal year 2004.

Counting AIDS Cases within EMAs Twice Results in Unequal Funding per Case Across States

States with EMAs receive more funding per AIDS case than jurisdictions without EMAs because cases within EMAs are counted twice. The number of AIDS cases used to allocate CARE Act Title I base grants for EMAs is also used in the allocation of 80 percent of Title II base grants for states. The remaining 20 percent is based on the number of AIDS cases in each state outside of any EMA. This 80/20 split was established by the CARE Act's 1996 amendments to address the fact that states with EMAs received more funding per case than states without EMAs. However, even with the 80/20 split, states with EMAs still receive more funding per AIDS case. States without an EMA receive no funding under the Title I distribution,

[8] 42 U.S.C. § 300ff-13(a)(3)(D)(i)(2000).

[9] Institute of Medicine of the National Academies, *Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act* (Washington, D.C.: The National Academies Press, 2004).

and thus, when total Title I and Title II CARE Act funds are considered, states with EMAs receive more funding per AIDS case. [10] Appendix I shows the combined fiscal year 2004 funding for all Title I and Title II funding received by each state.

Table 2 illustrates the effect of counting EMA cases twice by comparing the relationship between the percentage of a state's AIDS cases that are within an EMA's jurisdiction and the amount of funding a state receives per AIDS case. Table 2 shows that as the percentage of a state's AIDS cases within EMAs increases, the total Title I and II funding per AIDS case also increases for the state. For example, states with no AIDS cases in EMAs received on average $3,592 per AIDS case. States with 75 percent or more of their cases in EMAs received on average $4,955 per AIDS case, or 38 percent more funding than states with no EMA. If the total Title I and Title II funding had been distributed equally per AIDS case among all grantees, each state would have received $4,782 per AIDS case.

Table 2: Total CARE Act Title I and II Funding per AIDS Case, Fiscal Year 2004

Percentage of state's AIDS cases in EMAs	Average funding per AIDS case[a]
None	$3,592
Less than 50 percent	3,954
50 to 75 percent	4,717
75 percent or more	4,955

Source: GAO analysis of HRSA data.

[a]In order to isolate the effect of counting AIDS cases in EMAs twice, we excluded from our analyses the nine states and six territories that received minimum Title II base grant awards. Under Title II, states with less than 90 cases receive no less than $200,000 in Title II base grant and states with 90 or more cases receive at least $500,000.

The impact of counting EMA cases twice is that states with similar numbers of AIDS cases can receive different levels of combined Title I and Title II funding. For example, for fiscal year 2004 funding, Connecticut had 5,363 AIDS cases while South Carolina had 5,563 AIDS cases. However,

[10]For EMAs that cross state boundaries, we estimated the amount of funding received by each state. Using data obtained from HRSA, we calculated the number of AIDS cases from each state in these EMAs. We then calculated the percentage of AIDS cases in each state and allocated the EMA funding to each state based on this percentage. For example, approximately 96 percent of the cases in the Boston EMA are in Massachusetts and 4 percent are in New Hampshire. Consequently, we allocated 96 percent of the Boston EMA's funding to Massachusetts and 4 percent to New Hampshire.

Connecticut had two EMAs that accounted for 91.3 percent of its cases while South Carolina had none. Connecticut received $26,797,308 ($4,997 per AIDS case) in combined Title I and Title II funding while South Carolina, with 200 more cases, received $20,705,328 ($3,722 per AIDS case). Connecticut received 29 percent more funding than South Carolina, a difference of $6,091,980, or $1,275 per AIDS case.

The Tiered Allocation of Title II Funds for Emerging Communities Results in Funding Disparities Among States

The two-tiered division of Emerging Communities grants results in disparities in funding per case among states. In addition to the base grants for states, Title II provides a minimum of $10 million in supplemental grants to states for communities with populations greater than 50,000 that have a certain number of AIDS cases in the last 5 calendar years. The funding is equally split so that half the funding is divided among the first tier of communities with 500 to 999 reported cases in the most recent 5 calendar years while the other half is divided among a second tier of communities with 1,000 to 1,999 reported cases in that period. The funding is then allocated within each tier by the proportion of reported cases in the most recent 5 calendar years in each community.

In fiscal year 2004, the two-tiered structure of Emerging Communities funding led to large differences in funding per case because the total number of AIDS cases in each tier was not equal. Twenty-nine communities qualified for Emerging Communities grants in fiscal year 2004. Four of these communities had between 1,000 and 1,999 reported cases and 25 communities had between 500 and 999 cases. This meant that 4 communities with a total of 4,754 reported cases split $5 million while 25 communities with a total of 15,994 cases split the remaining $5 million. This resulted in the 4 communities receiving $1,052 per reported case while the other 25 received $313 per reported case. These 4 communities received 236 percent more funding per case than the other 25. If the total $10 million Emerging Communities funding had been distributed equally per case among the communities, each would have received $482 per reported case. Table 3 lists the 29 emerging communities along with their AIDS case counts and funding.

Table 3: Title II Emerging Communities in Fiscal Year 2004

State	Metropolitan area	AIDS cases reported in the most recent 5 calendar years	Emerging Communities funding per AIDS case reported in the most recent 5 calendar years
Tenn.	Memphis	1,588	$1,052
Tenn.	Nashville	1,123	1,052
La.	Baton Rouge	1,038	1,052
Ind.	Indianapolis	1,005	1,052
S.C.	Columbia	972	313
N.C.	Charlotte	875	313
Del.	Wilmington	801	313
Va.	Richmond	783	313
N.C.	Raleigh-Durham-Chapel Hill	775	313
Miss.	Jackson	722	313
Ky.	Louisville	705	313
N.Y.	Rochester	681	313
Fla.	Fort Pierce-Port St. Lucie	636	313
N.C.	Greensboro—Winston-Salem	617	313
Ala.	Birmingham	615	313
Okla.	Oklahoma City	608	313
Pa.	Pittsburgh	602	313
Mass.	Springfield	588	313
N.J.	Monmouth-Ocean	582	313
N.Y.	Buffalo-Niagara Falls	581	313
S.C.	Greenville	560	313
Ohio	Columbus	558	313
Wisc.	Milwaukee	558	313
Utah	Salt Lake City	555	313
Fla.	Sarasota	539	313
S.C.	Charleston	538	313
Ohio	Cincinnati	517	313
Fla.	Daytona Beach	514	313
R.I.	Providence	512	313
	Total	**20,748**	

Sources: GAO analysis of HRSA data.

Note: The 5 most recent calendar years are from 1998-2002.

Hold-Harmless Provisions and Grandfather Clause Benefit Certain Grantees

Titles I and II of the CARE Act both contain provisions that benefit certain grantees by protecting their funding levels. Title I has a hold-harmless provision that guarantees that the Title I base grant allocated to an EMA will be at least as large as a legislated percentage of a previous year's funding. The Title I hold-harmless provision has primarily benefited one EMA. Title I also contains a grandfather clause that has resulted in a large number of EMAs maintaining funding despite no longer meeting the eligibility criteria. One hold-harmless provision for Title II ensures that the total of Title II and ADAP base grants awarded to a state will be at least as large as the total of these grants it received the previous year. This provision has had little impact thus far, but it has the potential to reduce the amount of funding to states with severe need in ADAPs because it is funded out of amounts reserved for that purpose. The hold-harmless provision and the grandfather clause in Title I and the hold-harmless provisions in Title II protect grantees from decreases in funding from one year to the next, but they also make it more difficult to shift funding in response to geographic movement of the disease.

Title I Hold-Harmless Provision Has Primarily Benefited One EMA

In fiscal year 2004, the Title I hold-harmless provision primarily benefited the San Francisco EMA. The hold-harmless provision guarantees each EMA a specified percentage, as legislated by the CARE Act, of the base grant it received in a previous year regardless of how much a grantee's caseload may have decreased in the current year. An EMA's base funding is determined according to its proportion of AIDS cases. If an EMA qualifies for hold-harmless funding, that amount is added to the base funding and distributed together as the base grant. The San Francisco EMA received $7,358,239 in hold-harmless funding, or 91.6 percent of the hold-harmless funding that was distributed. The second largest beneficiary was Kansas City, which received $134,485, or 1.7 percent of the hold-harmless funding. Table 4 lists the fiscal year 2004 hold-harmless beneficiaries.

Table 4: Title I Hold Harmless Funding, Fiscal Year 2004

EMA	Hold-harmless funding	Percentage of hold-harmless funding	Hold-harmless funding per AIDS case	Base grant per AIDS case[a]	Percent of base grant due to hold-harmless funding
San Francisco, Calif.	$7,358,239	91.6%	$1,020	$2,241	45.5%
Kansas City, Mo.	134,485	1.7	104	1,325	7.8
Santa Rosa, Calif.	22,614	0.3	47	1,268	3.7
Sacramento, Calif.	36,456	0.5	29	1,251	2.3
Minneapolis-St.Paul, Minn.	33,770	0.4	27	1,248	2.1
Bergen-Passaic, N.J.	55,288	0.7	26	1,248	2.1
Jersey City, N.J.	58,310	0.7	24	1,245	1.9
Oakland, Calif.	50,744	0.6	18	1,239	1.4
New Haven, Conn.	42,573	0.5	14	1,236	1.2
Tampa-St. Petersburg, Fla.	44,908	0.6	12	1,233	0.9
San Jose, Calif.	12,097	0.2	11	1,232	0.9
Boston, Mass.	60,284	0.8	10	1,231	0.8
Nassau-Suffolk, N.Y.	21,212	0.3	8	1,230	0.7
Middlesex-Somerset-Hunterdon, N.J.	8,315	0.1	7	1,228	0.5
Jacksonville, Fla.	12,825	0.2	6	1,228	0.5
San Juan, P.R.	41,011	0.5	6	1,228	0.5
Seattle, Wash.	9,844	0.1	4	1,225	0.3
Denver, Colo.	6,745	0.1	3	1,225	0.3
Cleveland, Ohio	4,616	0.1	3	1,224	0.2
West Palm Beach, Fla.	8,523	0.1	2	1,224	0.2
Newark, N.J.	10,975	0.1	2	1,223	0.1
All Other EMAs	0	0	0	1,221	0.0
Total	**$8,033,563[b]**	**100.0%**			

Source: GAO analysis of HRSA data.

Note: An EMA's base funding is determined according to its proportion of AIDS cases. If an EMA qualifies for hold-harmless funding, that amount is added to the base funding and distributed together as the base grant.

[a]This was calculated by dividing the base formula funding received by each EMA by the number of AIDS cases in the EMA. However, because of rounding error, some of the calculations are slightly different than if the base formula funding per AIDS case without a hold-harmless benefit ($1,221) is added to the hold-harmless funding per AIDS case.

[b]Individual entries do not sum to total because of rounding.

The funding impact of the hold-harmless provision varies among the EMAs that benefit but it can be substantial. In order to place hold-harmless

funding in perspective, it is helpful to consider how much of an EMA's Title I base grant was made up of hold-harmless funding. EMAs that did not receive hold-harmless funding received approximately $1,221 in base grant funding per AIDS case. Fiscal year 2004 base grant funding per AIDS case in EMAs that received hold-harmless funding ranged from $1,223 (Newark) to $2,241 (San Francisco). Thus, San Francisco received $1,020 more in base grant funding per AIDS case than did EMAs that did not receive hold-harmless funding. This hold-harmless funding represents approximately 46 percent of San Francisco's base grant. Because of its hold-harmless funding, San Francisco, which had 7,216 AIDS cases in fiscal year 2004, received a base grant equivalent to what an EMA with approximately 13,245 AIDS cases (84 percent more) would have received based on the proportion of cases. Kansas City, the second largest hold-harmless grantee, received about what an EMA with 9 percent more AIDS cases would have received.

The San Francisco EMA's 2004 hold-harmless funding was linked to cumulative AIDS cases used to determine fiscal year 1995 funding. In fiscal year 2004 San Francisco was guaranteed to receive 89 percent of its fiscal year 2000 Title I base grant, but San Francisco's 2000 allocation was also held harmless under the 1996 CARE Act reauthorization. Under the 1996 reauthorization, EMAs were guaranteed 95 percent of their 1995 base grant in fiscal year 2000.[11] San Francisco was the only EMA to qualify for hold-harmless funding in 2000 because it was the only EMA that would have received less than 95 percent of its fiscal year 1995 base grant. This means that in fiscal year 2004 San Francisco was guaranteed approximately 85 percent of its fiscal year 1995 base grant of $19,126,679.[12] Prior to the 1996 reauthorization, funding was distributed among EMAs on the basis of the cumulative count of diagnosed AIDS cases (that is, all cases reported in an EMA both living and deceased since the beginning of the epidemic in 1981). Because the application of the Title I hold-harmless provision for San Francisco dates back to the 1996 reauthorization, San Francisco's

[11]The amounts guaranteed in the Title I hold-harmless provisions differed in the 1996 and 2000 CARE Act reauthorizations. In the 1996 reauthorization the guaranteed amounts ranged from 95 to 100 percent of the 1995 base grant. In the 2000 reauthorization the guaranteed amounts ranged from 85 to 98 percent of the 2000 base grant.

[12]The guaranteed amount is calculated by multiplying the two percentages (89 and 95) together. In other words, in fiscal year 2004 San Francisco was guaranteed to receive at least 89 percent of its fiscal year 2000 Title I base grant. Its fiscal year 2000 Title I base grant was guaranteed to be no less than 95 percent of its fiscal year 1995 Title I base grant.

Title I base grant is determined in part by the number of cumulative cases in the San Francisco EMA as of 1995.

Grandfathering Maintains Eligibility for EMAs That No Longer Meet Certain Eligibility Criteria

More than one half of the EMAs received Title I funding in fiscal year 2004 even though they were below Title I eligibility thresholds.[13] These EMAs' eligibility was protected under a CARE Act grandfather clause. Under a grandfather clause established by the 1996 amendments to the CARE Act, once a metropolitan area's eligibility is established, the area remains eligible for Title I funding even if the number of reported cases in the most recent 5 calendar years drops below the statutory threshold. We found that in fiscal year 2004, 29 of the 51 EMAs did not meet the eligibility thresholds, but their Title I funding was protected by a grandfather clause (see table 5). The number of reported AIDS cases in the most recent 5 calendar years in the 29 EMAs ranged from 223 to 1,941. Title I funding awarded to these 29 EMAs was about $116 million, or approximately 20 percent of the total Title I funding.

[13]To be eligible for Title I funding, an area must have reported more than 2,000 AIDS cases during the most recent 5 calendar years and have a population of at least 500,000. These criteria differ from those used to calculate funding allocations, which are determined using the number of AIDS cases. AIDS cases are calculated by applying annual national survival weights to the most recent 10 years of reported AIDS cases and adding the totals from each year. In the 1990 CARE Act, EMAs were defined as a metropolitan area with a cumulative count of more than 2,000 AIDS cases or a cumulative count of AIDS cases that exceeded one-quarter of one percent of its population.

Table 5: Grandfathered EMAs, Fiscal Year 2004

EMA	Number of AIDS cases reported in the most recent 5 calendar years	Total Title I funding
Riverside-San Bernardino, Calif.	1,941	$6,823,183
New Haven, Conn.	1,717	7,069,348
Oakland, Calif.	1,633	6,611,607
Nassau-Suffolk, N.Y.	1,560	5,951,789
Norfolk, Va.	1,502	4,820,201
Seattle, Wash.	1,459	5,842,615
Jacksonville, Fla.	1,423	4,863,093
Orange County, Calif.	1,422	5,233,329
St. Louis, Mo.	1,247	4,371,154
Jersey City, N.J.	1,226	5,884,194
Las Vegas, Nev.	1,182	4,473,401
Denver, Colo.	1,167	4,529,097
Austin, Tex.	1,149	3,800,250
Bergen-Passaic, N.J.	1,067	4,814,704
Hartford, Conn.	1,059	4,552,237
San Antonio, Tex.	1,034	3,833,443
Cleveland, Ohio	970	3,486,936
Portland, Oreg.	937	3,567,475
Fort Worth, Tex.	854	3,373,450
Kansas City, Mo.	822	3,240,813
Minneapolis, Minn.	794	3,093,915
Sacramento, Calif.	717	2,968,051
Ponce, P.R.	710	2,718,331
Middlesex-Somerset-Hunterdon, N.J.	682	2,723,697
San Jose, Calif.	656	2,656,550
Caguas, P.R.	411	1,816,647
Dutchess County, N.Y.	255	1,231,242
Vineland-Millville-Bridgeton, N.J.	238	847,898
Santa Rosa, Calif.	223	1,107,428
Total		**$116,306,348**

Source: GAO analysis of CDC and HRSA data.

Note: The 5 most recent calendar years are from 1998-2002.

As discussed earlier, some metropolitan areas are designated as emerging communities because their caseloads are not large enough to make them eligible for Title I funding as EMAs. However, some emerging communities had more reported AIDS cases in the last 5 years than some of the EMAs that have been grandfathered.[14] For example, for fiscal year 2004 Memphis, a designated emerging community, had 1,588 reported AIDS cases during the most recent 5 calendar years, which is more than the number of cases reported in 26 EMAs. This results in variability in funding per case caused by grandfathering EMAs.

Title II Hold-Harmless Funding Could Diminish ADAP Severe Need Grants in the Future

A Title II hold-harmless provision could diminish ADAP Severe Need grant amounts in the future because the provision and the grants are funded from the same set-aside of funds. If larger amounts are needed to fund the hold-harmless provision in the future, the Severe Need grant states could get less than the grant amounts they would otherwise receive.

Fiscal year 2004 was the first time that any states triggered this Title II hold-harmless provision, which was established by the 2000 amendments. Severe Need grants are funded by setting aside three percent of the total CARE Act Title II funding for ADAPs.[15] The Title II hold-harmless provision, also funded by the 3 percent set-aside for Severe Need grants, guarantees that the total of Title II and ADAP base grants made to a state will be at least as large as the grants made the previous year. In fiscal year 2004 eight states became eligible for this hold-harmless funding. To provide these jurisdictions with hold-harmless funding, HRSA officials told us they used funds from the 3 percent set-aside for Severe Need grants. In 2004, the 3 percent set-aside for Severe Need grants was $22.5 million. Of these funds, $1.6 million, or 7 percent, was used to provide this Title II

[14]Both EMA eligibility and emerging community funding are based on the number of AIDS cases reported in the most recent 5 calendar years.

[15]To be eligible for a Severe Need grant, a state must have met at least one of four eligibility criteria as of January1, 2000. It must have limited (1) the eligibility of ADAP clients to those with incomes at or below 200 percent of the federal poverty level, (2) the number of ADAP clients by using medical eligibility restrictions, (3) the number of antiretroviral drugs covered in its drug formulary, or (4) the number of opportunistic infection medications to less than 10 in its drug formulary. (Opportunistic infections are illnesses such as parasitic, viral, and fungal infections, and some types of cancer, some of which usually do not cause disease in people with normal immune systems.) Having met the eligibility criteria, a state can then apply for the Severe Need grants each year by agreeing to provide the statutorily required 25 percent state match through state funds or in-kind services.

hold-harmless protection. (See table 6.) The remaining $20.8 million, or 93 percent of the set-aside amount, was distributed in Severe Need grants.

Table 6: States that Received Title II Hold-Harmless Funding from Severe Need Set-Aside; Fiscal Year 2004

State	Hold-harmless amount
Arkansas	$23,705
Kansas	22,168
New Mexico	55,171
North Dakota	1,820
Oklahoma	96,423
Tennessee	1,300,502
Utah	119,695
Vermont	128
Total	**$1,619,612**

Source: HRSA.

The potential exists for this Title II hold-harmless provision to diminish the size of Severe Need grants in the future if larger amounts are needed to fund the hold-harmless protections. The total amount of Severe Need grant funds available in fiscal year 2004 to distribute among the eligible states was less than it would have been without the hold-harmless deduction. In fiscal year 2004 not all 25 of the states eligible for Severe Need grants made the required match in order to receive the grant. Consequently, the size of the severe need grants received by each state was not less than what they would have received if all eligible states made the match. In future years, if all of the eligible states make the match, and if there are also states that qualify to receive hold-harmless funds, the Severe Need grant states would get less than the amounts they would have otherwise received.

Funding Impact of Using HIV Case Counts Would Depend on the Adequacy of HIV Reporting Systems and the Number of Reported HIV Cases

If HIV case counts had been used with AIDS case counts in allocating Title II base funding, about half of the states would have received increased funding and the other half would have received less funding.[16] Under the 2000 CARE Act reauthorization, HIV case counts are required to be included in CARE Act funding formulas no later than fiscal year 2007. While all states have established HIV case reporting systems, there are currently characteristics of these systems that limit the use of HIV case counts in the distribution of CARE Act funds. In order to gauge the funding impact of using the data as they currently exist, we developed two theoretical approaches for doing so. Using these two approaches, we found that some fiscal year 2004 Title II base funding would have shifted to southern states if HIV case counts had been used with AIDS case counts in the distribution of funds.[17] We also found that funding would tend to shift to jurisdictions with older HIV reporting systems, regardless of their location. Changes in funding due to the inclusion of HIV cases would be largely offset, at least initially, if the funding formulas retained hold-harmless and minimum grant provisions.

Current HIV Case Reporting Systems Have Limitations for Providing Case Counts for Funding Allocations

In its 2004 report, IOM identified several limitations in the ability of states to provide HIV case counts for use in CARE Act funding allocations.[18] Among these limitations, IOM found that the maturity of HIV case reporting systems varies widely across states. The earliest HIV reporting systems were established in Colorado, Minnesota, and Wisconsin in 1985, while five jurisdictions implemented their systems since 2003. Case reporting systems need time to become fully mature and operational, and it takes time to make practitioners aware of the requirement to report new HIV cases and the methods for doing so. Existing cases also need to be reported and entered into the system. States with newer systems may not have collected and entered data on existing cases, and, consequently, may underreport the number of HIV cases in the state. Underreporting of HIV

[16]We chose Title II base grants to illustrate the effect of using HIV case counts in funding formulas. All of our analyses were conducted using estimated living AIDS cases.

[17]The Census Bureau lists the following jurisdictions as being in the South: Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and West Virginia.

[18]Institute of Medicine of the National Academies, *Measuring What Matters: Allocation, Planning, and Quality Assessment for the Ryan White CARE Act* (Washington, D.C.: The National Academies Press, 2004), pp. 87-134.

cases could result in jurisdictions receiving less funding than they would be entitled to based on the actual number of HIV and AIDS cases.

IOM also found that differences in how states report HIV case counts to CDC could preclude their use in the distribution of CARE Act funds. Some state HIV case reporting systems are name-based while others are code-based. Currently, CDC will only accept name-based case counts.[19] Therefore, state-reported HIV cases that use codes rather than names would not be counted in allocating CARE Act funds, if HIV case counts were used in funding formulas. Twelve states, the District of Columbia, and Philadelphia, PA, have some form of a code-based system rather than a name-based system.[20] CDC does not accept the code-based data principally because methods have not been developed to make certain that a code-reported HIV case is only being counted once across all reporting jurisdictions.[21] Table 7 shows whether state HIV case counts are accepted by CDC and the year in which each state established its HIV reporting system.

[19]CDC has established a set of performance standards for accepting case counts from HIV reporting systems. These standards include that case reporting be complete (greater than or equal to 85 percent of cases are reported) and timely (greater than or equal to 66 percent of cases reported within 6 months of diagnosis) and that evaluation studies demonstrate that the approach used to conduct surveillance must result in accurate case counts (less than or equal to 5 percent of reported cases are duplicates). As of June 2005, CDC has determined that the only systems which have been evaluated that meet these standards use confidential, name-based reporting. Some jurisdictions use codes instead of names to secure the privacy of the individuals being counted.

[20]Pennsylvania has a name-based reporting system for all areas of the state except Philadelphia. The city received special permission to establish a code-based system. Philadelphia implemented such a system in 2004, but it is separate from the Pennsylvania reporting system.

[21]CDC also has other concerns about code-based reporting. For example, code-based reporting places a greater burden on health care providers because submitted codes are frequently incomplete and require extensive follow-up by surveillance personnel with providers to resolve potential duplicate reports on the same person.

Table 7: CDC Acceptance of State HIV Case Counts and Year of Establishment of State HIV Reporting Systems

CDC-accepted		Not accepted	
Alabama (1988)	New Hampshire (2005)[b]	California (2002)	Massachusetts (1998)
Alaska (1999)	New Jersey (1992)	Delaware (2001)	Montana (2000)
Arizona (1987)	New Mexico (1998)	District of Columbia (2001)	Oregon (2001)
Arkansas (1989)	New York (2000)	Hawaii (2001)	Rhode Island (2000)
Colorado (1985)	North Carolina (1990)	Illinois (1999)	Vermont (2000)
Connecticut (2005)[a]	North Dakota (1988)	Maine (1999)	Washington (1999)
Florida (1997)	Ohio (1990)	Maryland (1994)	
Georgia (2004)	Oklahoma (1988)		
Idaho (1986)	Pennsylvania (2002)[c]		
Indiana (1988)	Puerto Rico (2003)		
Iowa (1998)	South Carolina (1986)		
Kansas (1999)	South Dakota (1988)		
Kentucky (2004)	Tennessee (1992)		
Louisiana (1993)	Texas (1999)		
Michigan (1992)	Utah (1989)		
Minnesota (1985)	Virginia (1989)		
Mississippi (1988)	West Virginia (1989)		
Missouri (1987)	Wisconsin (1985)		
Nebraska (1995)	Wyoming (1989)		
Nevada (1992)			

Sources: CDC, IOM, Connecticut, Kentucky, and Philadelphia.

[a]Connecticut established mandatory name-based HIV reporting in 2005. Previously, name-based reporting was only required for pediatric cases.

[b]New Hampshire established mandatory name-based HIV reporting in 2005. Previously, HIV cases could be reported using the patient name, a code, or no identifier at all.

[c]Name-based HIV reporting has been established in all parts of Pennsylvania except Philadelphia. Philadelphia was given permission by the state to establish code-based HIV reporting, and the system began in 2004, but data from Philadelphia are not accepted by CDC.

The Use of HIV Case Counts in Funding Formulas Would Change the Distribution of CARE Act Funds

While we are aware of some of the limitations of HIV data, we used two approaches to examine the potential impact of using HIV cases in addition to AIDS cases on fiscal year 2004 Title II base grant distributions. We conducted this analysis in light of the CARE Act requirement that HIV case counts be used for the distribution of Title I and Title II formula grants no later than fiscal year 2007. Some CARE Act fiscal year 2004 funding would have shifted if HIV and AIDS case counts had been used to allocate the

funds. Our analyses indicate that at most 14 percent of CARE Act Title II base funding would have shifted, with southern states being the primary beneficiaries. Changes could have resulted from the number of reported HIV cases and AIDS cases in each jurisdiction or differences in state HIV case reporting systems. However, many of the funding changes in our model would have been negated if we had applied hold-harmless and minimum grant provisions.

Methodological Approaches Used

We used two approaches to examine the impact of using HIV cases in addition to AIDS cases[22] on funding for Title II base grants in the 50 states, the District of Columbia, and Puerto Rico. We chose Title II base grants to illustrate the effect of using HIV case counts in funding formulas. Under the first approach, we used HIV case counts in addition to AIDS case counts for the 36 jurisdictions from which CDC accepted HIV data.[23] We then supplemented these data with only the AIDS case counts CDC received from the other jurisdictions because CDC does not accept their HIV data. Consequently, for some states and metropolitan areas we used HIV and AIDS case counts, but for others we used only AIDS case counts. This approach reflects the data that would be used if funding allocations were based on the HIV and AIDS case counts currently received by CDC. Under the second approach, we used the same HIV and AIDS case counts for the 36 jurisdictions as our first approach, but supplemented these data with the HIV case counts collected by the other 15 states and the District of Columbia from which CDC did not accept HIV data. We obtained these HIV case counts directly from these jurisdictions. For both approaches, we calculated the percentage of cases in each jurisdiction and estimated the fiscal year 2004 Title II base grant that each would have received. Our initial analyses assume that funding was distributed equally per AIDS case and that there were no hold-harmless or minimum grant provisions. We then estimated the impact of the hold-harmless and minimum grant provisions. Although there are limitations associated with each of the

[22]We used estimated living AIDS cases in these analyses, which is the measure used by HRSA in determining Title II base grants.

[23]In these analyses, Connecticut, Kentucky, and New Hampshire are classified as not having their HIV case counts accepted by CDC. Our analyses were conducted using fiscal year 2004 allocations, which were based on case reports as of June 30, 2003. At that time, Connecticut had name-based HIV reporting for only pediatric cases, but established name-based reporting for all cases in 2005. Kentucky had code-based reporting at that time and established name-based reporting in 2004. New Hampshire established mandatory name-based reporting in 2005, but previously accepted reports using the patient name, a code, or no identifier.

approaches, they indicate the general impact of using HIV and AIDS cases to distribute all CARE Act formula funding.

Impact on Title II Base Grants

Both approaches indicated that there would be some shifting of funds if HIV and AIDS case counts had been used to allocate CARE Act Title II base grants, with southern jurisdictions generally being among the areas that would have received increased funding. Under the first approach—using HIV and AIDS cases from 36 jurisdictions and only AIDS cases from 16 jurisdictions—about 14 percent or $38.9 million of Title II base grants would have shifted among grantees. Twenty-seven grantees would have received additional funding in their Title II base grants if HIV and AIDS cases had been used to allocate funding instead of just AIDS cases. Of the 27 that would have received more funding, 12 were in the South. Jurisdictions outside the South that would have received more funding include Colorado, New Jersey, and Ohio. All 3 would have each received more than $2 million in additional funding. Funding increases would have ranged from less than $50,000 in Iowa to almost $5 million in North Carolina, or from less than 5 to almost 100 percent. Twenty-five grantees would have received less funding. California, Georgia, and Illinois would have received the largest decreases in Title II base grants. Decreases would have ranged from about $100,000 in Idaho and Wyoming to almost $12 million in California. Percentage decreases would have ranged from less than 5 percent in New York to almost 80 percent in Montana.

The second approach — including the code-based HIV counts — yields a smaller shift in funding. Under this approach, approximately 10 percent or $28.4 million of fiscal year 2004 Title II base grants would have shifted. Of the 26 grantees that would have received additional funding, 11 are in the South. Funding increases for the 26 grantees that would have received additional funding would have ranged from less than $50,000 in Maine to about $4 million in North Carolina, or from 5 percent in Washington to 80 percent in Colorado. Among the states benefiting from this funding approach, Maryland, North Carolina, and Virginia would each have received increases of more than $2 million. Twenty-six grantees would have received less funding. California, New York, and Georgia, would have received the largest decreases. Decreases would have ranged from less than $50,000 in Iowa to $5 million in California. Percentage decreases would have ranged from less than 5 percent in Florida, Illinois, New Mexico, and Utah to 65 percent in North Dakota. Appendix II shows the results of these analyses for each state.

Differences in Case Reporting Systems Would Affect Distributions

One explanation for the changes in funding allocations when HIV and AIDS cases are used instead of only AIDS cases is the maturity of state HIV case reporting systems. We found that those states that would benefit from the use of HIV cases tend to be those with the oldest HIV case reporting systems. Those states with the oldest reporting systems include 11 southern states whose HIV reporting systems were implemented prior to 1995. As shown in table 8, states with long histories of collecting HIV case counts tend to have many more HIV cases compared with their number of AIDS cases than do states with less mature reporting systems. This is likely because states with newer systems do not have reports on many cases of HIV diagnosed before their reporting systems were established.[24] This can be illustrated by comparing Wisconsin and Delaware, 2 states with similar numbers of AIDS cases. Wisconsin began reporting HIV cases in 1985 while Delaware began in 2001. As of June 2003, the 909 reported HIV cases in Delaware was about 40 percent less than the 1,518 reported AIDS cases. In Wisconsin, there were about 50 percent more reported HIV cases and AIDS cases, or 2,287 HIV cases and 1,507 AIDS cases. This variability could be reduced as Delaware identifies more preexisting HIV cases. However, the variability between HIV cases and AIDS cases would remain if there was a difference in the actual number of HIV cases.

Table 8: Comparison of Reported HIV and AIDS Cases as of June 2003

HIV case reporting system start date	Number of states[a]	Ratio of HIV cases to AIDS cases
1985-1991	21	1.42
1992-1998	11	1.01
1999-2002	17	.68

Source: GAO analysis of CDC, HRSA, and state data.

[a]Georgia and Puerto Rico implemented their HIV reporting systems after 2002. Kentucky changed from a code-based to a name-based system in 2004 and was unable to provide HIV case data. In this table, Connecticut is classified as having established its reporting system in 2001 (and so is included in the 1999-2002 time period) since state officials provided us HIV case counts based on the system in operation as of June 2003. In this table, New Hampshire is classified as having established its reporting system in 1990 (and so is included in the 1985-1991 time period) because state officials provided us HIV case counts based on the system in operation as of June 2003.

[24]Other factors may also affect the ratio of HIV to AIDS cases in a reporting system. For example, some states with newer reporting systems were among the first to be affected by the HIV epidemic. This could mean that in those states there are relatively more AIDS cases and the ratio of HIV to AIDS cases would be lower than in states more recently experiencing an HIV epidemic.

Under either approach, jurisdictions that would receive increased funding allocations because of the use of HIV and AIDS case counts might do so because other jurisdictions did not yet have an accurate measure of HIV case counts. The larger the proportion of HIV cases within the total number of HIV and AIDS cases in a jurisdiction, the more a jurisdiction would benefit from the use of HIV cases in funding allocations. However, this increased funding could simply be the effect of a state's older reporting system, and not necessarily due to actual differences in the number of HIV cases. IOM has reported that it could take from 18 months to several years after the implementation of an HIV reporting system before there would be valid estimates of the number of people living with HIV. However, table 8 suggests that it could take even longer to get accurate case counts. The data in table 8 suggest that as an HIV case reporting system matures, it will record a higher ratio of HIV cases to AIDS cases. One state official we spoke with said that it could take 5 to 6 years before a reporting system's HIV case counts were complete.

Changes in Funding Would be Limited Initially if Certain Formula Provisions Were Maintained

Changes in funding caused by shifting to HIV cases and AIDS cases would be negated, at least initially, if the current hold-harmless or minimum grant amounts were maintained. Consider the situation in which a state received $2 million in its Title II CARE Act base grant award based on its AIDS case count. In the following year, the formula is changed so that HIV and AIDS cases are used to determine funding allocations, and the state is then only entitled to $1 million. However, there is a hold-harmless provision that guarantees the state 98 percent of what it received the previous year. The state would receive 98 percent of its $2 million allocation, or $1.96 million, largely offsetting the reduction in funding due to the shift to HIV and AIDS cases. Minimum award amounts could also affect the impact of using HIV and AIDS counts. If a jurisdiction qualified for $100,000 formula funding using HIV and AIDS case counts, but the minimum award was $500,000, the jurisdiction would not receive less funding because of the change to HIV and AIDS counts.

Under our first approach, 5 percent of Title II base grants would shift among grantees if the hold-harmless and minimum grant provisions were maintained while 14 percent would shift if they were not included. Under our second approach, 4 percent would shift instead of 10 percent. California, which would have had large reductions under both approaches if the hold-harmless provision was not maintained, would have had no change in funding under either approach if the current hold-harmless provisions were maintained. Appendix III shows the results of these analyses for each state.

State ADAP Eligibility Criteria and Funding Sources Vary Widely

Among state ADAP programs, there is wide variation in the eligibility criteria used to determine who is covered for ADAP services and in the funding sources available beyond each state's Title II ADAP base grant. States have flexibility in determining their ADAP program eligibility standards, including the income eligibility ceilings for ADAP clients, caps on spending per client, and the HIV and AIDS drugs included in their formulary. As a result, an individual eligible for ADAP services in one state may not be eligible in another. There is also wide variability in the additional funding sources that ADAPs may receive to help fund their programs. Beyond each state's Title II ADAP base grant for providing HIV and AIDS medications and related services, additional ADAP funding sources may include Title II Severe Need grants, non-federal transfers of Title II state or Title I EMA funds, state contributions, and other funding sources. States with waiting lists for ADAP services do not fit any particular pattern of eligibility criteria and funding sources.

Eligibility Criteria Contribute to Coverage Differences Among States

States set different eligibility criteria for their ADAP programs, so a person with HIV or AIDS at a certain income level and needing medication assistance may be an eligible ADAP client in one state, but not in another. Eligibility also varies among state Medicaid programs, which may provide HIV and AIDS services and drug assistance. The interaction between these two programs can affect which clients are eligible for ADAP services, and many individuals seeking ADAP coverage may not be aware that they are eligible for drug assistance through Medicaid.

One eligibility requirement where there is considerable variation among state ADAPs is the client income ceiling. The income ceilings among 52 state ADAPs for fiscal year 2004 ranged from the most restrictive at 125 percent of the federal poverty level,[25] or $11,638, in North Carolina to the most generous at 556 percent, or $51,764, in Massachusetts. Eleven states had eligibility ceilings at 200 percent or less of the poverty level.

Another eligibility criterion where there is wide variation among state ADAPs is the number of HIV and AIDS drugs covered under a state program's drug formulary. The number of drugs included in ADAP formularies in fiscal year 2004 varied widely from Colorado with 20 drugs

[25]The 2004 Department of Health and Human Services' federal poverty level for a single person was $9,310; the poverty levels are higher for Alaska ($11,630) and Hawaii ($10,700). Poverty level is not defined for Puerto Rico.

to four state ADAPs—Massachusetts, New Hampshire, New Jersey, and Washington—with open drug formularies.[26] Thirty-nine ADAPs had 100 or fewer drugs, including 15 with fewer than 50 drugs on their formularies. The CARE Act allows states to purchase health insurance to cover HIV and AIDS drugs for their clients. HRSA requires an ADAP to demonstrate that the insurance includes coverage for drugs comparable to those on the state's ADAP formulary.[27]

Determining whether an individual is eligible for state ADAP or state Medicaid services is important because the ADAPs serve as the individual's HIV and AIDS drug assistance program of last resort. Medicaid programs provide HIV and AIDS health care services, including medications, to eligible disabled individuals with low incomes. If an individual is eligible for a state's Medicaid drug assistance, the state ADAP should not provide the same services under its program. Twenty-three ADAPs reported requiring clients to have been denied Medicaid eligibility before the ADAP will cover them. To ensure that a prospective or current ADAP client is not eligible to be served by Medicaid, 42 of the 52 state ADAPs reported in ADAP grant year 2004[28] that they used a case manager review process to monitor an ADAP client's Medicaid eligibility, and 40 of the 52 ADAPs also reported using computer access to eligibility determinations to verify a client's Medicaid and ADAP eligibility.

Because it is important to ensure continuing therapy for HIV and AIDS clients once they begin taking medications, states may limit the number of ADAP clients they serve to prevent a budget shortfall. This could result in eligible clients being on an ADAP waiting list. States also use a variety of ADAP eligibility restrictions to limit the number of clients they serve. Of the 52 state ADAPs, 36 reported eligibility restrictions for ADAP grant year 2004, and 20 of the 36 used more than one. The restrictions most used were (1) an annual cap on individual incomes by 20 ADAPs, (2) a limitation on an individual's assets by 16 ADAPs, (3) capping ADAP enrollment by 7 ADAPs, (4) sliding scale copayments paid by individuals by 7 ADAPs, and (5) capping the amount expended per client for all HIV

[26]In the state ADAP profile reports for ADAP grant year 2004, Massachusetts, New Hampshire, and New Jersey each reported having 1,000 drugs on their ADAP formularies, and Washington reported it had 125 drugs on its formulary.

[27]In fiscal year 2003, 20 states reported that they used either funds from their Title II base ($3 million) or ADAP ($23.5 million) grants to purchase health care insurance.

[28]ADAP grant year 2004 covers the period April 1, 2004 through March 31, 2005.

and AIDS drugs by 6 ADAPs. Appendix IV provides a state-by-state summary of the reported restrictions.

A Large Percentage of ADAPs' Funds Received from Sources Other than the ADAP Base Grant

In addition to their Title II ADAP base grants, 46 of the 52 states ADAPs received funding from other sources for their programs in fiscal year 2004. There were five sources of additional funding across these 46 state ADAPs: (1) $20.8 million in Title II Severe Need grants (including $4.5 million in state match funds), (2) $26.9 million from Title II state funding transfers, (3) $10.9 million from Title I EMA funding transfers, (4) $194.8 million in state contributions, and (5) $169.3 million in other funds. When the additional funding source totals are compared among states as a percentage of the ADAP's CARE Act base grant, and as an amount per AIDS case, there is a significant range among the states. Appendix V provides a state-by-state summary of additional ADAP funding and the base grant and per AIDS case comparisons.

State ADAPs that received funding from sources other than their Title II base grant award include

- Sixteen of the 25 states eligible for ADAP Severe Need grants received grant amounts ranging from about $37,000 in Montana to about $6 million in Texas. States eligible for these grants must agree to match 25 percent of the funds.[29]
- Eighteen ADAPs reported receiving transfers from their states' Title II base grants ranging from about $65,000 in Maryland to $12.2 million in California.
- Nine of the 24 states with EMAs reported receiving Title I fund transfers from their EMAs for their ADAPs ranging from more than $65,000 for Nevada to about $6 million for New York.
- Thirty-five ADAPs reported receiving state contributions from their states ranging from about $8,000 in Ohio to about $64 million in California.
- Thirty-two ADAPs reported other funding sources ranging from about $7,000 in Montana to $64.5 million in New York. Other funding sources include additional funds from drug rebates[30] and HRSA approved carryover of ADAP CARE Act funds from one year to the next.

[29]According to HRSA, Puerto Rico is not required to provide matching funds for Severe Need grants.

[30]ADAPs can receive drug rebates through (1) the federal Section 340B drug discount program, (2) their states' negotiated rebates, or (3) the National Alliance of State and Territorial AIDS Directors' negotiated rebates.

Among states with additional funding sources, there is a significant range in amounts per AIDS case and percentages of the ADAP base grants. The highest amount of additional funding received per AIDS case was $3,604, or 171 percent of the base grant in Idaho and the lowest was $61 per AIDS case, or 3 percent of the base grant in the District of Columbia. ADAPs in six states did not receive any additional funding—Iowa, New Hampshire, New Mexico, Tennessee, Utah, and Wyoming.

Eligibility Criteria and Funding Sources Also Vary Among States with Waiting Lists

During fiscal years 2002 through 2004, some states had people eligible for their ADAPs' services on waiting lists and the states with ADAP waiting lists have remained relatively static in fiscal years 2002 through 2004. Sixteen, or about one-third, of the 52 states had ADAP waiting lists for at least 1 month during these 3 years. Seven of the 16 states had ADAP waiting lists in all 3 years. (See table 9.)

Table 9: States with ADAP Waiting Lists in at Least 1 Month of a Fiscal Year, Fiscal Years 2002-04

	State	FY2002	FY2003	FY2004
1	Alabama	•	•	•
2	Alaska		•	•
3	Arkansas			•
4	Colorado		•	•
5	Georgia	•		
6	Idaho		•	•
7	Indiana	•	•	•
8	Iowa			•
9	Kentucky	•	•	•
10	Montana	•	•	•
11	Nebraska		•	•
12	North Carolina	•	•	•
13	Oregon	•	•	•
14	South Dakota	•	•	•
15	West Virginia		•	•
16	Wyoming		•	
Total		**8**	**13**	**14**

Source: HRSA and GAO analysis.

The funding sources and eligibility criteria for states with waiting lists have varied just as considerably as for states without waiting lists, and there is no clear pattern between a state's funding sources or eligibility criteria and the existence of a waiting list. While 33 states that received additional funds did not have an ADAP waiting list in 2004, 13 of the 14 states with waiting lists also received additional funding beyond their ADAP base grant. For example, for

- **Title II Severe Need grants**: Eight of the 16 states that received Severe Need grants had waiting lists. Three of the 9 eligible states that did not apply for Severe Need grants in 2004—Alaska, Iowa, and South Dakota—also had ADAP waiting lists.
- **Title I EMA transfers**: One state ADAP of the nine that received a Title I transfer—Colorado—had an ADAP waiting list.
- **Title II state transfers**: Eight of the 18 ADAPs receiving Title II transfers had waiting lists.
- **State funds**: Nine of the 35 ADAPs that received state funds had waiting lists.
- **Other funding**: Of the 32 ADAPs reporting other funding sources, 10 had ADAP waiting lists.

Of the 14 states with ADAP waiting lists, 5 were among the top 10 for additional funding per AIDS case received—Idaho (1), South Dakota (2), Oregon (3), North Carolina (7), and Colorado (8). The remaining 9 states with waiting lists and their per AIDS case ranks were Montana (12), Alabama (18), Nebraska (23), Indiana (24), West Virginia (28), Kentucky (33), Arkansas (34), Alaska (42), and Iowa with no additional funds.

There also seems to be no clear pattern between eligibility criteria—such as a low income eligibility ceiling or a limited drug formulary—and a waiting list of clients that a state ADAP deems eligible but is unable to serve. For example, for

- **Client income eligibility levels**: North Carolina with the most restrictive level at 125 percent of the poverty level had a waiting list, and Massachusetts with the most generous level at 556 percent had no waiting list.
- **Eligibility restrictions**: Among the seven ADAPs that capped their ADAP enrollment, six had waiting lists. Five ADAPs that capped the amount they expend per client for all HIV and AIDS drugs included two states with waiting lists.
- **Drug formularies**: Among the 39 ADAPs with 100 or fewer drugs on their formularies, 13 had waiting lists.

When eligible clients are on state ADAP waiting lists, there are limited medication assistance options available to help them until they can be served by the ADAP. HRSA officials told us that case managers, who are not ADAP employees, are to assist ADAP-eligible clients in accessing options to act as stopgaps until clients can be provided ADAP services. Among the options are pharmaceutical manufacturers' patient assistance programs that provide free or cost-reduced drugs and non-ADAP pharmacy assistance programs provided by some EMAs using their Title I funds.[31]

Concluding Observations

The services provided under the Care Act have filled important gaps in communities throughout the country, but as Congress reviews this act, we believe it is important to understand how variable this funding can be. Today I have highlighted a few of the issues that are relevant to this review. For each of these issues, we found that the provisions of the CARE Act have impacted the extent to which funds have been distributed in proportion to the incidence of HIV and AIDS. It is clear that the level of funding available per case is quite variable depending upon where an individual lives. The way cases from EMAs are counted twice, the tiered allocation of funds to Emerging Communities, the hold-harmless provisions, and the grandfathering of EMAs have all resulted in considerably more funding going to some communities than others with equivalent numbers of cases. The inclusion of HIV cases in the funding formulas, while improving on the basis for funding allocations by reflecting cases that have not progressed to AIDS, would also result in variable funding depending upon the type and maturity of the reporting system used in each state. In addition, the flexibility given to states to shift funds, establish eligibility criteria, place limits on the medications covered, and cap enrollment, has resulted in great variability for ADAP services depending upon where an individual lives.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other members of the subcommittee may have at this time.

[31]In fiscal year 2003, 33 EMAs in 16 states used $33.3 million of their Title I funds to provide HIV and AIDS pharmaceutical assistance.

Contact and Acknowledgments

For future contacts regarding this testimony, please call Marcia Crosse at (202) 512-7118. Other individuals who made key contributions include Robert Copeland, Louise Duhamel, Cathy Hamann, James McClyde, Opal Winebrenner, and Craig Winslow.

Appendix I: Combined CARE Act Title I and Title II Funding by State, Fiscal Year 2004

State/territory	Combined Title I and Title II awards	AIDS cases	Percent of AIDS cases in EMAs	Total Title I and Title II awards per AIDS case
Alabama	$12,142,447	3,320	0%	$3,657
Alaska[a]	974,705	224	0	4,351
Arizona	18,635,537	3,978	73.5	4,685
Arkansas	4,933,831	1,466	0	3,366
California	223,607,373	42,479	88.9	5,264
Colorado	12,949,158	2,658	75.0	4,872
Connecticut	26,797,308	5,363	91.4	4,997
Delaware	5,340,795	1,518	0	3,518
District of Columbia	33,288,417	6,561	100.0	5,074
Florida	182,771,752	38,101	77.3	4,797
Georgia	54,483,301	11,226	67.6	4,853
Hawaii	3,298,130	988	0	3,338
Idaho[a]	1,019,352	220	0	4,633
Illinois	60,837,359	12,203	87.9	4,985
Indiana	11,402,950	3,095	0	3,684
Iowa	2,067,375	619	0	3,340
Kansas	3,881,999	959	34.2	4,048
Kentucky	7,170,005	1,937	0	3,702
Louisiana	29,740,454	6,555	48.1	4,537
Maine[a]	1,333,909	395	0	3,377
Maryland	61,230,030	12,203	93.6	5,018
Massachusetts	34,432,147	6,960	83.2	4,947
Michigan	24,046,130	5,215	68.8	4,611
Minnesota	7,139,028	1,427	88.7	5,003
Mississippi	9,454,950	2,747	0	3,442
Missouri	16,501,234	3,512	76.8	4,699
Montana[a]	847,196	147	0	5,763
Nebraska	1,887,660	525	0	3,596
Nevada	10,757,214	2,246	83.3	4,789
New Hampshire[a]	1,864,452	358	69.0	5,208
New Jersey	80,222,837	16,531	84.8	4,853
New Mexico	3,338,463	982	0	3,400
New York	298,549,361	59,226	88.6	5,041
North Carolina	22,668,734	6,083	0.1	3,727
North Dakota[a]	292,543	43	0	6,803

State/territory	Combined Title I and Title II awards	AIDS cases	Percent of AIDS cases in EMAs	Total Title I and Title II awards per AIDS case
Ohio	20,249,202	5,171	29.2	3,916
Oklahoma	6,343,022	1,687	0	3,760
Oregon	9,084,990	2,003	68.9	4,536
Pennsylvania	59,766,256	12,840	67.4	4,655
Puerto Rico	53,026,882	10,711	79.9	4,951
Rhode Island	3,189,276	906	0	3,520
South Carolina	20,705,328	5,563	0	3,722
South Dakota[a]	705,706	97	0	7,275
Tennessee	21,178,234	5,080	0	4,169
Texas	118,965,938	23,922	74.5	4,973
Utah	3,235,191	882	0	3,668
Vermont[a]	883,059	181	0	4,879
Virginia	32,149,863	6,872	63.2	4,678
Washington	17,349,313	3,776	69.8	4,595
West Virginia	2,335,062	618	11.3	3,778
Wisconsin	5,603,506	1,507	0.4	3,718
Wyoming[b]	360,347	76	0	4,741

Sources: GAO analysis of HRSA data.

[a]State received a Title II base award of $500,000, the minimum it could receive based on the number of AIDS cases in the state.

[b]State received a Title II base award of $200,000, the minimum it could receive based on the number of AIDS cases in the state.

Appendix II: Estimated Funding Changes Using HIV and AIDS Cases without Hold-Harmless and Minimum Grant Provisions

	Change in Title II case funding if CDC-accepted HIV case counts and AIDS case counts were used to distribute funding		Change in Title II base funding if HIV case counts from all states and AIDS case counts were used to distribute funding	
State/territory	Dollar change	Percent change	Dollar change	Percent change
Alabama	$2,480,000	61	$1,950,000	48
Alaska*	-270,000	-55	-290,000	-58
Arizona	1,220,000	38	810,000	25
Arkansas	840,000	47	630,000	35
California	-11,790,000	-38	-5,020,000	-16
Colorado	2,090,000	99	1,700,000	80
Connecticut	-1,360,000	-36	-1,420,000	-38
Delaware	-750,000	-41	-230,000	-13
District of Columbia	-1,520,000	-35	-1,800,000	-42
Florida	2,920,000	10	-150,000	-1
Georgia	-3,550,000	-38	-4,090,000	-43
Hawaii	-490,000	-41	-180,000	-15
Idaho*	-80,000	-17	-120,000	-24
Illinois	-3,210,000	-36	-70,000	-1
Indiana	1,170,000	31	760,000	20
Iowa	20,000	2	40,000	6
Kansas	210,000	21	-110,000	-11
Kentucky	-960,000	-41	-1,070,000	-45
Louisiana	2,070,000	33	1,340,000	22
Maine*	-210,000	-43	40,000	9
Maryland	-3,030,000	-36	3,000,000	35
Massachusetts	-1,920,000	-37	510,000	10
Michigan	1,160,000	27	660,000	15
Minnesota	660,000	64	500,000	49
Mississippi	1,580,000	47	1,180,000	35
Missouri	1,260,000	45	880,000	32
Montana*	-390,000	-79	-170,000	-34
Nebraska	140,000	23	80,000	13
Nevada	830,000	50	600,000	35
New Hampshire*	-310,000	-63	-122,000	-24
New Jersey	2,510,000	20	1,120,000	9
New Mexico	50,000	4	-60,000	-5
New York	-600,000	-1	-4,640,000	-11

State/territory	Change in Title II case funding if CDC-accepted HIV case counts and AIDS case counts were used to distribute funding		Change in Title II base funding if HIV case counts from all states and AIDS case counts were used to distribute funding	
	Dollar change	Percent change	Dollar change	Percent change
North Carolina	4,910,000	66	3,910,000	53
North Dakota[b]	-124,000	-62	-130,000	-65
Ohio	2,360,000	43	1,700,00	31
Oklahoma	980,000	48	730,000	36
Oregon	-630,000	-38	-290,000	-17
Pennsylvania	-2,370,000	-22	-3,120,000	-29
Puerto Rico	-2,970,000	-36	-3,460,000	-42
Rhode Island	-450,000	-41	-180,000	-16
South Carolina	2,280,000	34	1,540,000	23
South Dakota[a]	-290,000	-58	-310,000	-62
Tennessee	2,160,000	35	1,480,000	24
Texas	840,000	4	-1,010,000	-5
Utah	40,000	4	-50,000	-5
Vermont[a]	-370,000	-74	-260,000	-53
Virginia	3,040,000	51	2,260,000	38
Washington	-1,170,000	-38	160,000	5
West Virginia	170,000	24	90,000	13
Wisconsin	910,000	50	690,000	37
Wyoming[b]	-90,000	-47	-100,000	-51

Sources: GAO analysis of CDC and HRSA data for fiscal year 2004.

Notes: Rounded to nearest $10,000. For this testimony, we chose Title II base grants to illustrate the effect of using HIV case counts in funding formulas.

[a]State received a Title II base award of $500,000, the minimum it could receive based on the number of AIDS cases in the state.

[b]State received a Title II base award of $200,000, the minimum it could receive based on the number of AIDS cases in the state.

Appendix III: Estimated Funding Changes Using HIV and AIDS Cases with Hold-Harmless and Minimum Grant Provisions

	Change in Title II base funding if CDC-accepted HIV case counts and AIDS case counts were used to distribute funding		Change in Title II base funding if HIV case counts from all states and AIDS case counts were used to distribute funding	
State/territory	Dollar change	Percent change	Dollar change	Percent change
Alabama	$1,120,000	28	$960,000	24
Alaska[a]	0	0	0	0
Arizona	610,000	19	410,000	13
Arkansas	290,000	17	230,000	13
California	0	0	0	0
Colorado	1,530,000	72	1,340,000	63
Connecticut	-150,000	-4	-150,000	-4
Delaware	-410,000	-22	-410,000	-22
District of Columbia	-940,000	-22	-940,000	-22
Florida	-1,380,000	-5	-2,930,000	-10
Georgia	-1,350,000	-14	-1,350,000	-14
Hawaii	-70,000	-6	-70,000	-6
Idaho[a]	0	0	0	0
Illinois	-1,780,000	-20	-790,000	-9
Indiana	130,000	4	20,000	1
Iowa	-90,000	-11	-90,000	-11
Kansas	0	0	0	0
Kentucky	-400,000	-17	-400,000	-17
Louisiana	660,000	11	370,000	6
Maine[a]	0	0	0	0
Maryland	-1,650,000	-20	2,050,000	24
Massachusetts	-620,000	-12	10,000	0
Michigan	350,000	8	120,000	3
Minnesota	460,000	45	370,000	36
Mississippi	550,000	17	430,000	13
Missouri	710,000	26	530,000	19
Montana[a]	0	0	0	0
Nebraska	-20,000	-3	-40,000	-6
Nevada	520,000	31	390,000	23
New Hampshire[a]	0	0	0	0
New Jersey	600,000	5	0	0
New Mexico	-70,000	-6	-70,000	-6
New York	-1,730,000	-4	-1,730,000	-4

State/territory	Change in Title II base funding if CDC-accepted HIV case counts and AIDS case counts were used to distribute funding		Change in Title II base funding if HIV case counts from all states and AIDS case counts were used to distribute funding	
	Dollar change	Percent change	Dollar change	Percent change
North Carolina	2,340,000	32	2,050,000	28
North Dakota[b]	300,000	150	300,000	150
Ohio	890,000	16	660,000	12
Oklahoma	340,000	17	270,000	13
Oregon	-130,000	-8	-130,000	-8
Pennsylvania	-1,840,000	-17	-1,840,000	-17
Puerto Rico	-320,000	-4	-320,000	-4
Rhode Island	-30,000	-2	-30,000	-2
South Carolina	390,000	6	180,000	3
South Dakota[a]	0	0	0	0
Tennessee	420,000	7	220,000	4
Texas	1,140,000	-6	-1,140,000	-6
Utah	-60,000	-6	-60,000	-6
Vermont[a]	0	0	0	0
Virginia	1,510,000	26	1,200,000	20
Washington	-200,000	-7	-180,000	-6
West Virginia	-13,000	-2	-40,000	-5
Wisconsin	340,000	18	270,000	15
Wyoming[b]	300,000	150	300,000	150

Sources: GAO analysis of CDC and HRSA data for fiscal year 2004.

Notes: Rounded to nearest $10,000. For this testimony, we chose Title II base grants to illustrate the effect of using HIV case counts in funding formulas.

[a]State received a Title II base award of $500,000, the minimum it could receive based on the number of AIDS cases in the state.

[b]State received a Title II base award of $200,000, the minimum it could receive based on the number of AIDS cases in the state.

Appendix IV: ADAP Program Eligibility Restrictions Reported by 52 ADAPs, ADAP Grant Year 2004

	Restrictions						
ADAPs	Capped enrollment	Fixed copayment	Sliding scale copayment	Asset limitation	Annual income cap	Capped HIV/ AIDS expenditures per patient	Capped HIV/ AIDS expenditures or had wait lists or both for protease inhibitor drugs
Alabama							
Alaska							
Arizona							
Arkansas	•				•		
California			•		•		
Colorado	•			•	•		•
Connecticut							
Delaware			•	•			
District of Columbia				•	•		
Florida				•	•		
Georgia				•	•		
Hawaii				•			
Idaho	•					•	
Illinois						•	
Indiana							
Iowa							
Kansas		•					
Kentucky				•	•		
Louisiana				•			
Maine							
Maryland			•		•		
Massachusetts					•		
Michigan							
Minnesota				•	•		
Mississippi					•		
Missouri						•	
Montana	•						
Nebraska							
Nevada				•	•		
New Hampshire							
New Jersey					•		

	Restrictions						
ADAPs	Capped enrollment	Fixed copayment	Sliding scale copayment	Asset limitation	Annual income cap	Capped HIV/ AIDS expenditures per patient	Capped HIV/ AIDS expenditures or had wait lists or both for protease inhibitor drugs
New Mexico				•	•		
New York				•	•		
North Carolina	•						•
North Dakota					•		
Ohio					•		
Oklahoma	•					•	
Oregon			•	•	•		
Pennsylvania					•		
Puerto Rico							
Rhode Island					•		
South Carolina			•				
South Dakota	•					•	
Tennessee				•			
Texas		•					
Utah			•	•			
Vermont							
Virginia							
Washington			•	•			
West Virginia							
Wisconsin							
Wyoming							
Total	**7**	**2**	**7**	**16**	**20**	**5**	**2**

Source: HRSA and state ADAP profile reports.

Note: The ADAP 2004 grant year covers April 1, 2004, through March 31, 2005.

Appendix V: Additional ADAP Funding and its Percentage of the CARE Act Title II ADAP Base Grants and per AIDS Case by State

Table 10: Additional ADAP Funding Sources, Fiscal Year 2004

	Title II Severe Need grant						
State ADAP	ADAP Severe Need grant	State matching funds for Severe Need grant	Title II non-ADAP base grant transfer	Title I EMA transfer	State funding	Other funding sources	Total additional ADAP funding
Alabama	$824,913	$206,228	$0	B	$2,500,000	$0	$3,531,141
Alaska	0	0	0	B	50,000	0	50,000
Arizona	0	0	0	0	1,000,000	78,546	1,078,546
Arkansas	A	A	0	B	330,810	393,000	723,810
California	A	A	12,168,628	0	63,934,245	47,370,750	123,473,623
Colorado	660,427	165,107	136,000	560,254	934,134	3,212,522	5,668,444
Connecticut	A	A	0	0	606,678	0	606,678
Delaware	A	A	0	B	0	832,382	832,382
D.C.	A	A	0	0	400,000	0	400,000
Florida	A	A	1,916,336	0	9,000,000	0	10,916,336
Georgia	2,789,298	697,324	0	1,540,022	11,305,339	0	16,331,983
Hawaii	A	A	0	B	440,535	0	440,535
Idaho	54,663	13,666	261,150	B	163,461	300,000	792,940
Illinois	A	A	0	0	7,000,000	5,619,843	12,619,843
Indiana	A	A	2,720,419	B	0	102,331	2,822,750
Iowa	0	0	0	B	0	0	0
Kansas	A	A	0	B	400,000	550,000	950,000
Kentucky	481,282	120,320	100,000	B	90,000	199,462	991,064
Louisiana	1,628,705	407,176	0	0	0	422,638	2,458,519
Maine	0	0	0	B	57,638	125,327	182,965
Maryland	A	A	65,250	105,925	0	2,100,000	2,271,175
Massachusetts	A	A	0	104,819	747,990	1,900,000	2,788,809
Michigan	A	A	0	0	0	5,500,000	5,500,000
Minnesota	A	A	0	0	1,100,000	2,743,522	3,843,522
Mississippi	A	A	1,093,008	B	750,000	0	1,843,008
Missouri	A	A	771,167	1,549,422	669,000	1,913,547	4,921,136
Montana	36,525	9,131	178,548	B	0	7,120	231,324
Nebraska	130,445	32,611	74,000	B	115,938	160,000	512,994
Nevada	A	A	0	65,250	1,350,947	0	1,416,197
New Hampshire	A	A	0	B	0	0	0
New Jersey	A	A	0	0	0	13,050,000	13,050,000
New Mexico	A	A	0	B	0	0	0

State ADAP	Title II Severe Need grant: ADAP Severe Need grant	Title II Severe Need grant: State matching funds for Severe Need grant	Title II non-ADAP base grant transfer	Title I EMA transfer	State funding	Other funding sources	Total additional ADAP funding
New York	A	A	2,524,145	5,870,000	33,000,000	64,500,000	105,894,145
North Carolina	1,511,429	377,857	0	B	8,355,195	3,338,000	13,582,481
North Dakota	0	0	85,400	B	0	32,000	117,400
Ohio	A	A	0	300,000	7,843	20,000	327,843
Oklahoma	419,165	104,791	486,486	NA	786,000	361,000	2,157,442
Oregon	A	A	0	0	300,000	5,650,000	5,950,000
Pennsylvania	A	A	0	0	10,452,000	6,044,000	16,496,000
Puerto Rico	2,661,337	0[a]	3,455,671	0	2,093,000	0	8,210,008
Rhode Island	A	A	0	B	0	700,000	700,000
South Carolina	1,382,225	345,556	0	B	500,000	0	2,227,781
South Dakota	0	0	330,744	B	0	0	330,744
Tennessee	0	0	0	B	0	0	0
Texas	5,943,843	1,485,961	500,000	0	28,538,504	0	36,468,308
Utah	0	0	0	B	0	0	0
Vermont	0	0	0	B	175,000	130,000	305,000
Virginia	1,707,470	426,867	0	0	2,612,200	0	4,746,537
Washington	A	A	0	800,487	4,842,484	925,000	6,567,971
West Virginia	153,553	38,388	75,000	B	0	180,000	446,941
Wisconsin	374,441	93,610	0	B	186,658	855,317	1,510,026
Wyoming	A	A	0	B	0	0	0
Total	**$20,759,721**	**$4,524,593**	**$26,941,952**	**$10,932,179**	**$194,795,599**	**$169,334,307**	**$427,288,351**

Source: HRSA and GAO analysis.

A State was not eligible for a grant.

B State did not have an EMA.

[a]Puerto Rico is not required to provide match funds.

Table 11: Additional ADAP Funding as Percentage of ADAP Base Grant and per AIDS Case, Fiscal Year 2004

State ADAP	Total additional ADAP funding	ADAP base grant	Total additional ADAP funding as percentage of the ADAP base grant	Total additional ADAP funding per AIDS case
Alabama	$3,531,141	$7,004,635	50%	$1,064
Alaska	50,000	472,602	11%	223
Arizona	1,078,546	8,392,903	13%	271
Arkansas	723,810	3,116,716	23%	494
California	123,473,623	89,623,465	138%	2,907
Colorado	5,668,444	5,607,928	101%	2,133
Connecticut	606,678	11,315,018	5%	113
Delaware	832,382	3,202,722	26%	548
D.C.	400,000	13,842,594	3%	61
Florida	10,916,336	80,386,630	14%	287
Georgia	16,331,983	23,684,951	69%	1,455
Hawaii	440,535	2,084,512	21%	446
Idaho	792,940	464,163	171%	3,604
Illinois	12,619,843	25,746,254	49%	1,034
Indiana	2,822,750	6,529,924	43%	912
Iowa	0	1,305,985	0%	0
Kansas	950,000	2,045,495	46%	991
Kentucky	991,064	4,086,741	24%	512
Louisiana	2,458,519	13,829,935	18%	375
Maine	182,965	833,383	22%	463
Maryland	2,271,175	25,746,254	9%	186
Massachusetts	2,788,809	14,684,416	19%	401
Michigan	5,500,000	11,002,763	50%	1,055
Minnesota	3,843,522	3,010,727	128%	2,693
Mississippi	1,843,008	5,795,703	32%	671
Missouri	4,921,136	7,409,723	66%	1,401
Montana	231,324	310,145	75%	1,574
Nebraska	512,994	1,107,661	46%	977
Nevada	1,416,197	4,738,678	30%	631
New Hampshire	0	755,319	0%	0
New Jersey	13,050,000	34,877,598	37%	789
New Mexico	0	2,127,024	0%	0
New York	105,894,145	124,956,784	85%	1,788
North Carolina	13,582,481	12,834,095	106%	2,233

State ADAP	Total additional ADAP funding	ADAP base grant	Total additional ADAP funding as percentage of the ADAP base grant	Total additional ADAP funding per AIDS case
North Dakota	117,400	92,543	127%	2,730
Ohio	327,843	10,909,930	3%	63
Oklahoma	2,157,442	3,655,707	59%	1,279
Oregon	5,950,000	4,225,989	141%	2,971
Pennsylvania	16,496,000	27,090,216	61%	1,285
Puerto Rico	8,210,008	22,598,388	36%	767
Rhode Island	700,000	1,911,506	37%	773
South Carolina	2,227,781	11,736,984	19%	400
South Dakota	330,744	204,654	162%	3,410
Tennessee	0	12,018,438	0%	0
Texas	36,468,308	50,471,351	72%	1,524
Utah	0	1,980,565	0%	0
Vermont	305,000	382,007	80%	1,685
Virginia	4,746,537	14,498,751	33%	691
Washington	6,567,971	7,966,718	82%	1,739
West Virginia	446,941	1,303,875	34%	723
Wisconsin	1,510,026	3,179,514	47%	1,002
Wyoming	0	160,347	0%	0
Total	$427,288,351	$ 727,320,929	59%	-

Source: HRSA and GAO analysis.

Related GAO Products

Ryan White CARE ACT: Title I Funding for San Francisco. GAO/HEHS-00-189R. Washington, D.C.: August 24, 2000.

Ryan White CARE Act: Opportunities to Enhance Funding Equity. GAO/T-HEHS-00-150. Washington, D.C.: July 11, 2000.

HIV/AIDS: Use of Ryan White CARE Act and Other Assistance Grant Funds. GAO/HEHS-00-54. Washington, D.C.: March 1, 2000.

HIV/AIDS Drugs: Funding Implications of New Combination Therapies for Federal and State Programs. GAO/HEHS-99-2. Washington, D.C.: October 14, 1998.

Revising Ryan White Funding Formulas. GAO/HEHS-96-116R. Washington, D.C.: March 26, 1996.

Ryan White CARE Act of 1990: Opportunities to Enhance Funding Equity. GAO/HEHS-96-26. Washington, D.C.: November 13, 1995.

Ryan White CARE Act: Access to Services by Minorities, Women, and Substance Abusers. GAO/T-HEHS-95-112. Washington, D.C.: July 17, 1995.

Ryan White CARE Act of 1990: Opportunities Are Available to Improve Funding Equity. GAO/T-HEHS-95-126. Washington, D.C.: April 5, 1995.

Follow-up on Ryan White Testimony. GAO/HEHS-95-119R. Washington, D.C.: March 31, 14, 1995.

Ryan White CARE ACT of 1990: Opportunities Are Available to Improve Funding Equity. GAO/T-HEHS-95-91. Washington, D.C.: February 22, 1995.

Ryan White Funding Formulas. GAO/HEHS-95-79R. Washington, D.C.: February 14, 1995.

Ryan White CARE Act: Access to Services by Minorities, Women, and Substance Abusers. GAO/HEHS-95-94. Washington, D.C.: January 13, 1995.

United States Senate

WASHINGTON, DC 20510

June 23, 2005

The Honorable David M. Walker
Comptroller General of the United States
United States Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Walker:

As Senators representing states with high HIV/AIDS caseloads and populations served by Title I Eligible Metropolitan Areas (EMAs), we are concerned with the preliminary data as presented in the testimony of the Government Accountability Office (GAO) before the Subcommittee on Federal Financial Management, Government Information, and International Security of the Senate Homeland Security and Government Affairs Committee on Thursday, June 23. We hope that in the final report, the GAO will take into account the necessity for stable, continued funding for the Title I EMA program, which provides community-directed services, care and treatment to the vast majority of those living with HIV/AIDS in the United States.

We would like the GAO to address the following issues in its final report:

- **The role of the grandfather clause in ensuring service provision**
  In the *Ryan White CARE Act*, a clause from the 1996 reauthorization states that EMAs designated prior to fiscal year 1996 will retain their status in subsequent fiscal years. Even if the criteria for designation as an EMA are not currently met by several grantees, over 70% of the Americans living with AIDS reside in areas served by Title I funding. Clearly, the burden of the domestic epidemic is still disproportionately based in cities that receive Title I funding. We would ask that, in the final report, the GAO include a discussion of the barriers to care and treatment in EMAs that would arise were the grandfather clause to be lifted. We would also ask that you consider the role the grandfather clause has played in protecting areas with high prevalence rates, as defined in the *1990 CARE Act*. These areas would have been severely impacted by the 1996 reauthorization's elimination of the density factor from the Title I formula were it not for this grandfather clause.

- **The inadequacies of using a per capita formula in funding analyses**
  There has been some concern that the amount allocated to various regions does not represent an equal distribution, on a per capita basis, of funding. What such an analysis fails to consider is both the level of services provided and the cost of living in various areas. Per capita funding formulations do not address the scope of services provided and the true extent of need in high cost-of-living areas like New York City, San Francisco, and other EMAs. In

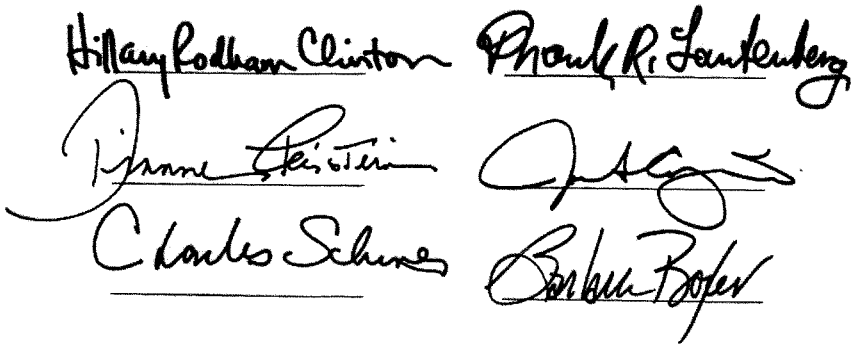
your report, we ask that the GAO consider both the range and actual cost of services provided in states and local communities prior to any analysis of funding distributions.

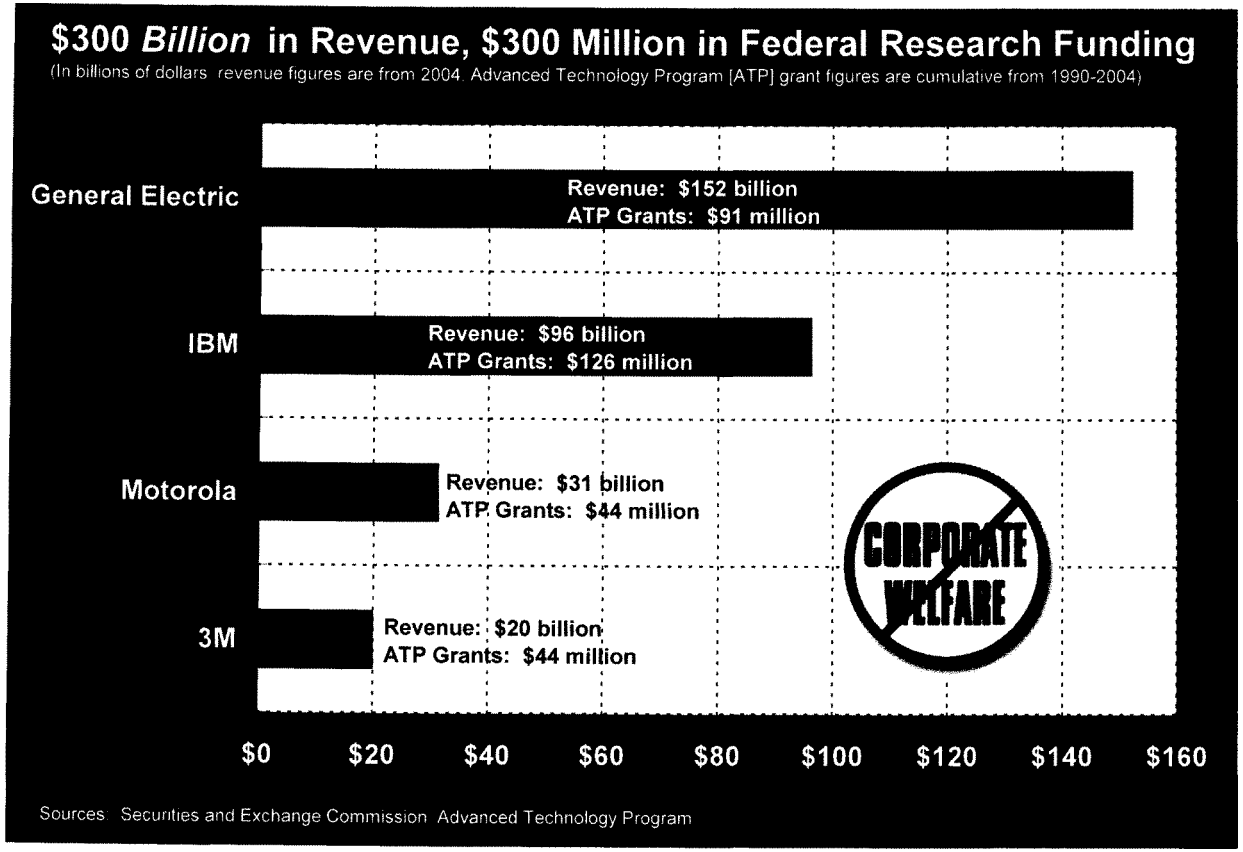
- **The continued need for separate Title I and Title II funding streams**

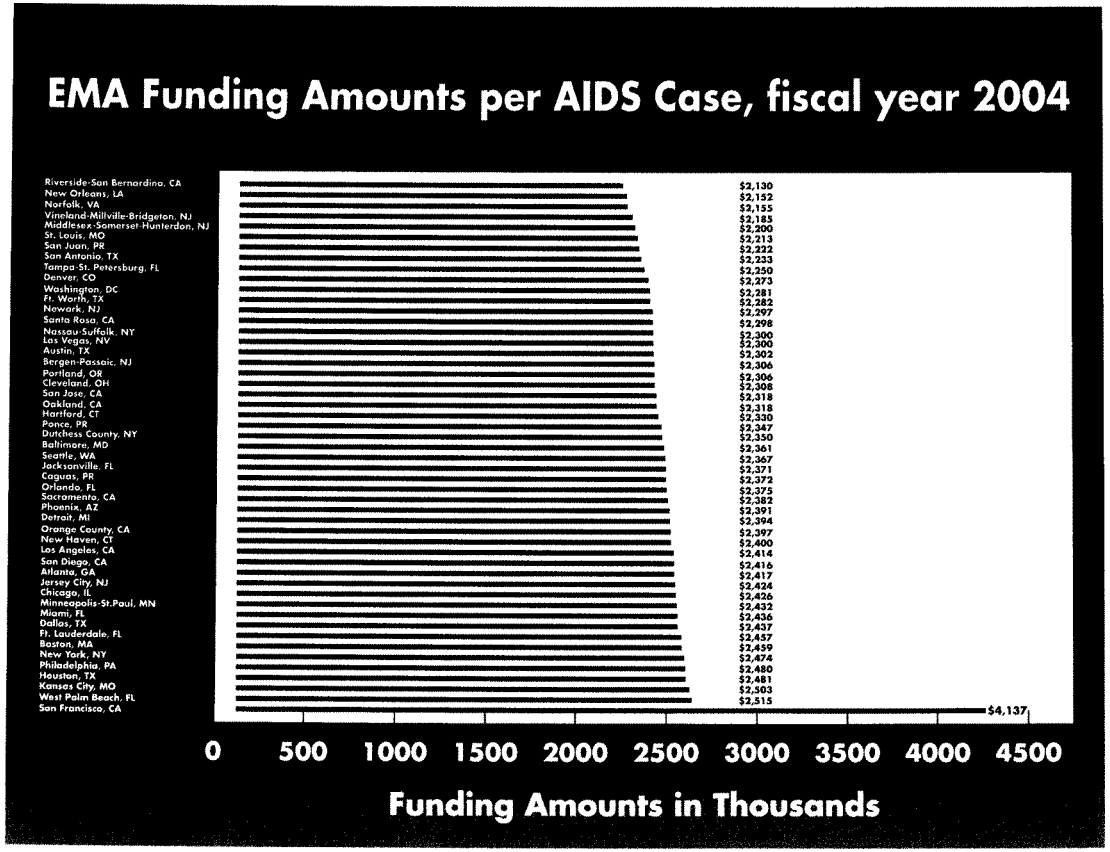
There is a perception that states with EMAs are somehow "double dipping" into *Ryan White CARE Act* funding, as such areas benefit from both Title I and Title II funding streams. However, such criticism fails to take into account differences between the local, community-driven services provided in EMAs, and the state-level services funded by Title II. This issue has already been addressed legislatively in the *CARE Act*. Formula allocations in Title II specifically place a greater weight on cases in non-EMA areas, so that more funding will be directed to non-EMA states. Changing such an allocation so that states receive funding only for cases located outside of EMAs would devastate the current AIDS service infrastructure, and result in delays or denials of care for the vast majority of people living with AIDS. We ask that when examining Title I vs. Title II funding issues, the GAO take into account the impact of reducing Title II funding upon service provision in these states with the greatest burden of cases.

Thank you for your consideration of our request.

Sincerely,




$300 Billion in Revenue, $300 Million in Federal Research Funding
(In billions of dollars revenue figures are from 2004. Advanced Technology Program [ATP] grant figures are cumulative from 1990-2004)
General Electric
Revenue: $152 billion
ATP Grants: $91 million
IBM
Revenue: $96 billion
ATP Grants: $126 million
Motorola
Revenue: $31 billion
ATP Grants: $44 million
3M
Revenue: $20 billion
ATP Grants: $44 million
CORPORATE WELFARE
$0
$20
$40
$60
$80
$100
$120
$140
$160
Sources: Securities and Exchange Commission Advanced Technology Program


EMA Funding Amounts per AIDS Case, fiscal year 2004
Riverside-San Bernardino, CA $2,130
New Orleans, LA $2,152
Norfolk, VA $2,155
Vineland-Millville-Bridgeton, NJ $2,185
Middlesex-Somerset-Hunterdon, NJ $2,200
St. Louis, MO $2,213
San Juan, PR $2,222
San Antonio, TX $2,233
Tampa-St. Petersburg, FL $2,250
Denver, CO $2,273
Washington, DC $2,281
Ft. Worth, TX $2,282
Newark, NJ $2,297
Santa Rosa, CA $2,298
Nassau-Suffolk, NY $2,300
Las Vegas, NV $2,300
Austin, TX $2,302
Bergen-Passaic, NJ $2,306
Portland, OR $2,306
Cleveland, OH $2,308
San Jose, CA $2,318
Oakland, CA $2,318
Hartford, CT $2,330
Ponce, PR $2,347
Dutchess County, NY $2,350
Baltimore, MD $2,361
Seattle, WA $2,367
Jacksonville, FL $2,371
Caguas, PR $2,372
Orlando, FL $2,375
Sacramento, CA $2,382
Phoenix, AZ $2,391
Detroit, MI $2,394
Orange County, CA $2,397
New Haven, CT $2,400
Los Angeles, CA $2,414
San Diego, CA $2,416
Atlanta, GA $2,417
Jersey City, NJ $2,424
Chicago, IL $2,426
Minneapolis-St.Paul, MN $2,432
Miami, FL $2,436
Dallas, TX $2,437
Ft. Lauderdale, FL $2,457
Boston, MA $2,459
New York, NY $2,474
Philadelphia, PA $2,480
Houston, TX $2,481
Kansas City, MO $2,503
West Palm Beach, FL $2,515
San Francisco, CA $4,137
0
500
1000
1500
2000
2500
3000
3500
4000
4500
Funding Amounts in Thousands

Hearing Background Materials

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(1) Ryan White CARE Act Background

(2) HIV/AIDS Statistics

(3) Federal HIV/AIDS Spending

(4) HIV Reporting

(5) AIDS Drug Assistance Programs

(6) Advancing HIV Prevention

(7) Baby AIDS

(8) Rapid HIV Tests

(9) Hold Harmless

(10) Submitted Testimony

(1) Ryan White CARE Act Background

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act is a federal program that provides primary health care and support services for those living with HIV/AIDS who have little or no health insurance.

Enacted in 1990, the CARE Act is administered through hundreds of grantees, which serve 571,000 people each year. The program has become the nation's third largest source of federal funding for HIV care, after Medicaid and Medicare.

The CARE Act was named after Ryan White, an Indiana teenager whose courageous struggle with HIV/AIDS and against AIDS-related discrimination helped educate the nation.

Order Code 98-476
Updated February 17, 2005

CRS Report for Congress
Received through the CRS Web

AIDS: Ryan White CARE Act

Judith A. Johnson and Paulette C. Morgan
Domestic Social Policy Division

Summary

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act makes federal funds available to metropolitan areas and states to assist in health care costs and support services for individuals and families affected by acquired immune deficiency syndrome (AIDS) or infection with the human immunodeficiency virus (HIV). The Act was reauthorized through FY2005 by legislation passed in October 2000. The CARE Act programs received $2.020 billion in FY2004. The Consolidated Appropriations Act 2005 (P.L. 108-447) provides $2.065 billion for Ryan White Programs in FY2005. Because of a mandatory 0.80% across-the-board rescission specified in P.L. 108-447, and an additional $25 million available from an evaluation set-aside, the total program level funding for FY2005 is $2.073 billion. The President has requested level program funding for FY2006, except for a $10 million increase in the AIDS Drug Assistance Program. The total amount requested is $2.058 billion for Ryan White Programs in FY2006; with the $25 million set-aside, the total for FY2006 would be $2.083 billion. This report will be updated periodically.

Background

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act makes federal funds available to metropolitan areas and states to provide a number of health care services for AIDS patients including medical care, drug treatments, dental care, home health care, and outpatient mental health and substance abuse treatment.

Legislation reauthorizing the Ryan White CARE Act is expected to be introduced during the 109th Congress. The CARE Act was reauthorized through FY2005 under the Ryan White CARE Act Amendments of 2000 (P.L. 106-345). P.L. 106-345 retained the basic structure of the Ryan White CARE Act but changed the formulas used to distribute Title I and Title II grants as discussed in the following sections. Additional changes made by P.L. 106-345 to the CARE program included the following: (1) requirements are established for the development of epidemiologic measures to identify HIV infected individuals not currently in care; (2) incentives are provided to states for HIV testing of pregnant women and infants; (3) incentives are established for implementing a partner notification program; (4) requires the development of quality management programs; (5) requirements are established for the development of a plan for the medical case

management of HIV positive prisoners who are released from custody; (6) requirements are included regarding the development of rapid HIV tests; (7) additional grants are provided to metropolitan areas with between 500 and 1,999 reported cases of AIDS over the previous five-year period.

The Act is administered by the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services (HHS). The Act is commonly identified by its legislative Titles I, II, III, and IV. It was enacted as Title XXVI of the Public Health Service Act and codified as Parts A, B, C, D, E, and F under 42 U.S.C. § 300ff-111. Funding for the individual titles appears at the end of the report.

Title I/Part A — Emergency Relief Grant Program. Title I provides funds to eligible metropolitan areas (EMAs) that are severely affected by the HIV epidemic. Services supported by Title I grants include community-based outpatient medical and dental care, rehabilitative services, home health and hospice care, transportation and housing assistance, nutrition services, and respite care. The program is intended to assist low-income or under-insured people living with HIV. A portion of each grant must be spent on services for women, infants and children with HIV disease. In FY1991, the first year Title I grants were awarded, 16 EMAs were identified; by FY2002, the number of EMAs had increased to a total of 51.[1]

About half of the Title I appropriation is distributed through formula grants. Currently, formula grants are distributed to EMAs in proportion to the estimated number of living AIDS cases in each EMA. The number of living AIDS cases is estimated from the number of reported AIDS cases over a 10-year period with weighting factors to reflect that not all reported cases are still alive. However, under P.L. 106-345, statistics on HIV incidence rather than AIDS cases would be used in the formula for determining Title I grant amounts by FY2005, but only if the Secretary of HHS determines the HIV incidence data are sufficiently accurate and reliable.

A hold harmless provision in the CARE Act dictates that an EMA shall not receive a formula grant that is less than a specified percentage of what it received in a base year defined in the statute. A hold harmless provision protects grantees from large decreases in funding from year to year. The hold harmless provision in Title I was changed by P.L. 106-345, and as a result some EMAs may receive less money than before. Under P.L. 106-345, an EMA cannot receive less than a percentage of the Title I formula grant it received in a base year. In the first year after the base year, it cannot receive less than 98% of what it received in a base year. By the fifth year, an EMA cannot receive a formula grant that is less than approximately 87% of what it received in the base year if HIV incidence data are included in the distribution formula, or 85% of what an EMA received in the base year if HIV incidence data are not used in the fifth year. The hold harmless provision is funded with money that would have been distributed through supplemental grants in Title I.

The remaining half of Title I funds are distributed via discretionary supplemental grants that are awarded based on the demonstration of additional need.

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[1] FY2004 Title I funding amounts for the 51 EMAs can be found at [http://www.hhs.gov/news/press/2004pres/20040301a.html].

Title I grants are made to the chief elected official of the city or county in the EMA that administers the health agency providing services to the greatest number of persons with HIV. The official must establish an HIV Health Services Planning Council, which sets priorities for care delivery according to federal guidelines. The Council may not be directly involved in the administration of any Title I grant. Membership of the Council must reflect the ethnic and racial make-up of the local HIV epidemic.

Title II/Part B — Care Grant Program. Title II awards formula grants to states and territories for home and community-based health care and support services. Services must be accessible to low-income individuals. Many states use Title II funds to provide services directly or through subcontracts with HIV care consortia. Consortia are associations of public and nonprofit health care and support service providers that assess needs and deliver services to individuals with HIV. Title II grants are also used to provide (1) health insurance coverage for low-income persons through Health Insurance Continuation Programs; and, (2) drug treatments under the AIDS Drug Assistance Programs (ADAPs) for individuals with HIV who have limited or no coverage from private insurance or Medicaid.[2]

Grants are awarded based on a formula that takes into account two factors: (1) the estimated number of living AIDS cases in the state; and (2) the estimated number of living AIDS cases in the state who are not in a Title I EMA. However, under P.L. 106-345, statistics on HIV incidence rather than AIDS cases would be used in the formula for determining Title II grant amounts by FY2005, but only if the Secretary of HHS determines the HIV incidence data are sufficiently accurate and reliable.

Two provisions can increase the Title II grant amount a state or territory receives above what it would receive as a result of the formula alone. A minimum grant provision dictates that no state shall receive less than $200,000 if it has less than 90 estimated living cases of AIDS or $500,000 if it has more than 90 estimated living cases of AIDS. A hold harmless provision dictates that a state shall not receive a grant that is less than a specified percentage of what it received in FY2000. These two provisions are funded by reducing the grant amounts received by all states and territories that do not receive a minimum grant amount or hold harmless grant amount. States with more than 1% of the total AIDS cases reported nationally must contribute state matching funds based on a formula. Grants may not be made to any state that does not make a good faith effort to notify a spouse of an HIV-infected patient that the spouse should seek testing. States must use a portion of each Title II grant on services for women, infants and children with AIDS.

P.L. 106-345 also changed the way funds would be allocated to states for the AIDS Drug Assistance Programs (ADAPs). Prior to P.L. 106-345, ADAP funds were distributed among states based on each state's proportion of AIDS cases. Under the new law, a brand-new grant program distributes 3% of ADAP funds to states that demonstrate a severe need to increase the availability of drugs. Criteria for awarding these grants are developed by the Secretary, taking into account eligibility standards, formulary composition, and the number of HIV-positive individuals not receiving drugs who are at

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[2] FY2004 Title II funding amounts can be found at [http://www.hhs.gov/news/press/2004pres/20040401b.html].

or below 200% of the federal poverty level. The remaining 97% of ADAP funds are distributed based on each state's proportion of AIDS cases.

Title III/Part C — Early Intervention Services. Title III provides early intervention grants to public and private nonprofit entities already providing primary care services to low-income and medically underserved people at risk for HIV. Title III grants are awarded to community and migrant health centers, homeless programs, local health departments, family planning programs, hemophilia diagnostic and treatment centers and other nonprofit community-based programs. Title III services include HIV testing, risk reduction counseling, case management, outreach, medical evaluation, transmission prevention, oral health, nutritional and mental health services, and clinical care.

Title IV/Part D — General Provisions. In its original enactment, Title IV authorized a number of different HIV-related programs; only one was ever funded: the pediatric demonstration grants. In the CARE Act's 1996 reauthorization, the pediatric demonstration grant program was replaced with a program of grants for coordinated services and access to research for women, infants, children, and youth. The grants enhance access to and linkage with clinical research supported by the National Institutes of Health (NIH), and are to be made in coordination with the NIH activities. The grants provide opportunities for women, infants, children, and youth to be voluntary participants in research of potential clinical benefit to individuals with HIV. Such individuals are provided health care on an outpatient basis, case management, referrals, transportation, child care, and other incidental services to enable participation.

Part E. Part E authorizes grants for emergency response employees and establishes procedures for notifications of infectious diseases exposure; Part E has never been funded.

Part F — Demonstration and Training. Part F provides support for the Special Projects of National Significance (SPNS) Program, the AIDS Dental Reimbursement (ADR) Program and the AIDS Education and Training Centers (AETCs). The SPNS program awards grants to public and nonprofit private entities for the development of innovative models of HIV/AIDS care, especially programs that deliver care to minority and hard-to-reach populations. The Secretary is required to use a percentage of funds appropriated under Titles I, II, III, and IV for these grants. The ADR program reimburses dental schools for their treatment of AIDS patients. The AETC program provides training for health providers in the prevention of perinatal HIV transmission and prevention and treatment of opportunistic infections. Both the dental and the AETC programs were transferred legislatively from Title VII of the Public Health Service Act.

Table 1. Federal Funding for the Ryan White CARE Act

($ in millions)

	Title I	Title II	(ADAP)	Title III	Title IV	Part E	Part F AETC	Part F ADR	Total
FY1991	87.8	87.8	—	44.9	19.5	0	17.0	—	257.0
FY1992	121.6	107.6	—	48.7	19.3	0	16.9	—	314.1
FY1993	184.8	115.3	—	48.0	20.9	0	16.4	—	385.4
FY1994	325.5	183.9	—	48.0	22.0	0	16.4	7.0	602.8
FY1995	356.5	198.1	—	52.0	26.0	0	16.3	6.9	655.8
FY1996	391.7	260.8	(52)	57.0	29.0	0	12.0	6.9	757.4
FY1997	449.8	417.0	(167)	69.6	36.0	0	16.3	7.5	996.3
FY1998	464.7	542.8	(285.5)	76.2	40.8	0	17.2	7.8	1,150.2
FY1999	505.0	737.7	(461.0)	94.3	46.0	0	20.0	7.8	1,410.9
FY2000	546.3	823.8	(528.0)	138.4	50.0	0	26.6	8.0	1,594.6
FY2001	604.2	910.9	(589.0)	185.9	65.0	0	31.6	10.0	1,807.6
FY2002	619.4	977.2	(639.0)	193.8	71.0	0	35.3	13.5	1,910.2
FY2003*	618.7	1,053.4	(714.3)	198.4	73.6	0	35.6	13.4	1,993.0
FY2004*	615.0	1,085.9	(748.9)	197.2	73.1	0	35.3	13.3	2,019.9
FY2005 Conference**	615.0	1,130.9	(793.9)	197.2	73.1	0	35.3	13.3	2,064.9
FY2005 Comparable***	610.1	1,121.8	(787.5)	195.6	72.5	0	35.1	13.2	2,048.3
FY2006 Request****	610.1	1,131.8	(797.5)	195.6	72.5	0	35.1	13.2	2,058.3

Source: DHHS FY2006 Health Resources and Services Administration Justification of Estimates for Appropriations Committees. May not add due to rounding.

* The total does not include an additional $25 million set-aside for evaluations. The $25 million set-aside is funded through an evaluation tap of amounts appropriated under the Public Health Service Act (PHSA). In 2003, the evaluation tap was 2.1%, as specified in conference report H.Rept.108-10; in 2004, the evaluation tap was 2.2%, as specified in conference report H.Rept.108-401.

**FY2005 Conference amounts do not include the 0.80% offset required by P.L.108-447. The FY2005 Conference total does not include an additional $25 million set-aside for evaluations. The $25 million set-aside is funded through a 2.4% evaluation tap of amounts appropriated under the PHSA, as specified in conference report H.Rept.108-792.

*** FY2005 Comparable amounts include the 0.80% offset required by PL.108-447. The 2005 Comparable total does not include an additional $25 million set-aside for evaluations.

**** FY2006 Request total does not include an additional $25 million set-aside for evaluations.

Congressman Tom A. Coburn, M.D.
(2nd District, Oklahoma)

October 30, 1997

Testimony of Rep. Tom A. Coburn, M.D., Before The Senate Labor & Human Resources Committee Regarding Current Issues Relating to HIV/AIDS

Chairman Jeffords and distinguished members of the committee, I come before you today not as a member of the House of Representatives, but as a practicing physician. In this capacity, I have cared for men, women and children from all walks of life over the past twelve years who have been infected by the deadly HIV virus. I have watched as many of these patients died very humiliating and agonizing deaths knowing that there was little I could do for them.

Each death has been heartbreaking and has made me ever more committed to doing whatever it takes to prevent another person from becoming infected with this horrible virus.

Since we have not yet discovered a cure or vaccine, our only defenses against the disease is preventing further infections and compassionately caring for those who have already been infected.

Much debate exists about the most effective prevention methods. As you know, I believe that S. 503, the HIV Prevention Act of 1997 introduced by Senator Don Nickles, outlines a comprehensive and scientifically sound national blue print to curtail the spread of HIV by re-instituting proven public health practices. While I would be happy to answer any questions about this bill, my testimony today will not focus on this proposal.

I believe that any effective prevention must be based on the most up-to-date and reliable information about the disease itself, such as how many Americans are now infected at the very least.

In 1986, the Centers for Disease Control announced that there were an estimated

one million Americans infected with HIV. In 1987, 1988, 1989, 1990 and 1991, the CDC made the same estimates. Today, even with AIDS deaths declining, the CDC estimate is virtually the same. The fact is that the CDC has no idea how many Americans are infected with HIV because they have failed to monitor the epidemic appropriately.

Our surveillance of the disease has focused on AIDS rather than HIV infection even though we have known since 1983 that AIDS is actually the most advanced stage of HIV infection and that it develops nearly ten years after infection. This system provides a decade-old snapshot of the epidemic rather than an up to date assessment. Therefore, we will not know how many Americans are infected with HIV today until 2007-- unless we refocus our surveillance system from AIDS to HIV infection.

Besides not knowing how many Americans are infected with HIV, our focus on AIDS instead of HIV has prevented scientists from discovering other important facts about the epidemic such as: How fast is the disease spreading? How are new infections being contracted? What communities have the highest rates of new infections? Are those infected receiving appropriate medical services? How effective are specific prevention interventions? How effective is treatment and what strains of HIV are becoming resistant to treatment?

By confidentially reporting new cases of HIV in the same manner we have with all AIDS cases, those responsible for control of the disease can more accurately determine the answers to these questions. Most importantly they can determine the current extent of the epidemic as well as future trends, rates of progression, direction of spread, possible changes in transmissibility and other critical factors of disease control. Such information allows for the development of long-term prevention strategies based on reliable data. It also allows us more accurately project the necessary financial resources that will be needed.

HIV reporting also benefits those who are infected by providing a more timely link to medical services and promoting more equitable allocation of government funding. Eligibility for Medicaid, for instance, is currently tied to the CDC definition of AIDS, which creates hardships for lower income individuals with HIV infection. To become eligible, they must wait until they either become seriously immunologically impaired or acquire opportunistic infections. The same has been true for HUD's Housing Opportunities for People With AIDS program. By focusing on AIDS, those groups that are now most at risk for HIV infection— women, children and racial minorities— would also benefit from more equitable federal and state funding

allocations.

With such benefits, why isn't HIV reported?

Every state has reported cases of AIDS by name since the disease was first recognized. This was done with little public or political controversy and is still conducted today in every state. However 28 states, which represent only a quarter of the epidemic, report HIV cases. Other states-- particularly those with higher concentrations of infections-- have been pressured to avoid HIV reporting. Civil libertarians and the AIDS activists have passionately resisted any move towards HIV reporting because they believe that such surveillance is an invasion of the privacy rights of the infected individual. (Interestingly enough, these same groups have been virtually silent about the rights of uninfected individuals.)

They also argue that HIV reporting discourages individuals from being tested. Preliminary results from a recent CDC study of high risk populations, however, discredited this argument and revealed that only two percent of those high risk individuals cited privacy concerns relating to HIV reporting as the main reason for avoiding HIV testing.

Until now these arguments have prevailed, even though health departments have a long history of maintaining confidentiality and the names of persons with HIV/AIDS have often been entered into other data bases such as those of Medicaid and drug assistance registries.

But now even the most vocal opponents of HIV reporting are reconsidering their opposition. With the advances in medical treatment for HIV and the passage of stringent legal protections for those with HIV at both the national and state levels, the benefits of HIV reporting clearly outweigh any perceived disadvantages.

In May of 1990, the Senate went on record by unanimously passing an HIV reporting and partner notification proposal which was offered by Senators Kennedy and Mikulski. More recently, the CDC recommended that states require health departments to report HIV in the same manner as other infectious diseases. *The New England Journal of Medicine*, the nation's most prestigious medical journal, has also endorsed mandatory national HIV reporting and partner notification. The American Medical Association and Americans for A Sound AIDS/HIV Policy have advocated confidential HIV name reporting for some time and other organizations within the AIDS community have just recently embraced this concept.

Clearly, if we are to get a better understanding of HIV, curtail its spread and provide timely medical assistance to those living with HIV, we must shift our surveillance focus from AIDS to HIV.

In fact, this was proposed by the first Presidential Commission on the Human Immunodeficiency Virus Epidemic nearly a decade ago in 1988. The recommendations of this commission were ignored then but still offer important insights which we should still embrace:

The CDC and every state should begin by recognizing that the terms "acquired immune deficiency syndrome" and "AIDS" are obsolete. The medical, public health and political communities must focus on the full course of the disease rather than on the later stages. Therefore the term "HIV disease", meaning infection with HIV regardless of whether the infection has progressed to AIDS, more correctly defines the medical condition.

Continual focus on AIDS rather than the entire spectrum of HIV disease has left our nation unable to deal adequately with the epidemic. Federal and state data collection efforts should focus on obtaining data as early as possible after infection occurs.

In addition to understanding the epidemic and identifying those who are either infected or at risk of infection, we must also guarantee a compassionate federal response for those who are already living with this horrible disease, such as guaranteeing access to protease inhibitors and other effective HIV therapies.

The CDC recently announced that deaths from AIDS had fallen by 26% from 1995 to 1996 due largely to the effectiveness of these new drug combinations. Despite this good news, many lower income infected Americans can not afford the recommended therapy which can cost up to $10,000 annually per person.

Funding shortages in the federal AIDS Drug Assistance Program (ADAP) have led at least 26 states to limit access to the medically necessary care leaving patients insecure and vulnerable. I believe that the opportunities provided and the lives which can be improved by these new treatments are too valuable to be shortchanged by a lack of federal commitment to ADAP and compassion for the infected.

Thank you very much for the opportunity to testify on this very important issue. I would be happy to answer any questions.

Congressman Tom A. Coburn, M.D.
(2nd District, Oklahoma)

March 2, 2000

Testimony of Rep. Tom A. Coburn, M.D.
Before the Health, Education, Labor, & Pensions Committee
United States Senate Hearing on
Ryan White CARE Act Reauthorization

Mr. Chairman, and Members of the Committee, I would like to thank you for the opportunity to testify before you today on the reauthorization of the Ryan White CARE Act.

As you know, I am a practicing physician who has cared for men, women and children from all walks of life affected by HIV/AIDS. And despite many of the amazing medical advances that have been made over the past decade, it still is a heart wrenching experience for me to have to tell any patient of mine that they are infected with this horrible virus that will eventually kill them.

I had the opportunity to serve with many of you on the Ryan White CARE Act conference committee during the 104th Congress. Much of the successes we have seen in recent years such as declining AIDS deaths and improvements in the lives of those living with HIV can be attributed to this Act, and in particular, the AIDS Drug Assistance Program (ADAP). However, new challenges confront us. Women, communities of color, adolescents and even older Americans are increasingly becoming impacted by HIV. But yet even as the face of AIDS changes, many of the issues we faced five and ten years ago are still before us today.

Over 665,000 Americans have been diagnosed with AIDS in the short time since this disease was recognized nearly 20 years ago. Over 400,000 of which have died. The Centers for Disease Control and Prevention estimates that today up to 900,000 Americans are living with HIV— many of which do not even know they are infected. And despite billions of dollars spent on prevention programs, every year 40,000 new HIV infections occur in the United States. This number has remained unchanged over the past decade. We must ask ourselves, "why are we

failing to halt— or even slow down— this epidemic?"

Current prevention messages ignore successful interventions that have historically curtailed other contagious diseases. Partner notification is an extremely effective tool for disease control, especially for women. This is because many HIV-infected women— 50 to 70 percent in some studies— do not engage in high risk behaviors but were infected by a partner who does. Without guaranteeing these unsuspecting victims a right to know that they are at risk, how else can they protect themselves?

Ten years ago, during the original Senate consideration of the Ryan White CARE Act, Senator Kennedy stated that "there is a duty to warn." But yet a decade later, there still is no right to know if you have been exposed to HIV. In fact, the Texas Supreme Court ruled in 1998 that there is "no statutory or common-law duty to notify" a woman "that she was at risk of contracting the HIV virus."

Stephanie Williams, a black mother from South Carolina, who believed she was in a mutually monogamous relationship was infected by her boyfriend who has since died of AIDS. Pam McCree, another African-American women, became infected in the same way. She only became aware of her status after the man who infected her died.

A woman who works at an inner city clinic in New York was forced to remain silent while one of her HIV-positive clients attempted to have a baby with his wife who was unaware of his status. Another New Yorker only learned that she was infected by her husband after their child was diagnosed with AIDS during an autopsy. A Hispanic woman from the Bronx discovered her status when her husband lay dying of a disease with no name and a counselor at the hospital suggested that she be tested for HIV.

These are not isolated incidents. All of these women were allowed to become infected by people they trusted. They did not know they were at risk and no one warned them. In some cases, the law forbade them from being notified. Partner notification is a simple matter of life and death. And all too often, silence does indeed equal death.

As more women become infected with HIV, more children have become affected by AIDS as well. Science, however, has provided a great opportunity to prevent most children from becoming infected themselves.

One of the most promising victories in the battle against AIDS was the 1994 finding that administration of the drug ZDV during pregnancy and childbirth could significantly reduce the chance that a child of an HIV-positive mother would be infected. Using Caesarean section during birth, coupled with ZDV, has been found to nearly eliminate mother-to-child HIV transmission. Even if treatment begins shortly after birth, transmission can still be considerably reduced according to a more recent study.

Despite these medical miracles, a significant number of women still are not tested for HIV during their pregnancy. As a result, countless children are needlessly infected every year with this incurable, devastating disease that will prematurely and unnecessarily claim their lives.

Five years ago, the House overwhelmingly passed a Ryan White reauthorization bill which would have required all pregnant women to be counseled and offered an HIV test. In the case that a woman did not receive prenatal care or her HIV status was otherwise unknown, the newborn would be tested. This approach ensured that no woman or child was left to slip through the cracks. The importance of such a policy was underscored just this week by a study printed in the Journal of the American Medical Association which found that infants are put at a significant risk of becoming infected from their mothers by breast-feeding.

As you know, the conference committee rejected the House position and instead asked the Institute of Medicine (IOM) to examine the issue and make a recommendation.

A year and a half ago— with little fanfare— the IOM issued its recommendation which urged "the adoption of a national policy of universal HIV testing, with patient notification, as a routine component of prenatal care. This position has been endorsed by the American Medical Association, the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics. Congress should follow suit and enact this recommendation which it requested.

No one will ever know how many babies died because we failed to address this issue during the last reauthorization. We must not condemn any more babies to early deaths.

In addition to women and children, communities of color are increasingly affected by HIV/AIDS. To better address the ever changing demographics of the epidemic we must shift our focus from AIDS, the end stage of the disease, to HIV. The current Ryan White CARE Act formulas award grants to cities and states based upon AIDS data. Because AIDS is the last stage of HIV disease and develops on average ten or more years after infection, this formula is blind to the current extent of the epidemic. This means that women, African-Americans and other demographic groups which have experienced significant increases in new HIV infections that have not yet progressed to AIDS have been neglected, shortchanged and often left to fend for themselves.

By refocusing funding formulas from AIDS to HIV cases, these groups will not only be ensured more adequate federal support, but they will also be guaranteed a greater role in determining how these funds are spent at the local level since planning councils are required by law to reflect the demographic make-up of the epidemic in an area. As long as these formulas are based upon AIDS data, federal resources will be directed to where the epidemic was a decade ago rather than where it is today and where it is headed.

There are many other issues which we should address during the reauthorization process. We must ensure that all states are provided adequate funding for their AIDS Drug Assistance Programs (ADAP). Cities and states should be given increased flexibility to use CARE Act funds to best meet the health care needs of individuals within their jurisdictions. And because we want to maximize the amount of our federal commitment that goes directly to those affected, we need to simplify grant applications and reduce unnecessary paperwork that consumes the time, money and resources of those who are on the front lines of the epidemic.

At the same time, we need to ensure that federal funds reach those for who it is intended for— those affected by HIV/AIDS. According to the Office of Special Investigations of the General Accounting Office, the Ryan White CARE Act is "ripe" for fraud and abuse.

In Puerto Rico, $2.2 million of federal AIDS funds were found to be defrauded. More than ten people have been convicted in this case already and the investigation is ongoing. This money— intended for those living with HIV/AIDS— was instead spent on political campaigns, bribes and personal uses. This is not an isolated incident as there have been several similar high profile cases during recent

years in Florida, North Carolina and Texas.

An audit in California found that mismanagement at the Los Angeles County AIDS program led to over a half million dollars being spent on employees who didn't provide AIDS services and ineffective monitoring of other federally funded programs. The audit found that the county AIDS office monitored only 13 of the 241 contracts it awards each year to groups providing $74 million worth of care and services. More than two-thirds of the contractors reviewed by the auditors provided services "at levels below contractual requirements." In one case, a contractor was paid $90,000 annually to treat 400 adolescent clients, but had provided services to only 10 during the first five months.

While these deplorable incidents do not reflect the vast majority of the good intentioned and dedicated organizations and individuals receiving federal support to provide HIV/AIDS care, the amount of money that has been stolen and misused is alarming. It is particularly unfortunate when we consider the impact in human terms. How many more patients could have been cared for with this money? How many more states with budget constraints could have expanded their drug assistance programs ? How many more lives could have been saved?

All in all, I believe we have two underlying goals for the Ryan White CARE Act. We must first make prevention the priority. Even one new case of HIV that could have been prevented is unacceptable. Forty-thousand more new infections this year is a failure. Second, we must ensure that we do not leave anyone behind by focusing on only AIDS and ignoring those with HIV. Such shortsightedness has left many communities unprepared for the devastation that they now confront. We must be sure they no longer have to face these challenges alone.

Thank you again for the opportunity to testify. I look forward to working with all of you to update and reauthorize this very important program.

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

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July 25, 2000

Extension of Remarks
By Rep. Tom A. Coburn, M.D.
Supporting Passage of H.R. 4807

Mr. Speaker,

As we consider H.R. 4807, which would reauthorize the Ryan White CARE Act, today, I would like to recognize three individuals who have worked tirelessly and made untold sacrifices to care for those living with HIV and to end the scourge of AIDS. The first is Jeanne White, the mother of Ryan White for whom this bill is named. The second is Shepherd Smith of the Children's AIDS Fund and the last is New York Assemblywoman Nettie Mayersohn. These are the true AIDS activists. We owe all three a debt of gratitude for their compassion, determination and courage.

I would also like to thank Congressman Waxman and Paul Kim of his staff for working with me to develop the bill before us today. This bill, co-sponsored by over 250 members of the House and supported by nearly every major AIDS advocacy group, will make important and long overdue changes to our federal response to HIV.

It has been nearly two decades since the disease which we now know as HIV/AIDS was first recognized. During this short period of time, nearly half a million Americans have died from the disease and almost a million others are believed to be living with HIV, many of whom are unaware that they are infected and are unknowingly passing the deadly virus onto unsuspecting others.

In so many ways, those charged with protecting the public health have allowed this epidemic to spread unabated through our society. The initial response to AIDS was late in coming and steps which should have been taken long ago still have not happened.

In 1994, for example, it was discovered that the AIDS drug AZT administered to an infected pregnant woman and to her child after birth could significantly reduce the newborn's risk of infection. Other studies have shown that even if given to the child after delivery, infection could be prevented. Yet six years later only two states— New York and Connecticut— have taken advantage of this medical miracle to save babies from AIDS.

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New York requires every baby born in the state be tested for HIV antibodies. This policy has resulted in the identification of every HIV-exposed baby and has ensured that over 98 percent of these babies and their mothers are provided life saving medical care. Connecticut has had similar success with its law which requires the testing of any newborn whose mother's status is unknown. Before the Connecticut law went into effect, the state had not reported a pediatric AIDS case in several years. Since enactment, several babies that would have otherwise been left to die from AIDS were quickly identified and provided care. One infant's diagnosis also resulted in the discovery that his two-year old sister had AIDS. Now both are receiving proper medical treatment.

Five years ago, this House overwhelming approved a similar proposal to save babies as part of the Ryan White CARE Act of 1995. It was stripped out of the final bill in conference. At that time AIDS activists had convinced members of the other chamber that such a policy would deter women from seeking prenatal care and even lead women to commit suicide in order to avoid testing. None of these "doomsday scenarios" have occurred in either New York or Connecticut. In fact, according to the New York Department of Health, rates of prenatal care in the state have been increasing. "There has been no detectable change in prenatal participation trends through 1997 that might be related to the newborn testing program," according to Dr. Guthrie Birkhead, Director of the state's AIDS Institute.

Has the great success of the New York law won over those who opposed the enactment of this policy which has saved so many lives?

The American Medical Association now endorses mandatory HIV testing for all newborns. The two groups which claim to represent the health care needs of women and children— The American College of Obstetricians and Gynecologists and the American Academy of Pediatrics— have only recently revised their policies to recommend that all pregnant women be tested for HIV. What about the babies of the women who do not get tested? According to the Institute of Medicine, fifteen percent of HIV infected pregnant women do not receive prenatal care. ACOG and APA still have no answer to help these innocent victims and both continue to oppose efforts to provide a safety net to protect the 15 percent of children whose lives are in serious jeopardy.

What about the activists who claimed women would take their own lives rather than allow their children to be identified and provided life saving treatment? In both New York and Connecticut they filed lawsuits to prevent enactment of the Baby AIDS laws. In Indiana, Delaware, California and other states, they have aggressively fought back any attempts to replicate the successful New York law that has saved so many lives.

And what is the Centers for Disease Control and Prevention doing to save these children? They still only recommend that all pregnant women be offered an HIV test and tout the reduction of children who are reported with AIDS. *"Only"* several hundred babies are infected a year according to the CDC estimates. Yet, like many of the numbers CDC provides, these estimates are unsubstantiated. According to the Institute of Medicine, most of the AIDS cases resulting from children born with HIV infection in the previous year have not yet been diagnosed or

reported and many children infected with HIV perinatally do not develop AIDS until they are substantially older. The fact is without proper screening, no one knows how many babies have been allowed to slip through the cracks and become infected either during birth or via breastfeeding.

We could today be celebrating the end of perinatal HIV transmission in America. Instead we are left guessing at how many hundreds of babies will die from a disease that could have been prevented.

The bill before us today recognizes the need take advantage of the available science to identify all newborns at risk and do everything we can to prevent perinatal infection. It will do this by making states eligible for up to $4 million in federal funds if they follow the successful New York and Connecticut Baby AIDS policies.

H.R. 4807 will also finally acknowledge the importance of partner notification in curtailing the spread of HIV. This policy, which is the most efficient tool to interrupt the spread of any disease, is touted as a key element in our nation's success reducing syphilis to its lowest levels in recorded history. The Wisconsin health department just last week announced that the number of new HIV cases reported in the state dropped by nearly half in the 1990s while the nation as a whole saw 40,000 new cases each year. The state credited an effective partner notification program which had been in effect since 1985. The state of Florida in testimony before the Commerce Committee earlier this month credited partner notification for the success the program has had in identifying individuals at risk and getting those who were unaware of their HIV infection into early treatment and care. New York state, which has the highest HIV/AIDS caseload in the U.S., enacted a similar law just last month.

Partner notification is an extremely effective tool for disease control, especially for women. This is because many HIV-infected women— 50 to 70 percent in some studies— do not engage in high risk behaviors but were infected by a partner who does. Without guaranteeing these unsuspecting victims a right to know that they are at risk, how else can they protect themselves?

Ten years ago when the Ryan White CARE Act was first debated. The Senate unanimously passed an amendment authored by Senators Ted Kennedy and Barbara Mikulski to require all states to conduct HIV partner notification in order to be eligible for CARE Act funds.

Senator Mikulski stated that the addition of this requirement was needed "to improve this legislation." Speaking in support of the amendment, Senator Kennedy acknowledged that, "it is difficult to argue against doing the utmost in terms of partner notifications." Senator Kennedy compared failing to conduct partner notification to having knowledge that someone's life is endangered and not warning them. "In a case in which there is a clear and present danger, there is a duty to warn," Kennedy asserted. Senator Orrin Hatch (R-UT) advocated for the amendment explaining that "I do not see how in the world we are going to solve this problem and how we are going to notify people who are in jeopardy of getting AIDS unless we have required contact tracing. ... Contact tracing is absolutely essential for the ending of this epidemic."

Senator William Armstrong (R-CO) praised the inclusion of the Kennedy/Mikulski amendment stating "I think the Kennedy amendment represents a strong step toward instituting responsible public health measures to slow the spread of this devastating epidemic. The Kennedy amendment, agreed to by voice vote, will ensure that the collection of accurate epidemiological information concerning the incidence of the HIV epidemic, and more importantly will allow those innocent individuals who are unknowingly placed at risk of infection to be notified of their risk." Responding to Senator Armstrong's statement, Senator Kennedy conceded "we agree with Senator Armstrong that partner notification is an essential tool in the fight against AIDS. ... In unanimously approving the amendment yesterday, I believe the Senate has done what is responsible and necessary."

Sadly, this provision was stripped in the House- Senate conference. We will never know how many of the half million Americans infected since that debate occurred could have been spared if such a prevention policy would have been enacted.

While Senator Kennedy insisted that "there is a duty to warn," in many states there still is no right to know if you have been exposed to HIV. In fact, the Texas Supreme Court ruled in 1998 that there is "no statutory or common-law duty to notify" a woman "that she was at risk of contracting the HIV virus." The consequences of this failure have been deadly.

Stephanie Williams, a black mother from South Carolina, who believed she was in a mutually monogamous relationship was infected by her boyfriend who has since died of AIDS. Pam McCree, another African-American woman, became infected in the same way. She only became aware of her status after the man who infected her died.

A woman who works at an inner city clinic in New York was forced to remain silent while one of her HIV-positive clients attempted to have a baby with his wife who was unaware of his status. Another New Yorker only learned that she was infected by her husband after their child was diagnosed with AIDS during an autopsy. A Hispanic woman from the Bronx discovered her status when her husband lay dying of a disease with no name and a counselor at the hospital suggested that she be tested for HIV.

These are not isolated incidents. All of these women were allowed to become infected by people they trusted. They did not know they were at risk and no one warned them. In some cases, the law forbade them from being notified. Partner notification is a simple matter of life and death.

The bill we are considering today would provide additional resources to states that have made saving lives with partner notification a priority. It is my hope that these additional resources will entice other states to follow the lead of Colorado, Wisconsin, New York and Florida and intervene to stop the spread of HIV and get those who are infected into care as soon as possible in order to maximize the treatment that is now available.

Another key component of this bill is the requirement to include prevention as part of care. Two year ago, the Commerce Committee heard testimony from a man who became

infected in part because federally supported AIDS organizations, including the CDC, told his partner that he did not have a responsibility to disclose his status. As a physician, I know it is extremely difficult for people to initially cope with being diagnosed with a terminal illness. But I also know that if provided proper advice most people will protect their own health as well as the health of others. This bill will empower those who are infected to protect others from infection by providing prevention counseling as part of the comprehensive care program. This includes providing advice on how to disclose one's HIV status to a potential partner and emphasizing to those living with HIV that they have a responsibility not to give the disease to anyone else.

Finally, this bill recognizes everyone living with HIV and guarantees access to life saving treatment to all who are infected. Current funding formulas are based on AIDS, the end stage of HIV infection and the CDC only recently recommended that states begin tracking the full scope of the epidemic rather than just AIDS.

Over twelve year's ago the first Presidential Commission on HIV warned that "continual focus on AIDS rather than the full spectrum of HIV disease has left our nation unable to deal adequately with the epidemic." The Commission noted that the "continued emphasis on AIDS has also impeded long-term planning efforts necessary to effectively allocate resources for prevention and health care." This observation was absolutely correct, yet ignored by the CDC and federal policy makers. The results have been devastating. While our attention was placed on AIDS, the virus silently spread through communities of color and more and more women became unknowingly infected. Only now are AIDS statistics revealing the path the virus took ten years ago, and the casualties are increasingly women and African Americans.

While women and African Americans comprise the majority of new HIV infections, they also receive less appropriate care according to a General Accounting Office report released earlier this year. This is a direct result of the CARE Act's misplaced emphasis on AIDS data in determining funding and priority setting.

Incorporating HIV data into funding formulas and prevention strategies will ensure we stay in front of the disease and that resources are directed to where the disease is headed rather than where it was a decade ago.

These changes will do much to improve our nation's response to HIV/AIDS by ensuring medical access to all of those who are infected and by providing the best possible care, which is prevention.

Let us not allow one more person to go without life saving treatment, let us not allow one more person to become needlessly infected and let us not allow one more baby to die from AIDS.

I would strongly urge my colleagues to support passage of this critically needed and long overdue bill.

Tom A. Coburn, M.D.
Press Release

FOR IMMEDIATE RELEASE
October 5, 2000

Contact: John Hart
(202) 225-2701

HOUSE PASSES RYAN WHITE CARE ACT

**** Please refer to Rep. Coburn's website (www.house.gov/coburn) for a bill summary ****

(Washington, D.C.) — The U.S. House of Representatives today unanimously passed (411 to 0) the Ryan White CARE Act Amendments of 2000, a bill authored by Reps. Tom Coburn (R-OK) and Henry Waxman (D-CA) that marks the most dramatic shift in the federal government's battle against HIV/AIDS in more than a decade. The legislation will now be sent to the Senate. The President is expected to sign the bill into law this year.

The bill reauthorizes and improves The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act that was passed by Congress in 1990. The reauthorization bill places a new emphasis on HIV prevention and corrects funding disparities among rural areas, women and communities of color. Today, the Centers for Disease Control and Prevention estimates that there are currently between 800,000 to 900,000 persons living with HIV in the United States, with 40,000 new infections annually.

"Two decades into the HIV/AIDS epidemic, our federal response to HIV/AIDS will include the proven public health policies which have been effectively utilized to curtail other contagious diseases. These include ensuring medical access to all who are infected, early intervention, reliable disease surveillance and partner notification. We will also, for the first time, recognize all of those living with HIV rather than focusing exclusively on those with AIDS," Coburn said.

"More than 12 years ago the first Presidential Commission on HIV warned that 'continual focus on AIDS rather than the full spectrum of HIV disease has left our nation unable to deal adequately with the epidemic.' The Commission noted that the 'continued emphasis on AIDS has also impeded long-term planning efforts necessary to effectively allocate resources for prevention and health care.' This observation was absolutely correct, yet ignored by the CDC and federal policy makers. The results have been devastating. What is even more tragic is that these results were avoidable. If the CDC had done its job correctly we would have had far fewer than 40,000 new infections annually. While our attention was placed on AIDS, the virus silently spread through communities of color and more and more women became unknowingly infected. Only now are AIDS statistics revealing the path the virus took ten years ago, and the casualties are increasingly women and communities of color.

"While women and African Americans comprise the majority of new HIV infections, they also receive less appropriate care according to a General Accounting Office report released

— more —

earlier this year. This is a direct result of the CARE Act's misplaced emphasis on AIDS data in determining funding and priority setting. Incorporating HIV data into funding formulas and prevention strategies will ensure we stay in front of the disease and that resources are directed to where the disease is headed rather than where it was a decade ago.

"All of these changes, while long overdue, will do much to improve our nation's response to HIV/AIDS by ensuring medical access to all of those who are infected and by providing the best possible care, which is prevention.

"There are many other noteworthy changes made by this bill. Waiting lists to access lifesaving HIV medications under the AIDS Drug Assistance Program will be eliminated. Prevention will be incorporated as part of the comprehensive care program. Planning Councils will be more representative of the infected population. Patients who rely on the CARE Act for their well being will be given a greater voice in priority setting. And accountability safeguards will ensure that federal AIDS funds will be spent on needed patient care.

"This bill will also provide federal assistance to states to ensure that all pregnant women with HIV and their children are identified and provided care. One of the most promising victories in the battle against AIDS was the 1994 finding that administration of the drug ZDV during pregnancy and childbirth could significantly reduce the chance that a child born to an HIV-positive mother would become infected. A more recent study found that even if treatment begins shortly after birth, perinatal transmission can still be considerably reduced. Yet despite these medical miracles, a significant number of women still are not tested for HIV during their pregnancy and hundreds of children are needlessly infected each year with an incurable disease that will prematurely claim their lives.

"This bill will provide up to $4 million annually to any state that makes identifying and ensuring proper care for HIV infected pregnant women and HIV-exposed newborns a priority. Unfortunately, only New York and Connecticut have done so to date, but both states have experienced great success.

"According to Dr. Guthrie Birkhead, the Director of the New York AIDS Institute. 'Universal newborn HIV testing has resulted in the identification of all HIV-exposed births' and 'has allowed hospital and health department staff to ensure that over 98% of HIV positive mothers are aware of their HIV status and have their newborns referred for early diagnosis and care of HIV infection.' Furthermore, Dr. Birkhead noted that rates of prenatal care 'have been increasing' and there 'has been no detectable change in prenatal participation trends . . . that might be related to the newborn testing program.' Just under 1,000 HIV infected New York women gave birth in 1998, about 16 percent of these women did not receive prenatal HIV testing. Therefore, between 100- 160 women may be learning their HIV status for the first time from testing conducted in the delivery setting.

"This bill will also provide additional resources to support partner notification programs so that everyone who has been exposed to HIV is given the right to know. In addition, it will empower those who are infected to protect others from infection by providing prevention counseling as part of the comprehensive care program. This includes providing advice on how to disclose one's HIV status to a potential partner and emphasizing to those living with HIV that they have a responsibility not to give the disease to anyone else," Coburn said.

###

(2) HIV/AIDS Statistics

The federal Centers for Disease Control and Prevention (CDC) estimates that between 1,039,000 and 1,185,000 Americans are living with HIV/AIDS.

However, due to a historic reluctance by CDC and many states to establish a surveillance system for the disease, there is no reliable, existing tool to determine the present size or demographics of the disease.

In 1986, the Centers for Disease Control announced that there were an estimated one million Americans infected with HIV. In 1987, 1988, 1989, 1990 and 1991, the CDC made the same estimates. Today, even with AIDS deaths declining, the CDC estimate is virtually the same. The fact is that the CDC has no idea how many Americans are infected with HIV because they have failed to monitor the epidemic appropriately.

Similarly, the CDC's guess on the number of new HIV infections has not changed for over a decade. The agency estimates that nearly 40,000 Americans will become newly infected with HIV this year. This estimate has remained unchanged for over a decade despite dramatic increases in federal HIV prevention funding. The amounts appropriated for CDC HIV prevention programs has nearly doubled from $480 million in 1992 to $936 million in 2003, yet the number of Americans newly infected remained unchanged.

What has changed is the communities that have become impacted. HIV is increasingly a disease that affects women and communities of color, although men who have sex with men continue to make up the largest proportion of those living with HIV.

CDC HIV/AIDS FACT SHEET

A Glance at the HIV/AIDS Epidemic

1-800-CDC-INFO (232-4636)
In English, en Español
24 Hours/Day
cdcinfo@cdc.gov
http://www.cdc.gov/hiv

June 2005

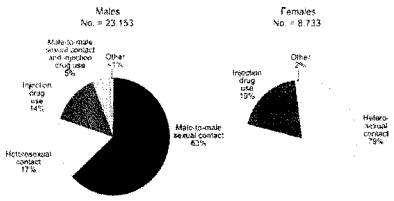
HIV/AIDS DIAGNOSES

At the end of 2003, an estimated 1,039,000 to 1,185,000 persons in the United States were living with HIV/AIDS [1]. In 2003, 32,048 cases of HIV/AIDS were reported from the 33 areas (32 states and the US Virgin Islands) with long-term, confidential name-based HIV reporting [2]. When all 50 states are considered, CDC estimates that approximately 40,000 persons become infected with HIV each year [1].

By Exposure

In 2003, MSM represented the largest proportion of HIV/AIDS diagnoses, followed by adults and adolescents infected through heterosexual contact.

Exposure categories of adults and adolescents who received a diagnosis of HIV/AIDS, 2003



No. = 31,886

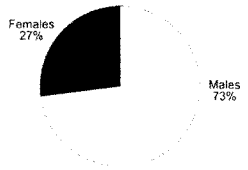
Note. Based on data from 33 areas with long-term, confidential name-based HIV reporting.

HIV/AIDS includes persons with a diagnosis of HIV infection (not AIDS), a diagnosis of HIV infection and a later diagnosis of AIDS, or concurrent diagnoses of HIV infection and AIDS.

By Sex

In 2003, almost three quarters of HIV/AIDS diagnoses were made for male adolescents and adults.

Sex of adults and adolescents who received a diagnosis of HIV/AIDS, 2003



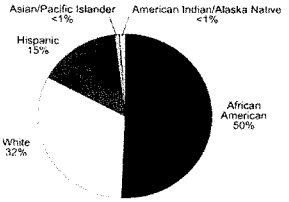
No. = 31,886

Note. Based on data from 33 areas with long-term, confidential name-based HIV reporting.

By Race/Ethnicity

Persons of minority races and ethnicities are disproportionately affected by HIV/AIDS. In 2003, African Americans, who make up approximately 12% of the US population, accounted for half of the HIV/AIDS cases diagnosed.

Race/ethnicity of persons (including children) who received a diagnosis of HIV/AIDS, 2003



No. = 32,048

Note. Based on data from 33 areas with long-term, confidential name-based HIV reporting. Includes persons of unknown race or multiple races.

TRENDS IN AIDS DIAGNOSES AND DEATHS

During the mid-to-late 1990s, advances in treatment slowed the progression of HIV infection to AIDS and led to dramatic decreases in AIDS deaths. Although the decrease in AIDS deaths continues (3% decrease from 1999 through 2003), the number of AIDS diagnoses increased an estimated 4% during that period [2].

Better treatments have also led to an increasing number of persons in the United States who are living with AIDS. From the end of 1999 through the end of 2003, the number of persons in the United States who were living with AIDS increased from 311,205 to 405,926—an increase of 30% [2].

Estimated AIDS diagnoses, deaths, and persons living with AIDS 1998–2002

	1999	2000	2001	2002	2003	Cumulative through 2003
Estimated AIDS diagnoses	41,356	41,267	40,833	41,289	43,171	929,985
Estimated AIDS deaths	18,491	17,741	18,524	17,557	18,017	524,060
Estimated Persons living with AIDS	311,205	334,731	357,040	380,771	405,926	NA

NA, not applicable (the category Estimated persons living with AIDS is cumulative).

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1. Glynn M, Rhodes P. Estimated HIV prevalence in the United States at the end of 2003. National HIV Prevention Conference; June 2005; Atlanta. Abstract 595.
2. CDC. *HIV/AIDS Surveillance Report, 2003* (Vol. 15). Atlanta: US Department of Health and Human Services, CDC; 2004:1–46. Available at http://www.cdc.gov/hiv/stats/2003surveillancereport.pdf. Accessed March 16, 2005.

For more information . . .

CDC Division of HIV/AIDS Prevention
http://www.cdc.gov/hiv
CDC HIV/AIDS prevention resources

CDC-INFO
1-800-232-4636
Information about personal risk and where to get an HIV test

CDC National HIV Testing Resources
http://www.hivtest.org
Location of HIV testing sites

CDC National Prevention Information Network (NPIN)
1-800-458-5231
http://www.cdcnpin.org
CDC resources, technical assistance, and publications

AIDSinfo
1-800-448-0440
http://www.aidsinfo.nih.gov
Resources on HIV/AIDS treatment and clinical trials

Associated Press
June 13, 2005 Monday 12:50 PM Eastern Time

More Than a Million in U.S. Lives With HIV

BY DANIEL YEE; Associated Press Writer
DATELINE: ATLANTA

For the first time since the height of the AIDS epidemic in the 1980s, more than a million Americans are believed to be living with the virus that causes AIDS, the government said Monday.

The latest estimate is both good and bad news - reflecting the success of drugs that keep more people alive and the failure of the government to "break the back" of the AIDS epidemic by its stated goal of 2005.

The Centers for Disease Control and Prevention said that between 1,039,000 and 1,185,000 people in the United States were living with HIV in December 2003. The previous estimate from 2002 showed that between 850,000 and 950,000 people had the AIDS virus.

The jump reflects the role of medicines that have allowed people infected with the virus to live longer, said Dr. Ronald Valdiserri, deputy director of the CDC's National Center for HIV, STD and TB Prevention.

"While treatment advances have been an obvious godsend to those living with the disease, it presents new challenges for prevention," Valdiserri said.

The challenges include overcoming a failure by the government to meet its 2005 goal of cutting in half the estimated 40,000 new HIV infections that have occurred every year since the 1990s. Then, Dr. Robert Janssen of the CDC pledged the government campaign would "break the back" of the epidemic.

CDC officials previously have said the country's HIV infection rate has been "relatively stable" and without change. As the National HIV Prevention Conference was set to begin this week, Valdiserri said no new infection data will be available until next year.

However, recent outbreaks of HIV and sexually transmitted diseases in major cities around the country offer a hint that new infections may be as high as 60,000 cases a year, rather than the government estimate of 40,000, said Dr. Carlos del Rio, an Emory University professor of medicine.

"The U.S. has had a clear failure in HIV prevention - I think the increase in prevalence is a reflection of that, of the poor job we do in HIV prevention," del Rio said.

He added that the higher number is not as surprising as why the country has not been able to curb new infections. He said the CDC hasn't been given adequate resources to tackle HIV prevention and that experts have focused too much on whether it's better to promote abstinence or condom use to stop the spread of the virus.

"We're debating too much what to do and are not doing enough," he said.

At the same time, reaching the 1 million mark is "a sign of both victory and failure," said Terje Anderson, executive director of the National Association of People Living With AIDS.

"Part of the reason the number is so big is we're not dying as before," he said. "But the other problem is we have not made a significant dent in new infections."

Estimating the number of Americans with HIV has always been a difficult task for health officials, but this year's figures are believed to be the most accurate ever thanks to wider case reporting.

In the 1990s, the CDC and other agencies generally agreed that between 600,000 and 900,000 people had the virus, according to the University of California-San Francisco's Center for HIV Information.

Previous estimates - as high as 1.5 million people - from the 1980s were later determined to be too high. For example, the CDC estimated in 1986 that between 1 million and 1.5 million people had HIV. In 1987, that was revised to 945,000 to 1.4 million and was refined in 1990 to 800,000 to 1.2 million.

The CDC's latest estimates indicate blacks account for 47 percent of HIV cases; gay and bisexual men make up 45 percent of those living with the virus that causes AIDS, the health agency believes.

In 2003, the rates of AIDS cases were 58 per 100,000 in the black population, 10 per 100,000 Hispanics, 6 per 100,000 whites, 8 per 100,000 American Indian/Alaska native population, and 4 per 100,000 Asian/Pacific Islanders.

The CDC also warned those demographics may soon change because heterosexual blacks, women and others infected after having high-risk sex (such as with someone with HIV, an injection-drug user or a man who has sex with other men) now account for a larger proportion of those living with HIV than those who are living with full-blown AIDS.

The Centers for Disease Control and Prevention announced Monday that more than 1 million Americans are now living with HIV. Here is the latest U.S. data:

Estimated number of HIV cases:
1,039,000 to 1,185,000 in December 2003

Number of new HIV infections:
40,000 per year

AIDS rate, by race or ethnicity:
Blacks: 58 per 100,000 black population
Hispanics: 20 per 100,000 Hispanic population
Whites: 6 per 100,000 white population

AIDS cases:
43,171 in 2003, a 4.3 percent increase from the 41,289 cases in 2002

AIDS deaths:
18,017 in 2003, a figure that has remained stable since 1999

HIV ignorance:
24 percent to 27 percent are unaware they are infected

HIV testing:
From 1998 to 2002, proportion of adults tested for HIV during routine doctor visit doubled

Source: Centers for Disease Control and Prevention

(3) Federal HIV/AIDS Spending

Federal spending on HIV/AIDS has increased dramatically over the past decade.

The federal government is expected to spend $19.7 billion in fiscal year 2005 on HIV/AIDS related services and programs. In fiscal year 1995, the amount was $7 billion, less than half of the current amount.

These amounts do not reflect the amounts spent by state, local and private sources.

Order Code RL30731

CRS Report for Congress
Received through the CRS Web

AIDS Funding for Federal Government Programs: FY1981-FY2006

Updated March 23, 2005

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AIDS Funding for Federal Government Programs: FY1981-FY2006

Summary

Federal government AIDS spending is estimated at $19.7 billion in FY2005: 65% is for treatment programs; research receives 15%; income support programs receive 10%; and prevention programs receive 10%. The government-wide request level for FY2006 is $21.1 billion. AIDS programs within the Department of Health and Human Services (HHS) account for 75% of the total amount spent on HIV/AIDS by the federal government. Funding for HIV/AIDS research, prevention and treatment programs within the HHS discretionary budget has increased from $200,000 in FY1981 to an estimated $6.27 billion in FY2005; the Administration's request for FY2006 is $6.28 billion. Funding for HIV/AIDS treatment within HHS entitlement programs has increased from $10 million in FY1983 to an estimated $8.6 billion in FY2005. Entitlement spending depends on the number of HIV/AIDS cases that qualify; the estimate for FY2006 is $9.5 billion for HIV/AIDS treatment within HHS entitlement programs.

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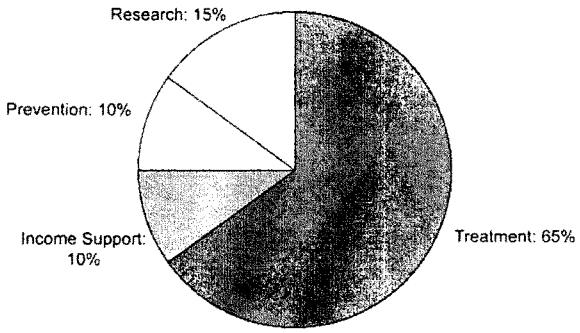
AIDS Funding for Federal Government Programs: FY1981-FY2006

AIDS (acquired immune deficiency syndrome) impairs the immune system and leaves affected individuals susceptible to certain opportunistic infections and cancer. Since 1981, a cumulative total of 929,985 AIDS cases in the United States have been reported to the Centers for Disease Control and Prevention (CDC).[1] Of this total, 405,926 persons were reported to be living with AIDS as of the end of December 2003. In addition to the total number of people living with AIDS, another 351,614 persons were known to be infected with the human immunodeficiency virus (HIV) (in the 32 states and the Virgin Islands that have been reporting confidential name-based HIV infection case numbers to CDC since 1999).

Federal government AIDS spending is estimated at $19.7 billion in FY2005 (see **Table 5**). The Bush Administration request for FY2006 is $21.1 billion. Of the total amount spent by the federal government on HIV/AIDS in FY2005, the majority (65%) of funding is for treatment programs; funding for research receives 15% of the total (see **Figure 1** and **Table 4**). The remaining amounts are for prevention programs (10%) and income support for persons with AIDS (10%).

Figure 1. Estimated Total Federal Spending on HIV/AIDS, by Function, FY2005

Total: $19.7 billion



Source: HHS Budget Office, Feb. 14, 2005.

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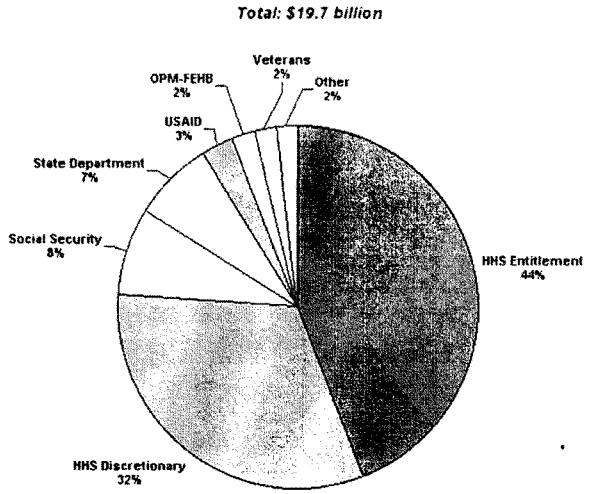
[1] CDC, *HIV/AIDS Surveillance Report*, 2003, vol. 15, p. 12.

AIDS programs within HHS (Health and Human Services) account for 75% of the total amount spent on AIDS by the federal government (see **Figure 2**). HHS entitlement funding supports the treatment of HIV/AIDS patients through Medicaid and Medicare, which are administered by the Centers for Medicare and Medicaid Services (CMS). HHS discretionary funding supports AIDS research and prevention programs, as well as treatment programs. **Table 2** provides a history of HHS discretionary funding for HIV/AIDS from the beginning of the epidemic in FY1981 to the present. As shown in **Figure 4** near the end of this report, funding for HIV/AIDS programs within HHS has increased markedly over the past decade as measured in constant 2000 dollars. However, most of the rise can be attributed to increased spending on Medicaid, Medicare, and treatment programs in the discretionary budget, largely through the Ryan White CARE Act program administered by the Health Resources and Services Administration (HRSA). The increase in HIV/AIDS research and prevention programs has been much less pronounced, and their portion of the total amount spent by HHS on HIV/AIDS has declined over the past decade (see **Figure 5**). For example, in FY1992 HIV/AIDS research and prevention programs at HHS accounted for 51% of the total amount spent by HHS on HIV/AIDS; by FY2005, such programs were about 27% of the total amount spent by HHS on HIV/AIDS, reflecting the growing amounts spent on treatment services under Medicaid and Medicare.

Figure 2. Estimated Total Federal Spending on HIV/AIDS, by Agency, FY2005



Source: HHS Budget Office, Feb. 14, 2005.
Note: OPM-FEHB: Office of Personnel Management-Federal Employees Health Benefits; **USAID:** U.S. Agency for International Development. See **Table 4.**

About 93% of FY2005 HHS discretionary funding for HIV/AIDS is allocated to three HHS agencies: the National Institutes of Health (NIH), which supports HIV/AIDS *research*; CDC, which supports HIV/AIDS *prevention* programs; and, HRSA, which administers the Ryan White CARE Act, an HIV/AIDS *treatment* program (see **Table 3** and **Table 4**). The budgets and activities of these three agencies are briefly described below, followed by a discussion of entitlement program spending on HIV/AIDS.

HHS Discretionary Funding: NIH, CDC, and HRSA

NIH. NIH is the principal agency of the federal government charged with the conduct and support of biomedical and behavioral research. NIH conducts research at its own 26 institutes and centers and supports over 50,000 scientists at 2,000 U.S. institutions. NIH funding for FY2005 was provided in P.L. 108-447 (H.R. 4818), and NIH estimates FY2005 funding for AIDS research at $2.92 billion. The Administration's request for FY2006 is $2.93 billion. Funding for AIDS research is distributed among the NIH institutes in accordance with the scientific priorities identified in the annual comprehensive plan for AIDS research developed by the institutes along with the Office of AIDS Research (OAR).

OAR was established in statute by the National Institutes of Health Revitalization Act of 1993 (P.L. 103-43) and given substantially enhanced authority and responsibility beyond the office NIH had established under the same name. Congress appropriated funds to OAR in FY1995. However, since FY1996, Congress has not provided a direct appropriation for the OAR (aside from amounts identified for the operations of the office itself). For FY2005, both the House and Senate reports (H.Rept. 108-636 and S. Rept 108-345) accompanying the Labor, HHS, and Education and Related Agencies Appropriation bills (H.R. 5006 and S. 2810) do not specify a funding amount for AIDS research at NIH. Instead, funding for AIDS research is included within the appropriation for each Institute/Center/Division of NIH, with decisions as to specific projects to fund and levels of funding left to the Director of NIH and the Director of OAR.

CDC. CDC works with community, state, national, and international public health agencies to prevent HIV infection and reduce AIDS-associated morbidity and mortality through its information and education programs. CDC also supports research, surveillance, and epidemiology studies on HIV/AIDS. In prior fiscal years, about 80% of CDC HIV funds were distributed to state and local agencies through cooperative agreements, grants, and contracts. CDC funding for FY2005 was provided in P.L. 108-447 (H.R. 4818). According to the HHS Budget Office, CDC will be spending $856 million on HIV/AIDS activities in FY2005, and the Administration's request for FY2006 is $851 million. In order to reflect CDC's new budget structure, which excludes administrative and management costs, the FY2005 figure was adjusted downward by $74 million by the HHS Budget Office.

HRSA. The HIV/AIDS Bureau within HRSA administers the Ryan White CARE Act, a four-part federal grant program designed to provide emergency relief and essential health care services to patients infected with HIV. The program funds hundreds of grantees that serve 533,000 people affected by HIV/AIDS each year. HRSA funding for FY2005 was provided in P.L. 108-447 (H.R. 4818). According

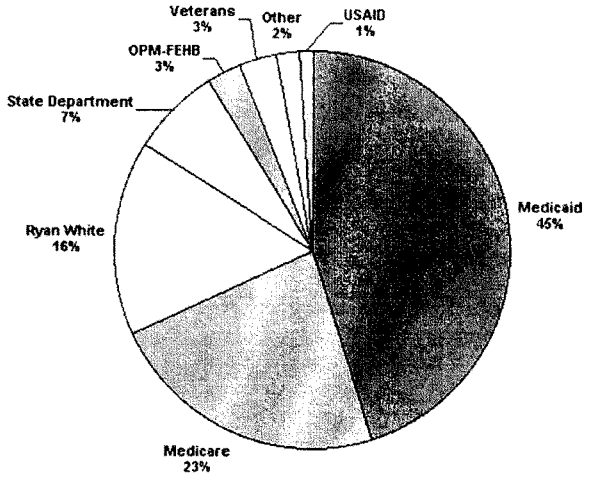
to the HHS Budget Office, HRSA will be spending $2.075 billion for Ryan White activities in FY2005. The Administration's request for FY2006 is $2.085 billion. The HRSA FY2005 budget figure was adjusted downward by the HHS Budget Office by $5 million, an amount that represented HRSA program management costs. (For further information on Ryan White programs, see CRS Report 98-476, *AIDS: Ryan White CARE Act.*)

HHS Entitlement Funding: Medicaid and Medicare at CMS

Medicaid. Medicaid is a federal-state matching entitlement program that provides medical assistance for eligible low-income persons and families and certain aged, disabled, and medically needy individuals. Within broad federal guidelines, each state designs and administers its own Medicaid program, resulting in wide variations among the states in coverage, benefits offered, and payment for services. The portion of a state's Medicaid budget provided by the federal government varies from 50% in relatively affluent states to 80% in poorer states. Medicaid is the largest source of federal funding for AIDS treatment and health care services (see **Figure 3**).

Figure 3. Estimated Federal Government Spending on HIV/AIDS Treatment, FY2005

Total: $12.7 billion



Source: HHS Budget Office, Feb. 14, 2005.
Note: OPM-FEHB: Office of Personnel Management-Federal Employees Health Benefits; **USAID**: U.S. Agency for International Development. **"Other"** includes the following: Substance Abuse and Mental Health; Health Emergency Fund; Department of Defense; Bureau of Prisons. See **Table 3.**

For FY2005, the federal share of Medicaid spending on AIDS treatment is estimated at $5.7 billion, and for FY2006 the federal share estimate is $6.3 billion. Total FY2006 federal and state Medicaid spending for AIDS treatment will be an

estimated $11.1 billion ($6.3 billion federal and $4.8 billion state).[2] According to CMS, approximately 55% of adults with AIDS and up to 90% of children with AIDS depend on Medicaid to pay for their care. In order to obtain Medicaid coverage, persons must belong to one of the categories of persons who can qualify for coverage (such as families with children and disabled persons) and have low income or deplete their income on the cost of their care. Medicaid plays an important role in needed health care for persons with HIV and AIDS because of its coverage of prescription drugs.

Medicare. Medicare is a federal health care insurance program for the elderly and certain disabled persons. In general, in order to qualify for coverage under Medicare, a person must be age 65 or older, disabled, or suffering from kidney failure (end-stage renal disease or ESRD). According to one estimate, by the end of 1996, about 12% of people living with AIDS were covered by Medicare; 83% of these beneficiaries qualified because of a disability,[3] the remainder were eligible because they were 65 or older or had ESRD.[4] The elderly qualify the month they turn 65, and those with ESRD qualify within three months of being diagnosed with irreversible kidney disease requiring dialysis or a kidney transplant. However, disabled people, including those with AIDS, must wait for a total of 29 months after a determination that they are disabled before they become eligible for Medicare coverage.[5]

Early in the epidemic, few individuals with AIDS survived the long waiting period. With improved drug therapies, the life expectancy of individuals with HIV has increased, and it is expected that the number able to qualify for Medicare coverage will continue to rise.[6] Medicare currently does not cover prescription drugs. The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (P.L. 108-173) provides for the implementation of a prescription drug program effective January 1, 2006. In the interim, the legislation requires the Secretary of HHS to establish a temporary prescription drug discount card program to provide discounts to persons who have elected to enroll in a card plan; this interim program also provides $600 in assistance in both 2004 and 2005 for low-income persons enrolled

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[2] Estimate based on average federal Medicaid assistance percentage (FMAP) for the Nation as a whole.

[3] An HIV-positive individual must have a recognized AIDS-defining illness in order to meet the disability classification.

[4] Nancy Fasciano et al., *Profile of Medicare Beneficiaries with AIDS: Application of an AIDS Case Finding Algorithm,* Executive Summary, Oct. 14, 1999. Submitted by Mathematica Policy Research, Inc.

[5] Disabled people begin collecting Social Security disability cash benefits five months after a determination that they are disabled and then must wait an additional 24 months for a total of 29 months before becoming eligible for Medicare.

[6] Combination drug therapies do not work for everyone with HIV. However, for individuals who are successfully treated, the drug therapies will keep them healthy longer, thereby preventing some from qualifying for disability.

in the card program.[7] For FY2005, funding for the care of persons with HIV/AIDS under Medicare is estimated to be $2.9 billion, and the estimate for FY2006 is $3.2 billion. Once Medicare's new outpatient prescription drug benefit is implemented in 2006, Medicare spending for persons with HIV/AIDS may increase significantly beyond current estimates.

Funding for Other AIDS Programs

HIV/AIDS Minority Initiative. In 1998 the White House announced a series of initiatives targeting appropriated funds for HIV/AIDS prevention and treatment programs in minority communities. The Congressional Black Caucus worked with the Clinton Administration to formulate the approach. For FY2005, a total of $398.7 million is provided to continue these activities. For FY2006, the Administration has requested $394.5 million. See **Table 1** below for further details.

Table 1. HIV/AIDS Minority Initiative
($ in millions)

Program	FY2003	FY2004	FY2005	FY2006
HRSA	130.3	129.6	128.5	128.5
CDC	97.1	97.3	97.0	97.0
NIH	4.9	—	—	—
SAMHSA	109.7	110.2	109.6	105.4
Minority Communities Fund	49.7	49.5	52.4	52.4
Office of Minority Health	10.2	10.2	10.2	10.2
Office of Women's Health	1.0	1.0	1.0	1.0
Total, Minority HIV/AIDS Initiative	**403.0**	**397.9**	**398.7**	**394.5**

Source: Table prepared by the Congressional Research (CRS) based on analysis from HHS Budget Office, Mar. 18, 2005.

Ricky Ray Hemophilia Relief Fund. The Ricky Ray Hemophilia Act of 1998 established within the Treasury Department a trust fund to provide compassionate payments of $100,000 to individuals who have blood clotting disorders, such as hemophilia, and who contracted HIV due to contaminated blood products administered between July 1, 1982 and December 31, 1987.[8] For FY2000, P.L. 106-113 provided (within the Office of the Secretary in the Public Health and

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[7] For further information, see CRS Report RL32283, *Medicare Endorsed Prescription Drug Discount Card Program*, by Jennifer O'Sullivan; and CRS Report RL32828, *Beneficiary Information and Decision Supports for the Medicare-Endorsed Prescription Drug Discount Card,* by Diane Justice

[8] Further information can be found at:[http://bhpr.hrsa.gov/rickyray/].

Social Services Emergency Fund) $75 million for the trust fund; $10 million of the total was for program management. The trust fund, known as the Ricky Ray Hemophilia Relief Fund, was administered by HRSA. Payments were made to eligible individuals who filed petitions (with the required documentation) postmarked between July 31, 2000 and November 13, 2001. Payments were made in the order in which the petitions were received. HRSA received more than 5,700 petitions. For FY2001 the trust fund was appropriated $580 million. According to the HRSA website, more than $555 million in compassionate payments have been made to more than 7,100 eligible individuals. All eligible petitions have been processed for payment. The Administration did not request appropriations for the trust fund for subsequent years because prior funding was sufficient to make compassionate payments on all eligible petitions. The trust fund was terminated in November 2003.[9]

International HIV/AIDS Programs. As indicated in **Table 6**, federal government spending on international HIV/AIDS programs in FY2005 is $2.59 billion; the Administration's request for FY2006 is $3.03 billion.[10] On January 28, 2003, President Bush announced in the State of the Union speech a new five-year $15 billion Emergency Plan for AIDS Relief.[11] The emergency plan targets countries with a very high prevalence of HIV infection: Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam, and Zambia. In the targeted countries, the goals of the five-year plan are to prevent 7 million new infections, provide treatment to 2 million HIV-infected people, and provide care for 10 million HIV-infected individuals and AIDS orphans. Details of the Administration's plans can be found in a report released by the Department of State on February 23, 2004.[12]

On June 19, 2002, President Bush announced the Mother-to-Child HIV Prevention Initiative, a $500 million program that targets the countries mentioned above that have been hard hit by the HIV/AIDS epidemic. The goal of the Mother-to-Child HIV Prevention Initiative is to improve health care delivery and reduce mother-to-infant transmission of HIV by 40% within five years.[13] The Administration requested $200 million in FY2003 and $300 million in FY2004. Funding for the

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[9] HRSA Newsbrief, Sept. 24, 2002. See the HRSA website at [http://newsroom.hrsa.gov/NewsBriefs/2002/rickyray.htm].

[10] For additional information, see CRS Report RS21181, *HIV/AIDS International Programs: Appropriations, FY2003-FY2006* by Raymond W. Copson, and CRS Issue Brief IB10050, *AIDS in Africa* by Raymond Copson.

[11] The U.S. Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 (H.R. 1298, P.L. 108-25), signed into law on May 27, 2003, authorizes $15 billion for international HIV/AIDS programs. On July 2, 2003, President Bush nominated Randall Tobias as coordinator for international HIV/AIDS assistance at the Department of State, a position created by H.R. 1298. The appointment has the rank of ambassador, reporting directly to the Secretary of State.

[12] U.S. State Department, *The President's Emergency Plan for AIDS Relief.* Feb. 23, 2004. 103 p. [http://www.state.gov/documents/organization/29831.pdf].

[13] President Bush's International Mother and Child Prevention Initiative, June 19, 2002, at [http://www.whitehouse.gov/news/releases/2002/06/20020619-1.html].

Initiative was provided by the Foreign Operations appropriation through the U.S. Agency for International Development (USAID) and the Labor, HHS appropriation through international HIV/AIDS programs at CDC. Congress provided $140 million for the Mother-to-Child HIV Prevention Initiative in FY2003 ($100 million through USAID and $40 million through CDC) and full funding of $300 million for FY2004 ($150 million via both USAID and CDC). For FY2005, the Administration has proposed continuing the Mother-to-Child HIV Prevention Initiative within the budget of the Department of State.

A third program, the Global Fund to Fight AIDS, Tuberculous and Malaria, was first proposed at the July 2000 G-8 Summit in Okinawa.[14] The purpose of the Global Fund is to attract, manage and disburse funding through a public-private partnership dedicated to the reduction of infections, illness and death caused by these three diseases in countries in need. The concept of the Global Fund was unanimously endorsed at a special session on HIV/AIDS held by the United Nations General Assembly in June 2001. The Global Fund was established in January 2002 as a charitable foundation in Geneva, Switzerland; the first round of grants was approved in April 2002. U.S. support of the fund occurs through USAID and HHS.[15]

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[14] Fact Sheet, Office of the Spokesman, U.S. Department of State, Dec. 13, 2002, at [http://www.state.gov/r/pa/prs/ps/2002/15583.htm].

[15] For further information, see CRS Report RL31712, *The Global Fund to Fight AIDS, Tuberculosis and Malaria: Background and Current Issues*, by Raymond W. Copson and Tiaji Salaam.

Table 2. HHS Discretionary Funding for HIV/AIDS

($ in thousands)

Year	Funding	$ Increase over prior year	% Increase over prior year
FY1981	$200	—	—
FY1982	5,555	$5,355	2,678%
FY1983	28,736	23,181	417%
FY1984	61,460	32,724	114%
FY1985	108,618	47,158	77%
FY1986	233,793	125,175	115%
FY1987	502,455	268,662	115%
FY1988	962,018	459,563	94%
FY1989	1,304,012	341,994	36%
FY1990	1,592,756	288,744	22%
FY1991	1,891,232	298,476	19%
FY1992	1,963,414	72,182	4%
FY1993	2,079,591	116,639	6%
FY1994	2,568,682	489,091	24%
FY1995	2,700,498	131,816	5%
FY1996	2,897,923	197,425	7%
FY1997	3,267,220	369,297	13%
FY1998	3,536,519	269,299	8%
FY1999	4,094,489	557,970	16%
FY2000	4,546,326	451,837	11%
FY2001	5,225,645	679,319	15%
FY2002	5,788,553	562,908	11%
FY2003	6,093,846	305,293	5%
FY2004	6,242,501	148,655	2%
FY2005 enacted	6,266,701	24,200	0.4%
FY2006 request	6,283,986	17,285	0.3%

Source: Table prepared by the Congressional Research Service (CRS) based on analysis from HHS Budget Office, Feb. 14, 2005.

Table 3. HHS Discretionary Funding for HIV/AIDS, by Agency

($ in thousands)

Agency	FY1998	FY1999	FY2000	FY2001	FY2002	FY2003	FY2004*	FY2005*	FY2006 Req.
FDA	$76,690	$70,400	$76,317	$75,818	$75,818	$72,830	$73,847	$74,482	$74,482
HRSA	1,154,508	1,415,847	1,599,231	1,815,000	1,917,200	2,024,962	2,066,861	2,075,296	2,085,296
IHS	3,540	3,649	3,770	3,810	3,886	3,940	4,013	4,074	4,198
CDC	624,944	656,590	687,164	859,045	931,141	936,426	862,854	855,526	850,880
NIH	1,602,814	1,792,739	2,004,428	2,247,015	2,499,458	2,716,218	2,849,952	2,920,551	2,932,992
SAMHSA	65,607	91,894	110,347	156,677	169,034	170,614	171,205	169,943	168,311
AHRQ	1,719	1,839	1,787	3,381	2,913	1,825	2,017	2,100	2,300
OS	6,697	61,531	63,282	64,899	64,103	67,681	62,637	65,529	65,527
Global AIDS Trust Fund	— -	— -	— -	— -	125,000	99,350	149,115	99,200	100,000
Total	$3,536,519	$4,094,489	$4,546,326	$5,225,645	$5,788,553	$6,093,846	$6,242,501	$6,266,701	$6,283,986

Source: Table prepared by the Congressional Research Service (CRS) based on analysis from HHS Budget Office, Feb. 14, 2005.

* CDC figures have been adjusted downward to reflect the new budget structure at CDC that excludes administrative and management costs. The FY2004 adjustment was about -$68 million, and the FY2005 adjustment was about -$74 million.

FDA: Food and Drug Administration; **HRSA:** Health Resources and Services Administration; **IHS:** Indian Health Service; **CDC:** Centers for Disease Control and Prevention; **NIH:** National Institutes of Health; **SAMHSA:** Substance Abuse and Mental Health Services Administration; **AHRQ:** Agency for Healthcare Research and Quality; **OS:** Office of the Secretary (includes the Office of HIV/AIDS Policy, Office for Civil Rights, Office of Minority Health, Office of Women's Health and the Public Health and Social Services Emergency Fund/Minority Communities Fund); **Global Aids Trust Fund:** While budgeted in NIH, HHS contributions to the Global Fund to Fight HIV/AIDS, Malaria, and Tuberculosis are not reflected in the NIH HIV/AIDS spending figures, but are accounted for separately.

Table 4. Total Federal Government Spending on HIV/AIDS by Function

($ in millions)

Agency/Department	FY2004 Actual					FY2005 Enacted					FY2006 President's Budget				
	Research	Prevent	Treatmt	Income support	Total	Research	Prevent	Treatmt	Income support	Total	Research	Prevent	Treatmt	Income support	Total
FDA	$74	—	—	—	$74	$74	—	—	—	$74	$74	—	—	—	$74
HRSA	—	22	2,045	—	2,067	—	2	2,073	—	2,075	—	2	2,083	—	2,085
IHS	1	3	—	—	4	1	3	—	—	4	1	3	—	—	4
CDC	—	863	—	—	863	—	856	—	—	856	—	851	—	—	851
NIH	2,850	—	—	—	2,850	2,921	—	—	—	2,921	2,933	—	—	—	2,933
SAMHSA	—	41	131	—	171	—	40	130	—	170	—	40	128	—	168
AHRQ	2	—	—	—	2	2	—	—	—	2	2	—	—	—	2
OS	—	13	—	—	13	—	13	—	—	13	—	13	—	—	13
PH emergency fund	—	35	14	—	50	—	37	15	—	52	—	37	15	—	52
Global AIDS trust fund		75	75		149		50	50		99	—	50	50	—	100
HHS discretionary	$2,927	$1,052	$2,264	—	$6,243	$2,998	$1,001	$2,267	—	$6,267	$3,011	$997	$2,276	—	$6,284
-CMS/Medicaid	—	—	5,400	—	5,400	—	—	5,700	—	5,700	—	—	6,300	—	6,300
-CMS/Medicare	—	—	2,600	—	2,600	—	—	2,900	—	2,900	—	—	3,200	—	3,200
Subtotal, HHS	$2,927	$1,052	$10,264	—	$14,243	$2,998	$1,001	$10,867	—	$14,867	$3,011	$997	$11,776	—	$15,784
Social Security — DI	—	—	—	$1,050	$1,050	—	—	—	$1,136	$1,136	—	—	—	$1,169	$1,169
Social Security — SSI	—	—	—	415	415	—	—	—	455	455	—	—	—	440	440
Veterans Affairs	8	35	359	—	402	8	35	390	—	432	$8	$35	$412	—	455
Defense Department.	32	17	56	—	105	36	17	57	—	110	22	18	58	—	98
Agency for Int. Dev.	—	764	199	—	963	—	522	124	—	646	—	433	50	—	483
Justice/Bureau of Prisons	—	2	15	—	17	—	2	18	—	20	—	2	19	—	21
State Department	—	213	425	—	638	—	460	916	—	1,376	—	675	1,297	—	1,972
Labor Department	—	11	—	—	11	—	2	—	—	2	—	—	—	—	—
Education Dept.	—	-	—	—	-	—	-	—	—	-	—	—	—	—	—
HUD	—	—	—	295	295	—	—	—	282	282	—	—	—	268	268
OPM-FEHB	—	—	343	—	343	—	—	370	—	370	—	—	370	—	370
Subtotal, Non-HHS	$40	$1,042	$1,396	$1,760	$4,239	$44	$1,038	$1,875	$1,873	$4,830	$30	$1,163	$2,206	$1,877	$5,276
Total, federal government	$2,967	$2,094	$11,660	$1,760	$18,481	$3,042	$2,039	$12,742	$1,873	$19,696	$3,041	$2,160	$13,982	$1,877	$21,060

Source: Table prepared by the Congressional Research Service (CRS) based on analysis from HHS Budget Office, Feb. 14, 2005. **HHS**: Department of Health and Human Services; **CMS**: Centers for Medicare and Medicaid Services; **DI**: Disability Insurance; **HUD**: Department of Housing and Urban Development; **SSI**: Supplemental Security Income; **OPM-FEHB**: Office of Personnel Management-Federal Employees Health Benefits.

Table 5. Federal Government Spending on HIV/AIDS: FY1982-FY2006

($ in millions)

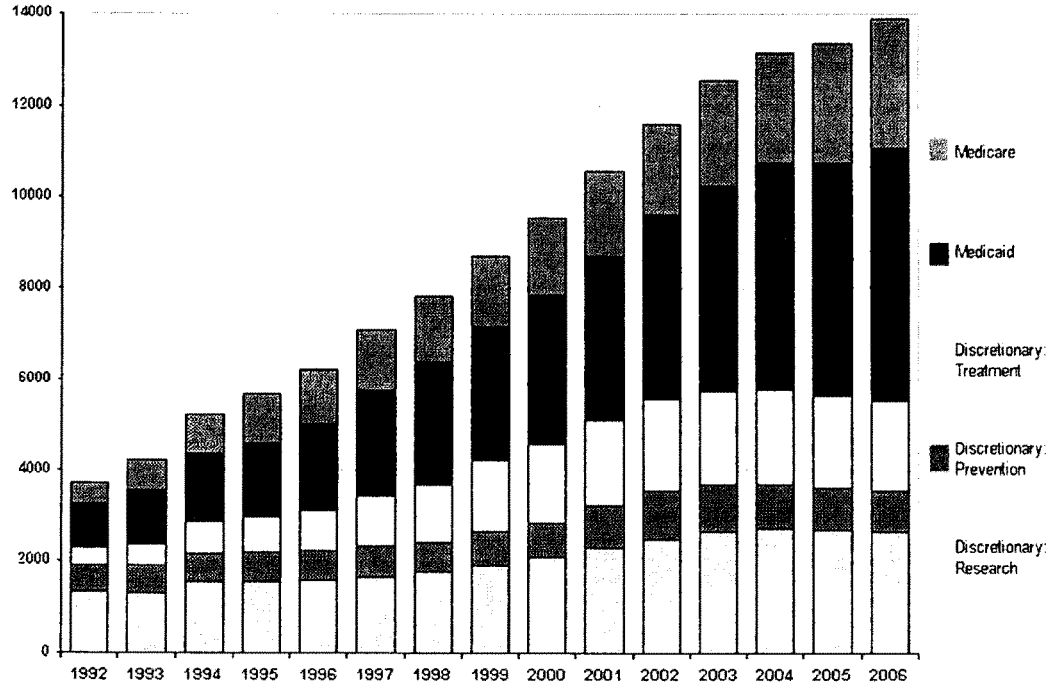
Year	HHS			SS		VA	Defense	AID	DoJ-Prisons	State	Labor	HUD	OPM-FEHB	Education	Total
	Discretionary	CMS													
		Medicaid	Medicare	DI	SSI										
1982	$6	—	—	—	—	2	—	—	—	—	—	—	—	—	$8
1983	$29	10	—	—	—	5	—	—	—	—	—	—	—	—	$44
1984	$60	30	—	5	1	7	—	—	—	—	—	—	—	—	$103
1985	$109	70	5	10	3	8	—	—	—	—	—	—	—	—	$205
1986	$234	130	5	30	5	20	79	—	—	—	—	—	5	—	$508
1987	$502	200	15	55	15	51	74	—	1	—	1	—	8	—	$922
1988	$962	330	30	95	20	78	53	30	1	—	1	1	13	1	$1,615
1989	$1,304	490	55	150	35	136	86	40	2	1	1	—	22	—	$2,322
1990	$1,592	670	110	184	55	220	124	71	5	1	1	—	37	—	$3,070
1991	$1,891	870	180	266	95	258	127	78	5	1	1	—	61	—	$3,833
1992	$1,967	800	400	372	150	279	125	94	5	1	1	48	103	—	$4,345
1993	$2,079	1,000	600	481	200	299	155	117	5	1	1	100	175	—	$5,213
1994	$2,569	1,300	800	568	250	312	127	115	6	1	1	156	193	—	$6,398
1995	$2,700	1,500	1,000	631	250	317	110	120	6	1	1	171	212	—	$7,019
1996	$2,898	1,800	1,100	684	250	331	98	115	6	—	1	171	226	—	$7,680

Year	HHS			SS		VA	Defense	AID	DoJ-Prisons	State	Labor	HUD	OPM-FEHB	Education	Total
	Discretionary	CMS													
		Medicaid	Medicare	DI	SSI										
1997	$3,267	2,200	1,300	738	275	350	84	117	7	—	2	196	241	—	$8,777
1998	$3,537	2,600	1,400	787	305	378	95	121	7	—	2	204	253	—	$9,689
1999	$4,094	2,900	1,500	828	330	401	86	139	7	—	2	225	266	1	$10,779
2000[a]	$4,546	3,300	1,700	870	370	345	97	200	8	—	2	232	279	1	$12,025
2001[a]	$5,226	3,700	1,900	919	340	405	108	430	15	—	11	257	292	1	$14,184
2002	$5,789	4,200	2,050	961	390	391	96	510	16	—	11	277	297	—	$14,988
2003	$6,094	4,800	2,400	1,019	395	396	82	774	17	141	11	290	321	—	$16,739
2004	$6,243	5,400	2,600	1,050	415	402	105	963	17	638	11	295	343	—	$18,481
2005	$6,267	5,700	2,900	1,136	455	432	110	646	20	1,376	2	282	370	—	$19,696
2006[b]	$6,284	6,300	3,200	1,169	440	455	98	483	21	1,972	—	268	370	—	$21,060

Source: Table prepared by the Congressional Research Service (CRS) based on analysis from HHS Budget Office, Feb. 14, 2005. May not add due to rounding.
a. FY2000 Total includes $75 million for HRSA Ricky Ray Hemophilia program and FY2001 Total includes $580 million for HRSA Ricky Ray Hemophilia program.
b. FY2006 is the Administration's request.

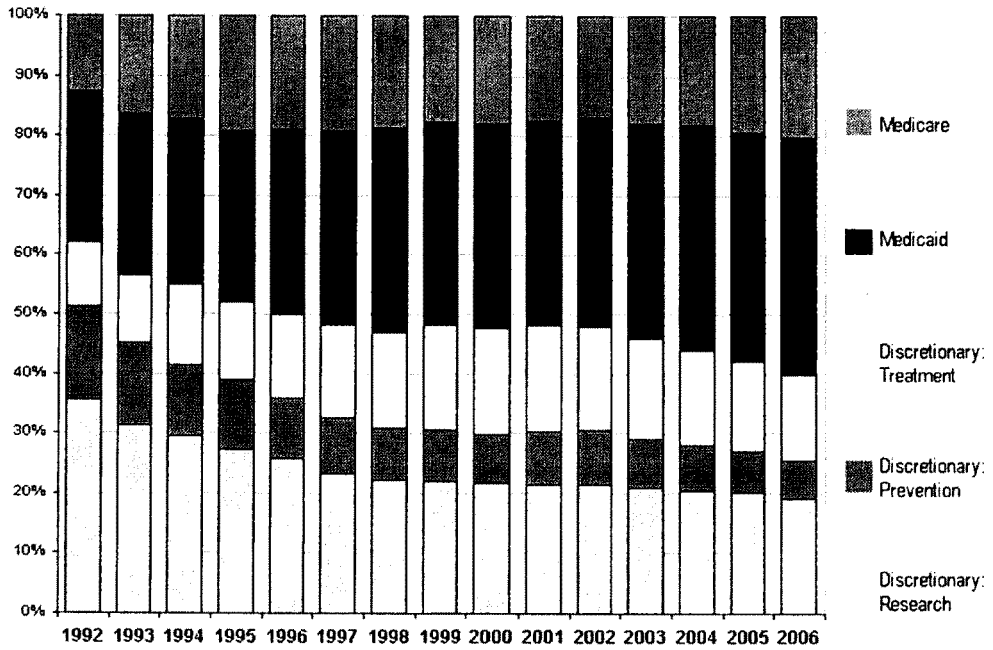
HHS: Department of Health and Human Services; Discretionary AIDS budget; **CMS:** Centers for Medicare and Medicaid Services; **SS:** Social Security; **DI:** Disability Insurance; **SSI:** Supplemental Security Income; **VA:** Veterans Affairs; **AID:** U.S. Agency for International Development; **DoJ-Prisons:** Department of Justice, Bureau of Prisons; **HUD:** Department of Housing and Urban Development; **OPM-FEHB:** Office of Personnel Management-Federal Employees Health Benefits

Figure 4. HHS Spending on HIV/AIDS Programs



Source: HHS Budget Office, Feb. 14, 2005. FY2005 is enacted; FY2006 is based on the Administration's budget request.

Figure 5. HHS HIV/AIDS Spending by Program/Function as a % of Total



Source: HHS Budget Office, Feb. 14, 2005. FY2005 is enacted; FY2006 is based on the Administration's budget request.

Table 6. Federal Government Spending on International HIV/AIDS Programs by Function

($ in millions)

Agency/Department	FY2004 Actual				FY2005 enacted				FY2006 President's Budget			
	Research	Prevent	Treatment	Total	Research	Prevent	Treatment	Total	Research	Prevent	Treatment	Total
Centers for Disease Control	—	125	—	125	—	124	—	124	—	124	—	124
National Institutes of Health	317	—	—	317	332	—	—	332	350	—	—	350
Global AIDS trust fund	—	75	75	149	—	50	50	99	—	50	50	100
Subtotal, HHS	**$317**	**$200**	**$75**	**$591**	**$332**	**$173**	**$50**	**$555**	**$350**	**$174**	**$50**	**$574**
Defense Department	—	4	—	4	—	7	—	7	—	—	—	—
Agency for International Development	—	764	199	963	—	522	124	646	—	433	50	483
State Department	—	213	423	638	—	460	916	1,376	—	675	1,297	1,972
Labor Department	—	10	—	10	—	2	—	2	—	—	—	—
Subtotal, Non-HHS	**—**	**991**	**623**	**1615**	**—**	**991**	**1,040**	**2,031**	**—**	**1,108**	**1,347**	**2,455**
Total	**$317**	**$1,191**	**$698**	**$2,206**	**$332**	**$1,165**	**$1,090**	**$2,587**	**$350**	**$1,282**	**$1,397**	**$3,029**

Source: Table prepared by the Congressional Research Service (CRS) based on analysis from HHS Budget Office, Feb. 14, 2005. May not add due to rounding.
HHS: Department of Health and Human Services.

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SECTION: Section A; Page 1; Column 2; National Desk

New Challenge to Idea That 'AIDS Is Special'

By SHERYL GAY STOLBERG

Behind the swinging glass doors that welcome visitors to the Gay Men's Health Crisis is a world where H.I.V. is not just a deadly virus, but also a ticket to a host of unusual benefits.

At the center, the nation's oldest and largest AIDS social-service agency, almost everything is free: hot lunches, haircuts, art classes and even tickets to Broadway shows. Lawyers dispense advice free. Social workers guide patients through a Byzantine array of Government programs for people with H.I.V., and on Friday nights dinner is served by candlelight.

The philosophy underlying the niceties and necessities is "AIDS exceptionalism." The idea, in the words of Mark Robinson, executive director of the organization, is that "AIDS is special and it requires special status." That is a concept that has frequently been challenged by advocates for people with other diseases.

Now some advocates for people with AIDS are quietly questioning it themselves.

With death rates from the disease dropping for the first time in the history of the 16-year-old epidemic, the advocates suggest, it is time to re-examine the vast network of highly specialized support services for people with H.I.V. Some people are growing increasingly uncomfortable with the fact that the Government sets aside money for doctors' visits, shelter and drugs for people with AIDS but that it does not have comparable programs for other diseases.

"Why do people with AIDS get funding for primary medical care?" Martin Delaney, founder of Project Inform, a group in San Francisco, asked in an interview. "There are certainly other life-threatening diseases out there. Some of them kill a lot more people than AIDS does. So in one sense it is almost an advantage to be H.I.V. positive. It makes no sense."

Mr. Delaney, a prominent voice in AIDS affairs since the onset of the epidemic, is calling on advocates to band with people working on other diseases in demanding that programs for AIDS be replaced with a national health care system.

He complained that organizations like the Gay Men's Health Crisis had been "bought off" by the special status given to AIDS.

"We took our money and our jobs," Mr. Delaney wrote in the Project Inform newsletter in the summer, "and we dropped out of the national debate."

That criticism has not won many fans within "AIDS Inc.," as some call the cottage industry of agencies that care for H.I.V. patients. But Mr. Delaney's article, "The Coming Sunset on AIDS Funding Programs," has set off an intense debate.

"I think Delaney knows that he is putting out a provocative, stimulating kind of discussion," said Jim Graham, executive director of the Whitman-Walker Clinic in Washington, a counterpart to Gay Men's Health Crisis. "This is the whole discussion about AIDS exceptionalism. I think AIDS is an exceptional situation. AIDS is caused by a virus. That infectious virus is loose in America. And when you have a virus, an infectious situation such as this, it takes an exceptional response."

Yet many people involved with AIDS say some change is in order. Many programs created in response to the epidemic were intended as stopgaps, to help the dying in the health emergency. Some of the money that pays for free lunches at Gay Men's Health Crisis, for instance, is from the Federal Emergency Management Agency, which usually works on natural disasters like hurricanes and earthquakes.

But it is becoming clear that the AIDS crisis is long term. New treatments appear to be turning the disease from a certain death sentence to a chronic manageable illness. Accepting the projection that the epidemic will last for at least another generation, advocates say, the Government and private agencies need to take a hard look at spending in the coming years.

"We are not going to die, at least not all of us, and at least not all so soon," said Bill Arnold, co-chairman of the ADAP Working Group, a coalition in Washington that is lobbying the Government to add money to its AIDS Drug Assistance Program. "A lot of us are saying that the AIDS network or AIDS Inc. or whatever you want to call it, this whole network that we have created in the last 15 years, needs to be reinvented. But reinvented as what?"

That question is provoking considerable anxiety among employees at the estimated 2,400 service agencies in the United States, several hundred of which are in New York City.

The agencies offer an array of services including sophisticated treatment advice and free dog walking. Although most are tiny, some have grown into huge institutions financed by Federal, state and local government dollars, as well as contributions.

Critics say the organizations cannot possibly re-examine themselves because they have become too dependent on the Government.

"They have all become co-opted by the very system that they were created to hold accountable," Larry Kramer, the playwright, said.

Mr. Kramer founded Gay Men's Health Crisis in 1981, but has long been critical of the group. "It's staffed with a lot of people who have jobs at stake," he said.

With 280 employees and 7,000 volunteers, the program is the biggest and busiest agency of its kind. For many with human immunodeficiency virus, the organization and its lending library, arts-and-crafts center and comfortably decorated "living room" offer a home away from home, a place where, as one participant said, "your H.I.V. status is a nonevent." For some, the hot lunches often provide the only nutritious meals the patients get all day. For others, they are simply a source of community.

Craig Gibson, 31, of the Bronx, is one of 10,000 people a year who seek services there. Several days each week, Mr. Gibson goes to the living room to play cards after lunch.

"You come here, you see your friends," he said one afternoon. "Today they had a great chicken parmesan."

A walk through the lobby shows the power and success of AIDS philanthropy. A huge plaque in the entryway lists dozens of donors who have contributed $10,000 or more, including three who have given more than $1 million. Even so, 19 percent of the $30 million annual budget comes from Government sources, Mr. Robinson said.

"We still need this extraordinary short-term help," he said.

But Mr. Robinson said he was aware that the financing might not last forever. Even as the organization expands, it is doing so with an eye toward eventually scaling back. It just spent $12.5 million to renovate its new headquarters in a simple but expansive 12-story brick building on West 24th Street.

Mr. Robinson, a former accountant, said the building was designed so that any

other business could easily move in. The lease is relatively short, 15 years.

The agency, he added, has realized that it cannot afford to be all things to all people. Until recently, Mr. Robinson said, "anybody with H.I.V. or AIDS could walk into our advocacy department, and virtually anything that was wrong with their life was addressed."

"If they were having problems with their landlord," he said, "we would deal with it. If they needed an air-conditioner, we would deal with it. Now we are really trying to focus on what is specifically related to AIDS."

To understand why Mr. Robinson and others say they believe AIDS deserves special status, a person has to go back to the response to AIDS in the days when it was known as the "gay cancer." The Government and the rest of society all but ignored the illness, forcing the people who were affected -- by and large homosexuals -- to fend for themselves.

"The original reaction," Mr. Arnold said, "was in response to: 'This is not our problem. We don't like you. Go away and die.' "

"By the time you have got 200,000 to 300,000 people dead," he said, "they all have friends. They all have relatives. That's a lot of people impacted. So now you have some critical mass."

That mass has translated into a political force -- and significant Federal money. In his budget proposal for 1998, President Clinton has asked Congress to allocate more than $3.5 billion for AIDS programs, including $1.5 billion for AIDS research at the National Institutes of Health and $1.04 billion for the Ryan White Care Act, which provides medical care, counseling, prescription drugs and dental visits for people with H.I.V.

If Congress enacts the plan, AIDS spending would increase 4 percent over last year, and 70 percent over 1993, when Mr. Clinton took office.

In a paradox, some doctors say the array of services makes it harder to care for people whose behavior puts them at risk for AIDS, but who are not yet infected.

"We're trying to figure out how to provide services to H.I.V.-negative people to help them stay negative," said Dr. Michelle Roland, who treats indigent patients at San Francisco General Hospital. Many of Dr. Roland's patients are drug abusers, people at high risk.

"The truth is," she said, "we have a lot more access to resources for H.I.V.-positive

people for drug treatment, education and housing."

While advocates for people with other diseases often lobby vociferously for more money for research, the notion of exceptionalism -- that a particular illness deserves special Government status -- is unique to AIDS, and it is generating a backlash.

For years, the American Heart Association has gone to Capitol Hill budget hearings with charts showing that more research money was spent per patient on AIDS than on heart disease. Advocates for people with Parkinson's disease have done the same. It will not be long, Mr. Delaney argues, before people with those and other diseases follow suit, demanding Ryan White-style programs for themselves.

Some authorities, including the president of the American Foundation for AIDS Research, Dr. Arthur Ammann, said Mr. Delaney was correct in pushing for universal health care. "We've got to form an alliance with these other diseases," Dr. Ammann said, "and say, None of us is going to get adequate health care the way the system is going."

But others call Mr. Delaney naive.

"It's interesting to muse about what he says," said Mr. Graham of the Whitman-Walker Clinic. "But it's both undesirable and impossible. So what's the point of talking about it?"

Naive or not, in challenging exceptionalism Mr. Delaney has clearly broken a taboo.

"We sort of question it among ourselves behind closed doors," said Mark Hannay, a member of the New York chapter of Act Up, the AIDS Coalition to Unleash Power. "Like, isn't this nice, but we're the only ones getting it."

(4) HIV Reporting

Current law requires that reported cases of HIV infection serve as the basis of Ryan White CARE Act funding formulas.

AIDS was first recognized in 1981. HIV was identified as the cause of the disease in 1984 and a diagnostic test for HIV antibodies was approved in 1985. Yet, CDC did not recommend that states begin reporting cases of HIV infection until 1998.

While all states report cases of AIDS, the end stage of HIV infection, and a host of other diseases, as of 2005, many states, including California, still have not enacted accurate and reliable HIV reporting systems.

As a result, it is virtually impossible to determine the true scope of the epidemic in the United States. This lack of knowledge has compromised both prevention and care efforts.

The "Report of the Presidential Commission on the Human Immunodeficiency Virus Epidemic" released in June 1988 correctly warned that "the term 'AIDS' is obsolete. 'HIV infection' more correctly defines the problem. The medical, public health, political, and community leadership must focus on the full course of HIV infection rather than focusing on the disease (ARC and AIDS). Continual focus on AIDS rather than the entire spectrum of HIV disease has left our nation unable to deal adequately with the epidemic. Federal and state data collection must now be focused on early HIV reports, while still collecting data on symptomatic disease."

Due to the failure to enact a reliable and accurate HIV reporting system, CDC has in the past utilized "blind tests" in which individuals were tested for HIV without their knowledge

and the results were never disclosed, but rather used to estimate the size of the epidemic. This approach was discontinued after ethical concerns were raised.

CDC has also skewed the understanding of HIV risk factors with its "no identifiable risk" (NIR) category of exposure. This unusual classification assumes that heterosexual risk is unlikely, unless the infected patient can clearly demonstrate they became infected from a member of the opposite sex. As a result, heterosexual transmission of HIV in the U.S. may be grossly underestimated by the current surveillance system and falsely reassure the public about the risks of heterosexual transmission.

Impact of HIV Names Reporting on Testing

Studies have found that names reporting does not discourage HIV testing

The published scientific literature has concluded that HIV names reporting is not a deterrent to HIV testing or treatment.

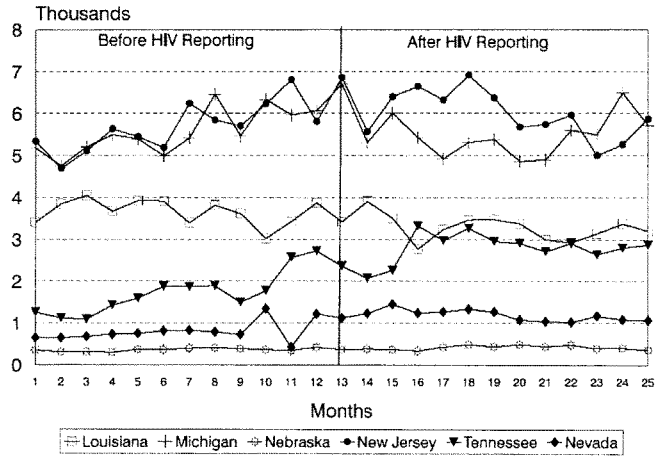
A study published in the November 2002 edition of the *American Journal of Public Health* found that name-based HIV surveillance programs were not a deterrent to HIV testing or treatment. The researchers concluded that "Overall, reporting polices seemed to be a minor factor in the HIV testing decisions of individuals at risk" and that these should "allay concerns about whether implementing name-based HIV case surveillance serves as a deterrent to HIV testing." In fact, the most common reasons reported by the participants in the current study for not being tested for HIV were "fear of learning they were HIV positive and the belief that they were HIV negative." (*American Journal of Public Health* 2002;92:1757). The study was funded by the CDC.

In a study published in the journal *AIDS*, researchers from the University of California at San Francisco and nine state health departments surveyed high-risk persons about the perceptions and knowledge of HIV testing and HIV reporting practices. In this survey, only 15 percent of the respondents knew whether HIV infection was reportable to the health department in their state of residence. When asked about factors that may have delayed their seeking HIV testing, only 2 percent of the respondents surveyed cited "reporting to the government" as the main reason. The researchers concluded name-based HIV reporting policies were not associated with avoiding HIV testing because of worry about reporting. (Hecht, Frederick M., et. al. Does HIV reporting by name deter testing?, *Journal of Acquired Immune Deficiency Syndromes,* August 18, 2000; 14(12):1801-1808.) This study was also supported by CDC.

To determine the effect of changes in reporting policies on actual testing behaviors among persons seeking testing at publicly funded HIV counseling and testing sites, CDC and six State health departments reviewed data routinely collected from these sites to compare HIV testing patterns in the 12 months before and the 12 months after the implementation of HIV case reporting. In these areas, the number of HIV tests increased in four States and decreased in two States; however, these declines were not statistically significant (Figure 4). In fact, one state with

a decline in HIV testing during the evaluation period had a decreasing trend in HIV tests before HIV surveillance was implemented.
All states included in the study utilized names-based reporting. Thus, these data do not suggest that HIV case reporting by name adversely affected test-seeking behaviors overall. The study was published in *JAMA*. (Nakashima AK, et. al. Effect of HIV reporting by name on use of HIV testing in publicly funded counseling and testing sites. *Journal of the American Medical Association* 1998;280:1421-1426.)

Figure 4. Number of tests performed in publicly-funded HIV counseling and testing sites the year before and the year after HIV reporting laws were implemented, by month*



*Excludes sites performing <50 tests during 25 months surrounding HIV reporting; HIV reporting implementation - Louisiana (Feb 1993), Michigan (Apr 1992), Nebraska (Sep 1995), New Jersey (Jan 1992), Tennessee (Jan 1992), Nebraska (Sep 1995), Nevada (Feb 1992)

A recent survey of 208 HIV test takers in four California counties found that a preference for non-name codes over name-based HIV reporting. In a second sample of 226 California HIV test takers, a majority reported that they would be likely to receive an HIV test even if it required their name to be confidentially reported, although a larger percentage preferred the option of an anonymous test. Regardless of the preference, there is little evidence in this survey to indicate name based confidential HIV reporting would deter testing (Charlebois, Edwin D MPH, PhD., *et. al.* Potential Deterrent Effect of Name-Based HIV Infection Surveillance. *Journal of Acquired Immune Deficiency Syndromes*. June 1, 2005.; 39(2):219-227).

States with names reporting have not reported declines in HIV testing

A review of three states—Florida, New York, and North Carolina-- that enacted HIV names reporting during the past decade found no link between the implementation of HIV names reporting and the number of HIV tests performed.

The state of Florida began reporting of HIV cases by name on July 1, 1997. According to the Florida Department of Health "it appears that HIV reporting has had little or no overall effect on HIV testing patterns in Florida. At-risk persons continue to test in very high numbers." In 2000, Florida participated in the CDC's HIV testing Survey project which found that out of 276 individuals tested for HIV, only four participants mentioned delayed testing because they were worried their names would be reported to the government. Of these four, none gave this as their main reason for delayed testing" (Correspondence from Dr. John O. Agwunobi, Secretary of the Florida Department of Health, to Congressman Mark E. Souder, May 6, 2002).

Implementation of HIV reporting by name in New York began on June 1, 2000 after a high profile debate within the state's legislature. In order to measure the impact of HIV reporting on testing behaviors, HIV testing levels were tracked statewide, by testing setting, within demographic categories and HIV risk factor. The "findings indicate no discernable deterrent effect of the HIV Reporting and Partner Notification legislation on HIV testing behavior. This was true for statewide testing levels, and for testing levels in each of the categories." In the year 2001 alone, the state received a total of 454,552 laboratory reports and 7,053 provider reports (Correspondence from Dr. Antonia C. Novello, Commissioner of New York Department of Health, to Congressman Mark E. Souder, June 24, 2002).

North Carolina began HIV reporting by name in 1990. According to the state's health department, "At the time named reporting was implemented, we did not have an adequate tracking system for HIV testing. Anecdotal information indicates that testing increased dramatically between 1990 and 1991. The HIV Counseling and Testing Services database maintained since 1991 provides documentation that testing continued to increase from 1992 to 1997" (Correspondence from Evelyn Foust, Head of the North Carolina HIV/STD Prevention and CARE Branch, to U.S. House Subcommittee on Criminal Justice, Drug Policy and Human Resources, June 28, 2002).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUL 5 2005

Dear Colleague:

In order to achieve the goal of nationwide, high-quality HIV data, the Centers for Disease Control and Prevention (CDC) *recommends* that all states and territories adopt confidential name-based surveillance systems to report HIV infections. CDC is strengthening its official guidance and encouraging all states to use a single, accurate system that can provide national data to monitor the scope of the HIV/AIDS epidemic, plan for and evaluate prevention and care programs, and focus our efforts on the people most at risk.

While most areas (currently 43 state and local health departments) use confidential name-based reporting of HIV infection, some (currently 14 state and local health departments) use code-based or name-to-code methods. Regardless of the method used, personal identifiers are removed before data is provided to CDC. Stringent standards are in place to protect the confidentiality of this data.

Rapid implementation of a scientifically accurate and reliable system of national HIV reporting can only occur with the adoption of a standard system of patient identification that will be used by all states. CDC's policy is to report HIV infection and AIDS case surveillance data only from areas conducting confidential name-based reporting because this reporting has been shown to routinely achieve high levels of accuracy and reliability. HIV surveillance that is conducted using coded patient identifiers has not been shown to routinely produce equally accurate, timely, or complete data to that conducted using confidential name-based surveillance methods. Code-based and name-to-code systems are also more expensive to implement than name-based systems. Currently, only confidential name-based HIV reporting, integrated with AIDS surveillance data, can be used by states to identify and remove cases that are counted in more than one state (a process called de-duplication) before they are reported to CDC's national surveillance database. Furthermore, use of confidential name-based reporting for HIV is consistent with all other infectious diseases reporting, including AIDS.

CDC *recommends* that all states conduct HIV reporting using the same name-based approach currently used for AIDS surveillance nationwide. It is critical that all areas move as quickly as possibly to an integrated, confidential name-based HIV/AIDS reporting system. CDC is committed to providing the technical assistance necessary to make this method of reporting occur rapidly and with minimal disruption to ongoing HIV/AIDS surveillance. For states currently using code or name-to-code systems, CDC will provide technical assistance in transitioning to confidential name-based reporting upon request. For further information, or to request technical assistance, you may contact Dr. Matthew McKenna, Acting Deputy Director for Science, Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, CDC, telephone (404) 639-2050.

As always, thank you for your continued, dedicated efforts to prevent HIV infection in the United States and around the world.

Sincerely,

Julie Louise Gerberding, M.D., M.P.H.
Director

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BERNARD SANDERS, VERMONT, INDEPENDENT

February 20, 2004

Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson,

When the Ryan White CARE Act, Public Law 101-381, was enacted nearly 15 years ago, much was still not known about HIV and AIDS. Few medical therapies were available to treat the disease. The epidemic was believed to be almost entirely centered in a few metropolitan areas. Many believed that counting cases of AIDS, the end stage of HIV infection, was a reliable means to determine the size and scope of the epidemic.

Today, HIV affects every state in our Nation. Medical breakthroughs have dramatically transformed HIV infection for many into a chronic, manageable disease and, thereby, have delayed the onset of AIDS.

But while the face of AIDS has changed, the funding structure of the CARE Act has not. The CARE Act, for instance, continues to distribute federal funds based upon the number of AIDS cases in a state or city. Yet, AIDS cases comprise only a fraction of the total population of those living with HIV. The misplaced emphasis on AIDS as a basis for CARE Act funding ignores the vast majority of those with HIV. This has resulted in funding disparities that have, in part, created waiting lists for AIDS treatment for hundreds of patients. Studies have shown those with HIV but not AIDS are much more likely to be women, African Americans, Hispanics, and those who live in rural areas.

In 2000, Congress sought to eliminate these disparities and treat all people with HIV/AIDS equally under the CARE Act by incorporating all those living with HIV, rather than just those diagnosed with AIDS, in funding formulas. Public Law 106-345 specifically states that "for fiscal year 2005 and subsequent fiscal years, the cases counted for each 12-month period beginning on or after July 1, 2004, shall be cases of HIV disease rather than cases of acquired immune deficiency syndrome." The law also requires that "Not later than July 1, 2004, the Secretary shall determine whether there is

data on cases of HIV disease from all eligible areas (reported to and confirmed by the Director of the Centers for Disease Control and Prevention) sufficiently accurate and reliable for" determining CARE Act grant amounts.

Such data is now being collected in every state and will be available to serve as the basis for such decisions beginning in fiscal year (FY) 2005 as required by law. I therefore urge you to rule that this data is sufficiently accurate to serve as the basis for CARE Act funding formulas beginning in FY 2005.

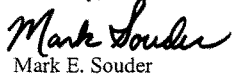
It is important to make this determination for the following reasons:

(1) **This data provides a more reliable basis for funding.** In June 1988, the first Presidential Commission on the Human Immunodeficiency Virus Epidemic appointed by Present Ronald Reagan concluded that "the term 'AIDS' is obsolete. 'HIV infection' more correctly defines the problem. The medical, public health, political, and community leaders must focus on the full course of HIV infection rather than concentrating on later stages of the disease. Continual focus on AIDS rather than the entire spectrum of HIV disease has left our nation unable to deal adequately with the epidemic. Federal and state data collection efforts must now be focused on early HIV reports, while still collecting data on symptomatic disease." All states now report cases of both HIV and AIDS. While the data from some of these states, particularly those experimenting with code-based systems, may not be entirely complete, the data they are now recording provide a far more accurate basis for funding formulas than continuing to focus on the small fraction of cases that are represented by AIDS cases. As an example, Wisconsin has collected HIV data since 1986. In 2003, Wisconsin reported 237 cases of AIDS and 365 cases of HIV infection. The state therefore received funding based upon only 39 percent of its total HIV/AIDS caseload. According to new data released this month by the Centers for Disease Control and Prevention (CDC), since New York City began tracking HIV in 2001, nearly three-fourths of individuals diagnosed with HIV did not meet the clinical definition of AIDS. Under existing formulas, only 27 percent of these 6,478 patients with HIV reported in New York City are now recognized for the purpose of federal funding. This 27 percent is clearly an insufficient, inaccurate and unreliable basis for funding. Even a state with an incomplete HIV reporting system would be expected to be able to account for more than 27 percent of its HIV/AIDS population. Clearly it is more reliable to base funding on 70 or 80 percent of a given population than on a mere 27 percent. Basing funding on HIV cases will provide financial incentives to states to improve surveillance systems and to identify those who are infected and to get them into care.

(2) **This data ensures more equitable distribution of federal funding.** The AIDS Drug Assistance Program (ADAP), funded under Title II of the Ryan White CARE Act, is the final safety net for Americans with HIV who have no other means of accessing medication and for low-income people who are

Thank you for your continued leadership on HIV/AIDS and for your attention to this matter.

Sincerely,



Mark E. Souder
Chairman,
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

underinsured or lack adequate prescription coverage. Currently, 15 states are restricting access to treatment, and nearly 800 patients are on ADAP waiting lists. Many of these patients reside in states that would significantly benefit from more equitable funding formulas, including Alabama, Alaska, Arkansas, Colorado, Idaho, Indiana, Kentucky, Montana, North Carolina, Oklahoma, Oregon, South Dakota, Washington, West Virginia and Wyoming. Providing equitable funding based upon HIV and AIDS data would help eliminate funding disparities and greatly assist these states in ensuring that all Americans with HIV have access to life-saving medications.

(3) **More patients with HIV will be reached under CDC's new prevention initiative.** In April 2003, CDC launched a new initiative, "Advancing HIV Prevention: New Strategies for a Changing Epidemic." According to the CDC, the new approach "is aimed at reducing barriers to early diagnosis of HIV infection and increasing access to quality medical care, treatment, and ongoing prevention services. The HIV initiative emphasizes the use of proven public health approaches to reducing the incidence and spread of disease. As with other sexually transmitted diseases (STDs) or any other public health problem, principles commonly applied to prevent disease and its spread will be used, including appropriate routine screening, identification of new cases, partner notification, and increased availability of sustained treatment and prevention services for those infected." The success of this program depends in part on the availability of treatment for those who are diagnosed. States that succeed in this initiative should be rewarded with financial resources to care for those who are identified early and treated to prevent the onset of AIDS.

(4) **"Hold harmless" protections exist to prevent instability in funding.** Recognizing that any formula change could result in funding fluctuations, Congress included a "hold harmless" provision to ensure the AIDS care provided in every state and city is not destabilized as a result of formula changes or other factors. In FY 2005, for example, no area can receive "less than 98 percent of the amount of the grant made for the area" in FY 2004. This protection will guarantee that no area is negatively impacted while transitioning to equitable funding formulas that recognize all those living with HIV and AIDS.

If the Director of the CDC cannot confirm that national HIV data is "sufficiently accurate and reliable" to serve as a basis of CARE Act funding beginning in FY 2005 as required by law, the Subcommittee would request that the CDC provide a detailed explanation (1) as to why the agency does not have "sufficiently accurate and reliable" data on the size and scope of the disease after more than twenty years into the epidemic and (2) of the efforts being taken to ensure such data does exist. (3) Please also provide a list of states and/or eligible metropolitan areas funded under Title I of the CARE Act that the CDC has determined do not have "sufficiently accurate and reliable" HIV data.

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

JUN 30 2004

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515

Dear Chairman Barton:

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act Amendments of 2000 included a provision calling for "Studies by the Institute of Medicine," (see Section 501 under Public Law 106-345). Specifically, this provision requires a study of States' HIV surveillance systems and their adequacy and reliability for the purpose of using such data as a basis for CARE Act formula grant allocation. In addition, the Secretary of Health and Human Services is asked to review the recommendations in the Institute of Medicine study and make a determination regarding the use of HIV data for CARE Act formulas by July 1, 2004.

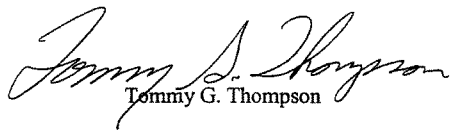
The Institute of Medicine report entitled "Measuring What Matters: Allocation, Planning and Quality Assessment for the CARE Act" examined the following issues: First, whether States' HIV surveillance systems provide for the reporting of cases of infection with the virus in a manner that is sufficient to provide adequate and reliable information on the number of such cases and the demographic characteristics of such cases, both for the State in general and for specific geographic areas in the State; and second, whether HIV case reports are sufficiently accurate for purposes of developing formulas for grants under Titles I and II of the CARE Act. The study considered issues of State capability and comparability of data across jurisdictions, whether HIV data would be a more accurate measure of disease burden, and whether material variation and equitable allocations would result.

The report included 10 specific findings relative to the use of HIV data and other factors related to the equitable allocation of resources under a formula. While the Committee supported Congressional intent to incorporate data into the allocation formulas that reflect the evolving needs of the epidemic, their major overall finding was "that States' HIV reporting systems are neither ready nor adequate for purposes of the Ryan White CARE Act allocation." And while a series of recommendations was put forth to improve the consistency, quality, and comparability of HIV case reporting, its first recommendation was that "For at least the next 4 years, HRSA should continue to use estimated living AIDS cases in the CARE Act Titles I and II formulas."

The intent of this letter is to let you know that I have made a determination that HIV data not be used for purposes of making formula grants under Titles I and II of the Ryan White CARE Act, and that estimated living AIDS cases continue to be utilized until such time as high quality HIV data are available nationwide. We will continue to work with States to support an HIV surveillance system that ensures the collection of such data.

Please call me if you have any thoughts or questions.

Sincerely,



Tommy G. Thompson

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Michael F. Easley, Governor

Carmen Hooker Odom, Secretary

June 28, 2002

Roland Foster
U.S. House of Representatives
Subcommittee on Criminal Justice, Drug Policy and Human Resources
B-373 Rayburn HOB
Washington, DC 20515

Dear Mr. Foster:

Thank you for your questions regarding the HIV and AIDS issues in North Carolina. Attached, you will find the answers to your questions and I have included supportive documentation on several of the issues.

You will also find a copy of our latest draft of the "Statement of Prioritized Populations," dated June 24, 2002. The North Carolina Statewide Community Planning Group met on June 25, 2002 to finish work on this document.

Please call me at 919-733-9490 if you need additional information.

Sincerely,

Evelyn M Foust

Evelyn Foust, MPH
Head, HIV/STD Prevention and Care Branch

cc: Steve Cline
Leah Devlin
Julie Scofield
Satana DeBerry
Patricia Funderburk Ware

June 24 Draft

Statement of Prioritized Populations
Submitted by
The North Carolina HIV Prevention Community Planning Group

The Statewide Community Planning Group (SCPG) recognizes these overarching factors as necessary considerations in prioritizing funding for HIV prevention in North Carolina:

- Racial and ethnic minorities represent the bulk of the prevalence of HIV/AIDS in North Carolina;
- Those already infected with HIV are an important target population;
- Regional epidemiological data should be considered when making funding decisions;
- Those with repeat STD infections are at high risk for HIV infection;
- The subpopulations presume high risk behavior (ie unprotect anal/oral/vaginal sex, and/ or sharing drug paraphernalia).

The following behavioral populations are based on data collected by the Prioritization Task Force that is detailed in the attached report:

I. Heterosexual Contact (HSC): (subpopulations are not prioritized)
- HIV+
- Minorities – particularly African Americans, Native Americans & Latinos ages 13-49*
- Commercial Sex Workers (CSWs), males and females ages 13-49*
- Adolescent males and females ages 13-19*
- People over 49

II. MSM: (subpopulations are not prioritized)
- HIV+
- Minorities – particularly African Americans, Native Americans & Hispanics/Latinos ages 13-49*
- Down Low
- Adolescent males ages 13-19*

III. IDU: (subpopulations are not prioritized)
- HIV+
- Minorities – particularly African Americans, Native Americans & Latinos ages 13-49*
- Homeless
- Caucasian men and women ages 13-49*

The SCPG Task Force determined through its research that MSM/IDU is an emerging population that needs further study. A planning committee, which includes SCPG members and staff, will develop and implement a MSM/IDU needs assessment and training of appropriate CBOs within the next year to help us better understand how we can reach this priority population.

The SCPG recognizes that some interventions are appropriate to target towards the general population but also recognizes that targeting prevention to the above groups will yield better results, since the risk they engage in is known. Those whose risk is reported as "no identifiable risk" fit into this category, but it should be noted that heterosexuals who cannot determine if they had sex with someone who was HIV positive are classified under this heading, even though their primary risk for HIV is heterosexual contact.

*The SCPG recognizes that 11 and 12 years olds are important targets for prevention since they are at an age where they might be deciding whether or not to have sex or may have already had it. The state's epidemiological profile does not report data in such a way that we can easily identify the risk of 11 and 12 year olds, so they are not listed as part of the subpopulations.

North Carolina HIV/STD Prevention and Care Branch
Response for Roland Foster
U.S. House of Representatives Subcommittee on
Criminal Justice, Drug Policy and Human Resources

(1) North Carolina requires the confidential reporting of HIV cases by name. Has there ever been any breach of confidentiality or privacy associated with HIV names reporting? How have HIV testing rates been affected by HIV names reporting?

To our knowledge, we have not had a breach of a patient's confidentiality related in any way to named reporting by state or local health department staff. The HIV Counseling and Testing Services databases maintained since 1991 provides documentation that testing continued to increase from 1992 to 1997.

AIDS reporting was implemented in North Carolina in 1983 and HIV infection reporting by name was added in 1990. North Carolina has had a strong history of adherence to patient confidentiality for all communicable diseases. Within the HIV/STD Prevention and Care Unit, our guidelines for patient record security have been in place far longer and are in many cases more stringent than the recent Centers for Disease Control guidance for HIV surveillance security. The commitment to confidentiality extends beyond record storage and includes specific training for all staff who work in our organization. To our knowledge, we have not had a breach of a patient's confidentiality related in any way to named reporting by state or local health department staff.

Evaluation of HIV testing rates with regard to the effect on testing by the implementation of named reporting is not possible for us to do at this time. At the time named reporting was implemented, we did not have an adequate tracking system for HIV testing. Anecdotal information indicates that testing increased dramatically between 1990 and 1991. The HIV Counseling and Testing Services databases maintained since 1991 provides documentation that testing continued to increase from 1992 to 1997. Our only data available about testing rates is from the testing in publicly funded clinics, however. We have no information about the testing occurring in the private sector.

2) Anonymous testing is no longer available in the state. How have HIV testing rates been affected by the decision to do away with anonymous testing? For what reasons were anonymous testing discontinued?

Since the elimination of anonymous testing, HIV testing rates have moved back to the expected rates. North Carolina's elimination of anonymous testing on May 1, 1997 was the result of the belief that a critical part of HIV counseling and testing was the ability to ensure that persons who were HIV positive were referred to appropriate medical follow-up services.

North Carolina's elimination of anonymous testing on May 1, 1997 was the result of the belief that a critical part of HIV counseling and testing was the ability to ensure that persons who were HIV-positive were referred to appropriate medical follow-up services. Our opinion was and still is that we can improve the likelihood of those referrals being made if we can better

ensure post-test counseling occurs. In 1991, anonymous testing was discontinued in 82 of North Carolina's 100 counties with the remaining 18 counties providing both anonymous and named testing services. In 1993 anonymous testing availability was restored to all counties until the anonymous test option was removed statewide in 1997. Testing behaviors during the initial 1991-1993 period were evaluated and conflicting results published by two groups of authors (Kassler et. al. (1997) and Hertz-Picciotto et. al. (1996)). Copies of both articles are included for your use (Attachments A and B). In addition, a letter to the editor of the *Journal of the American Public Health Association* by Michael Moser commenting on the two articles is included (Attachment C). In Kassler's article, the authors demonstrate that testing (especially for persons at highest risk) declined immediately after the partial elimination of anonymous testing but had started to return to the pre-policy change rates by the time anonymous testing was returned to all sites. In addition, once anonymous testing was again available in all sites, there was no significant increase in the proportion of tests that were conducted under the anonymous test protocols in the health departments. Hertz-Picciotto's analysis did not include the evaluation of testing after anonymous testing was made available in all sites and her conclusions do not include the continued increase of named testing even in counties where anonymous testing was available during the restrictive test period.

We have also evaluated testing behavior since anonymous testing was eliminated and those results are contained in the ***privileged*** communication that has been accepted for publication in the *Journal of Public Health Management and Practice* (Attachment D). We found a similar sequence of decline in testing among high risk clients, especially men who have sex with other men (MSM) that was transient and testing rates have moved back to the expected rates. You should note that even with the availability of anonymous testing, we found a steady decline in the number of clients, even among high-risk groups, who requested anonymous testing in our local health departments. In our experience, clients will accept name-based HIV testing. North Carolina has implemented HIV and syphilis testing in Non-traditional Testing Sites (NTS) to accommodate need for testing in locales and at times that are convenient to clients. The NTS HIV positivity rate in CY-2001 was 1.5% compared to 0.7% for other CTS. We believe this approach along with our documented commitment to confidentiality and professionalism has been one of the reasons persons have continued to access testing in spite of the lack of an anonymous testing option. More detailed information on the NTS program can be found in Attachment E.

All individuals identified by HIV testing are required to be reported to the health department. Our rules allow for self-notification of partners by patients, but we have found that when patients are interviewed and given the option to have staff assistance with partner notification, they usually accept the assistance. In 2001, of the HIV partners who were tested after notification and counseling, 21 of these partners were positive and were unaware of their status, **that is 1 HIV positive individual in every 5 partners tested,** as indicated in the following graph.

HIV Partners - Results of Partner Notification **N=1251**

Previously Tested Positive	337	26.7%		
Newly Notified and Counseled	773	61.8%		
Newly Tested	490	63.4%		
Newly tested Positive			103	21.0%
Newly tested Negative			352	79.0%
Not Currently Tested	283	36.6%		
Not Notified or Counseled	141	11.3%		

(3) The American Medical Association recommends mandatory newborn testing for HIV. Does the state require routine testing of newborns for syphilis, HIV or any other disease or condition? If not, is there any consideration being given to implement such a policy-- along with links to appropriate treatment-- to eliminate perinatal HIV transmission? Why or why not?

North Carolina does not require HIV testing for newborns although testing for syphilis may be required under specific circumstances. While testing of newborns can identify babies who can benefit from antiretroviral therapy, we believe the better approach to reducing perinatal transmission is to identify HIV-infected pregnant women and provide anti-retroviral therapy during pregnancy/delivery.

North Carolina does not require HIV testing for newborns although testing for syphilis may be required under specific circumstances. There is a requirement for prenatal testing for syphilis and recent changes in our public health rules encourage providers to test pregnant women for HIV infection unless the woman declines testing (often referred to as an opt out approach). Our approach is consistent with a mechanism to reduce perinatal transmission by directing our testing efforts toward the mother.

The number of infants born with HIV infection has significantly decreased from the 19 in 1993 to 2 in 2002, even though the relative incidence of HIV has increased through the 1990s among women. Women represented 22.7% of all HIV disease reports in 1990, but by 2000, represented 34%.

While testing of newborns can identify babies who can benefit from antiretroviral therapy, we believe the better approach to reducing perinatal transmission is to identify HIV-infected pregnant women and provide anti-retroviral therapy during pregnancy/delivery. This is consistent with the recent American College of Obstetricians and Gynecologists (ACOG) policy position.

North Carolina Public Health and ACOG joined together to form a partnership in March 1999 to identify barriers to HIV counseling and testing of pregnant women and strategies for addressing them. They invited key stakeholders from across the state to join in the partnership efforts, including family physicians, nurse-midwives, health educators, academics, and others.

This partnership has been instrumental in guiding policy development in North Carolina for HIV testing and treatment in pregnant women and newborns. This partnership is described in attachment F ***"North Carolina Providers Partnership on Perinatal HIV."***

(4) What improvements could be made in the cooperativeness the state receives in working with federal agencies, including the Centers for Disease Control and Prevention?

North Carolina, as well as most states, depend on the Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA) for technical assistance and a significant proportion of funding for HIV/STD Prevention, Surveillance, Ryan White Titles II and ADAP. North Carolina, CDC and HRSA maintain cooperative working relationships that are beneficial to all parties.

Staff of the North Carolina HIV/STD Prevention and Care Branch work closely with the National Alliance of State and Territorial AIDS Directors (NASTAD). NASTAD has developed recommendations for streamlining the CDC HIV Prevention Cooperative Agreement application process, improving the community planning process and increasing support for the implementation of comprehensive HIV prevention programs (Attachment G). North Carolina supports these recommendations and encourages their adoption by CDC.

(5) North Carolina has previously implemented restrictions on ADAP enrollments. What changes-- at the state and federal level or otherwise-- need to be addressed in order to prevent future restrictions on access to AIDS medicine by those living with HIV/AIDS?

In order to prevent the necessity of imposing additional future restrictions to access to AIDS medications for individuals living with HIV/AIDS – at least to the greatest extent possible – North Carolina's HIV/STD Prevention and Care Branch makes the following recommendations:

(a) We are concerned about inequities in terms of access to medications and, inevitably, in health outcomes between and within states. Additional funding, above and beyond the President's budget, is clearly required. Most national HIV/AIDS organizations (NASTAD and NORA, as examples) recommend an increase of $162 million for FY 2003, resulting in a total Federal ADAP "earmark" of $801 million. Securing this additional funding is critical for states like North Carolina.

In addition, sufficient federal Ryan White (RW)/ADAP funds should be distributed to states in a manner to assure that "minimum standards" can be achieved in all states. Specifically, the public health services recommended HIV/AIDS drug formulary should be available to all HIV positive individuals at or below 300% of the federal poverty level without regard to where they live.

Note: In FYs 2000 and 2001, NC was among the top 10 states in the total State funds appropriated for ADAP, and among the top 5 states in the percentage of the total ADAP

Program represented by State appropriated funds. ("*National ADAP Monitoring Project – Annual Report - April 2002*")

(b) Increase funding for HIV and other STD prevention activities and mental health/substance abuse services, so the increased number of new cases could be slowed. This is especially critical in the southeastern states, which are experiencing the most rapid increase in the number of new HIV and AIDS cases of any area in the nation. If one looks at the incidence of AIDS (and where positive at HIV infection), the South was under-represented in the epidemic until the mid - 90's. Of the 34 states that reported HIV incidence in 2001, NC reported the 4th highest total number of cases, 1,081. North Carolina has a mixture of urban and rural areas, as does most of the South. Although the large metropolitan areas have historically reported more AIDS cases, CDC reports that the smaller metropolitan and nonmetropolitan areas, especially in the South, also share a significant burden of the AIDS epidemic. These places may face different challenges than the larger areas to provide adequate care and services to the affected populations. (Attachments H and I)

(c) Congress should pass the "Early Treatment for HIV Act." While individual states would still have to "opt in" to this Medicaid option, removing the requirement for demonstrating budget neutrality to CMS would enable a number of states to expand Medicaid coverage. The expanded coverage would apply to asymptomatic HIV+ individuals, and allow a significant number of individuals currently on ADAP to be moved to Medicaid. In NC, where federal Medicaid pays ~2/3 of the cost of Medicaid services, this would result in:
   (1) cost savings to the ADAP Programs, which could then use its funds to cover individuals not qualifying for Medicaid; and
   (2) improved access to more comprehensive medical, pharmaceutical and other services for those that do qualify for Medicaid.

State of New York
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ANTONIA C. NOVELLO, M.D., M.P.H., Dr. P.H.
Commissioner

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June 24, 2002

Hon. Mark E. Souder, Chairman
Member of Congress
U. S. House of Representatives
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
B 373 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Souder:

Thank you for your recognition of New York State's success in responding to the HIV epidemic, especially in the area of perinatal HIV transmission. We appreciate the opportunity to inform your committee on the implementation of the state HIV Reporting and Partner Notification Law implemented June 1, 2000.

The new HIV law and regulations mandate named HIV reporting by providers and laboratories conducting HIV-related tests on residents of New York State. In addition, providers are mandated to report any known contacts of newly diagnosed cases of HIV infection. Much of the first 18 months of implementation were focused on building highly secure, confidential systems for the collection and processing of data. All 72 laboratories mandated to report are currently reporting either electronically or by paper. In the year 2001 alone, we received a total of 454,552 laboratory reports (this includes multiple reports per person) and 7,053 provider reports. I have enclosed a report on the first seven months of implementation, from June through December 2000, that includes preliminary data from that time period. The responses to your specific questions are as follows:

1. As stated in the enclosed report, the number of HIV reports received were double the number of AIDS case reports received. Significant differences in the age, gender and racial/ethnic distribution of cases are noted when comparing the newly diagnosed HIV cases to AIDS cases. This new information is providing New York State with a better understanding of the magnitude of the epidemic and of what is occurring at the front end of the epidemic. Differences in risk of transmission are also evident, but this information on risk is not currently complete enough to draw valid conclusions.

2. The inclusion of HIV cases, in addition to AIDS cases, will be much more useful to New York State prevention programs because it will provide more accurate information on which populations are currently being impacted by the epidemic. In addition, much more valuable information on adolescent HIV infections is being obtained, which will allow better targeting of resources and evaluation of prevention efforts aimed at this population. Care programs will also benefit from HIV data because the total number of persons in need of care will be more accurately reflected, as well as the geographic distribution.

3. There have been no documented breaches of confidentiality in the State prior to or after the implementation of HIV reporting. Security and confidentiality of HIV/AIDS data is a priority in New York State. A great amount of effort and resources has gone into building security into all aspects of HIV/AIDS surveillance and partner notification activities, including securing all computer systems, physical environments and conducting in-depth, ongoing confidentiality training for all staff involved in these activities.

4. In order to measure the impact of HIV reporting on testing behaviors in New York State, HIV testing levels were tracked statewide, by testing setting (i.e., anonymous [exclusive of New York City], community-based confidential, substance abuse treatment, etc.), and within categories of sex, race/ethnicity, age, and HIV risk factor. Several possible HIV reporting law intervention points were examined, representing initial passage of the legislation, passage of the regulations implementing the legislation, and the timing of post-implementation training campaigns. Preliminary findings indicate no discernible deterrent effect of the HIV Reporting and Partner Notification legislation on HIV testing behavior. This was true for statewide testing levels, and for testing levels in each of the categories detailed above. In addition, preliminary analyses suggest that post-test counseling return rates also appear unaffected by the law. Preliminary analyses of Medicaid data also failed to detect an effect from the HIV reporting legislation.

5. Partner notification is still voluntary in New York State under the new HIV Reporting and Partner Notification Law. Providers are required to report "known" contacts. The intent of the law is to expand partner notification activities in New York State by encouraging providers to discuss partner notification with their patients and routinely offer partner notification assistance. As noted in the enclosed report, the number of partner notifications conducted during the first seven months of implementation was nearly four times that documented prior to the legislation in 1998.

6. Partner notification activities focus on notifying partners of their exposure to HIV and getting them tested. Currently there is no information available on the proportion of those partners testing positive for HIV entering care. Special studies need to be conducted to obtain this information.

7. There have been no documented cases of domestic violence as a result of the implementation of the HIV Reporting and Partner Notification Law. The law makes special reference to domestic violence and the regulations require that a domestic violence screen be conducted when discussing partner notification with the patient. During the first seven months of implementation, two percent of reported notifications were deferred due to domestic violence concerns.

8. Discussions with partner notification program staff and supervisors conducted as a part of routine quality assurance reveal no adversarial responses from physicians or index cases as a result of case investigations.

9. The New York State HIV Reporting and Partner Notification Law has been effective in providing a better understanding of the HIV epidemic in New York State, and enhancing the partner notification activities conducted by providers and health department staff.

10. In situations where there is an out of state contact of a New York State resident, the New York State Department of Health (DOH) partner notification staff will provide the name of the contact to the State Health Department's partner notification staff of the state where the contact resides. The state of residence staff will then follow-up and notify the contact. NYSDOH requests and documents the closure/disposition on all partners referred "out-of-jurisdiction" (i.e., whether partner was notified, and if tested, results of the HIV test). When the disposition is not reported back to New York State within a specified time frame, New York State contacts the other jurisdiction to ascertain the outcome.

    Lack of HIV reporting in surrounding states does not appear to hinder New York State's surveillance, because laboratories are mandated to report tests conducted on New York State residents even if they are tested in another state. An individual will not be reported if they falsify their state of residence, but there is no way of determining to what extent this occurs.

    It is difficult to assess the impact of "partner notification" infrastructure in other states on New York State's effectiveness with partner notification. We have little knowledge of the specific level of intervention being made by different states and localities in trying to locate and inform partners, but we understand that staffing available for partner notification may be an issue in other states.

11. New York State has received some "one time" funding from CDC for implementing HIV reporting. CDC funding for core HIV/AIDS surveillance has been level since 1997, with the exception of a five percent cost of living increase in 2001. The majority of resources and staff have been funded by the State.

Federal funding levels that support partner notification available through CDC have remained level for over a decade, antedating implementation of HIV reporting in New York. By comparison, based on data for Upstate New York (New York City is a separate funding jurisdiction), workload has increased substantially from 200-400 investigations prior to HIV reporting to currently over 2,500 each year.

I hope this information is useful. Should you need further information, please do not hesitate to contact us.

Sincerely,

Antonia C. Novello, M.D., M.P.H., Dr. P.H.
Commissioner of Health

Enclosure

Implementation of the New York State HIV Reporting and Partner Notification Law: Report on Activities Conducted 6/1/2000 through 12/31/2000

March 2002

Implementation of the New York State HIV Reporting and Partner Notification Law: Report on Activities Conducted 6/1/2000 through 12/31/2000

Introduction:

On June 1, 2000, the New York State Department of Health (NYSDOH) implemented the HIV Reporting and Partner Notification Law passed in 1998. The law enhances the existing AIDS case reporting system by adding reporting of human immunodeficiency virus (HIV) and HIV-related illness by health care providers and laboratories to the State Commissioner of Health. The law also mandates reporting of known contacts of persons with HIV and AIDS to allow for the provision of partner notification assistance, and the conducting of a domestic violence screen to determine if such risk exists before proceeding with partner notification.

This expanded reporting of HIV infection allows more accurate epidemiologic surveillance to better monitor the HIV epidemic and provides the basis for targeted planning, resource allocation and evaluation of public health initiatives. Enhanced partner notification allows more exposed individuals to learn their HIV status and receive early diagnosis and treatment if infected. The partner notification process also increases the opportunities for patient education regarding HIV risk reduction education to prevent future transmission.

Operationally, HIV/AIDS surveillance activities are the sole responsibility of the NYSDOH and New York City Departments of Health (NYCDOH), while partner notification activities are conducted by a combination of NYSDOH, NYCDOH and county health department staff. The implementing regulations indicate that all newly diagnosed cases of HIV infection and any known contacts reported by physicians merit priority consideration for partner notification. Cases outside of New York City are referred for partner notification evaluation to the 13 participating county health commissioners and NYSDOH regional PartNer Assistance Program (PNAP) staff. New York City cases are transferred to NYCDOH HIV/AIDS Surveillance Program. The HIV/AIDS Surveillance Program forwards those cases for which the provider has requested partner notification assistance to the Contact Notification Assistance Program (CNAP) staff.

An accurate accounting of the burden of the HIV epidemic on New York State is also important in relation to federal resource allocations. The federal Ryan White CARE Act reauthorization of 2000 calls for the distribution of funds to the states based on the number of HIV cases (rather than AIDS cases) by the year 2004. By that date, New York State will have three years of expanded HIV reporting experience and will be in a good position to ensure that its share of federal resources are based on an accurate and complete representation of the State=s reported HIV cases.

Program Activities/Methods:
Surveillance:

During the first year of implementation, state-of-the-art computer systems were developed to receive, process and transfer HIV/AIDS reports in a highly confidential and secure manner. All NYSDOH, NYCDOH and other local health department personnel were trained in

handling highly confidential information. Office renovations were made and other security precautions were taken to comply with the strict security standards of the federal Centers for Disease Control and Prevention and the NYSDOH.

By the end of December 2000, 78 of the 80 clinical laboratories performing HIV related tests were transmitting HIV/AIDS reports to the NYSDOH. The last two laboratories were reporting by the end of January 2001. A total of 164,446 laboratory reports were received and processed from 6/1/2000 through 12/31/2000. Since HIV infected individuals in care may receive up to three to four CD4 and HIV viral load tests a year, the majority of these reports were duplicate reports for the same individuals. These duplicate reports ensured a complete case count but necessitated the development of efficient and effective matching procedures to identify newly reported cases for assignment to the NYSDOH and NYCDOH surveillance staff for field follow-up. This follow-up involves chart reviews to gather the required surveillance information in order to confirm a case as HIV, HIV-related illness or AIDS.

Partner Notification:

In all areas outside of New York City, PNAP staff, who are a mix of state and participating county staff, routinely contact the health care provider regarding reports of newly diagnosed HIV infection for the purpose of offering voluntary partner notification assistance even if the provider did not specifically request PNAP assistance. PNAP staff also contact the providers regarding reported cases of HIV illness and AIDS where the provider has listed known contacts or requests assistance. Due to the volume of reports from New York City providers, New York City CNAP staff contact only those providers who request CNAP assistance. In addition to partner notification activity generated by medical provider reports, both PNAP and CNAP staff continue to receive requests for partner notification assistance not related to HIV reporting directly from New York State providers and out-of-state providers whose patients have partners in New York State. PNAP staff also contact providers by telephone to follow up on laboratory reports of newly diagnosed infections for which a provider report has not been received. In New York City cases, HIV Surveillance program staff hand deliver letters to providers who are late in completing provider report forms.

Program Outcomes / Results:
Surveillance:

As of May 31, 2001, a total of 16,866 HIV/AIDS cases with HIV-related laboratory testing or provider diagnosis from 6/1/2000 through 12/31/2000 were confirmed as HIV, HIV-related illness or AIDS (Table 1). Of the confirmed cases, 2,817 (17%) were initial HIV diagnoses, 9,036 (53%) were HIV illness diagnoses and 5,013 (30%) were AIDS. A total of 12,144 cases, or 72%, were New York City residents, while 4,722 cases, or 28%, were from counties outside of New York City. The proportions are the same when HIV and AIDS cases are considered separately. The totals presented in Table 1 include all confirmed cases reported through May 31, 2001, who were tested from 6/1/2000 through 12/31/2000. As was the case with AIDS case reporting in the past, these totals are preliminary and will increase as surveillance follow-up is completed and additional cases are confirmed.

Partner Notification:

As of May 31, 2001, health care providers reported a total of 3,564 cases that were tested from 6/1/2000 through 12/31/2000, of which 3,230 (91%) were initial HIV diagnoses (Table 2). Statewide, 51% (1,825) of the cases reported by health care providers included partner information. For cases outside of New York City, 60% included partner information, while 50% did so for New York City cases.

Table 3 summarizes the status of partner notification activity for partners of index cases tested from 6/1/2000 through 12/31/2000, conducted by medical providers and PNAP/CNAP staff. A total of 2,342 partners were reported, 593 (25%) outside of New York City, and 1,749 (75%) in New York City. In total, 1,290 partners, or 55% of all partners reported for the seven-month period, were notified. Notifications by providers and CNAP staff are in progress for 93 (3%) additional partners. This number of documented partner notifications is more than four times greater than the number of partner notifications documented in 1998, prior to implementation of the legislation. Notifications were completed on 380, or 64% of the 593 partners outside of New York City. In New York City, notifications were completed for 910, or 52%, of the 1,749 known partners.

Fourteen percent (14%) of partners outside of New York City and 23 percent of partners in New York City could not be notified because there was insufficient information regarding the location of the partner to initiate the notification process. This information was lacking either because the index case did not know it or the provider did not report the information. The Medical Provider Report Form has been modified recently to include more specific locating information in an attempt to reach more partners.

Throughout the first year, information and training on domestic violence (DV) screening was widely disseminated to providers and PNAP/CNAP staff. Table 3 shows that of the 2,342 reported partners, two percent (2%) of notifications were deferred because of DV concerns. The DV protocol requires immediate referral to needed services and delineates a follow-up process to determine if and when the notification can safely occur.

Epidemiology of HIV Infection:

Tables 4 and 5 are a comparison of the newly diagnosed HIV and AIDS cases tested from 6/1/2000 through 12/31/2000, by gender, race and age. Information on risk for transmission is incomplete because laboratory reports do not include this information. This information will be made available after a full surveillance investigation with chart review has been completed for all reported cases.

The gender, age and race/ethnicity distributions differ substantially for newly diagnosed HIV and AIDS. (Table 4) Among newly diagnosed HIV cases outside of New York City, there is a greater proportion of females (34%) than among AIDS cases (27%). In addition, the proportion of younger cases under 30 years of age among those diagnosed with HIV (18%) is nearly twice that of cases diagnosed with AIDS (11%). Among the newly diagnosed HIV cases, there is a smaller proportion of white cases than among the AIDS cases (23% vs 30%) and a greater proportion of black cases among newly diagnosed HIV cases than among AIDS cases (52% vs

46%). The proportion of Hispanic cases was similar for HIV and AIDS cases (25% and 24% respectively).

The comparison of New York City newly diagnosed HIV and AIDS cases indicates similar patterns in gender, age and race/ethnicity distributions. Among new New York City HIV cases, there was a greater proportion of females (42%) than among AIDS cases (30%). There was also a greater proportion of younger cases under 30 years of age among those diagnosed with HIV (21%) than among AIDS cases (9%). Among newly diagnosed HIV cases, there was a smaller proportion of white cases (12%) and a greater proportion of black cases (54%) than among AIDS cases where whites represented 19% of cases and blacks 49% of cases. There was little difference in the proportion of Hispanic cases among newly diagnosed HIV cases and AIDS cases (33% and 31% respectively).

Summary:

To ensure the security and confidentiality of the information collected and processed under the new HIV Reporting and Partner Notification Law, much program activity during the first year of implementation was devoted to building the required infrastructure for collecting, processing and transferring this information among the state, city and participating county health departments. These activities focused on ensuring highly trained staff, secure electronic systems designed to receive and handle a large volume of reports, and secure physical environments.

Since most of the first seven months of implementation were devoted to startup activity, the HIV reporting and partner notification for this time period were incomplete and therefore too preliminary to draw final conclusions. However, even with incomplete reporting, 2,817 cases of new HIV infection, 9,036 cases of HIV illness and 5,013 cases of AIDS tested during the first seven months of implementation were confirmed. In addition, 1,290 partners of HIV infected individuals were notified of their possible exposure. An additional 93 were in the process of being notified. This number of documented partner notifications is more than four times greater than the number of partner notifications documented in 1998, prior to implementation of the legislation. As anticipated, the characterization of the newly diagnosed HIV cases differs substantially from that of AIDS cases in both New York City and the rest of New York State, providing better information for meeting HIV prevention and care needs in New York State.

Table 1
Number of Unduplicated HIV/AIDS Reports[1] Confirmed by Region
for Cases Tested/Diagnosed 6/1/2000 - 12/31/2000, New York State

Confirmed Cases:	NYS Outside NYC		NYC		Total NYS	
	Number	Percent	Number	Percent	Number	Percent
Initial HIV Diagnosis	672	14%	2,145	18%	2,817	17%
Initial HIV Illness	2,534	54%	6,502	53%	9,036	53%
Initial AIDS Diagnosis	1,516	32%	3,497	29%	5,013	30%
Total Cases Confirmed	**4,722**	**100%**	**12,144**	**100%**	**16,866**	**100%**

1 Cases reported through 5/31/2001

NYS = New York State
NYC = New York City

Table 2
Number of Medical Provider Forms Received[1] for HIV/AIDS Cases Tested/Diagnosed
6/1/2000 - 12/31/2000, New York State

Type of Report:	NYS Outside NYC		NYC		Total NYS	
	Number	Percent	Number	Percent	Number	Percent
Initial HIV Diagnosis						
Reports w/Partner Information	257	58%	1,377	49%	1,634	51%
Reports w/o Partner Information	185	42%	1,411	51%	1,596	49%
Total HIV Diagnosis Reports	**442**	**100%**	**2,788**	**100%**	**3,230**	**100%**
Initial HIV Illness and AIDS						
Reports w/Partner Information	91	65%	100	51%	191	57%
Reports w/o Partner Information	48	35%	95	49%	143	43%
Total HIV Illness and AIDS Reports	**139**	**100%**	**195**	**100%**	**334**	**100%**
Total Reports						
Reports w/Partner Information	348	60%	1,477	50%	1,825*	51%
Reports w/o Partner Information	233	40%	1,506	50%	1,739	49%
Total Reports	**581**	**100%**	**2,983**	**100%**	**3,564**	**100%**

1 Cases reported through 5/31/2001

*A total of 2296 partners were reported by providers and an additional 46 through direct referral to PNAP/CNAP for a total of 2,342 partners

NYS = New York State
NYC = New York City

Table 3
Notification Status of Partners of Index Cases Tested 6/1/2000 - 12/31/2000* or Partners directly referred to PNAP/CNAP by Region
New York State

Notification Status of Partners:	Region					
	NYS Outside NYC		NYC		Total NYS	
	Number	Percent	Number	Percent	Number	Percent
Provider[1] attests to notification completed[2]	205	35%	882	50%	1,087	46%
Notified by PNAP/CNAP in response to provider or lab report[3]	139	23%	18	1%	157	7%
Notified by PNAP/CNAP through direct referrals[4]	36	6%	10	1%	46	2%
Provider attests that notification is in progress	0	0%	57	3%	57	2%
PNAP/CNAP notification in progress	0	0%	36	2%	36	1%
Notification deferred due to risk of domestic violence	27	5%	19	1%	46	2%
Insufficient locating information to conduct notification	85	14%	403	23%	488	21%
Lost to follow-up	41	7%	24	2%	65	3%
Other[5]	60	10%	300	17%	360	16%
TOTAL PARTNERS	593	100%	1,749	100%	2,342	100%

* Data reported through 5/31/01

NYS = New York State
NYC = New York City

1. NYC, county and state operated STD clinics are included in this category.
2. Included reports where the provider attests to notifying the partner, the index case notifying the partner or that the partner already knew their HIV status.
3. Includes circumstances where the provider requested PNAP/CNAP assistance on the provider report form or where the PNAP staff follow-up on a laboratory report.
4. Includes cases that were referred directly to PNAP/CNAP that were outside the new reporting procedures.
5. Includes notifications that could not be conducted because the partner died, lived out of state, other mitigating circumstances. Note; out of state partners are referred to the state health department of the state where the partner resides

Table 4
Confirmed HIV/AIDS Cases[1]
Diagnosed 6/1/2000 - 12/31/2000 by Gender and Age
New York State, Excluding New York City

	HIV Diagnosis		AIDS	
	Number	Percent	Number	Percent
Gender				
Male	408	61%	1,100	73%
Female	231	34%	416	27%
Unknown	33	5%	0	0%
Total	**672**	**100%**	**1,516**	**100%**
Age Group				
<20	21	3%	29	2%
20-24	43	6%	27	2%
25-29	63	9%	100	7%
30-39	271	41%	597	39%
40-49	212	32%	551	36%
50+	62	9%	212	14%
Total	**672**	**100%**	**1,516**	**100%**
Race/Ethnicity				
White	**98**	**23%**	**436**	**30%**
Black	**229**	**52%**	**677**	**46%**
Hispanic	**108**	**25%**	**353**	**24%**
Asian/Pacific Islander	**1**	**0%**	**4**	**0%**
Native American	**2**	**0%**	**1**	**0%**
Total	**438**	**100%**	**1,471**	**100%**

1. Cases reported through 5/31/2001

Table 5
Confirmed HIV/AIDS Cases[1]
Diagnosed 6/1/2000 - 12/31/2000 by Gender and Age
New York City

	HIV Diagnosis		AIDS	
	Number	Percent	Number	Percent
Gender				
Male	1,232	57%	2,436	70%
Female	898	42%	1,061	30%
Unknown	15	1%	0	0%
Total	2,145	100%	3,497	100%
Age Group				
<20	54	3%	28	1%
20-24	152	7%	61	2%
25-29	234	11%	202	6%
30-39	842	39%	1,224	35%
40-49	604	28%	1,274	36%
50+	259	12%	708	20%
Total	2,145	100%	3,497	100%
Race/Ethnicity				
White	238	12%	668	19%
Black	1,048	54%	1,725	49%
Hispanic	647	33%	1,073	31%
Asian/Pacific Islander	18	1%	26	1%
Native American	4	0%	3	0%
Other	3	0%	0	0%
Total	1,958	100%	3,495	100%

1. Cases reported through 5/31/2001

Jeb Bush
Governor

John O. Agwunobi, M.D., M.B.A.
Secretary

May 6, 2002

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
United States House of Representatives
B 373 Rayburn House Office Building
Washington, DC 20515-6143

Dear Representative Souder:

I received your April 22 letter and would like to thank you and the subcommittee for expressing an interest in Florida's HIV/AIDS surveillance system and partner notification activities. I appreciate the opportunity to respond to the questions raised. Please refer to the enclosed document, which addresses the questions in detail.

The Florida Department of Health is very proud of our HIV/AIDS surveillance system and feel that it is one of the best in the nation. The relationship between HIV/AIDS surveillance and partner notification is an excellent example of programmatic integration between two bureaus within the Florida Department of Health, which provides many public health benefits for Florida's citizens and visitors.

I have enclosed a copy of the Monthly Surveillance Report and the January and April issues of *Data at a Glance*, a quarterly publication of the Early Intervention Section of the Bureau of HIV/AIDS. I hope this information is helpful. If you have any further questions or would like clarification on any of our responses, please contact Thomas Liberti, Chief of the Bureau of HIV/AIDS, at (850) 245-4477.

Sincerely,

John O. Agwunobi, M.D., M.B.A.
Secretary, Department of Health

JOA/bg
Enclosures
cc: Thomas Liberti
Karla Schmitt, Chief
Bureau of STD

Florida's Responses to Questions from Subcommittee on Criminal Justice, Drug Policy and Human Resources

1. *What are the initial results of the HIV data collection? Has the addition of HIV cases expanded the understanding of the state's epidemic in comparison to relying merely on AIDS reports?*

   The state of Florida began reporting HIV cases on July 1, 1997. From July 1997 through March 2002, Florida's confidential HIV infection reporting system has identified 24,964 newly diagnosed HIV cases that do not meet the AIDS case definition. Of the 34 states that have named HIV infection reporting, Florida ranks first in the total number of HIV cases reported.

   Because of more effective therapies that slow the progression of HIV disease, AIDS surveillance data no longer reliably reflect the trends in disease transmission and do not accurately represent the need for prevention and care services. (Morbidity and Mortality Weekly Report, Vol. 48, No. RR-13, Centers for Disease Control and Prevention, 12/10/99). This is best illustrated by comparing the demographics of Florida's AIDS and HIV cases. Of the total cases reported through 2001, whites accounted for 45% of male AIDS cases but only 33% of male HIV cases. Conversely, the percent of black males was higher among HIV cases at 48%, compared with AIDS cases, at 38%. Few differences are noted between the adult AIDS and HIV cases among females by race/ethnicity. Although difficult to ascertain, racial differences between HIV and AIDS cases could be related to a testing artifact, or they could represent a change in trends in the epidemic.

2. *Has the collection of HIV cases in addition to AIDS been useful to state prevention and care programs?*

   HIV/AIDS surveillance data play a vital role in how Florida determines HIV/AIDS resource needs, allocation methodologies and program planning and implementation. The HIV/AIDS Prevention Plan, both statewide and at the regional partnership level, is based on the Epidemiological Profile developed from HIV/AIDS surveillance data. These data are an integral part of the priority setting methodology. HIV/AIDS data are also a major component of the Ryan White Patient Care needs assessment. In addition, living HIV cases are part of the allocation methodology for new Ryan White consortia funding for primary care.

   Development of successful prevention and patient care messages and initiatives must be based on data and targeted to appropriate audiences. The addition of HIV data has increased the ability to tailor messages and programs to specific sub-populations.

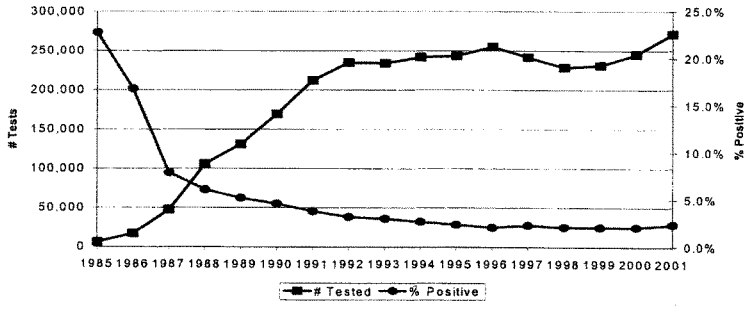
3. *Have there been any documented cases of breaches of confidentiality in the state as a result of HIV reporting?*

   There have been no breaches of confidentiality as a result of HIV reporting.

4. *Has the number of HIV tests been affected as a consequence of HIV reporting?*

HIV testing levels at registered, publicly-funded, testing sites increased rapidly through the early 1990s. After 1992, the number of tests performed increased slowly, peaking at just over 255,000 in 1996. The testing volume dropped by over 13,000, or approximately 5% per year, in 1997 and 1998. A small increase in 1999 was followed by much larger increases in 2000 and 2001, and testing levels are now at their highest in

Figure 1a. HIV Tests Conducted in Florida and Seropositivity Rates, 1985-2001



five years (See Figure 1a).

In 2000, Florida participated in the HIV Testing Survey (HITS) project, funded by the National Centers for Disease Control and Prevention. HITS is an anonymous, cross-sectional survey. The core HITS study populations represent three critical populations at high risk for HIV infection: MSM, IDU, and high-risk heterosexuals.

The objectives of HITS are to:

- assess the reasons and barriers that influence persons to seek or avoid HIV testing;
- assess knowledge of state policies for HIV surveillance;
- assess HIV testing patterns among persons at-risk for HIV;
- conduct behavioral surveillance among persons at risk for HIV infection;
- evaluate the representativeness of HIV surveillance data;
- collect data for local HIV prevention and community planning, and,
- assess prevention effectiveness.

Of the 276-HIV negative HITS respondents who indicated they had been tested in the past 12 months, only four mentioned they delayed testing because they were worried their names would be reported to the government. Of these four, none gave this as their main reason for delaying testing.

It appears that HIV reporting has had little or no overall effect on HIV testing patterns in Florida. At-risk persons continue to test in very high numbers in both county health department and community-based settings.

5. *How has the number of partners being notified regarding possible HIV-exposure been affected by the new law?*

The number of partners notified regarding their possible exposure to HIV has increased. When comparing year 1996, prior to the implementation of HIV infection reporting, and year 2001, partner counseling and referral services (PCRS) were offered to a greater number of HIV-positive persons during 2001. In 1996, 2,915 HIV-positive clients identified through public health screening sites were assigned to the Bureau of STD for PCRS. During 2001, 3,707 HIV-positive persons that were identified through public and private screening venues were assigned for follow-up. This represents a 27.2% increase in the number of persons offered partner counseling and referral services.

6. *Has any increased partner notification contributed to earlier intervention for those at risk and treatment for those who were unaware of their HIV status?*

The Bureau of STD makes referrals to virtually all HIV-positive persons who are offered PCRS as well as their sex/needle sharing partners. The increased PCRS activities and referrals have resulted in a significant increase of infected persons who seek screening, counseling and early intervention services. Of the persons located and counseled due to their exposure to HIV in 1996, 6% were newly identified cases. This percentage has increased to 11% during 2001.

7. *Have there been any documented cases of domestic violence in the state as a result of the partner notification program?*

Currently, the Bureau of STD does not collect data on domestic violence related to HIV PCRS activities.

8. *Has partner notification been well received by those who initially were diagnosed with HIV and by those who were notified that they had been exposed?*

The majority of persons who are recently diagnosed with HIV infection are receptive to having their partners notified of their possible exposure to HIV infection through PCRS. Of the 2,247 HIV-positive persons offered PCRS in 2001, 67% accepted the offer in the interest of preserving their confidentiality and in having a well-trained public health counselor notify their partners.

Among the partners that were notified of a possible exposure in 2001, 85% were receptive to referrals and screening for HIV testing.

9. *Would you consider Florida's HIV reporting and partner notification program to be an effective policy?*

Yes, PCRS serves as an ideal means for HIV-positive persons to have their sex/needle partners notified of their exposure and yet preserve their own confidentiality. Without PCRS as an option, many persons who have been exposed would not learn of their exposure and ultimately, those partners who are positive would unknowingly expose others to the virus. Since HIV infection reporting was implemented, 6,625 partners who were unaware of their exposure were notified by public health.

10. *A patchwork of HIV reporting and partner notification law exists among the states surrounding Florida. How is HIV partner notification handled in situations where individuals who may reside outside of Florida have been exposed to HIV by someone living in Florida and vice versa? Does the lesser emphasis on partner notification or lack of HIV surveillance in surrounding states in any way hinder Florida's HIV program?*

    In 1989, the Centers for Disease Control and Prevention (CDC) developed a policy for the communication of HIV related disease intervention information between public health jurisdictions. During 2001, Florida received and/or communicated HIV related information to all 50 states, Puerto Rico and the Virgin Islands. Cooperation in communicating and accepting HIV related information varies based on state statutes and policies and in some instances has affected notification services in Florida.

11. *Is the federal government – particularly the CDC-providing adequate support for Florida's HIV surveillance and partner notification activities?*

    The HIV/AIDS Surveillance cooperative agreement with CDC has been level funded for years. As a result, the current level of funding does not support personnel costs for a full year and must be covered with carry-over funds or one-time funds from CDC. Florida implemented HIV infection reporting without any increases to the number of surveillance staff. As a result, caseloads have doubled for existing staff.

    Florida ranks number one in the nation for total HIV cases reported, number two in total pediatric AIDS cases reported and number three in the total adult AIDS cases reported. In addition, Miami had the highest rate of AIDS cases per 100,000 reported through December of 2000 for metropolitan areas with populations of 500,000 or more, Ft. Lauderdale ranked number three and West Palm Beach ranked number four, according to the Year-end Edition, Vol. 12, No. 2 of the CDC's HIV/AIDS Surveillance report.

    In light of these facts, increased funding for core HIV/AIDS surveillance would be highly beneficial, and would result in more completeness of reporting. Increased funding would allow for more thorough medical records reviews and would allow for follow-up on cases reported without an identified risk exposure.

    Also, present funding levels are not adequate for STD staff to offer PCRS to all newly infected persons, or to follow-up on all potential partners for the initial PCRS services.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

AUG 16 2001

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Chairman Souder:

This is in response to your letter to Dr. Helene Gayle regarding HIV prevention and surveillance activities. Enclosed are the Centers for Disease Control and Prevention's responses to your questions. Please let me know if you need additional information. An identical letter is being sent to Representative Dave Weldon, M.D., who cosigned your letter.

Sincerely,

Jeffrey P. Koplan

Jeffrey P. Koplan, M.D., M.P.H.
Director

Enclosure

Centers for Disease Control and Prevention's
Responses to Questions on HIV Reporting Programs
Addressed in Chairman Mark Souder's and Dr. Dave Weldon's
Letter of March 30, 2001

The legal authority for notifiable disease reporting is under the purview of the States. With input from the Centers for Disease Control and Prevention (CDC), the Council of State and Territorial Epidemiologists (CSTE) recommends diseases and conditions for which States should require reporting of cases for the purposes of public health monitoring and follow-up. Individual States then choose whether or not to enact laws, rules, or regulations requiring such case reporting. Identifying information on cases, including patient and provider names, addresses, and other contact information is usually reported to facilitate public health follow-up. States voluntarily report these cases to CDC without identifiers. CDC generally provides funding and technical assistance, recommended best practices, and other guidance to assist State and local surveillance programs in disease reporting.

Question:

As of today, how many states have enacted HIV reporting programs? Of those states that are experimenting with UIs , how many have been approved as meeting the CDC criteria? Could you explain why the CDC's recommendations for reporting cases of AIDS, the end stage of HIV disease, differ from those made for HIV reporting?

Response:

Surveillance practices for HIV and AIDS have evolved over time in response to changes in the epidemic and advances in treatment and knowledge about HIV disease and AIDS. Following the first recognized AIDS cases in 1981, all States enacted laws or regulations for mandatory AIDS case reporting, and they voluntarily report cases of AIDS to CDC. Currently, all States and U.S. territories conduct confidential name-based surveillance for AIDS. In 1997, CSTE adopted a resolution to add HIV infection to the National Public Health Surveillance System and recommended that all States and territories implement confidential HIV reporting.[1] In December 1999, CDC advised all States and territories to conduct HIV case surveillance for adults and children as an extension of their AIDS surveillance activities and to adopt or enact such confidentiality protections as necessary to meet or exceed those referenced in the CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome.[2] As of July 2001, 33 States, the Virgin Islands, and Guam have implemented HIV case surveillance using the same confidential system for name-based case reporting for both HIV infection and AIDS. Two additional States are using this method for pediatric HIV surveillance only. Six States and Puerto Rico are currently using some type of code-based identifiers, rather than patients' names, to report HIV cases. Four States have implemented reporting by using a name-to-code system. In these four States, names are initially reported and after services and referrals are offered, names are then converted to codes. Most of the seven remaining States

(Georgia, New Hampshire, Oregon, California, Connecticut, Pennsylvania, and Hawaii) and the District of Columbia are considering implementation of HIV reporting.

Question:

Does this double standard for reporting different stages of the same disease hinder or make public health surveillance activities more difficult?

Response:

Of the six States and one territory using UI codes, all the codes are different and CDC is currently unable to use existing data systems to receive such data; therefore, HIV data from States with code-based reporting are not currently included in CDC reports. Based on published evaluations, CDC has concluded that name-based HIV surveillance systems are currently the most likely systems to meet the necessary performance standards and provide the quality data necessary to direct community prevention and treatment programs.[3-12] However, CDC recognizes that some States have adopted, and others may elect to adopt, coded case identifiers for public health reporting of HIV infection. Within available resources, CDC will continue to provide technical assistance to all State and local areas to continue or establish HIV/AIDS surveillance systems and to evaluate their surveillance programs using standardized methods and criteria whether they use name-based or coded identifiers.[2]

Question:

Can you assure us that by allowing states to experiment with coded surveillance systems--which even the CDC has found to be faulty--that data will be properly and fully reported so that these disparities will indeed be eliminated?

Response:

CDC has adopted minimum performance standards that all States must meet over time. These standards were published in the recent Guidelines on national HIV case surveillance.[2] The performance standards recommend using methods that provide complete and timely data, result in accurate case counts, and ensure that demographic and risk information is complete. In addition, States must collect the recommended standard data in a reliable and valid manner, allow matching to other public health databases (e.g., death registries) to benefit specific public health goals, and allow identification and follow-up of certain individual cases, such as perinatally exposed infants, to identify infection status. To date, of those States that have implemented HIV reporting using non-name-based methods, none has completed CDC evaluations addressing all performance standards. However, Massachusetts and Washington have had time to establish routine surveillance methods for collecting HIV. An evaluation of how well the code identifies one and only one person has been completed for these States. Both report that the current system meets this aspect of the recommended performance standards.

Other performance criteria have not yet been evaluated in these States. One other State, which previously published their initial evaluation, is currently conducting CDC-recommended modifications to their evaluation methods.[13] CDC will continue to work with States to complete these evaluations, strengthen their systems, and promote comparability of data throughout the United States.

Integrated HIV/AIDS surveillance systems are needed to provide the most representative and complete information to appropriately target prevention efforts for affected populations. Surveillance data have been successfully used to monitor changes in the epidemic and affected populations. For example, since 1982, AIDS surveillance data have shown that racial and ethnic minority populations are disproportionately affected. Also, smaller declines in AIDS incidence and deaths among racial and ethnic minority populations compared to whites have been reported. States have used this information to target both prevention and treatment programs. However, identifying reasons for differences among racial and ethnic minorities will require more than HIV case reporting because case reports alone cannot identify barriers to testing and care. To further address racial disparities, CDC has also implemented a variety of supplemental surveillance activities integrated with behavioral surveillance that focuses on risk-, testing-, and care-related behaviors in at-risk and infected populations. Currently, these supplemental surveillance activities are conducted in only a few States, but are needed in many more areas. In addition, CDC is conducting a number of studies looking at the social and cultural context in which risky behaviors occur.

Finally, CDC has funded several academic centers to conduct research regarding the behavioral context of initiating high-risk sexual and drug use among young adults, including racial and ethnic minorities. Other research studies are addressing social networks and community factors associated with high risk for HIV infection.

Question:

The CDC was directed to make grants available to states which have enacted newborn testing laws. Has the CDC dispensed--or at least made states aware of the availability of--these funds? If not, what is the timetable for doing so? Will the CDC request funding for these perinatal HIV prevention grants in the remaining fiscal years of the CARE Act reauthorization?

Response:

On June 20, 2001, CDC announced the availability of approximately $4.0 million one-time supplemental funds to support Perinatal Prevention Activities under Program Announcement 99004. Awards are expected to begin on or about September 1, 2001. The President's Budget for CDC for fiscal year (FY) 2002 does not include these funds.

Approximately half of the funds will be available to New York, Connecticut, New Jersey, and Florida. The remaining funds will be available to the 11 other States and District currently

receiving funds for the prevention of perinatal HIV transmission: Georgia, California, Texas, Puerto Rico, District of Columbia, Maryland, Illinois, Massachusetts, Pennsylvania, South Carolina, Louisiana, and Delaware.

Activities that can be supported by this funding will include, but are not limited to, outreach to increase the number of HIV-infected women who seek prenatal care; education and technical assistance to increase the number of women who receive HIV counseling and testing in prenatal care; community-level interventions such as social marketing and educational campaigns; provider education and training; case management of difficult-to-reach women; targeting of special populations such as prisoners and drug abusing women; linkages with Medicaid/managed care systems; evaluation of the above activities; and provision of treatment for HIV-infected women and their infants.

Question:

In light of the significant success of the New York state Baby AIDS law in identifying all newborns at risk and providing linkages to care for over 98 percent of those identified while increasing prenatal participation rates, would you agree the universal HIV testing of newborns offers a valuable intervention for HIV prevention and care?

Response:

The New York law's major effect appears to be associated with increased efforts by providers to offer prenatal voluntary counseling and testing.[14-15] Increased prenatal voluntary counseling and testing offers the best chance of maximally reducing the risk of perinatal transmission because it increases the opportunity to lower maternal viral load to nondetectable levels near delivery and provide chemoprophylactic therapy to the baby during labor, delivery, and afterwards. States other than New York have excellent prenatal voluntary counseling and testing rates in the absence of mandatory HIV testing in newborns. For example, data on HIV testing in 1998 indicated that in Arkansas 85 percent of pregnant women were tested during pregnancy or at delivery. In Colorado and Florida, these numbers were 79 percent and 84 percent, respectively. Focusing testing on newborns is less likely to prevent perinatal HIV transmission than efforts to (1) encourage pregnant women to seek testing during pregnancy, (2) encourage providers to increase prenatal voluntary counseling and testing, and (3) provide antiretroviral interventions to women during their pregnancy.

Based on data from all States, including New York, the *U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women* are being revised. The revised guidelines should be published in late summer and will strengthen the recommendations that all pregnant women be tested for HIV, emphasize HIV testing as a routine part of prenatal care, recommend that providers explore and address reasons for refusal of testing, and place more emphasis on HIV testing and treatment at the time of delivery for HIV-positive women who have not received prenatal testing and chemoprophylaxis.[16]

Question:

In CDC's "HIV Prevention Strategic Plan Through 2005" there is extensive discussions on the need to eliminate "stigma" associated with activities that place an individual at high risk for HIV transmission. It is our belief that, in many ways, our culture has actually stigmatized activities that do NOT increase HIV risk, such as abstinence and virginity. What efforts is the CDC making to address the stigmas associated with these healthy lifestyle choices?

Response:

CDC believes that abstinence is absolutely the best choice for adolescents, and abstinence should be the primary focus when counseling adolescents about sexuality issues. Many of CDC's materials address virginity and abstinence as strategies to prevent transmission of HIV, and CDC provides information on abstinence, delaying age of first intercourse, and monogamy along with other HIV prevention information. A list of selected documents that promote or encourage abstinence is attached.

Question:

On August 3, 2000, the CDC sent a letter to Reps. Tom Coburn, M.D. and Henry Waxman regarding steps being taken to better define behavioral risks for HIV acquisition and transmission. The concern is that the CDC's current "no identifiable risk" classification is biased against heterosexual transmission reporting, which could be detrimental to addressing the prevention needs of certain groups, particularly communities of color. Could you bring us up to date on what the CDC has done to address this disparity?

Response:

CDC has conducted the following activities to measure the accuracy and improve the completeness of surveillance risk information:

- Hosted a risk consultation in July 2000; planning a larger meeting in 2001 to identify the best scientific approaches to improving completeness and accuracy of risk information among persons with HIV or AIDS.
- Supported State and local surveillance programs in investigations of cases reported with no risk. Historical results of these investigations (through December 1999) show that cases among 16 percent of men and 68 percent of women initially reported without risk were probably heterosexually acquired.
- Conducted a risk validation study that found reclassification rates of persons initially reported with no risk were consistent with those from routine investigations. However, this study also found that 24 percent of men and 13 percent of women initially reported with heterosexual risk were misclassified. Taking into account the misclassification in both directions, the net effect (if all States could investigate such cases) would likely be

an underestimate of heterosexual transmission of about 1 percent among men and about 3 percent among women.[12]

In addition, in FY 2001, funding will be available for the following activities:

- Approximately $1.2 million in funds will be awarded competitively to 6 to 8 areas to evaluate integrated HIV/AIDS surveillance systems, including criteria to obtain risk data on 85 percent of cases or a representative sample.
- Approximately $1 million will be awarded to 10 or more areas for activities to improve the quality and completeness of HIV/AIDS surveillance data, including targeted record reviews and sampling strategies to obtain risk data. Two awards of $100,000 each will be targeted to American Indians and Asian Pacific Islanders to collect behavioral risk data.
- Approximately $1.7 million in funds will be competitively awarded to additional areas to collect behavioral risk data in at-risk and infected persons who are racial/ethnic minorities.

Finally, States were awarded nearly $2 million in supplemental funds in 2001 to enhance HIV/AIDS case reporting activities.

Question:

Could you elaborate on what areas of HIV prevention--both in the U.S. and abroad--you believe policy makers should pay most attention to during the 107th Congress?

Response:

Domestically, we believe we should focus on activities designed to achieve the goal outlined in CDC's HIV Strategic Plan, i.e., to cut new infections in half by 2005. In this regard, one important activity is the Serostatus Approach to Fighting the Epidemic (SAFE), CDC's prevention program for HIV-positive persons. SAFE expands current CDC programs to focus on the prevention needs of HIV-infected individuals, increases knowledge of HIV serostatus, and links people to care and prevention services. CDC is also concerned with the health status of young persons in our nation, especially the risk associated with three interrelated problems: HIV infection, other STDs, and teen pregnancy. As recently reported in CDC's June 1 *Morbidity and Mortality Weekly Report*, successive waves of young people are at risk for HIV, particularly young men who have sex with men. CDC's challenge is to bring our knowledge of effective prevention interventions to bear on populations who may not easily be reached or for whom HIV prevention may be less relevant than other pressing problems in their lives.

Internationally, we believe that it is critical to expand our HIV/AIDS prevention, care, and treatment efforts overseas. Through our Global AIDS Program, CDC is establishing programs in 24 countries in Africa, Asia, and Latin America to:

- Reduce HIV transmission through primary prevention of sexual, mother-to-child, and blood-borne transmission.
- Improve care and treatment of HIV/AIDS, STDs, and opportunistic infections.
- Strengthen the capacity of countries to collect and use surveillance data and to manage national HIV/AIDS programs.

Other important international efforts include operational research concerning the provision of antiretroviral drugs, as well as continued research to develop vaccines, microbicides, and inexpensive but effective interventions to prevent mother to child transmission.

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Selected documents in the National Prevention Information Network (NPIN) that promote or encourage abstinence:

Fact Sheet - Combating Complacency in HIV Prevention
CD Rom - CDC HIV/AIDS Information
Guidelines - Guidelines for Effective School Health Education to Prevent the Spread of AIDS
Brochure - Family Guide to HIV/AIDS Prevention (English and Spanish)
Information Kit - Business Responds to AIDS Manager's Kit
Information Kit - Labor responds to AIDS Manager's Kit
Fact Sheet - Primary HIV Infection Associated with Oral Transmission
Fact Sheet - What you need to know about Trichomoniasis
Fact Sheet - What you need to know about Gonorrhea
Brochure - Taking Action to Prevent AIDS
Guidelines - Compendium of HIV Prevention

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October 21, 1997

Ms. Helene D. Gayle, M.D., M.P.H.
Associate Director
Centers for Disease Control and Prevention
714B Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Gayle,

It has come to my attention through various sources that the Centers for Disease Control and Prevention (CDC) is developing HIV surveillance guidelines and that the agency will require states to enact mandatory name reporting of cases of HIV infection. One recent news report claimed that states had already received "a federal request to report cases of human immunodeficiency virus."

As you know, I believe that HIV reporting is essential in addressing the HIV/AIDS epidemic. By confidentially reporting cases of HIV instead of relying merely on cases of AIDS, we can more accurately determine the current extent of the epidemic as well as future trends, rates of progression, direction of spread, possible changes in transmissibility and other critical factors of disease control. Such information allows for the development of long-term prevention strategies based on reliable data. HIV reporting benefits those who are infected by providing a link to medical services and partner notification. It also allows us to develop more equitable allocations of government funding.

I would, thus, encourage the CDC to require that all states and cities receiving CDC funding implement HIV name reporting in as timely a manner as possible.

I would also request that I be informed of any decision regarding HIV reporting when it is made.

If you have any questions or if I can be of any assistance, please feel free to contact me or Roland Foster of my staff at (202) 225-2701.

Sincerely,

Tom A. Coburn, M.D.
Member of Congress

PRINTED ON RECYCLED PAPER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30333

January 23, 1998

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515

Dear Dr. Coburn:

Thank you for your letter concerning HIV name reporting. I apologize for the delay in responding to your letter.

CDC is working with States and territories to improve general surveillance to obtain the best data regarding changes in this epidemic. CDC has a long history of working closely and collaboratively with States and other partners to address surveillance needs; however, as you may know, there is increasing general agreement that national HIV case surveillance would facilitate marked improvements in prevention and treatment programs.

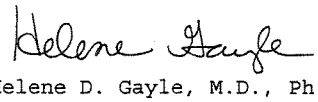
Consensus, however, has not been reached on the most acceptable and efficient way to conduct this expanded surveillance for HIV infection. In this regard, CDC proposes to extend national AIDS surveillance to include HIV infection case surveillance in all States and territories and is currently developing recommendations that will include performance standards and other technical guidance to assist all States and territories in implementing HIV case surveillance as an extension of their AIDS surveillance activities.

The January 9 *Morbidity and Mortality Weekly Report (MMWR)* entitled "Evaluation of HIV Case Surveillance Through the Use of Non-named Unique Identifiers--Maryland and Texas, 1994-1996" addresses the use of non-named HIV surveillance. The *MMWR* summarizes a 3-year collaboration by CDC and these States to evaluate non-named, unique identifier (UI) surveillance for HIV

infection. A copy of this *MMWR* is enclosed for your information. Also as requested, we will continue to keep you informed of our decisions regarding HIV reporting.

We appreciate your interest in and attention to public health measures to promote, monitor, and strengthen HIV prevention in the United States, and hope this information is helpful.

Sincerely yours,



Helene D. Gayle, M.D., Ph.D.
Director
National Center for HIV, STD,
and TB Prevention

Enclosure

CDC

January 9, 1998 / Vol. 46 / Nos. 52 & 53

MMWR™

MORBIDITY AND MORTALITY WEEKLY REPORT

1245 Update: Isolation of Avian Influenza A(H5N1) Viruses from Humans — Hong Kong, 1997–1998
1247 Rubella Among Crew Members of Commercial Cruise Ships
1250 Enhanced Medical Assessment Strategy for Barawan Somali Refugees — Kenya, 1997
1254 Evaluation of HIV Case Surveillance Through the Use of Non-Name Unique Identifiers — Maryland and Texas, 1994–1996

Evaluation of HIV Case Surveillance Through the Use of Non-Name Unique Identifiers — Maryland and Texas, 1994–1996

Notifiable disease reporting laws or regulations in states and territories require reporting of acquired immunodeficiency syndrome (AIDS) cases, including patient and physician names, to state or local health authorities. As of January 1, 1998, a total of 31 states were conducting name-based human immunodeficiency virus (HIV) case surveillance by using the same methods as surveillance for AIDS. However, because of concerns about name-based HIV surveillance, Maryland and Texas implemented HIV surveillance using non-name unique identifiers (UI)*. This report summarizes a 3-year collaboration by CDC and these states to evaluate UI surveillance for HIV infec-

*Reporting in Maryland is exempted for nonstate residents; persons who are tested at anonymous test sites; are blood, semen, or tissue donors; and participants of certain research projects. No exemptions to reporting exist in Texas.

HIV Case Surveillance — Continued

tion; the findings indicate some limitations to the use of a Social Security number-based UI for HIV surveillance.

In both Maryland and Texas, UI surveillance for HIV was implemented in early 1994, and both used the same 12-digit numeric UI code (comprising the last four digits of the patient's Social Security number [SSN], six-digit [month/day/year] date of birth [DOB], one-digit code for race/ethnicity, and one-digit code for sex). HIV-infection reports included residence data, diagnosing facility, and date of test, but did not include mode of HIV exposure. In both states, UI HIV surveillance databases were maintained separately from name-based AIDS surveillance databases.

Evaluation criteria included the proportion of reports with full UI codes, timeliness and completeness of HIV reporting, and potential for matching the UI-based case reports to alternate databases. In Texas, selected HIV reports also were evaluated for ability to follow back UI reports to patient records; in Maryland, provider compliance with maintaining patient surveillance logs was assessed. During July 1994–December 1996, Maryland reported 6412 AIDS cases and received 9971 HIV-infection reports, and Texas reported 12,041 AIDS cases and received approximately 23,000 HIV-infection reports.

Maryland

In 1993, the Maryland legislature mandated UI reporting of both positive HIV tests and patients with CD4+ T-lymphocyte counts of <200 cells/μL (CD4+)[†]. Health-care providers requesting HIV or CD4+ tests are required to construct the UI code for each patient, include the code on the laboratory slip, and record it in a surveillance log that matches the UI to patient identifiers (e.g., medical record number, patient name, or other patient code) for purposes of case investigation and follow up. Laboratories licensed by Maryland are required to submit the UI-based reports to the state health department through the local health departments.

Of 9971 HIV-infection reports entered during July 1994–December 1996, all UI elements were present for 7119 (71%) (Table 1). Element-specific presence ranged from 78% (SSN) to 98% (DOB and sex). The proportion of reports with full UI increased during July 1994–June 1996, and declined slightly during July–December 1996. The median time from date of HIV test to receipt of report by the state health department was 20 days (range: 1–847 days). During October–November 1997, all 72 providers in nine counties of eastern Maryland (the counties reported 3% of AIDS cases in Maryland in 1996) for whom laboratories had submitted HIV-infection reports were contacted to determine the proportion of providers who maintain the required surveillance log linking UI to patient identifiers; 32 (44%) of these providers maintained logs.

Completeness of HIV-infection reporting was estimated by comparison to cases of AIDS reported in the AIDS surveillance registry. Of AIDS cases with dates of HIV diagnosis from July 1995 through June 1996, data elements to construct UI were available for 633 (85%) cases. Of these, 319 (50%) matched to HIV-infection reports with full UI in the UI database (Table 2).

Data from the Maryland HIV counseling and testing (C&T) system (excluding sites offering only anonymous HIV tests) were used to evaluate the proportion of records

[†]HIV-infected persons with a CD4+ T-lymphocyte count of <200 cells/μL meet the 1993 expanded AIDS surveillance case definition and are reportable by name for AIDS surveillance.

HIV Case Surveillance — Continued

TABLE 1. Number of reports of HIV infection and percentage of reports that included data elements for unique identifiers (UIs), by reporting period — Maryland (MD) and Texas (TX), July 1994–December 1996

Reports/Data element	State	July–Dec. 1994	Jan.–June 1995	July–Dec. 1995	Jan.–June 1996	July–Dec. 1996	Overall
Total no. reports	MD	2,238	1,691	1,866	1,881	2,295	**9,971**
	TX*	3,932	3,399	3,597	2,852	2,339	**16,119**
Data element†							
Social Security number	MD	69.6	73.1	81.2	83.5	84.5	**78.4**
	TX	56.7	68.6	65.0	69.5	75.2	**66.0**
Date of birth	MD	95.2	96.3	98.7	99.3	98.8	**97.6**
	TX	88.4	89.8	93.1	96.8	97.6	**92.6**
Sex	MD	96.8	97.2	98.7	99.2	99.4	**98.3**
	TX	91.5	97.5	98.4	99.1	97.9	**96.6**
Race/Ethnicity	MD	85.8	88.5	91.6	94.0	89.9	**89.8**
	TX	80.8	91.6	94.4	97.1	95.4	**91.1**
% Reports with full UI	MD	61.3	65.9	74.9	78.5	76.5	**71.4**
	TX	51.8	61.9	61.6	66.5	71.3	**61.6**

*Excludes approximately 7000 records that had three or more missing UI data elements.
† Proportion of all reports containing specific UI data elements.

with full UI and completeness of HIV-infection reporting. In early 1995, counselors were instructed to obtain UI code information from clients and record the UI on the HIV C&T record. During 1995–1996, a total of 1093 records with a positive HIV test were entered into the C&T database; of these, all UI elements were present for 94%. HIV C&T reports for persons who had HIV diagnosed from July 1995 through June 1996 were matched to the UI database. Of the 528 reports, 276 (52%) matched.

Texas

In 1994, the Texas Board of Health amended regulations to require named reporting of HIV-infected children aged <13 years and UI reporting of HIV-infected adolescents and adults. Both health-care providers ordering an HIV test and laboratories performing the test report confirmed HIV infections to the Texas Department of Health (TDH) through the local health departments. Neither providers nor laboratories are required to maintain registries linking UI to patient identifiers.

Approximately 23,000 HIV-infection reports were received at TDH during the evaluation period. Since 1995, TDH excluded approximately 7000 paper HIV reports with three or more missing UI data elements. Of 16,119 HIV-infection reports entered into the UI database, all UI elements were present for 9923 (62%) (Table 1). Element-specific presence ranged from 66% (SSN) to 97% (sex). Overall, 60% of reports were submitted in periodic batches, which had a longer time from date of HIV test to receipt by TDH (median: 173 days; range: 26–974 days) than the 40% of reports submitted individually (median: 59 days; range: 2–906 days).

Completeness of HIV-infection reporting was estimated by comparison to AIDS surveillance data using the same methodology as in Maryland. Data elements to construct UI were available for 1762 (79%) of AIDS cases with dates of HIV diagnosis in the

HIV Case Surveillance — Continued

TABLE 2. Percentage completeness of HIV-infection reporting, availability of unique identifier (UI) data elements in alternate databases, and sources of report — Maryland and Texas, July 1994–December 1996

Characteristic	Maryland (n=9,971)	Texas (n=16,119)
Completeness of reporting		
HIV*	50.4	26.0
CD4+ T-lymphocyte count*	44.4	NA†
HIV§	52.3	NA
Availability of UI data elements in alternate databases		
Birth¶	No	No
Death	Yes	Yes
Sexually transmitted disease	No	No
Tuberculosis	No	No
Drug assistance**	Yes	Yes
Medical assistance††	Yes	No
Hospital discharge	No	No
Source of HIV report		
Public	30%§§	77%§§
Private	70%¶¶	23%***

*AIDS cases reported through July 1997 compared with the UI database.
†Not available.
§HIV cases diagnosed from July 1995 through June 1996 in HIV counseling and testing sites compared with the UI database.
¶Used for pediatric AIDS surveillance only.
**Federal- and state-funded medication program.
††Federal- and state-funded medical-assistance program.
§§Includes local health departments and state laboratory.
¶¶Includes community-based organizations and private clinics and laboratories.
***Includes community-based organizations, hospitals, private physicians, clinics, and laboratories.

specified period (Table 2). Of these, 454 (26%) matched to HIV-infection reports with full UI in the UI database.

To evaluate the feasibility of epidemiologic follow up, TDH sampled 765 HIV-infection reports submitted during January 1995–June 1996, in six areas of the state, reflective of variation in geography, demography, HIV morbidity, and reporting sources. Of these, 456 (60%) could be matched to a client record using any combination of UI (including records without full UI), health-care provider name, date of test, residential information, and other locally available information. Matched records that were missing the SSN data element (n=208) were reviewed to determine whether these data could be located. SSN could not be located for 120 (58%) of these records.

Reported by: L Solomon, DrPH, L Eldred, DrPH, J Markowitz, PhD, P Ryan, MS, G Benjamin, MD, Maryland Dept of Health and Mental Hygiene. AS Robbins, PhD, DW Hamaker, SA King, MA, SK Melville, MD, MC Thomas, MS, DM Simpson, MD, State Epidemiologist, Texas Dept of Health. Div of HIV/AIDS Prevention–Surveillance and Epidemiology, National Center for HIV, STD, and TB Prevention, CDC.

HIV Case Surveillance — Continued

Editorial Note: HIV and AIDS surveillance data are needed to provide reliable population-based data to guide public health programs. During 1995–1996, the first declines in the incidence of AIDS-opportunistic infections and AIDS deaths were reported in the United States (6% and 23%, respectively), in part, as a result of increasingly effective HIV therapy (*1*). On the basis of revised HIV treatment guidelines (*2*), the impact of treatment advances on AIDS trends is expected to continue and will reduce the usefulness of AIDS data alone to monitor HIV-infection trends and morbidity. CDC and other public health and advocacy organizations have recognized the need for national HIV case surveillance while continuing to discuss the relative merits of HIV surveillance methods based on numeric codes compared to the name-based approach employed for AIDS surveillance (*1,3*).

CDC uses established criteria to evaluate performance of public health surveillance systems to provide accurate data to target prevention and care programs (*4*). States conduct active surveillance using existing name-based clinical and public health records to decrease the reporting burden on providers, eliminate duplicate reports, and facilitate epidemiologic follow-up. These methods enable AIDS surveillance to attain high performance standards as reflected by completeness of reporting (>85%) (*5*) and documentation of risk exposures (≥93% of cases) (*6*). Evaluation of name-based HIV surveillance has shown 74%–97% completeness of reporting (*7*; CDC, unpublished data, 1997), and documentation of risk exposures (≥76% of cases) (*6*). Secure and confidential surveillance practices are required as a condition for receipt of federal resources for HIV and AIDS surveillance. At the state level, the most comprehensive protections of medical data apply to government-held data, and most specifically to HIV-related data (*8*). Names are removed before encoded and encrypted AIDS or HIV surveillance data are transmitted to CDC.

The evaluations in Maryland and Texas indicated that the use of UIs limits the performance of an HIV surveillance system and complicates efforts to collect risk-behavior information. Both systems demonstrated timely reporting. Although data from both states indicated increases in reporting of the SSN data element during the evaluation period, overall 22% of reports in Maryland and 34% in Texas were missing the SSN element, which contributed to a high rate of incomplete case reporting. The follow-back investigation in Texas suggests that SSNs are not readily available in client or medical records but, in the controlled environment of the Maryland HIV C&T system, counselors were able to collect SSNs for most clients. The completeness of reporting also may be affected by the ability of providers and laboratories to use UIs as part of routine HIV-testing practices. For example, one large laboratory providing HIV-testing services in Maryland did not report HIV infections during the evaluation period. The difficulty in collecting HIV data when persons are tested out of state also may affect completeness of reporting and the ability to eliminate duplicate reports. Maryland is continuing to evaluate its UI surveillance system, and Texas is exploring alternative HIV surveillance systems with input from community groups.

Effective HIV surveillance systems must include HIV risk information; however, this information often is not available at the time of the initial UI case report, and follow-up with health-care providers is necessary. To supply follow-up information, health-care providers must use lists or other mechanisms to link the UI to patient identifiers. The UI approach complicates efforts to collect this information and increases the number of lists of HIV-infected persons that could be disclosed in a breach of confidentiality.

(Continued on page 1271)

HIV Case Surveillance — Continued

CDC has recommended that all states and territories conduct HIV case surveillance as an extension of their AIDS surveillance systems (*1*). In addition, CDC is developing technical guidance to enhance security practices, standardize confidentiality laws and regulations, and promote uniform standards for HIV case surveillance systems. These guidelines will assist states and territories in implementing HIV case surveillance using data-collection and data-storage methods that provide high quality HIV surveillance data while assuring the confidentiality of surveillance information.

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June 19, 1998

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20515

Dear Secretary Shalala,

It has come to my attention that the Centers for Disease Control and Prevention has developed HIV surveillance guidelines for the states but the issuance of these has been delayed by your Department.

It is my understanding that these guidelines were forwarded to HHS several weeks ago and have since been stalled within the Department. To my knowledge, the issuance of guidance recommendations to the states by the CDC in the past has been conducted in a timely manner as a relatively routine practice. These guidelines should be treated in the same.

I have heard that state health departments have been awaiting these directives and have grown increasingly frustrated with the unduly delay. Like many in the public health community, I believe the issuance of guidance from CDC will assist in the development of improved surveillance and inevitably save lives.

I would request that the Department release the CDC's HIV surveillance guidelines immediately. If the Department is not prepared to issue these guidelines at this time, I would like to know why.

Thank you for your attention to this matter. I look forward to hearing from you soon. If you have any questions, please feel free to contact me or Roland Foster of my staff at (202) 225-2701.

Sincerely yours,

Tom

Tom A. Coburn, MD
Member of Congress

cc: Thomas J. Bliley, Jr.
Chairman, House Committee on Commerce

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

SEP 25 1998

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515-3602

Dear Dr. Coburn:

Thank you for your letter regarding the issuance of new Federal guidelines for national HIV surveillance. I apologize for the delay in responding.

As you may know, discussions with our Federal, State, and local partners have been underway for many months regarding the draft guidelines. Through this process, we have learned a great deal and appreciate the input from our many colleagues and partners. We are making every effort to complete the necessary steps regarding this complex issue, and we anticipate publication of the proposed guidelines in the *Federal Register* (*FR*) as soon as those steps are completed. A period for public comment will follow publication of the proposed guidelines in the *FR*. Please be assured that all of the concerns you have raised in your letter, and those received during the public comment period, will be carefully considered in the formulation of new recommended guidelines for HIV surveillance.

Thank you for your interest in this important public health matter.

Sincerely,

Donna E. Shalala

Donna E. Shalala

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

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December 14, 1998

Technical Information and Communications Branch
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Centers for Disease Control and Prevention
Atlanta, GA 30333

To whom it may concern:

As both a practicing physician and a member of Congress, I applaud the CDC's decision to require states to conduct HIV surveillance. Effective HIV case reporting by all states will provide more accurate information about disease trends and ensure enhanced targeting of prevention and care services.

I would recommend that the final guidelines for HIV Case Surveillance require rather than merely recommend states to conduct name-based reporting linked with partner notification.

Name reporting provides a much more accurate and reliable system to link populations affected by HIV with preventive and medical services than code-based reporting. This is extremely important since we now have the ability to help many of those who are infected with HIV stay healthy longer if they are identified early. With name reporting and partner notification, more individuals in this critical early stage of infection will be identified and linked with optimal medical care.

As you know, the CDC concluded earlier this year that tracking HIV by using names is more reliable, efficient and accurate than by using unique identifier (UI) codes. A CDC study "revealed several problems with the UI systems, including a high number of reports with incomplete codes (approximately 30- 40%), low rates of completeness in reporting (approximately 25- 50% complete), difficulty in conducting follow-up on specific cases, and the absence of behavioral risk data in this system."

Texas, one of the only two states which currently utilize UIs, recently concluded that "it appears that name-based reporting is the best system to provide both accurate information on the epidemic and the ability to follow-up on reports of infection" and is in the process of switching to a name-based system. With the exception then of Maryland, every state with HIV surveillance currently uses a name-based system.

Contrary to the claims of AIDS activists, UIs may not protect patients' confidentiality any better than name-reporting systems. In order to provide follow-up information, health care providers need to use lists or other means to link the patient with the UI. "The UI approach

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complicates efforts to collect this information and increases the number of lists of HIV-infected persons that could be disclosed in a breach of confidentiality," according to the CDC report.

AIDS activists have also inaccurately claimed that names-based HIV reporting has been found to deter individuals, particularly those at highest risk for HIV infection, from testing for and treatment of HIV. CDC supported the University of California at San Francisco and nine state health departments to survey high-risk persons about the perceptions and knowledge of HIV testing and HIV reporting practices. In this survey, only 15% of the respondents knew whether HIV infection was reportable to the health department in their state of residence. When asked about factors that may have delayed their seeking HIV testing, only 2% of the respondents surveyed cited "reporting to the government" as the main reason.

CDC and six health departments reviewed data routinely collected from public-funded HIV counseling and testing sites to compare HIV testing patterns in the 12 months before and the 12 months after the implementation of HIV name reporting. In these areas, the number of HIV tests increased in three states (16- 63%), remained level in two states (-2%, 5%), and decreased in one state (-11%). The state with a decline in HIV testing during the evaluation period had a decreasing trend in HIV tests before HIV surveillance was implemented.

It should be noted that every state requires the reporting by name of individuals diagnosed with AIDS, which is merely the end stage of HIV infection. This has been done for over a decade without breaches of confidentiality or deterring individuals from being tested. Local health departments have successfully protected the identities of over 641,000 individuals who's names have been reported in the first 17 years of the epidemic.

Such success protecting confidentiality would indicate that anonymous testing, which prevents both surveillance and partner notification, is unnecessary and counter-productive to effective prevention efforts. Evidence suggests that eliminating anonymous testing does not discourage testing. In fact, when anonymous testing was eliminated in North Carolina, HIV testing increased by 45%.

Finally, I would strongly recommend that the CDC link HIV case surveillance with partner notification programs. Partner notification is extremely important to disease control because it is the only timely way to alert those in danger of infection. It is the standard public health procedure for curtailing the spread of virtually all other sexually transmitted diseases and has been credited in part for the fact that syphilis cases in the U.S. have fallen to the lowest levels in history. Therefore, effective HIV prevention should involve both HIV surveillance and partner notification.

Thank you for considering my recommendations and please do not hesitate to contact me if I can be of any further assistance.

Sincerely yours,

Tom

Tom A. Coburn, MD
Member of Congress

http://www.latimes.com/news/local/la-me-hiv25jul25,0,4674808.story?coll=la-home-local

July 25, 2005

HIV Tracking System May Be Scrapped

California uses codes instead of names to protect patient privacy, but even some former supporters say coding is too cumbersome.

By Charles Ornstein
Times Staff Writer

It was heralded as a way for California to closely track the spread of HIV without compromising patient privacy or civil rights. Rather than reporting infected patients by name, public health agencies would identify them by codes.

Despite its lofty intentions, however, California's 3-year-old reporting system for the human immunodeficiency virus has become a bureaucratic morass.

Laboratories are reporting incomplete or erroneous codes to health departments. Doctors' offices aren't keeping required logs of their HIV-positive patients. Public health officials say their backlog of cases numbers in the thousands as they spend hours chasing bad information.

Countless cases are believed to be lost in the system. As a result, health authorities throughout the state say they cannot effectively monitor the epidemic or direct scarce dollars where they are most needed.

"We've done our best to make this system succeed," said Gordon Bunch, director of the HIV epidemiology program at the Los Angeles

County Department of Health Services. "Despite our best effort, it has failed."

Even some original supporters of the code system, which was implemented in July 2002, say it is inevitable that the state will have to scrap it and start over.

The U.S. Centers for Disease Control and Prevention does not consider codes accurate enough, and federal officials are poised to withhold funding from states that rely on them.

California ultimately stands to lose up to $50 million annually in federal money designated to treat HIV patients and prevent the spread of the virus, a state task force estimated last year.

Michael Montgomery, chief of the state Office of AIDS, strongly backed the code system at first, but since has come to believe that a names-reporting system would work better.

"It's just a question of when we do it," Montgomery said about the switch.

California took an unusual — and more expensive — approach in choosing to track HIV differently from other diseases. Every other reportable disease is tracked by name in a confidential database. That includes full-blown AIDS cases, which are caused by HIV and can develop 10 or more years after HIV infection.

Because AIDS cases often take so long to progress, they are not necessarily a good indicator of current HIV infection patterns.

Just seven states and the District of Columbia track HIV strictly by alphanumeric codes. California is the only state among the five largest that uses an HIV reporting system that differs from the way it tracks AIDS, acquired immune deficiency syndrome.

Under the current reporting system, laboratories and doctors that test patients report HIV-positive cases to county health departments using codes that include birthdates, gender and elements of a person's last name. The counties, in turn, report their coded data to the state,

which passes the information to the federal government.

The decision to track HIV this way came after several years of contentious debate. The California Legislature sided with those who raised concerns about possible breaches of patient privacy and resulting discrimination.

Code supporters argued that the very prospect of a leak would keep many people from being tested for HIV.

That mistrust persists among patients today, said Dr. Michael Gottlieb, a prominent Los Angeles physician who has been treating HIV-infected patients for the life of the epidemic. Their concerns are not unfounded, he said, because a "significant stigma" continues to be attached to gays and drug users, who are disproportionately affected by HIV.

And names-reporting systems have suffered security breaches elsewhere, Gottlieb and others said. He cited an incident this year in Palm Beach County, Fla., in which a confidential list of HIV/AIDS patients was mistakenly e-mailed to 800 health department employees.

"I'm uncomfortable with the state having names," Gottlieb said. "It's a potentially very damaging list."

But California public health authorities say they have taken sufficient measures to guard against such breaches. And after three years, they say, they have enough experience to conclude that codes don't work.

Codes have made it difficult, and in some cases impossible, for county health officials to exchange information with doctors, eliminate duplicative reports and link HIV with reports of other diseases, these critics say.

The existing system also has hampered follow-up and nullified the option of tracking and notifying the sexual partners of a person who tests positive.

Several advocacy groups for HIV patients in California have held out hope that the federal government would decide to accept data from the state's code-based system and keep its funding intact. But even they acknowledge the chances of that are almost nil.

Earlier this month, the director of the CDC issued a public letter saying it is critical that all states move as quickly as possible to a names-based HIV reporting system because the country needs a "single, accurate system that can provide national data to monitor the scope of the HIV/AIDS epidemic."

Some Republicans in Congress have added to the pressure.

"I'm just telling you — it's a terrible system," said Sen. Tom Coburn (R-Okla.) a physician and one of the strongest opponents of coded reporting.

"It's not accurate and it's not going to accomplish what it needs to accomplish. California is at risk of losing a ton of money to help the very people" that they contend that they want to help, he said.

California would not be the first state to drop its codes. Texas and Kentucky have made the switch, hoping to maintain federal funding and more easily track the epidemic.

A bill in the California Legislature that would have required switching to names reporting stalled earlier this year, but state officials and advocacy groups predicted it would be resurrected before long.

"I wouldn't be surprised to see this conversation revisited very soon in Sacramento," said Darrel Cummings, chief of staff for the Los Angeles Gay & Lesbian Center, an initial opponent of names reporting.

Cummings said the center has consulted legal experts to ensure that any names-based system would protect patient confidentiality.

Between July 2002 and last month, the state received 37,937 reports of patients with HIV, considerably fewer than the 80,000 HIV cases once estimated statewide.

It is believed that a quarter to a third of those who are infected do not know it, so the difference does not entirely result from reporting flaws.

Through the end of June, Los Angeles County had reported 13,914 HIV cases to the state, according to the California Department of Health Services. But the county still has a backlog of nearly 10,000 potential cases to be investigated, said Dr. Douglas Frye, medical director of the county's HIV epidemiology unit.

Frye said the cumbersome nature of the code system has prevented the county from looking into possible HIV cases quickly and reporting them to the state promptly. Each potential case is taking, on average, a year to investigate, more than twice the goal.

"We're whittling it down, but it's very slow," he said.

Montgomery, the state AIDS director, says it's time to admit the experiment has failed.

"It really creates a labor-intensive and burdensome system that makes it very difficult for health departments to carry out their responsibilities," he said.

Health agencies have had problems even when they have dispatched staff to individual doctors' offices to collect data from medical records. Public health workers have only the codes as a reference, and many of the doctors' offices keep track of their cases primarily by names. Without a log matching the two, finding the records can take hours.

At one doctor's office in San Francisco, 35 cases have been locked out of the state reporting system because officials were unable to match codes with patients' records.

Even so, public health staffers find that up to half the time cases they've been sent to investigate match one already reported.

San Francisco had reported 5,753 cases as of last month but still has 2,500 waiting to be investigated. Some of those involve duplicate reports, but officials can't say how many.

"I think it's a waste of money, personally, to put resources into a reporting system that doesn't really function very well," said Dr. Sandra Schwarcz, director of the HIV/AIDS epidemiology section of the San Francisco Department of Public Health.

Still, some lawmakers resist the switch to names reporting. They say it isn't clear to them that the state will lose federal funding. Should that change, they say, they will relent.

"I did not want California to become the poster child for the Bush administration's switch to names reporting," said state Sen. Sheila Kuehl (D-Santa Monica). "We need to really see that the funding is tied to" the switch.

Montgomery said there is no room for delay, because it can take four years for a new system to get off the ground and for the data to be accepted by the CDC.

Opponents "are not fully appreciating the temperature in Washington and what the intention of Congress is," he said. "I think we're going to be hurt."

Los Angeles Times
July 31, 2004

CALIFORNIA PERFORMANCE REVIEW

Targeted Areas: Human Services

A proposal to track new HIV cases by name instead of code could be the most vexing part of a health system overhaul.

By Carla Rivera
LA Times Staff Writer

Using names to track new HIV cases rather than anonymous codes is likely to provoke one of the most emotional debates among the proposals to reorganize the state's vast health and welfare system.

Concerns over protecting patients' privacy had already created divisions among medical professionals and activists.

In 2002, public health officials began requiring doctors and laboratories to report new HIV cases to the state using a unique identifier — an alphanumeric code — rather than a name.

But the code-based system is "labor intensive, less accurate and more complex than the name-based system" and puts at risk $50 million in federal funding, the government-streamlining panel concluded.

The plan noted that 36 other states use name-based reporting and that California is the only state among the five largest that requires codes for HIV reporting and names for reporting AIDS patients.

The State Office of AIDS lacks the money to even evaluate its current reporting system and show that it meets criteria established by the national Centers for Disease Control and Prevention, the report concluded. The CDC considers code-based data to be unreliable.

Some medical professionals and AIDS activists endorsed the change Friday, saying the code-based system is too cumbersome and that doctors and laboratories are not reporting cases because of the added paperwork.

"The purpose of epidemiology is to track diseases and to find hotspots, and from that standpoint the current system is unworkable," said Michael Weinstein, president of the AIDS Healthcare Foundation, which runs 12 HIV clinics in California. "The unique identifier is complicated to report, and it's hard to determine whether a person is being counted twice."

But others contended that using patients' names would compromise confidentiality and make them less likely to get tested.

"We need to do everything we can to encourage people to get tested, and there are people at risk who would not with a names-based system," said Fred Dillon, director of policy and communications for the San Francisco AIDS Foundation. "Even with name reporting, many jurisdictions say they don't have the time to report, so to say this would fix the system completely is false."

Health and human services is the state's second-largest area of expenditure, encompassing $24.6 billion in general fund money and 29,700 employees.

To save money and improve efficiency, the panel proposed fundamental changes in services for children, the disabled, elderly, welfare recipients and child-care providers.

HHS14 Make California's HIV Reporting System Consistent With its AIDS Reporting System, and Improve AIDS Reporting

Summary
California uses a code-based system for reporting Human Immunodeficiency Virus (HIV) cases and a name-based system for reporting cases of Acquired Immunodeficiency Syndrome (AIDS). The code-based system is labor intensive, less accurate and more complex than the name-based system and risks the loss of federal funding. California should make its HIV reporting system consistent with its name-based AIDS reporting system, and improve its AIDS reporting to identify additional unreported cases.

Background
Public health officials use disease reporting to monitor public health, develop prevention strategies, set priorities and evaluate programs, allocate resources and facilitate research. [1] California requires health care providers to confidentially report more than 80 diseases and conditions to local health officers. [2] All states require reporting of HIV and AIDS. [3] All states use confidential name-based systems for reporting AIDS and all other reportable diseases and conditions, except HIV.

AIDS has been reportable in California for more than 20 years. Since AIDS cases represent later stages of the disease, AIDS data are less useful than HIV data for public health professionals to monitor the epidemic, and target and evaluate prevention programs. [4] Public health professionals need accurate HIV case data in addition to AIDS data to assess the spread and impact of the HIV/AIDS epidemic. California responded to this need by implementing codebased HIV reporting in July 2002. Local health departments have already reported almost 31,000 cases of HIV, representing more than 35 percent of reported cases of individuals living with HIV/AIDS in California. [5] California is one of only seven states that have an HIV reporting system that is solely code-based.

AIDS reporting system
Local health departments identify between 95 and 98 percent of California's AIDS cases through active surveillance. [6] Local health departments actively seek case information from health care providers and other data sources, complete the case report form, assure the accuracy and completeness of the data, and forward the data to the state's HIV/AIDS Case Registry. [7] State health staff verify data accuracy and forward the information to the Centers for Disease Control (CDC) using a secure, electronic data system. [8] The HIV/AIDS Case Registry and local health departments rely on patient names and other data elements for epidemiologic follow-up and to assure the accuracy and uniqueness of each case. The AIDS reporting system is confidential in that only authorized public health staff has access to patient names, which are protected with security systems at the federal, state and local levels.

Implementation of HIV reporting

California law prohibits name-based HIV reporting, and previous attempts to change this through legislation and ballot initiative have failed. [9] California HIV/AIDS advocates have strongly opposed any form of name-based HIV reporting in the past due to confidentiality concerns, but supported a code-based system for HIV cases. Legislation that would have codified such a system failed to pass. [10] In 1999, California began developing regulations to create a code-based HIV reporting system and implemented HIV reporting on July 1, 2002.

Thirty-six states have implemented name-based HIV reporting, five use name-to-code systems, two allow client choice of name or code and seven, including California, use a code-only system. [11] Texas, Puerto Rico and Kentucky, which used code-based HIV reporting systems, have changed to name-based systems. [12]

Threat to federal funding

California received more than $223 million in Ryan White Comprehensive AIDS Resources and Emergency (CARE) Act funds in Federal Fiscal Year (FFY) 2004 for Titles I and II, of which approximately $174 million is by formula that uses AIDS case data. [13] Beginning as early as FFY 2005 and no later than FFY 2007, the federal government will include CDC-confirmed HIV case data in the Ryan White CARE Act funding formula. [14] CDC considers HIV data from codebased systems to be unreliable and will not accept the data and is unlikely to confirm them for use in allocating Ryan White funds. [15] If the federal government does not include California's HIV data and relies solely on its AIDS data, it could cost the state up to $50 million annually in Ryan White CARE Act funds and cause reduced services to clients. [16]

California is the only state among the five largest that uses an HIV reporting system different than its AIDS reporting system. [17] The other four, New York, Florida, Texas, and New Jersey, use name-based HIV reporting systems and will have an advantage over California when CDC confirms their HIV data for the Ryan White funding formula. By not changing to a name-based HIV reporting system, California risks losing its fair share of Ryan White CARE Act funds when the funding formula changes.

If California chooses to retain its code-based HIV reporting system and secure its fair share of federal funds, it must demonstrate that its system meets CDC criteria and negotiate acceptance of its data. The original budget for HIV reporting included $235,000 for evaluation, and the State Office of AIDS recently estimated that it could cost up to $500,000 to formally evaluate the system and determine whether the system meets CDC's minimum performance standards for completeness, timeliness, accuracy and risk information. [18] However, the Office of AIDS does not have funds available to evaluate its HIV reporting system.

Code-based HIV reporting is unnecessarily burdensome

Under the current system, laboratories must create partial codes and providers must complete them. Providers and laboratories find the code-based HIV reporting system confusing and more time intensive than the name-based AIDS reporting system. Furthermore, the code-based system is prone to error and makes it difficult for local health departments to follow up with providers and complete case reports in

a timely manner. [19]

Local health departments must often provide technical assistance to providers on the correct method of reporting cases and completing forms. This means that local health department staff may see client names in the course of ensuring proper record matching and completion of case reports. If the local health department staff cannot see the records, they must rely on the providers. Providers are generally unwilling to do the matching because of workload concerns and complexity.

The State Office of AIDS staff must work with local health departments to ensure data accuracy prior to forwarding data to CDC, and the code-based HIV reporting system requires more work than a name-based system to resolve accuracy and duplicate reporting issues. The Office of AIDS has lost positions and funding to support code-based HIV reporting as well as AIDS reporting. [20]

Concerns about name-based HIV reporting
Opponents of name-based HIV reporting express concerns about confidentiality, but the HIV reporting system has the same measures that protect the confidentiality of AIDS case reporting. California has statutory protections for public health records, which the state has enhanced for HIV and AIDS, and state and local health departments must adhere to federal security and confidentiality standards. California has had no documented or reported cases of illegal or inappropriate disclosure of case information from the state's AIDS Case Registry.

Advocates are also concerned that a name-based system will deter people from HIV testing. However, no states with name-based HIV reporting systems have seen sustained patterns of lower HIV testing after implementation. Advocates raised this concern about implementing a code-based system in California, but there has been no decline in HIV testing in the state since reporting began in July 2002. [21] Finally, Californians still have access to anonymous testing sites in which healthcare providers do not know the name of the client and are also exempt from HIV reporting. [22]

Implementing name-based HIV reporting and improving AIDS reporting
No additional resources are needed to make the HIV reporting system consistent with the AIDS reporting system. The name-based AIDS reporting system is already in place, and the HIV cases are reported in the same database. California can change the HIV reporting system and all providers, laboratories and the state and local health departments can fully convert to the name-based system within six months. State and local health staff would update the current code-based files as new data are received, which state staff estimated they could complete within 12 months. [23]

California has not maximized opportunities to improve its reporting of AIDS (non-HIV) cases. Physicians currently monitor CD4+ cell counts, an element of the body's immune response system, to determine the impact of HIV on a person's immune system. [24] Lab reporting of low CD4+ counts is an excellent source of data for potential unreported AIDS cases, and California is one of only 13 states that do not require it. [25] Low CD4+ reporting will identify unreported AIDS cases and will help California qualify for additional federal funds.

Recommendations

A. **The Governor should work with the Legislature to expressly permit name-based HIV reporting.**

B. **Following passage of legislation to implement name-based HIV reporting, the Department of Health and Human Services should amend the California Code of Regulations for disease reporting to repeal the current HIV reporting regulations, which require a non-name code and add HIV to the regulation that allows confidential reporting of all other diseases, including AIDS, by name.**

C. **The Department of Health Services, or its successor, should amend the California Code of Regulations for disease reporting to add laboratory reporting of low CD4+ counts to local health departments no later than July 1, 2005.**

Fiscal Impact
Using the FFY 2004 formula appropriations as the funding base, the state risks a loss of up to $50 million annually in Ryan White CARE Act funds if the CDC does not confirm California's (and other code-based states) reported HIV cases for FFY 2007. [26] Using the CDC's data estimates for June 2000, California's estimated living HIV cases represent a range of 39 to 49 percent of the state's combined HIV and AIDS cases. This represents a substantial contribution to a revised CARE Act funding formula. [27] California can prevent this loss if it conforms its HIV reporting system to its name-based AIDS reporting system. [28]

California will avoid an approximate cost of $235,000 to $500,000 needed to evaluate its codebased HIV reporting system. [29] Without a demonstration that California's HIV reporting system meets its criteria, CDC will not consider accepting data from any states with code-based systems.

California will improve the business climate for providers and laboratories that have experienced additional workload caused by a code-based system. State and local health department staff will realize workload efficiencies and can devote more time to ensuring accuracy of information and improving timeliness of HIV and AIDS reporting. The savings cannot be estimated at this time.

The state can implement these recommendations within existing resources.

Endnotes
[1] Centers for Disease Control and Prevention, "Overview of Public Health Surveillance," by Denise Koo, MD, MPH http://www.pitt.edu/~super1/lecture/lec3011/005.htm (last visited May 7, 2004) (slide presentation).
[2] California Code of Regulations, Title 17, Division 1, Chapter 4, Subchapter 1, Article 1.
[3] The Institute of Medicine of the National Academies, "Measuring What Matters: Allocation, Planning and Quality Assessment for the Ryan White CARE Act" (Washington, D.C. 2003), pp. 76-80. All states implemented AIDS reporting in the early 1980s. States implemented HIV reporting over an 18-year period with the first states beginning in 1985 and the last state beginning in 2003.
[4] National Alliance of State and Territorial AIDS Directors, "HIV Prevention Fact Sheet, The AIDS Continuum," Washington, D.C., May 2002 (fact sheet); and National Alliance of State and Territorial AIDS

Directors, "HIV Prevention Fact Sheet, HIV Surveillance," Washington, D.C., May 2002 (fact sheet). The time from HIV infection to AIDS can average 10 years and ranges from 5 to 20 years.
[5] Department of Health Services, Office of AIDS, "California HIV Case Surveillance Report "(April 30, 2004), http://dhs.ca.gov/ps/ooa/Statistics/pdf/Stats2004/apr04HIVmerged.pdf (last visited June 7, 2004); and Department of Health Services, "AIDS Surveillance Report for California" (April 30, 2004), http://dhs.ca.gov/ps/ooa/Statistics/pdf/Stats2004/apr04AIDSmerged.pdf (last visited June 7, 2004).
[6] E-mail from Juan Ruiz, acting chief, HIV/AIDS Epidemiology Branch, California Department of Health Services, Office of AIDS (April 15, 2004).
[7] California Code of Regulations, Title 17, Division 1, Chapter 4, Subchapter 1, Article 3.5, Section 2653.15.
[8] Centers for Disease Control and Prevention, "CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome, Morbidity and Mortality Weekly Report" (December 10, 1999), http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm (last visited June 15, 2004), pp. 10-11. Before sending the data to the CDC, state staff removes all personal identifiers. To help the CDC compare AIDS case data to what already exists in its databases, states and territories generate a 4-digit code from the patient's last name using the Soundex system. The CDC uses Soundex and date of birth to match and unduplicate cases to assure an accurate, unduplicated count for each state and territory. The CDC works with states to resolve potential duplicate cases since it does not have identifying information. 374 Issues and Recommendations
[9] Health & S. C. Section 120975. California statute permits disclosure under specified conditions but not for public health disease reporting.
[10] State of California, Legislative Counsel, "Official California Legislative Information" (AB 1663 veto message) http://www.leginfo.ca.gov/pub/97-98/bill/asm/ab_1651-1700/ab_1663_vt_19980929.html (last visited June 15, 2004); and State of California, Legislative Counsel, "Official California Legislative Information," (AB 103 veto message) http://www.leginfo.ca.gov/pub/99-00/bill/asm/ab_0101-0150/ab_103_vt_19991010.html (last visited June 15, 2004). Governor Pete Wilson vetoed AB 1663 in 1998 stating that a code-based system was inadequate. Governor Gray Davis vetoed AB 103 in 1999 and recommended the department seek federal assistance to fully fund the costs of a code-based system. California did not receive federal funding for the code-based system and subsequently appropriated $2.8 million from the General Fund to implement it.
[11] The Institute of Medicine of the National Academies, "Measuring What Matters: Allocation, Planning and Quality Assessment for the Ryan White CARE Act," pp. 76-80. Name-to-code systems collect and use the clients' names to match and unduplicate case reports, then convert to a code and destroy the names within a specified period of time. Besides California, the code-based states are Hawaii, Illinois, Maryland, Massachusetts, Rhode Island, and Vermont. Delaware, Maine, Montana, Oregon and Washington use name-to-code systems. Connecticut and New Hampshire allow use of name or code.
[12] Commonwealth of Kentucky, General Assembly, 2004 Regular Session, House Bill 82 (04 RS HB 82/EN), http://www.lrc.ky.gov/record/04rs/hb82.htm (last visited June 15, 2004). Kentucky will change its code-based HIV reporting system to a name-based system effective January 1, 2005; and the Institute of Medicine of the National Academies, "Measuring What Matters: Allocation, Planning and Quality Assessment for the Ryan White CARE Act," p. 80. Texas and Puerto Rico changed to a name-based HIV reporting system in January 1999 and January 2003 respectively.
[13] Department of Health Services, Office of AIDS, "CARE Act Consolidated Funding-All Titles Sorted by Alpha Order" (Sacramento, California, April 27, 2004). California's nine Title I Eligible Metropolitan Areas received $102 million in Ryan White funds for FY2004, and the State received $121 million in Title II funds in FY2004.
[14] Health Services and Resources Administration, HIV/AIDS Bureau, "A Compilation of the Ryan White CARE Act of 2000," Sections 2603(a)(3)(C)(i)-2603(a)(3)(D)(ii), http://hab.hrsa.gov/law/compile.htm (last visited May 10, 2004).
[15] Interview with Dr. Robert Janssen and staff, Centers for Disease Control and Prevention, National Center for HIV, STD and TB Prevention, Division of HIV/AIDS Prevention-Surveillance and Epidemiology, Atlanta, Georgia, April 28, 2004. CDC staff says that it would take six years to develop standard mechanisms to evaluate code-based HIV reporting systems, conduct evaluations, conduct studies for unduplicating interstate data, and implement the findings. The CDC staff states that this process is necessary for confirming HIV cases from code-based systems, and they do not have the resources to do this.
[16] Letter from Senator Dianne Feinstein, Senator Ted Kennedy and 13 other members of Congress to the Centers for Disease Control and Prevention, May 4, 2004. The members asked the CDC to accept HIV case data from code-based states.
[17] The Centers for Disease Control and Prevention, "HIV/AIDS Surveillance Report 2002," Vol. 14, Table 14. http://www.cdc.gov/hiv/stats/hasr1402/2002SurveillanceReport.pdf (last visited May 11, 2004). The top five states (in descending order), New York, California, Florida, Texas, and New Jersey

represented 57 percent of the nation's AIDS cases reported as of December 2002.
[18] E-mail from Vince Torres-Gil, Department of Health Services, Office of AIDS (April 20, 2004); and e-mail from Barbara Bailey, Department of Health Services, Office of AIDS (May 12, 2004); and Centers for Disease Control and Prevention, The California Performance Review A Government for the People for a Change 375 "CDC Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome, Morbidity and Mortality Weekly Report" (December 10, 1999), p. 13.
[19] Interview with Glennah Trochet, M.D., Sacramento County Department of Health and Human Services, Sacramento, California (March 23, 2004); interview with Maree Kay Parisi, San Francisco Department of Public Health, San Francisco, California (April 14, 2004); interview with Michael Bursaw, San Diego County Health and Human Services Agency, San Diego, California (April 15, 2004); interview with Alexander F. Taylor, San Bernardino County Department of Public Health, San Bernardino, California (April 15, 2004); and interview with Gordon Bunch and staff, Los Angeles County Department of Health Services, Los Angeles, California (May 3, 2004).
[20] E-mail from Vince Torres-Gil, Department of Health Services (April 20, 2004). California appropriated $2,828 million in FY 2000-2001 for development, training, implementation and evaluation of HIV reporting, of which the Office of AIDS received $1.369 million for positions and contracts and allocated $1.431 million to local health departments for surveillance personnel.
[21] E-mail from Deanna Sykes, Department of Health Services, Office of AIDS (April 12, 2004).
[22] California Code of Regulations, Title 17, Division 1, Chapter 4, Subchapter 1, Article 3.5, Section 2643.10(g) and Section 2643.20. Once a client enters the health care system, all HIV testing is confidential (versus anonymous), and providers must report positive results.
[23] Interview with Jim Creeger, chief, HIV/AIDS Case Registry, Department of Health Services, Office of AIDS, April 26, 2004. The change would relieve laboratories from creating a partial code and relieve providers from completing the code and maintaining a cross reference of codes to case files.
[24] A CD4+ count of less than 200 per microliter (uL) or less than 14 percent of total T-lymphocytes in combination with a positive HIV test constitutes an AIDS case.
[25] The Institute of Medicine of the National Academies, "Measuring What Matters: Allocation, Planning and Quality Assessment for the Ryan White CARE Act," pp. 117-118. As of April 2003, California, Alabama, Arizona, Florida, Georgia, Michigan, Minnesota, Montana, North Carolina, North Dakota, South Dakota, Vermont and Virginia do not have CD4+ reporting.
[26] Three factors will determine the amount of federal Title I and II formula funds received by California's Ryan White CARE Act grantees: federal appropriations for Title I and Title II, the formula and California's HIV and AIDS data. This estimate presumes no change in the funding formula or federal appropriations.
[27] Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, "Procedure Used to Estimate the Number of Adolescents and Adults Living with HIV Infection, but not AIDS, in Areas without Name-based HIV Reporting before 1994," Atlanta, Georgia, August 2002 (internal report). The CDC states limitations to the modeled estimates, which are not substitutes for HIV case surveillance data.
[28] Congress could mitigate the funding loss for California and other coded states if it includes "hold harmless" provisions in the next reauthorization of the Ryan White CARE Act or increases the appropriations to the extent that they counteract losses due to the formula change. In past reauthorizations of the reauthorized CARE Act, Congress included "hold harmless" provisions to minimize losses resulting from formula changes at about 1 percent per year.
[29] E-mail from Barbara Bailey, Department of Health Services, Office of AIDS (May 12, 2004).

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Report System on HIV Cases Falters;

Health officials say some doctors and clinics are failing to comply with the fledgling program. The growing pains put federal funding at risk.

By Charles Ornstein, Times Staff Writer

California's HIV reporting system has been hobbled in its first six months by the failure of some doctors and clinics to provide the data required by law, county health officials say.

If the problems are not resolved, authorities say, they won't be able to track the epidemic's spread. And California risks coming up short as early as next year, when the federal government begins linking its treatment and service grants to the number of state HIV cases.

"It's a disaster," Dr. Steven Miles, a physician at the UCLA Center for Clinical AIDS Research and Education, said of the new reporting system.

So far, the state has been informed of only a fraction of the casesthat officials believe are out there: 9,155 through Dec. 31 out of 80,000 projected by federal officials.

Moreover, the cases have been reported unevenly: Orange County, with a population of nearly 3 million, submitted 829 HIV cases while Los Angeles County, with almost 10 million residents, reported just 1,064.

Los Angeles County officials say their figure will soon increase by at least 700, after they process cases already submitted by medical providers. Even so, officials still have to find and track an estimated 20,000 HIV cases in the county.

The tracking system, set up under state rules that took effect July 1, requires medical providers and laboratories to report all new HIV infections. Each patient is given an alphanumeric code to protect privacy. Doctors are required to provide additional medical information, as well as data on race and risk factors.

The system was designed to help public health officials better track the disease and target prevention and treatment dollars. Previously, the state required reporting of AIDS cases only, which meant that officials often learned of HIV infections 10 or more years after they had occurred. HIV, the human immunodeficiency virus, causes AIDS.

Although most laboratories are reporting their results to local health departments, some doctors are balking, saying the requirements are too burdensome. Others aren't complying because they aren't versed in the new regulations.

"I'd like to help them, but I really don't have the time to do the paperwork that they're asking me, so I'm not doing it," said Dr. Bisher Akil, a Los Angeles physician who treats about 200 HIV and AIDS patients,.

Michael Montgomery, director of the Office of AIDS at the California Department of Health Services, said growing pains are to be expected in the first few years of a new tracking system. "Nobody thought it was going to be easy," he said. All in all, Montgomery said, "it looks to me that we're escaping the problems that some of the other states are experiencing."

For instance, Montgomery said, most of the HIV case reports contain information on patients' risk factors -- such as drug use and sexual orientation -- that other states have struggled to compile.

The most daunting part of building an HIV reporting system comes in the first months. Public health agencies must collect information on all HIV cases, new and old, even those that go back many years. The expectation is that, after a couple of years, doctors will have reported all old cases, and tracking new cases will be much more manageable.

But Los Angeles County officials said the first six months have been more difficult than they had expected. Because of incomplete or nonexistent information from medical providers, the county reported fewer than 10% of the more than 7,000 potential cases identified by laboratory tests through December.

Before a case can be reported to the state, county officials must receive data from a medical provider.

"If we don't change, it's going to take us several years" to get existing cases reported, "and we don't have that much time," said Gordon Bunch, director of HIV epidemiology with the Department of Health Services.

Officials in Ventura County say they have grown so frustrated that they have threatened to fine several medical providers who didn't report their cases.

"This is an incredibly imperfect system that we're working with," said Lynn Bartosh, a community service coordinator with Ventura County Public Health. "This is exactly what we were wanting to avoid."

Some doctors and clinics say the use of codes hampers the new system's efficiency and usefulness. They note that all other reportable diseases are tracked by patient name.

"It was a bad idea legislatively and it's a worse idea in practice," said Michael Weinstein, president of the AIDS Healthcare Foundation in Los Angeles, which had advocated reporting of HIV by name.

Bunch concedes that the county would be a lot further along if it used names in reporting HIV cases. But he said the code system deserves an opportunity to prove itself. Six months "would be far too premature to call it a failure."

Montgomery said reluctant doctors need to realize that the state's ability to track HIV cases will be directly correlated to federal funding for services.

Some health departments have had better luck with physician reporting than others.

"There was a lot of effort put into helping people understand" how the new system works, "and maybe that made a big difference for us," said Penny Weismuller, of the Orange County Health Care Agency.

San Francisco health authorities said they have been successful largely because city workers go to physicians' offices to collect the necessary information themselves from patients' medical records.

Providers are "really swamped," said Dr. Sandra Schwarcz, the city's director of HIV/AIDS statistics. "I'm sure they're going to prioritize taking care of a patient over sending in a case report form."

Los Angeles County officials said they are starting to take the same approach, and many clinics say they welcome the county's assistance. To add incentive, L.A. County officials plan to make timely reporting a condition of grant funding.

Miles of UCLA said he finds it ironic that county health workers are being allowed to peruse medical records, complete with patient names, when the whole goal of code reporting was to protect patients' privacy.

But Dr. Douglas Frye, a medical epidemiologist with the Los Angeles County HIV epidemiology program, said the names may be seen but are not recorded. In any case, the stakes for making the system work are high for the county and the state.

"Los Angeles County historically has reported 35% of the cases in the state," Bunch said. "If we fail, the state fails."

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August 12, 1998

The Honorable Pete Wilson
Governor Of California
State Capitol, First Floor
Sacramento, California 95814

Dear Governor Wilson:

I am writing to as both a member of Congress and a practicing physician who has cared for patients with HIV/AIDS to urge you to oppose AB 1663 which is pending in the California Assembly. As you may know, AB 1663 would establish an HIV Surveillance Task Force to "develop a uniform, statewide system to report cases of HIV that would be based on a unique code or other method that does not report the names of individuals infected with HIV." While I believe that it is essential for all states to conduct HIV case reporting, AB 1663 is a dangerous bill for many reasons which I have outlined below. I hope that you will take a moment to review my concerns.

This bill ignores the recommendations of the Centers for Disease Control and Prevention regarding HIV case surveillance.

- The CDC has concluded that tracking HIV by using names rather than unique identifier (UI) codes is more reliable, efficient and accurate. The study "revealed several problems with the UI systems, including a high number of reports with incomplete codes (approximately 30- 40%), low rates of completeness in reporting (approximately 25- 50% complete), difficulty in conducting follow-up on specific cases, and the absence of behavioral risk data in this system." (*Morbidity and Mortality Weekly Report*, Vol. 46, No. 52; January 9, 1998)

- Texas, one of the two states which currently utilize UIs, recently concluded that "it appears that name-based reporting is the best system to provide both accurate information on the epidemic and the ability to follow-up on reports of infection."

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UIs do not provide additional patient confidentiality protections.

- UIs may not protect patients' confidentiality any better than name-reporting systems according to CDC. In order to provide follow-up information, health care providers need to use lists or other means to link the patient with the UI. "The UI approach complicates efforts to collect this information and increases the number of lists of HIV-infected persons that could be disclosed in a breach of confidentiality," CDC reports.

This bill places politics above public health by gagging open discussion.

- AB 1663 not only bars name reporting, but specifically states that the surveillance task force shall not even "consider the relative merit of such a system." This 'gag clause' places politics above public health by banning a free discussion of alternatives, specifically the most commonly used system which is already used for AIDS reporting. What could possibly be the benefit of barring the consideration of the 'merits' of any option?

The bill misrepresents the impact of name-based reporting.

- AB 1663 states "names-based HIV reporting has been found to deter individuals, particularly those at highest risk for HIV infection, from testing for and treatment of HIV." This statement is misleading and unfounded.

- CDC supported the University of California at San Francisco and nine state health departments to survey high-risk persons about the perceptions and knowledge of HIV testing and HIV reporting practices. In this survey, only 15% of the respondents knew whether HIV infection was reportable to the health department in their state of residence. When asked about factors that may have delayed their seeking HIV testing, only 2% of the respondents surveyed cited "reporting to the government" as the main reason.

- CDC and six health departments reviewed data routinely collected from public-funded HIV counseling and testing sites to compare HIV testing patterns in the 12 months before and the 12 months after the implementation of HIV name reporting. In these areas, the number of HIV tests increased in three states (16- 63%), remained level in two states (-2%, 5%), and decreased in one state (-11%). The state with a decline in HIV testing during the evaluation period had a decreasing trend in HIV tests before HIV surveillance was implemented.

- Currently, every state— including California— requires the reporting of individuals diagnosed with AIDS, which is merely the end stage of HIV infection, and has done so without breaches of confidentiality or deterring individuals from being tested. Local health departments in California have successfully protected the identities of over 100,000 names that have been reported in the first 15 years of the epidemic.

The bill violates federal law, jeopardizing California's eligibility for millions of dollars of federal grants.

- AB 1663 states that "individual case reports shall not be used for contact tracing or partner notification programs." This violates federal law (P.L. 104-146) which requires states to notify past and present spouses of HIV-infected individuals. By failing to do so, California would no longer be eligible for millions of dollars in federal HIV/AIDS grants.

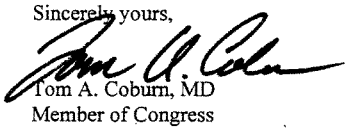
The bill puts lives at risk by preventing effective early intervention.

- Partner notification is extremely important to disease control because it is the only timely way to alert those in danger of infection. It is the standard public health procedure for curtailing the spread of virtually all other sexually transmitted diseases and has been credited in part for the fact that syphilis cases in the U.S. have fallen to the lowest levels in U.S. history.

- AB 1663 prohibits HIV surveillance data for partner notification. Therefore, many individuals at risk are never warned and consequently become infected or do not discover that they are infected until they are already sick with AIDS-related illnesses. By this point, they have been denied the medical care that can prolong their lives and stave off illness and may have infected others unknowingly.

Once again, I encourage you to oppose this legislation and to develop a bill based upon sound public health rather than politics that protects both the confidentiality of those infected with HIV and the health of those at risk of infection. If I can be of any assistance to this endeavor, please do not hesitate to contact me.

Sincerely yours,



Tom A. Coburn, MD
Member of Congress

TAC/rrf

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

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September 2, 1998

The Honorable Pete Wilson
Governor of California
State Capitol, First Floor
Sacramento, CA 95814

Dear Governor Wilson,

Following up on my letter of August 12th, **I am writing to urge you to veto AB 1663** requiring HIV case reporting in California using a unique identified code (UI).

As I mentioned in my previous correspondence, in addition to being a member of Congress, I am also a practicing physician who has cared for patients with HIV/AIDS. In this capacity, I am gravely concerned that enactment of this legislation could endanger lives, hinder the performance of effective public health and jeopardize California's eligibility for millions of dollars in federal grants.

Unquestionably, all states should have an HIV surveillance system linked with partner notification and appropriate medical care. While AB 1663 portends to establish such a system, the truth is that it hinders the ability to effectively track or interrupt the spread of HIV.

The Centers for Disease Control and Prevention (CDC) has concluded that tracking HIV by names is more reliable, efficient and accurate than by UIs as mandated by AB 1663. A CDC study "revealed several problems with the UI systems, including a high number of reports with incomplete codes (approximately 30- 40%), low rates of completeness in reporting (approximately 25- 50% complete), difficulty in conducting follow-up on specific cases, and the absence of behavioral risk data in this system." Texas, one of the two states which currently utilize UIs, recently concluded that "it appears that name-based reporting is the best system to provide both accurate information on the epidemic and the ability to follow-up on reports of infection" and is in the process of switching to a name-based system. Furthermore, contrary to the claims of proponents, UIs do not provide additional patient confidentiality protections. In order to provide follow-up information, health care providers need to keep lists to link the patient with the UI. "The UI approach complicates efforts to collect this information and increases the number of lists of HIV-infected persons that could be disclosed in a breach of confidentiality," CDC reports. Having an ineffective system is not much better than having no system at all.

Most disturbingly, AB 1663 would completely hinder and essentially prevent partner notification of those exposed to HIV, including spouses as required by federal law. As drafted, AB 1663 provides countless disincentives and no incentives for physicians or the public health department to perform any notifications. The bill states that notification "is permissive" not

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required or even encouraged and that "no physician has a duty to notify any person." Furthermore, a whole paragraph of conditions that must be met is mandated upon a health care professional before a notification can occur. As a physician who knows first hand the burden of existing state and federal laws and regulations, I can assure you that very few health care providers will make the effort to meet these conditions for numerous reasons. For those who do believe that they have a duty to protect the public health, the threat of a law suit— which is encouraged by the immense civil penalties for disclosure established under this bill— will further discourage notification. As a co-author of the Ryan White CARE Act Amendments of 1996, I believe that these provisions violate the federal spousal notification requirement and, therefore jeopardizes California's eligibility for millions of dollars in HIV prevention grants.

Once again, I urge you to veto this legislation and encourage the legislation to develop a bill based upon sound public health that protects both the confidentiality of those infected and the health of those not infected. If I can be of any assistance to this endeavor, please do not hesitate to contact me.

Sincerely yours,

Tom

Tom A. Coburn, MD
Member of Congress

TAC/rrf

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

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(918) 542-5337
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October 2, 1998

The Honorable Pete Wilson
Governor of California
State Capitol, First Floor
Sacramento, CA 95814

Dear Governor Wilson,

Thank you for your courage and wisdom in vetoing AB 1663 which would have required a code-based HIV surveillance system in California.

If enacted, this bill would have been a significant detriment to effective HIV reporting and partner notification, both of which are essential elements of contagious disease control.

As you stated in your veto message to the members of the California Assembly, "concerns over privacy and discrimination do not warrant designing a reporting system that does not adequately provide for partner notification" and that such concerns "should not interfere with what must be our highest priority, interrupting the chain of HIV transmission." California's public health authority has successfully protected the identities of over 100,000 names that have been routinely reported with AIDS over the past 15 years. There is no indication that such protection could not be guaranteed for those infected with HIV, but not yet diagnosed with AIDS.

If California would have enacted a code-based reporting system, other states may have followed suit which could have resulted in countless other innocents becoming hapless victims of the deadly and fatal AIDS virus. Your veto, however, will ensure that such a misguided policy will not be enacted in California.

Like you, I would hope that the California legislature would revisit this issue again next year and pass a bill which would ensure accurate and reliable HIV surveillance and partner notification.

Thank you again for your courage and leadership on this issue. I wish you the best of luck with your future endeavors.

Sincerely yours,

Tom Coburn

Tom A. Coburn, MD
Member of Congress

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STATE OF CALIFORNIA-HEALTH AND HUMAN SERVICES AGENCY

GRAY DAVIS, *Governor*

DEPARTMENT OF HEALTH SERVICES
714 P STREET, ROOM 1253
P.O. BOX 942732
SACRAMENTO, CA 94234-73200
(916) 657-1425

June 1, 2001

Mr. Roland Foster
Professional Staff Member
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
House Committee on Government Reform
B373 Rayburn H.O.B.
Washington, DC 20515

Dear Mr. Foster:

Thank you for your recent electronic communication to me and to Michael Montgomery, Chief, Office of AIDS, regarding California's proposed regulations for reporting human immunodeficiency (HIV) infections.

The Department of Health Services, Office of AIDS (DHS/OA) has lead responsibility for coordinating state programs, services, and activities related to HIV/AIDS, and therefore received the charge to develop and implement a non-name system of HIV reporting for California.

The following information is in direct response to the questions within your email and will provide you with a more complete understanding of the efforts DHS is making to implement a successful system of HIV reporting for California.

- **"As you develop regulations to set up such a system could you please forward whatever information you deem appropriate to me?"**

We have developed proposed regulations for reporting HIV by a non-name code. The public comment period for these regulations began Friday, March 30, 2001, and will continue until 5 p.m. (PST), Monday, May 21, 2001. For your convenience, we have requested that the Office of Regulations mail a copy of the regulations package to you. Additional copies of the regulations, the accompanying "Statement of Reasons" and information about the public proceedings are available via the OA website at http://www.dhs.ca.gov/AIDS/, or from the Office of Regulations. Requests to the Office of Regulations may be made by phone (916) 654-0381, fax (916) 657-1459, or email (regulation@dhs.ca.gov) and should include the Department regulation control number R-19-00 as well as the name and mailing address of the person requesting a copy of the package.

- **"I would also be interested in knowing how closely you are working with the CDC and if you intend to actively seek the input of the state's public health community and the public."**

Since AIDS became a reportable condition in California in 1983, the OA has worked closely with the Centers for Disease Control and Prevention (CDC), the public health community, and the public to assess the impact of AIDS on the people of California. During the development stage for the proposed HIV reporting regulations, the OA created the HIV Surveillance Work Group, composed of over 30 individuals representing other state agencies, local health departments, advocates, laboratories, those infected or affected by HIV/AIDS and the medical community. A representative from CDC is included in this group. The workgroup met September 25, 2000, and will reconvene following the public comment period. During the September meeting, the CDC representative and technical staff from other states that currently use a non-name reporting system provided suggestions for our proposed system; several of these suggestions were incorporated into the proposed regulations.

The OA also consulted with multiple individuals and/or agencies that will be impacted by HIV reporting in our state, including other state agencies; public and private laboratories; California local health officers; confidential counseling and testing site coordinators; advocates and individuals; and a major health maintenance organization.

In addition, it is important to inform you that CDC has indicated their support of California's effort to implement a non-name system of reporting HIV by providing one-time funding in the amount of $500,000. These funds will be used for pre-implementation studies to ensure that the proposed system meets CDC standards. The OA also anticipates a system evaluation by the CDC, and looks forward to working with them on that assessment.

- **"How many diseases or conditions does the state currently have designated as reportable? How many of these are reported by name and how many by unique identifier?"**

The approximately 80 currently reportable diseases or conditions in California can be found in the California Code of Regulations, Title 17, Subchapter 1, Article 1, Sections 2500-2503 (also available at http://www.dhs.ca.gov/ps/dcdc/html/disbindex.htm). All, including AIDS, are reportable by name.

- **"Has there ever been a breach of confidentiality in the state's AIDS surveillance system?"**

The OA has never experienced a breech of security in the AIDS surveillance system. Maintaining the confidentiality of AIDS case information is the number one priority of all the staff associated with AIDS surveillance. The confidentiality policies and procedures of state and local surveillance programs are consistent with CDC standards for security of HIV/AIDS surveillance data. The Department will implement those same high quality standards in our HIV reporting system.

- **"Will the state require that AIDS diagnosis be reported by code? If not, what is the rationale for treating AIDS and HIV infection differently?"**

California will continue to report AIDS by name, as mandated in the California Code of Regulations. The primary rationale for reporting HIV and AIDS differently is that current California statute prohibits the reporting of HIV infection by name. HIV reporting by name has been legislatively proposed a number of times in California and has received broad opposition from AIDS community advocates, AIDS service providers and people living with HIV/AIDS. Through California' s Budget Act of 2000-2001, DHS/OA was given the charge to develop and implement a non-name system of HIV reporting.

- **"Also, does the state currently record the names of HIV-infected individuals receiving treatment under Medi-Cal? If so, will Medi-Cal be required to convert these patient's names into unique identifiers as well? If so, has such a conversion been approved by HCFA? If not, could you explain the rationale for using names for treatment purposes and codes for surveillance activities?"**

Just as in any other area of medical service provision, HIV-infected individuals who are Medi-Cal beneficiaries do provide identifying information, including names, to their health care providers. The operations system of the Medi-Cal program retains the names of all beneficiaries to allow for medical review and payment services but does not include beneficiary names when creating expenditure reports. The Medi-Cal provider, upon laboratory notification of a confirmed HIV test, will create a non-name code for the Medi-Cal beneficiary and report the HIV infection to the local health department. The reporting system will not be retroactive and Medi-Cal's operations system will not be involved in any part of the HIV reporting process.

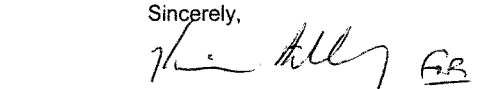
The rationale for using names for HIV treatment purposes, but a code for HIV surveillance is based on the principles of practice for health care providers as well established methods of public health surveillance. In accordance with accepted principles of practice, practitioners must establish and maintain a clinical record for

every individual receiving care and services. Any patient who receives medical care must supply his or her name as part of this record. It is a generally accepted principle that the health care institution or practitioner providing care maintains the primary patient record. Statutes and/or licensing regulations grant the practitioner control over the physical document, and give the patient rights to the information contained in the record. The patient generally has control over the release of patient-identifiable (confidential) information except in circumstances identified by case law and by federal or state statutes and regulations. The California Code of Regulations mandates the reporting of an AIDS diagnosis by name, yet state statutes prohibit revealing an HIV-infected individual's name in the absence of an AIDS diagnosis, except under specified circumstances.

California is one of just a few states without some type of HIV reporting system. Lack of this information limits the state's ability to perform epidemiologic analysis to help monitor and project the extent of the epidemic. In the absence of statute to allow HIV reporting by name, and in the interest of public health, we have developed a non-name system of HIV reporting. The demographic information (e.g. race/ethnicity, age, mode of transmission) that will be collected from the HIV confidential case report forms will supply the data necessary to perform effective HIV surveillance while protecting the privacy of those who are HIV infected, as mandated by law.

Thank you again for expressing an interest in the process California has followed for developing and implementing a non-name system of HIV reporting in our state. If you have additional questions or concerns, please feel free to contact Mr. Michael Montgomery, Chief, Office of AIDS at (916) 323-7415.

Sincerely,



Diana M. Bontá, R.N., Dr.P.H.
Director

cc: Mr. Michael Montgomery, Chief
Office of AIDS
Department of Health Services
611 North Seventh Street, Suite A
Sacramento, CA 95814-0208

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary
for Legislation

Washington, D.C. 20201

September 9, 1997

The Honorable Tom Coburn
U.S. House of Representatives
429 Cannon House Office Building
Washington, D.C. 20515

Dear Congressman Coburn:

Knowing of your continued concern regarding unlinked HIV testing of newborn blood specimens, I would like to inform you that the Centers for Disease Control and Prevention (CDC) will pursue surveillance methodologies that do not include HIV serosurveys using any type of blood specimens of newborns without identification.

CDC will continue discussion with HIV prevention partners to identify alternative approaches to monitor HIV trends in women of childbearing age.

Dr. Satcher has recommended this approach and the Department has concurred.

Sincerely,

Richard J. Tarplin
Assistant Secretary for Legislation

Congress of the United States
House of Representatives
Washington, DC 20515

October 1, 1997

Ms. Helene D. Gayle, M.D., M.P.H.
Associate Director
Centers for Disease Control and Prevention
714B Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Gayle,

In the past we have discussed our opposition to unlinked, or "blind", HIV tests of pregnant women and newborns. As you know, we feel that such tests are unethical because they deny those who test positive the knowledge of their status and thus prevent them from seeking medical care and taking precautions to prevent infecting others. CDC recently assured us that such surveillance methodologies would not be used to test newborns.

However, it has come to our attention that the CDC is either now, or may have in the past, conducted "blind" HIV tests on prisoners, patients in select hospitals and on other populations. We would, obviously, have the same ethical concerns for "blind" tests in these settings as we did with the newborn tests.

Could you please verify or refute that such tests are being conducted or have been conducted in the past. If such "blind" HIV tests were conducted on populations other than newborns, could you please provide the dates, locations and descriptions of these surveillance programs.

Thank you for your assistance. We look forward to a timely response. If you have any questions, please do not hesitate to contact us.

Sincerely,

Tom A. Coburn, MD
Member of Congress

Gary L. Ackerman
Member of Congress

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta, GA 30333

January 28, 1998

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515

Dear Dr. Coburn:

Thank you for your letter regarding human immunodeficiency virus (HIV) serosurveillance (blinded or unlinked tests) supported by the Centers for Disease Control and Prevention (CDC). I apologize for the delay in responding to your letter.

As a part of a national surveillance system to monitor the HIV epidemic in the United States, CDC, in collaboration with State and local health departments, other Federal agencies, blood collection agencies, and medical research institutions, began in 1988 to conduct standardized HIV seroprevalence surveys in high risk groups of the U.S. population. These blinded surveys were initiated at a time when less was known about the epidemiology of HIV and fewer therapeutic options were available. These surveys were critical to public health efforts because they were the only way to provide a valid estimate of the number of persons who were infected with HIV. The objective of these surveys was to provide Federal, State, and local health officials with data to monitor the course of the epidemic on a national and local scale to target resources and design, implement, and evaluate prevention and treatment strategies that are more applicable to the affected populations. As indicated in the September 9, 1997, letter to you from Mr. Richard J. Tarplin, Assistant Secretary for Legislation (copy enclosed), CDC is not conducting surveillance methodologies that include HIV serosurveys using any type of unidentified blood specimens from newborns.

As you know, blinded surveys are a widely accepted and standard public health tool and are used to acquire unbiased information that often forms a basis for the design of critical population-based public health interventions and activities. Regarding the HIV surveys, these are conducted in a variety of clinical

settings using residual blood specimens that were collected and tested for other reasons. Currently, we are conducting anonymous unlinked serosurveys in STD clinics, drug treatment centers, and adolescent clinics but not in prisons. The surveys are limited in number (88 sites) and are focused on high-risk populations where changes in the epidemic might be expected to be detectable first. Most importantly, the surveys are conducted in facilities with a policy of offering counseling and voluntary HIV testing to all patients; therefore, anyone whose blood is included in the survey has already had the opportunity to learn their HIV serostatus.

To provide more information on when and where these surveys have been conducted, we have enclosed the National Serosurveillance Summaries from 1989 through 1993 (the most recent comprehensive summary) and other published reports on HIV serosurveillance issues.

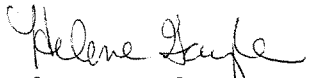
The results of these seroprevalence studies have provided vital information that has facilitated the national response to the AIDS epidemic. Specifically, the results have been used to:

- Track the emergence of HIV disease by monitoring its movement among targeted populations.
- Develop effective HIV prevention strategies that respond to the epidemiologic data.
- Assist community planning groups and State and local health departments in making decisions regarding how and where to use resources most effectively.
- Target educational efforts for certain populations.
- Determine the need for further epidemiologic studies about demographic and behavioral characteristics in at-risk populations.
- Reinforce the use of appropriate universal precautions by health care workers.

However, as we have previously discussed, CDC is assessing the role of these surveys in light of the evolution in the HIV epidemic, new knowledge, and approaches to prevention and treatment.

We appreciate your interest in and attention to public health measures to promote, monitor, and strengthen HIV prevention in the United States, and hope this information is helpful. I would be pleased to brief you on this critical issue. An identical letter is being sent to Congressman Gary Ackerman who cosigned your letter.

Sincerely yours,



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

Enclosures

Serosurveillance summaries 1989 - 1993

Published reports on HIV serosurveillance issues:

1. Dondero TJ and Curran JW. Serosurveillance of Human Immunodeficiency Virus Infection. Am J Pub Hlth 1991; 81:561-2.

2. Hull HF, Bettinger CJ, Gallaher M, et al. Comparison of HIV-antibody prevalence in patients consenting to and declining HIV-antibody testing in an STD clinic. JAMA 1988; 260:935-8.

3. Bayer R, Lumey LH, Wan L. The American, British and Dutch responses to unlinked anonymous HIV seroprevalence studies: an international comparison. AIDS 1990; 4:283-290.

4. Dondero TJ and Gill ON. Large-scale HIV serologic surveys: what has been learned? AIDS 1991; 5 (suppl 2):S63-S69.

5. Dondero TJ. Current estimates of HIV prevalence and incidence: sources and data. Health Policy 1989; 11:115-124.

6. Dondero TJ, Pappaioanou M, Curran JW. Monitoring levels and trends of HIV infection: the Public Health Service's HIV surveillance program. Public Health Reports 1988; 103:213-220.

7. Pappaioanou M, Dondero TJ, Petersen LR, Onorato IM, Sanchez CD, Curran JW. The family of HIV seroprevalence surveys: objectives, methods, and uses of sentinel surveillance for HIV in the United States. Public Health Reports 1990; 105:113-119.

8. Pappaioanou M, George JR, Hannon WH, Gwinn M, Dondero TJ, Grady GF, Hoff R, Willoughby AD, Wright A, Novello AC, Curran JW. HIV seroprevalence surveys of childbearing women -- objectives, methods, and uses of the data. Public Health Reports 1990; 105:

9. Prevots DR, Allen DM, Lehman JS, Green TA, Peterson LR, Gwinn M. Trends in human immunodeficiency virus seroprevalence among injection drug users entering drug treatment centers, United States, 1988-1993. Am J Epid 1996; 143:733-742.

10. Janssen RS, St. Louis ME, Satten GA, Critchley SE, Petersen LR, Stafford RS, Ward JW, Hanson DL, Olivo N, Schable CA, Dondero TJ, and the Hospital Surveillance Group. HIV infection among patients in U.S. acute care hospitals - Strategies for the counseling and testing of hospital patients. N Eng J Med 1992; 327:445-452.

11. CDC. Recommendations for HIV testing services for inpatients and outpatients in acute-care hospital settings. MMWR 1993;42(No. RR-2):1-6.

Congress of the United States
House of Representatives
Washington, DC 20515

February 4, 1998

Helene D. Gayle, M.D. M.P.H.
Associate Director
Centers for Disease Control and Prevention
714B Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Dr. Gayle,

Thank you for your response to our letter regarding human immunodeficiency virus (HIV) serosurveillance (blinded or unlinked tests) supported by the Centers for Disease Control and Prevention (CDC). We were displeased at the length of time it took for you to respond.

We were very disappointed to learn that the CDC is still conducting blind tests. As you know, we feel that such tests are unethical because they deny those who test positive the knowledge of their status and thus prevent them from seeking medical care which can improve their lives and taking precautions to prevent infecting others.

In your letter, you state that the surveys are being conducted in 88 sites. We would request a complete listing of these sites by name and location.

Additionally, you stated that these sites offered voluntary HIV testing to all patients. Do you know how many of those who tested positive in the blind tests actually received another HIV test voluntarily?

Thank you for your assistance. We look forward to a timely response. If you have any questions, please do not hesitate to contact us.

Tom A. Coburn, M.D.
Member of Congress

Gary Ackerman
Member of Congress

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

March 30, 1998

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515

Dear Dr. Coburn:

Thank you for your follow-up letter regarding human immunodeficiency virus (HIV) serosurveillance (blinded or unlinked tests) supported by the Centers for Disease Control and Prevention (CDC).

I would like to correct information that was provided to you in our January 28, 1998, response. In that letter, we stated that surveys are being conducted in 88 sites. Actually, HIV seroprevalence surveys are being conducted in only 51 sites. We apologize for this error.

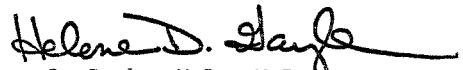
These 51 sites comprise 21 drug treatment centers, 19 sexually transmitted disease (STD) clinics, and 11 adolescent clinics. Enclosed is a listing of the 51 sites by location. To protect the confidentiality of the participating programs and patients, CDC does not reveal the names of the individual clinics.

As noted in our earlier correspondence to you, these serosurveys are conducted in facilities with a policy of routinely offering counseling and voluntary HIV testing to all patients. Information about voluntary HIV testing among those whose blood specimens were included in these blinded serosurveys was not collected prior to 1997. Data from 1997, which are preliminary and represent in some sites very small numbers of people, indicate extreme variability in the results. For example, for blood specimens tested through blinded surveys at STD clinics, a range of 10 to 70 percent of specimens that were HIV-positive were from clients documented to have been voluntarily tested for HIV on that visit. Similarly, data collected from serosurveys at drug treatment centers indicate that a range of 3 to 74 percent of specimens from the blinded survey were from patients who had documented HIV counseling and testing on that visit. What is not known is the proportion of people included in these samples who declined voluntary testing because they already knew

their serostatus. Data are not yet available from the adolescent clinics participating in the serosurveys.

We appreciate your continued interest in our public health measures to promote, monitor, and strengthen HIV prevention in the United States. I hope this information is helpful. An identical letter is being sent to Congressman Gary Ackerman, who cosigned your letter.

Sincerely yours,



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

Enclosure

HIV Serosurveillance Survey Sites Supported by the CDC

STD Clinics		Number
Chicago, IL		2
Denver, CO		1
Washington, DC		2
Miami, FL		1
Atlanta, GA		1
Houston, TX		3
Los Angeles, CA		3
New Orleans, LA		1
Detroit, MI		1
Newark, NJ		1
New York, NY		2
San Francisco, CA		1
	Total	**19**

Drug Treatment Centers		Number
Washington, DC		1
Atlanta, GA		1
Chicago, IL		1
Los Angeles, CA		3
New Orleans, LA		1
Detroit, MI		1
Newark, NJ		3
New York, NY		4
Puerto Rico		1
Seattle, WA		3
San Francisco, CA		1
Oakland, CA		1
	Total	**21**

Adolescent Clinics		Number
Miami, FL		1
Houston, TX		3
Los Angeles, CA		1
Baltimore, MD		2
New York, NY		1
Dallas, TX		3
	Total	**11**

Congress of the United States

Washington, DC 20515

April 15, 1998

Dr. Helene Gayle
Director
National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention
Atlanta, GA 30333

Dear Dr. Gayle:

Thank you for your recent letter regarding blind HIV testing. We hope that you can provide further interpretation of the data that you cited in your letter.

For example, you stated that at STD clinics, ten to seventy percent of the individuals who tested positive for HIV under the blind survey had been voluntarily tested for HIV on that specific visit. What sort of methodology was used to arrive at such widely disparate statistics and what, if any conclusions, can we draw from them? Additionally, we would appreciate it if you can provide additional information or statistics about the people who did not receive voluntary testing or counseling. Did all of these individuals refuse testing or were they were not even offered testing and counseling in the first place?

It would appear that it is still difficult to justify blind studies even at facilities with policies of "routinely" offering voluntary counseling and testing because of the high numbers of individuals who left these facilities unaware that they were HIV positive.

We hope to hear back from you in a timely manner. If you have any questions, please do not hesitate to contact us.

Sincerely,

GARY L. ACKERMAN
Member of Congress

TOM COBURN, M.D.
Member of Congress

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

July 10, 1998

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515

Dear Dr. Coburn:

Thank you for your letter regarding human immunodeficiency virus (HIV) data on blinded seroprevalence studies. I apologize for the delay in responding.

As we have previously described, the unlinked surveys are conducted only in clinics with a policy of routinely offering voluntary HIV counseling and testing to all patients. Our previous correspondence cited preliminary data indicating that in selected sexually transmitted disease (STD) clinics, the proportion of HIV-positive persons receiving voluntary HIV testing on a given visit varied from 10 to 70 percent. The methodology employed was to compare the number of anonymously collected HIV-positive specimens with all those voluntarily collected HIV specimens on a given day. Information on voluntary testing was abstracted from clinic records. Of note, these results are based on relatively small numbers of HIV-positive specimens, ranging from 7 to 200 in the seven cities with available data.

Although all individuals are offered voluntary counseling, the reasons for not receiving testing are not routinely documented in clinic records, so they cannot be determined in an unlinked survey. There are many reasons why people visiting an STD clinic on a given day might not accept an HIV test. It is possible that some STD clinic clients have been previously tested and already know their HIV infection status; these people would tend not to seek repeat testing. Others may refuse testing for a variety of personal reasons. Historically, settings of high HIV prevalence such as STD clinics also have a low percentage of people returning for their HIV test results. Numerous studies have been conducted to increase our understanding of why people do not accept testing or return for test results, with varying results.

The Centers for Disease Control and Prevention (CDC) agrees that increasing the number of HIV-positive people who know their infection status is an important goal. Enclosed is a list of steps CDC is undertaking to accomplish this.

Although we understand your concerns and certainly share many of them related to people's knowledge of their HIV serostatus, the

fact remains that many people continue to refuse testing that is routinely offered in many settings. This situation would exist even in the absence of the blinded seroprevalence studies.

Until recently, AIDS case surveillance was considered to accurately reflect patterns of HIV transmission. Delayed progression of HIV disease following the introduction of highly active antiretroviral therapy, as well as differential access to therapy, has resulted in AIDS case surveillance no longer being representative of HIV epidemiology. Therefore, CDC has suggested that all States institute surveillance of HIV infection in addition to their AIDS surveillance activities. A weakness of HIV surveillance is that only confidential (identified by name or another unique identifier) HIV test results will be reported, so the completeness and quality of results is heavily affected by the test-seeking behavior of HIV-infected persons. Blinded surveys, on the other hand, provide unbiased seroprevalance data about populations at high risk (including different racial and ethnic groups and exposure categories), uninfluenced by testing behavior. Such populations are likely to be under-represented using other surveillance approaches.

On June 5, 1998, CDC's Office of the Director and the National Center for HIV, STD, and TB Prevention hosted a consultation with external experts on the ethics of anonymous unlinked HIV serosurveys. Panel members which included epidemiologists, bioethicists, and community leaders, were asked for their opinion on the following question: **"In balancing the opportunity to obtain important information about HIV for public health services with an individual's right to know his/her HIV status in order to benefit from current therapies and their right to consent to research, are anonymous unlinked serosurveys ethically justified today?"** Each panel member thought the blinded serosurveys were ethically justified in today's environment. However, several of the panel members suggested that the program continue to review these studies for how the data were being used and to ensure their optimal use at the local level where the data were collected. Several panel members also encouraged CDC to expand the surveys into populations that were not currently being examined and into populations of both high and low risk for HIV infection, such as prisoners and groups more representative of the general population.

The value of this surveillance tool has increased now that CDC has developed technology that identifies recent HIV infections using single blood specimens from blinded seroprevalence surveys, thus allowing measurement of incidence of HIV infection from cross-sectional surveys. Until now, HIV incidence (the number of new infections occurring each year) had been difficult to measure

accurately, although this is the single most important epidemiologic parameter for deciding where resources should be targeted and for evaluating prevention efforts. The altered significance of AIDS case surveillance data, the incomplete nature of HIV surveillance, the bias inherent in HIV surveillance data due to testing behavior, the objective nature of blinded surveys, and the ability to measure incidence through blinded seroprevalence surveys all support the utility and maintenance of these surveys.

CDC believes that various approaches are necessary to track the epidemic of HIV/AIDS, as no single approach can provide all the relevant information. Blinded seroprevalence surveys are just one important component of our surveillance efforts.

I assure you that we are working diligently to address these issues, and we appreciate your continuing interest in this important work to increase our understanding of the scope and nature of the HIV epidemic in our country and ensure equitable distribution of public health resources and services to affected communities. I hope this information is helpful to you. An identical letter is being sent to Representative Gary L. Ackerman who cosigned your letter.

Sincerely yours,

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

Enclosure

Steps the Centers for Disease Control and Prevention
Is Taking To Assist Its Partners in Increasing
the Number of HIV-positive People Who Know Their Serostatus

- Through the HIV prevention community planning process, many planning groups and/or State health departments have undertaken initiatives to increase awareness of HIV serostatus. These include street outreach, risk-reduction counseling, and community-level interventions to assist people in assessing their risks and encouraging those at risk to seek counseling and testing (C&T) services.

- CDC maintains close partnerships with national nongovernmental organizations that promote awareness of serostatus. For example, CDC provides funds each year to the National Association of People With AIDS in support of "HIV Testing Day," held annually on June 27.

- CDC is currently developing a targeted campaign to encourage individuals at increased risk for HIV infection to seek testing and, if infected, get early treatment. This is tentatively planned for launch in late 1998 as a public-private partnership.

- CDC provides funds to support free and anonymous testing opportunities to facilitate access to service providers for people at risk who have significant concerns about confidentiality.

- CDC supports research related to communications strategies and behavioral interventions that are effective in encouraging people at risk to seek C&T and other prevention services.

- CDC provides training for personnel at C&T sites (e.g., client-centered counseling, quality assurance).

- CDC has revised partner notification and C&T guidelines to clarify tasks, timeliness, and responsibilities. This will assist service providers nationwide in providing higher quality counseling and testing services that should encourage more people to return for test results.

- CDC has co-sponsored satellite broadcasts for service providers on client-centered counseling and new HIV testing technologies (i.e., rapid tests and home collection kits) and on partner notification and prevention case management.

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

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August 28, 2000

Helene D. Gayle, M.D. M.P.H.
Director, National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30333

Dear Dr. Gayle,

It has been over two years since we last corresponded regarding HIV serosurveillance ("blind" or "unlinked" tests) supported by the Centers for Disease Control and Prevention (CDC).

As you know, I feel that these tests are highly unethical because they deny those who do test positive the knowledge of their status and thus exclude them from seeking medical care which can improve their lives and from taking precautions to prevent infecting others.

I am curious to know if the CDC is still conducting "blind tests." If so, in light of the available medical care that can improve and enhance the lives of many living with HIV/AIDS, has the CDC re-evaluated the ethics of these "blind tests?" Could you also provide me with a summary of the locations and types of sites at which these tests are being administered?

When I last heard from you on this matter, up to 90 percent of those found to be HIV-positive through these government funded tests at some clinics did not themselves receive an HIV test. As you know, this means that at these locations, nine out of ten individuals that the CDC diagnosed as infected, were never alerted. Has this number changed? Besides merely making testing available at these sites, is anything being done to encourage these individuals who are infected but not aware of their status to get tested and enrolled into care?

Thank you for your assistance. I look forward to a timely response. If you have any questions, please do not hesitate to contact me.

Sincerely,

Tom A. Coburn, M.D.
Vice Chair
Commerce Subcommittee on Health and Environment

429 CANNON HOUSE OFFICE BUILDING
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(202) 225-2701 Fax: (202) 225-3038

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E-mail: rep.coburn@mail.house.gov
Web site: www.house.gov/coburn

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA
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March 21, 1996

Dr. Helena Gayle
Centers for Disease Control and Prevention
26 Executive Park Drive
Atlanta, GA 30333

Dear Dr. Gayle,

It has recently come to my attention that the CDC has an unusual classification for heterosexuals who acquire HIV or AIDS.

Is it true that unless a heterosexual has sex with someone who is either bisexual, an IV drug user, someone with hemophilia, a transfusion recipient of HIV or known to have HIV they are not classified as a heterosexual AIDS or HIV case but rather as a "risk not identified"? If true, I would very much appreciate a rational for such a contorted classification system. Doesn't this ultimately prove to be highly discriminatory against those people today who are most affected by HIV and AIDS heterosexually; namely, those in communities of color?

If we base much of our allocation of resources on groups that are affected by this disease, how can we accurately allocate resources to those who need them most if they are not properly classified? It is my understanding that the U.S. Conference of Mayors, for example, gave 13 of 16 of their previous year's grants to either gay or bisexual men. Yet the greatest increases are not in that area, but rather among heterosexuals, particularly in African American and Hispanic communities and women.

As a practicing physician who sees this disease increasingly among heterosexuals, I am very concerned that the CDC-- because of its classification system-- is not giving adequate information and warning to those who are increasingly at risk for acquiring this disease. I would very much appreciate your explanation of this strange occurrence as quickly as possible.

I would also hope that heterosexuals who acquire HIV heterosexually from any heterosexual be classified as a heterosexual AIDS or HIV case as quickly as possible. That way we can get a better read on the extent of HIV/AIDS in the heterosexual population and help those most at risk.

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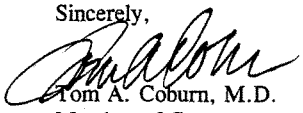
Thank you very much for your assistance with this matter. Please do not hesitate to contact me if you have any questions.

Sincerely,



Tom A. Coburn, M.D.
Member of Congress

cc: Rep. Thomas Bliley
Rep. Michael Bilirakis
David Satcher, M.D.

TAC: rf

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

MAY 14 1996

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515-3602

Dear Dr. Coburn:

This is in response to your letter regarding classification of heterosexuals with HIV infection or AIDS.

The Centers for Disease Control and Prevention's (CDC) AIDS surveillance system counts HIV infection and AIDS cases only once within a hierarchy of exposure categories. (See the enclosed *HIV/AIDS Surveillance Report* [*HASR*].) Persons with AIDS who reported specific heterosexual contact with someone with or at increased risk for HIV infection and who had no other behavioral risks are classified as "heterosexual contact" cases. Persons with AIDS who report no history of exposure to HIV through any of the transmission modes listed in the hierarchy of exposure categories are classified as "risk not reported or identified" cases. (See Table 3 from the enclosed *HASR*.) These cases include persons who are currently under epidemiologic investigation by local health department officials; persons whose exposure history is incomplete because they are deceased, declined to be interviewed, or were lost to follow-up; and persons who were interviewed or for whom other follow-up information was not available and no exposure mode was identified. Persons who have an exposure mode identified at the time of follow-up are reclassified into the appropriate exposure category. (See Figure 7 from the enclosed *HASR*.)

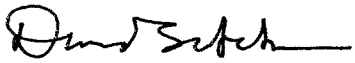
The percentage of 1995 cases initially reported with risk not reported or identified will decrease over time because State and local health departments conduct follow-up epidemiologic investigations of these persons. Of the 61,028 AIDS cases reported to CDC through December 1995 with no risk reported or identified, 38,300 (72 percent) have been reclassified with a risk factor; the remaining 22,728 (37 percent) open cases are still under investigation. (Please refer to the Technical Notes in the enclosed *HASR* for a more detailed description of these cases.)

The enclosed *Morbidity and Mortality Weekly Report* (*MMWR*) article, "Heterosexually Acquired AIDS--United States, 1993," also contains additional information on further clasification changes to promote more consistent risk ascertainment among persons reported with AIDS.

We are constantly progressing in our knowledge of HIV infection and AIDS, including the patterns of HIV transmission. Consequently, we routinely review our surveillance system to make sure it maintains pace with the evolving epidemic as evidenced by the classification changes mentioned above.

I appreciate your interest in this important public health issue, and hope this information is helpful.

Sincerely,



David Satcher, M.D., Ph.D.
Director

Enclosures

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May 14, 1996

Dr. Helene Gayle
Centers for Disease Control and Prevention
26 Executive Park Drive
Atlanta, GA 30333

Dear Dr. Gayle,

I sent you a letter March 21, 1996 regarding the CDC's unusual classification for heterosexuals who acquire HIV or AIDS.

I inquired whether or not it was true that unless a heterosexual has sex with someone who is either bisexual, an IV drug user, someone with hemophilia, a transfusion recipient of HIV or known to have HIV they are not classified as a heterosexual AIDS or HIV case but rather as a "risk not identified"? If true, I would very much appreciate a rational for such a contorted classification system. Doesn't this ultimately prove to be highly discriminatory against those people today who are most affected by HIV and AIDS heterosexually; namely, those in communities of color?

If we base much of our allocation of resources on groups that are affected by this disease, how can we accurately allocate resources to those who need them most if they are not properly classified? It is my understanding that the U.S. Conference of Mayors, for example, gave 13 of 16 of their previous year's grants to either gay or bisexual men. Yet the greatest increases are not in that area, but rather among heterosexuals, particularly in African American and Hispanic communities and women.

As a practicing physician who sees this disease increasingly among heterosexuals, I am very concerned that the CDC-- because of its classification system-- is not giving adequate information and warning to those who are increasingly at risk for acquiring this disease. I would very much appreciate your explanation of this strange occurrence *as quickly as possible*.

I would also hope that heterosexuals who acquire HIV heterosexually from any heterosexual be classified as a heterosexual AIDS or HIV case as quickly as possible. That way we can get a better read on the extent of HIV/AIDS in the heterosexual population and help those most at risk.

I would appreciate a timely response. Do not hesitate to contact me if you have any questions.

Sincerely,

Tom A. Coburn, M.D.
Member of Congress

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUL 25 1996

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515-3502

Dear Dr. Coburn:

Thank you for your follow-up letter regarding classification of HIV exposure categories for heterosexuals reported with AIDS.

As part of its surveillance system, the Centers for Disease Control and Prevention (CDC) documents all possible HIV exposure categories for persons reported with AIDS. (Please see Table 17 of the enclosed *HIV/AIDS Surveillance Report [HASR]* for a list of the multiple exposure categories that have been reported among persons with AIDS.) For classification purposes, however, persons with more than one possible mode of HIV exposure are usually classified in only one risk category, such as the one that reflects the most probable means of infection.

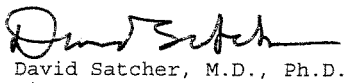
CDC recognizes that the exact mode of transmission for each individual who reports multiple risks usually cannot be established and continues to monitor the classification of all persons reported with HIV infection and AIDS. Several studies have shown that the current classification system has proven highly accurate in categorizing persons who became infected with HIV through heterosexual contact. For example, CDC has conducted a study specifically investigating persons reported with AIDS whose HIV exposure category was classified as heterosexual contact or no identified risk. The study data indicated that AIDS surveillance trends accurately reflect heterosexual transmission of HIV. However, the study also found that persons with AIDS whose HIV exposure is classified as heterosexual contact may have additional behavioral risks that could have led to classification in another exposure category (for example, injecting drug use) and that some persons for whom no identified risk was found may actually have acquired HIV infection heterosexually. Thus, the data on AIDS cases resulting from heterosexual contact in the *HASR* may be slightly conservative. Enclosed is a copy of the abstract from the study, "Does Misclassification of HIV Exposure Impact AIDS Trends among Heterosexuals in the United States?," which was presented at the XI International Conference on AIDS in Vancouver, Canada, July 7-12, 1996.

Another study which has assisted CDC's efforts to monitor the HIV exposure classification of persons with AIDS is the "Supplement to HIV/AIDS Surveillance (SHAS) Project." This Project provides additional information on transmission and infected individuals by collecting information through individual interviews that is not usually available in patients' medical records. One aspect of this project concerns heterosexual transmission of HIV. Enclosed is a recent article from the SHAS Project, "Risk Behaviors of Persons with Heterosexually Acquired HIV Infection in the United States: Results of a Multistate Surveillance Project." Another article from the SHAS Project, "Characteristics of Women 50 Years of Age or Older with Heterosexually Acquired AIDS," is scheduled for publication in the August issue of the *American Journal of Public Health*. This article highlights that women over 50 years of age who had heterosexually acquired HIV infection were less likely to perceive risk and may have fewer opportunities to be tested.

CDC will continue to monitor the accuracy of the current classification system for HIV exposure for persons with AIDS. Should data indicate that changes are needed, we will certainly examine methods to more accurately classify exposure categories. At present, however, data indicate that the current system is very accurate in monitoring exposure categories, despite classification problems for persons with AIDS who report multiple exposure categories.

We appreciate your interest in and concerns about this important public health issue. I hope this information is helpful.

Sincerely,



David Satcher, M.D., Ph.D.
Director

Enclosures

Congress of the United States
House of Representatives
Washington, D.C. 20515

June 19, 2000

Jeffrey P. Koplan, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
1600 Clifton Road, NE.
Atlanta, Georgia 30333

Dear Dr. Koplan,

Thank you for making your staff available earlier this week to discuss the CDC's "no identifiable risk" (NIR) classification for reported HIV/AIDS cases with members of our staff. We appreciate the CDC's attentiveness to addressing our questions regarding this issue.

As you know, the question has been raised whether the heterosexual and NIR categories as currently defined may result in systematic underreporting of heterosexual cases, which could be detrimental to addressing the prevention needs of certain groups, particularly communities of color.

This classification system may have been satisfactory early in the epidemic, but the changing dynamics of the HIV/AIDS epidemic require a timely reassessment and refinement of current classification methods. We applaud the CDC's recognition of State efforts to accomplish these goals, including Virginia's efforts to identify NIR cases with multiple sex partners. Your staff has indicated that your agency is also currently reassessing HIV/AIDS case classification methods to ensure the most adequate understanding of the disease and its modes of transmission and to properly allocate and target resources to those groups that are increasingly at risk of infection, such as African American females.

Based on this understanding, we urge you to commit to an agenda of coordinated actions with the States and patient advocates, including a scientific review of risk assessment methodologies, the development and validation of rigorous sampling techniques, the promulgation of formal guidance for HIV risk monitoring to the States, the provision of technical assistance to State and local health authorities, and the expansion of the CDC's current pilot projects with interested States. You can be sure of our support for the additional resources necessary for CDC to implement this ambitious but important agenda.

Finally, we appreciate your commitment to hold an expert consultation with scientific, public health, and community partners on this issue, and to consult with us and our designees prior to the meeting in the very near future.

We look forward to your response outlining the steps you intend to take and a timetable for accomplishing them and your estimate of the resources necessary to assist States to achieve these goals. Thank you again for your attention to this matter. We look forward to working with you to ensure the best possible classification of reported HIV/AIDS cases.

Sincerely,

TOM COBURN
Member of Congress

HENRY A. WAXMAN
Member of Congress

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

AUG 3 2000

The Honorable Tom A. Coburn, M.D.
House of Representatives
Washington, D.C. 20515

Dear Dr. Coburn:

Thank you for your letter expressing your concern about the accuracy of current HIV/AIDS risk categorizations used in the Centers for Disease Control and Prevention's (CDC) surveillance activities. As you indicate, our staffs have had an opportunity to discuss this issue, and I am writing to reassure you that CDC remains committed to developing and maintaining HIV surveillance strategies for the collection of accurate data on behavioral risks for HIV acquisition and transmission and to outline for you specific actions that are underway or planned.

First, we share your concerns. We, too, want to make sure that classifications are as accurate as possible and that case reports reflect the most probable route of infection. The current shift from a national AIDS surveillance system to integrated State and local HIV/AIDS surveillance systems only reinforces the need for the most accurate behavioral risk data. Such data are critical for assuring the optimal allocation of resources for prevention and treatment at the State and local levels. Comparability of data across States is also necessary so that CDC can provide reliable data to other Federal agencies and Congress for national planning and resource allocation.

In this regard, CDC is developing an *Action Plan for Monitoring Behavioral Risks for HIV,* which we are moving aggressively to implement. Action steps include the following:

- CDC hosted a small, limited-attendance meeting on July 25 to review findings from scientific studies of heterosexual-contact and no-identified-or-reported-risk (NIR) cases and to outline action steps for improving the completeness and accuracy of risk information collected through case surveillance and supplemental projects and activities.

- CDC is also planning a consultation for early 2001 with a larger group of experts from around the country to review current HIV incidence and prevalence data by geographic area and risk group to (1) examine CDC's assumptions of "hierarchical" risk classification, (2) summarize available data from surveillance and research studies to promote the use of best practices for categorizing risk groups, (3) determine the most efficient methods for risk ascertainment in all States, and (4) critically assess current and planned behavioral surveillance activities for enhanced surveillance program planning. This consultation will assist in making any necessary adjustments to the current risk classification system. Again, you and your designees are invited to attend, and we will consult with your staff about the meeting as you have requested.

- CDC will convene a meeting of surveillance staff representing all State health departments in September 2000 to provide technical assistance and program guidance for evaluating the performance of surveillance systems, including the collection of behavioral risk data. The purpose of the meeting is to assist States to achieve the standards for best practices established in CDC's published guidelines for conducting HIV case surveillance.

Other proposed activities to be included in the Action Plan are as follows:

- Using available data to develop statistical adjustments to provide accurate estimates of the distribution of risk groups in HIV populations.

- Performing a review of publications on the heterosexual HIV/AIDS epidemic. A summary of selected articles is enclosed (Tab A).

- Performing a review of available scientific studies on the completeness, accuracy, and validity of risk data currently collected through HIV/AIDS case surveillance. A summary of selected studies is enclosed (Tab B).

- Implementing collaborative actions with State and local health departments during the next few years to enable them to collect behavioral surveillance data in targeted populations to accurately monitor trends in the epidemic, direct prevention services, and assess whether target populations are receiving such services.

- Estimating the resources that State and local health departments will require to implement behavioral risk surveillance activities (e.g., sampling methodology, medical record reviews, interactions with case reporting sources, and patient interviews) among at-risk-populations and reported cases of HIV and AIDS.

We appreciate your interest in and concerns about these important public health issues, and I hope this information is helpful. An identical letter is being sent to Representative Henry A. Waxman who cosigned your letter.

Sincerely,

Jeffrey P. Koplan

Jeffrey P. Koplan, M.D., M.P.H.
Director

Enclosures:
Tab A - Summary of Selected Publications on the Heterosexual HIV/AIDS Epidemic
Tab B - Summary of Selected Scientific Reviews of Behavioral Risks for HIV Transmission

SUMMARY OF SELECTED PUBLICATIONS ON THE HETEROSEXUAL HIV/AIDS EPIDEMIC

Since 1985, CDC has emphasized the role that high risk heterosexual sex plays in HIV transmission in the United States. The highest risk sexual contacts include sex with persons at risk of HIV (MSM, IDU) and persons known to have HIV or AIDS. The first cases attributed to heterosexual contact were in sex partners of injection drug users. Later, CDC highlighted the potential for sustained ongoing heterosexual transmission among persons not otherwise recognized to have risks for HIV (i.e. not MSM, IDU, or known to have HIV/AIDS) but who have high-risk heterosexual behaviors. Several studies were launched to better characterize such behaviors and to promote standards in categorizing high-risk heterosexual behaviors. A few highlights from published articles on heterosexual transmission follow:

Epidemiologic notes and reports: heterosexual transmission of human T-lymphocyte virus type III/lymphadenopathy-associated virus.
MMWR 1985;34:561-3.

First MMWR article focusing on heterosexual transmission – description of first 133 cases classified as heterosexual contacts (118 women and 15 men).

"While additional evidence for female-to-male transmission of HTLV-III/LAV in the United States is being sought, it would be prudent to assume that such transmission occurs."

Current trends update: heterosexual transmission of acquired immunodeficiency syndrome and human immunodeficiency virus infection -- United States.
MMWR 1989;38:423-4, 429-34.

"Both AIDS surveillance and HIV seroprevalence follow up studies indicate that an appreciable proportion of HIV infection among women in the United States is acquired through heterosexual contact. Because HIV seroprevalence is greater in men, a woman is more likely than a man to have an infected heterosexual partner... the predominance of heterosexually-acquired HIV infections in women of reproductive age has important implications for perinatal HIV transmission; nearly 30% of children with AIDS were infected by their mothers who acquired infection through heterosexual contact."

Heterosexually Acquired AIDS -- United States, 1993.
MMWR 1994;43:155-160.

"From 1991 though 1992, persons with acquired immunodeficiency syndrome (AIDS) who were infected with human immunodeficiency virus (HIV) through heterosexual transmission accounted for the largest proportionate increase in reported AIDS cases in the United States."

"Other persons with AIDS also may have become infected through heterosexual contact. For example, of the 86,961 persons cumulatively classified as IDUs, approximately 12,600 also reported heterosexual contact with a person at risk. In addition, after follow up investigations are

completed, some persons currently classified as "risk not reported" will be found to have risks for heterosexual transmission. To develop more accurate estimates of the proportion of AIDS cases resulting from heterosexual transmission, CDC is collaborating with 6 state and local health departments to evaluate the validity and accuracy of heterosexual risk information reported to surveillance programs." [This refers to the "MTV" project described later in this document.]

AIDS in women in the United States: recent trends.
Wortley PM, Fleming PL. JAMA 1997:911-916.

This article summarizes trends in AIDS incidence in women through 1995, focusing on the increasing number of women who acquired HIV through heterosexual contact.

"Incidence trends for AIDS in women grouped by year of birth reveal successive cohorts of women at risk for HIV infection as they reach adolescence and young adulthood, an effect more pronounced for women infected through heterosexual contact than IDU, consistent with heterosexual transmission continuing to increase after IDU-related transmission slowed in the mid 1980's...Women born between 1970 and 1974 began to be infected through heterosexual contact in the late 1980's, as demonstrated by a sharp increase in AIDS incidence in this group between 1991 and 1995. These young women became sexually active at a time when HIV prevalence in men had reached a high ... The pattern observed here raises concern that future generations of young women will become infected with HIV as they reach the age of sexual activity initiation."

Trends in heterosexually acquired AIDS in the United States, 1988 through 1995.
Neal JJ, Fleming PL, Green TA, Ward JW. Journal of Acquired Immune Deficiency Syndrome 1997;14:465-474.

This article presents trends in AIDS attributable to heterosexual transmission and attempts to differentiate persons infected by a partner with a primary risk, such as injection drug use or male-male sex (primary heterosexual transmission) and persons infected by partners who were infected heterosexually (secondary heterosexual transmission).

"The disagreement concerning the potential for more widespread HIV transmission among the heterosexual population reflects the lack of data that clearly differentiate between two different populations of heterosexually infected populations – those infected through primary and those infected through secondary heterosexual transmission. Most cases of heterosexually acquired AIDS are attributed to primary heterosexual transmission, such as sex with IDU. Persons who are at risk of becoming HIV infected through secondary heterosexual transmission may not be easily identified. Because they may not belong to any of the recognized groups targeted by established education and prevention programs, many persons will not perceive themselves or their partners to be at risk and may represent a potential for more widespread heterosexual transmission in the United States."

SUMMARY OF SELECTED SCIENTIFIC REVIEWS OF BEHAVIORAL RISKS FOR HIV TRANSMISSION

During the past decade, CDC has collaborated with state and local health departments in conducting a number of studies to assess the accuracy of risk data and to promote improvements in reporting of HIV transmission risks through HIV/AIDS surveillance. Several are highlighted here:

Risk Misclassification Study

Publication:

Nwanyanwu OC, Conti LS, Ciesielski CA, *et al.* Increasing frequency of heterosexually transmitted AIDS in southern Florida: artifact or reality? *Am J Public Health* 1993:83:571-3.

Background and Objectives:

A disproportionate number of heterosexually acquired AIDS cases were being reported from Florida: 24% of all US AIDS cases attributed to heterosexual contact had been reported from Florida through 1991, compared with 9% of all US AIDS cases attributed to other modes of exposure.

The male-to-female ratio of heterosexually acquired AIDS cases in Florida was 1.4, compared with a male-to-female ratio <1 (attributable to higher efficiency of male-to-female heterosexual transmission than female-to-male) in all other States.

Unusual findings prompted record review and interview study to identify possible misclassification of risk

Results:

36 of 168 heterosexual-contact cases (21%) were reclassified into other exposure categories based on record review.

Of 132 cases that could not be reclassified based on record review, 97 were among persons available for interview. Risk was reclassified for 14 persons (14% of those interviewed).

Follow-up record review and interviews resulted in reclassification of 50 (30%) of 168 cases initially reported as heterosexually acquired.

After adjustment for reclassification, the male-to-female ratio was 1.0.

31.3% of 32 men who were interviewed but not reclassified had anorectal pathologies suggesting that some of them may have had sexual intercourse with other men but did not report this behavior.

Conclusion:

Increase of heterosexually acquired AIDS in Florida was occurring at a lower rate than

originally had been reported.

Mode of Transmission Validation (MTV) Project

Publication:

Klevens RM, Fleming PL, Neal JJ, Li J, and the Mode of Transmission Validation Study Group. Is there really a heterosexual AIDS epidemic in the United States? Findings from a multisite validation study, 1992-1995. *Am J Epidemiol.* 1999;149;75-84.

Background and Objectives:

Objectives of MTV Project were to validate mode of exposure for cases initially reported as heterosexually acquired and determine proportion of cases initially reported with no risk that may have been heterosexually acquired.

Six sites: Alabama, California, Florida, New Jersey, New York City, Texas

Project period: 1992-1995

Results (heterosexually acquired cases):

Of 1,952 persons classified as having heterosexually acquired HIV, 82% validated as having heterosexual risks for HIV infection documented in medical reports.

The likelihood that a case could not be validated as heterosexually acquired (i.e., information on other risks was found on medical record or follow up, but no information to document heterosexual contact as the likely mode of HIV infection) was greater for male cases initially reported as heterosexually acquired than for female cases (24% vs. 13%).

Of 799 males cases initially reported as heterosexually acquired:

76% validated as heterosexually acquired
9% reclassified to MSM category
12% reclassified to IDU category
3% reclassified to hemophilia category
3% reclassified to transfusion category

Of 1,153 females cases initially reported as heterosexually acquired:

87% validated as heterosexually acquired
13% reclassified to IDU category
<1% reclassified to hemophilia category

Results (NIR cases):

52% of NIR cases among men and 62% of cases among women were reclassified based on risk information identified by medical record review.

Of 415 males cases initially reported as NIR:

23% reclassified to MSM category

15% reclassified to IDU category
2% reclassified to MSM/IDU
12% reclassified as heterosexual
1% reclassified transfusion category
48% risk not identified*

Of 219 females cases initially reported as NIR:
21% reclassified to IDU category
38% reclassified as heterosexually acquired
3% reclassified to transfusion category
38% risk not identified*

Conclusion:
Most reports of heterosexually acquired AIDS were validated.

* High risk sexual behaviors were identified for some of these cases that remained NIR. These findings led to the development of ongoing studies of high-risk heterosexual behaviors and efforts to model behavioral risk data collected through interview projects.

MTV Abstracts:

Klevens RM, Fleming PL, Neal JJ, Li J, and the MTV Study Group. Does misclassification of HIV exposure impact AIDS trends among heterosexuals in the United States? [Abstract Th.C.340]. XIth International Conference on AIDS, Vancouver, British Columbia, July 1996.

This abstract was a precursor to *AJE* paper based on medical record reviews. Conclusion was that risk information on most AIDS cases reported as heterosexually acquired was validated.

Klevens RM, Fleming PL, Neal JJ, Li J, and the MTV Study Group. How common is secondary transmission of HIV in the US? [Abstract 43438]. 12th World AIDS Conference, Geneva, Switzerland, July 1998.

Summary: Using MTV Project *interview* data, authors assessed the frequency with which persons with heterosexually acquired AIDS knew the HIV risk behaviors of their sex partners. Although most heterosexually acquired AIDS cases were in persons whose partners were known to have a primary risk (e.g., MSM, IDU, receipt of contaminated blood, blood products, organ, or tissue), 16% of men and 24% of women were potentially infected through secondary heterosexual transmission.

REVIEW

Is there an epidemic of HIV/AIDS among heterosexuals in the USA?

H W Haverkos, R C Chung, L C Norville Perez

Postgrad Med J 2003;**79**:444–448

The Centers for Disease Control and Prevention (CDC), Atlanta, reports HIV infections and AIDS cases in the United States biannually. Trends in the distribution of HIV/AIDS cases according to sex, race or ethnic group, and various categories of exposure to HIV were analysed. The groups in which there were the greatest percentage increases over time were the group with heterosexual contact and the group for whom the risk factors were not reported or identified. The CDC should be encouraged to provide additional information regarding sexual and drug-using behaviours of those patients listed as "undetermined".

Few issues related to AIDS have generated as much interest and debate in the USA as heterosexual transmission of HIV and its potential importance to the epidemic. In the book *Crisis: Heterosexual Behavior in the Age of AIDS* published in 1988, sex therapists Masters *et al* screened 3805 men and women in Atlanta, Los Angeles, New York, and St Louis, and observed that HIV had spread among heterosexual American adults.[1] In 1990, civil rights journalist Michael Fumento published *The Myth of Heterosexual AIDS* and suggested that the US Public Health Service was exaggerating the epidemic among heterosexuals to garner increased research funds.[2] In a 1988 review article on the epidemiology of AIDS, the proportion of cases attributed to heterosexual transmission had not increased relative to other risk groups.[3] Where is the HIV/AIDS epidemic going in the USA in the 21st century? What can be learned from the Centers for Disease Control and Prevention (CDC) surveillance data for AIDS and HIV infection?

METHODS

Since 1981, the CDC has tabulated and reported AIDS cases in the USA and listed patients by exposure categories. Since 1993, the CDC has tabulated and reported HIV infection not AIDS, in those states and territories willing to report such data. We analysed CDC HIV/AIDS surveillance year end reports from 1983 to 2001, examining changes in the definitions of exposure categories, and trends in the incidence of AIDS cases and HIV infections as reported.[4]

Using the CDC hierarchical definition of exposure categories, we constructed five mutually exclusive categories among adults/adolescents. First, "gay" men or men who have sex with men includes all males over the age of 13 years at diagnosis who reported any sex with males and includes those who also reported having injected drugs not prescribed by a physician. Second, injection drug users includes both men who deny sex with men and females who reported ever injecting drugs not prescribed by a physician. Third, blood transfusion recipients include adults and adolescents who deny male homosexuality and injection drug abuse and have been a recipient of whole blood, blood components, or tissues. Blood recipients also included persons with haemophilia and coagulation disorders who have received fractionation proteins. Fourth, heterosexual contact cases are defined as those who deny male homosexuality, injection drug use, and receipt of any blood products and reported heterosexual contact with a person with HIV/AIDS or at increased "risk" for HIV/AIDS. "Risk" is defined as men who have sex with men, injection drug users, or blood recipients. Fifth, "undetermined" or risk not specified refers to all other patients whose mode is unknown or not clearly specified. This undetermined group includes patients under investigations, who died, were lost to follow up, or refused interview, and patients not meeting a risk category definition listed above after interview. Heterosexual contact patients were further subdivided by the reported risk of the identified sexual partner, or if a partner was not identified as a bisexual man, injection drug user, or blood transfusion recipient, those heterosexual contact patients are listed as having sex with a partner of "undetermined risk" with HIV/AIDS. Children, all patients less than 13 years of age at HIV or AIDS diagnosis are listed without regard to exposure category. We tabulated data by gender, racial or ethnic group, and exposure category for AIDS cases from 1981–2001, and HIV infection from 1993–2001, charting the total numbers of reported patients and percentages of exposure categories.

RESULTS

Table 1 lists the number of patients with AIDS reported each year from 1983–2001; the number of HIV infections, without AIDS, reported each year, and numbers of states/US territories reporting HIV infection from 1993–2001.[4] The definition of AIDS for case reporting expanded several times, including the inclusion of additional opportunistic infections in 1987 and to include additional diagnoses and laboratory indicators of immunodeficiency in 1993.[5 6] The 1993 change in the case definition of AIDS, the increasing use of highly active antiretroviral therapy for HIV infected persons, and the increasing number of

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Table 1 AIDS and HIV cases reported by the CDC from 1981 to December 2001, United States

Year	No with AIDS	No with HIV infection, not AIDS	No of states/territories reporting HIV infection
1981–1983	3064	0	0
1984	4530	0	0
1985	8354	0	0
1986	13097	0	0
1987	20620	0	0
1988	32311	0	0
1989	35238	0	0
1990	43339	0	0
1991	45506	0	0
1992	47106	0	0
1993	106949	15047	26
1994	80691	18598	27
1995	74180	15206	28
1996	69151	13769	30
1997	60634	14514	30
1998	48269	19391	33
1999	46400	21417	34
2000	42156	21704	36
2001	43150	35575	39
Total	816149	174026	–

Source: reference 4.

Table 2 Cases of AIDS reported in USA in 1986, 1991, 1996, and 2001 according to category of exposure

Exposure category	1986	1991	1996	2001	% Change*
Adult/adolescent					
1. Gay men	9416 (72)	26326 (58)	30283 (44)	14767 (34)	–38
2. Injecting drug users	2136 (16)	11155 (25)	17027 (25)	7473 (17)	+1
3. Blood recipients	405 (3)	1030 (2)	869 (1)	324 (1)	–2
4. Heterosexual contact	485 (4)	3387 (8)	8821 (13)	6904 (16)	+12
5. Undetermined	468 (4)	2925 (7)	11473 (17)	13515 (31)	+27
Children	187 (1)	683 (2)	678 (1)	175 (0)	–1
Total	13097 (100)	45506 (100)	69151 (100)	43158 (100)	–

Source: reference 4.
*Percent change calculated by subtracting % in 1986 from % in 2001.
Notes: See text for definitions of exposure categories.
1. Gay men include all men who report sex with men and those men who also report injecting drug use.
2. Injecting drug users excluding men who have sex with men.
3. Blood recipients include adults/adolescents who deny male homosexual behaviour and injecting drug use, and are haemophiliac or transfusion recipients of blood or blood components.
4. Heterosexual contact include adults/adolescent who deny male homosexual behaviour, injecting drug use, haemophilia, and previous blood or blood components, *and* report heterosexual contact with a person with HIV or AIDS, a bisexual male, injecting drug user or blood recipient.
5. Undetermined includes patients who do not meet any of the definitions above (see text).
Children include all those under age 13 years at time of diagnosis regardless of exposure category.

states/territories reporting HIV infection complicate the interpretation of surveillance data.

The classification schema to count AIDS patients by exposure categories has been modified by CDC as clinicians and epidemiologists learned more about the epidemiology of HIV transmission, however exposure categories have always been listed hierarchically. Patients with multiple characteristics are tabulated in the group listed first. The definition of heterosexual contact and undetermined patients changed several times between 1984 and 1989, and has remained the same since 1989. Heterosexual contact patients were first reported in 1984 and included those who denied male homosexuality, intravenous drug use, Haitian origin, or haemophilia and reported heterosexual contact with a person with AIDS or at risk for AIDS. In 1985, the Haitian category was incorporated into heterosexual contact patients if such patients reported sex with a person with AIDS or at risk for AIDS. Haitian patients not reporting sex with a person with AIDS or at risk for AIDS were listed as "None of the above/other"/"as persons born in countries in which most AIDS cases have not been associated with known risk factors".[4] In 1986, the "None of the above/other" category was renamed "Undetermined". Undetermined included "patients on whom risk information is incomplete (due to death, refusal to be interviewed, or loss to follow up), patients still under investigation, men reported *only* [italics added] to have had heterosexual contact with a prostitute, and interviewed patients for whom no specific risk was identified". In 1989, the CDC acknowledged that some of these "undetermined" patients may represent "unrecognised" heterosexual transmission of HIV.[5]

Table 2 lists the reported patients with AIDS according to exposure categories in 1986, 1991, 1996, and 2001. Homosexual or bisexual men, including those gay men who injected drugs, accounted for 72% of all cases reported in 1986 and 34% in 2001. The groups in which there were the greatest percentage increases over time were the group with heterosexual contact category (4%–16%) and the group for whom risk

Table 3 Heterosexual contact cases of AIDS reported in USA in 1988, 1991, 1996, and 2001 by attributed partner source exposure category

Heterosexual by identified partner source	1988*	1991	1996	2001	% Change*
With bisexual male	88 (6)	147 (4)	306 (3)	192 (3)	–3
With injecting drug user	847 (55)	1798 (53)	2790 (32)	1486 (22)	–33
With blood recipient	39 (3)	108 (3)	148 (2)	45 (1)	–2
Born in pattern-2 country†	379 (25)	510 (15)	–	–	–
Sex with person born in pattern-2 country	21 (1)	44 (1)	–	–	–
With undetermined	167 (11)	780 (23)	5577 (63)	5181 (75)	Calculation is not appropriate due to definition changes
Total	1541 (100)	3387 (100)	8821 (100)	6904 (100)	–

Source: reference 4.
*1988 was the first year that CDC reported the number of heterosexual contact cases further subdivided by identified partner source.
†Pattern-2 was observed in areas of central, eastern, and southern Africa and in some Caribbean countries. In those countries, most of the reported cases occur in heterosexuals; the male-to-female ratio is approximately 1:1; and perinatal transmission is more common than in other areas. CDC stopped reporting patients by birth in pattern-2 countries in 1993 (see text and reference 4).

factors were not reported or identified (4%–31%). Furthermore, a shift or movement of AIDS into the heterosexual community is suggested by evaluating the trends in proportions of the "risk identified for partners" of heterosexual transmission patients (table 3). Fifty five percent of heterosexual contact patients identified injection drug users as their partner source in 1988, 22% in 2001. Eleven percent of heterosexual contact patients reported source partners with undetermined HIV or AIDS risk in 1988, 75% in 2001.

Investigators conducting AIDS surveillance have been criticised because AIDS represents the most advanced stages of HIV infection. HIV infection progresses to AIDS after a long incubation period, in many cases as long as 10 years or more after HIV infection. Highly active antiretroviral therapies became available in the mid-1990s and may further delay the progression of HIV infection to AIDS.[10] In 1993 CDC began reporting data from a number of states and territories on persons reported with HIV infection who have not yet developed AIDS (table 1). By December 1993, 26 states had laws or regulations requiring confidential reporting by name of persons with confirmed HIV infection (1993 report[1]). By December 2001, 35 states, American Samoa, Guam, Mariana Islands, and the Virgin Islands had such laws or regulations. New York State first reported HIV data in June 2000 and accounts for the increase in the HIV infections in 2001 (table 1). The data for HIV infection (not AIDS) shows similar trends as that reported for AIDS.[3] For example, 36% of all new HIV infections reported in 1993 were among gay men, 23% in 2001. Undetermined cases accounted for 29% of reported HIV infections in 1993, 54% in 2001 (data not shown).

The heterosexual HIV and AIDS epidemics in the USA have occurred predominantly in the African-American and Hispanic populations.[11] Table 4 shows the number of AIDS cases of selected exposure categories by gender and race/ethnicity reported in 1991, 1996, and 2001.

DISCUSSION

We have reviewed AIDS and HIV surveillance data collected by CDC. These data demonstrate a shift of the epidemic from "gay" men and injection drug users to heterosexual contacts and those in the "undetermined" category. We also consider these data supportive of the hypothesis that primary transmission from "high risk" group members to heterosexual contacts continues to occur and that secondary and tertiary transmission from heterosexuals of "lower risk" to others is occurring and increasing.

There are several surveillance research issues raised by these data. The most obvious is to interpret cases of HIV and AIDS among those in the "undetermined" category. The AIDS risk classification system evolved into a hierarchical system based on reports of risk in the 1980s. This system evolved as new groups were identified with AIDS—that is, "gay" men, injecting drug users, Haitian-Americans, haemophiliacs, blood transfusion recipients, heterosexual men and women, health care workers. This system was effective at understanding routes of transmission, even before an aetiological agent was identified. However, the rationale for a hierarchical system no longer exists and creates a systematic bias in estimating HIV transmission among heterosexuals, who are at the lowest level of the system.

The current definition of "heterosexual contact" cases is too restrictive and leads to a gross underestimation of heterosexual transmission of HIV in the USA. A heterosexual contact patient is currently defined as a person who denies other risk factors—that is, homosexuality, injecting drug use, blood recipient, *and* has had heterosexual contact with a person with HIV infection or AIDS or at risk for AIDS—that is, male homosexual, injecting drug user, blood transfusion recipient. All other cases among self reported heterosexuals not meeting this definition are placed in the undetermined category. This includes an unknown, but apparently growing, number of women who report prostitution (commercial sex work) or multiple heterosexual partners, but cannot or will not identify a sexual contact with HIV or AIDS. Similarly, an unknown number of men who report multiple sexual contacts, including contacts with commercial sex workers, and/or a history of one or more sexually transmitted diseases, are currently listed in the undetermined group. Several states, that is, Massachusetts, New York, Virginia, have developed a separate category, "presumed heterosexual transmission", to distinguish those cases likely to be transmitted heterosexually from those in which data are not available, due to death or refusal to be interviewed. CDC should take the lead in defining and reporting sexual transmission data in this burgeoning group of patients, currently listed as "undetermined".

There appears to be at least two separate and unequal epidemics in the USA segregated by race and sexual orientation. The initial outbreak occurred among gay, predominantly white men, exploded rapidly across urban areas of the USA, and appears now to be decreasing. A later epidemic arose within the heterosexual, predominantly African-American community, initially fuelled by heterosexual injecting drug users, and concentrated in the southern USA.[11] The increasing number and proportion of African-American men and women in the "undetermined" category may underestimate the heterosexual nature of the latter epidemic.

Table 4 AIDS cases according to gender and race/ethnicity of selected exposure categories in USA, 1991, 1996, and 2001

	1991 (cumulative) No (%)	1996 No (%)	2001 No (%)	% Change†
Total (all cases)	206392	69151	43158	–
All males	183569 (89)	54997 (80)	31994 (74)	−15
All females	22823 (11)	14154 (20)	11164 (26)	+15
Males*	181696	54653	31901	
White	104180 (57)	23341 (43)	11164 (35)	−21
Black	47037 (26)	20199 (37)	13895 (44)	+17
Hispanic	28624 (16)	10337 (19)	6289 (20)	+4
Other	1422 (1)	646 (1)	510 (2)	+1
Females*	21225	13820	11082	
White	5466 (26)	2888 (21)	2040 (18)	−8
Black	11156 (53)	8147 (59)	7023 (63)	+10
Hispanic	4400 (21)	2629 (19)	1894 (17)	−4
Other	150 (1)	122 (1)	111 (1)	0
Gay male	131497	30283	14767	
White	90572 (69)	17719 (59)	7427 (50)	−19
Black	24118 (18)	7689 (25)	4605 (31)	+13
Hispanic	15165 (12)	4386 (14)	2433 (16)	+ 4
Other	1177 (1)	439 (1)	283 (2)	+ 1
IDU: male	35048	12333	7280	
White	7017 (20)	2530 (21)	1281 (18)	−2
Black	16798 (48)	6349 (51)	4049 (56)	+8
Hispanic	11083 (32)	3377 (27)	1857 (26)	−6
Other	73 (0)	57 (0)	85 (1)	+1
IDU: female	10705	4694	3410	
White	2268 (21)	1105 (24)	660 (19)	−2
Black	6185 (58)	2713 (58)	2106 (62)	+4
Hispanic	2191 (20)	845 (18)	618 (18)	−2
Other	41 (0)	25 (1)	24 (1)	+1
Heterosexual contact: female	7249	5522	4142	
White	1700 (23)	1165 (21)	707 (17)	−6
Black	3784 (52)	3038 (55)	2606 (63)	+11
Hispanic	1694 (23)	1257 (23)	781 (19)	−4
Other	47 (1)	52 (1)	42 (1)	0
Heterosexual contact: male	4687	3299	2762	
White	813 (17)	609 (18)	403 (15)	−2
Black	3307 (71)	1871 (57)	1705 (62)	−9
Hispanic	548 (12)	785 (24)	613 (22)	+10
Other	12 (0)	30 (1)	39 (1)	+1
Undetermined: male	6114	8159	8909	
White	2287 (37)	2130 (26)	2051 (23)	−14
Black	2269 (37)	4152 (51)	4803 (54)	+17
Hispanic	1432 (23)	1713 (21)	1896 (21)	−2
Other	78 (1)	107 (1)	140 (2)	+1
Undetermined: female	1561	3317	4606	
White	414 (27)	537 (16)	727 (16)	−11
Black	828 (53)	2256 (68)	3086 (67)	+14
Hispanic	292 (19)	476 (14)	740 (16)	−3
Other	22 (1)	30 (1)	45 (1)	0
Children	3471	678	175	
White	739 (21)	98 (14)	33 (19)	−2
Black	1844 (53)	429 (63)	113 (65)	+12
Hispanic	854 (25)	145 (21)	26 (15)	−10
Other	25 (1)	4 (1)	3 (2)	+1

Source: reference 4. IDU, injection drug user.
Notes: 1993 was the first year that CDC reported the annual incidence of AIDS cases by exposure categories further subdivided by race. Cumulative numbers from 1981–91 reported in 1991 column.
†Percent change was calculated by subtracting percent of subgroup in 1991 from percent of subgroup in 2001.
*Includes only those patients >13 years of age at diagnosis (adolescents/adults).
(A) White includes whites, non-Hispanic.
(B) Black includes African-Americans, non-Hispanic.
(C) Other includes Asians, Pacific Islanders, American Indians, and Alaska natives.
(D) Gay male includes men who have sex with men and men who have sex with men and inject drugs.
(E) Numbers do not always add due to missing data.

In summary, heterosexual transmission of HIV and AIDS appears to be increasing in the USA and may be grossly underestimated by our present surveillance system. An insidious epidemic can be identified within the African-American heterosexual community that demands immediate attention. The increasing proportion of "undetermined" transmission may represent a large number of heterosexual cases that are not counted as such. The importance of recognising the true incidence and prevalence of HIV infection and AIDS among heterosexuals is a public health issue. The under-estimation of the heterosexual transmission rate falsely reassures the public and may actually increase the likelihood of HIV infection and AIDS in the general population over the next several decades.

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Key points

- The proportions of patients with incident HIV infection and AIDS are increasing among heterosexuals and "undetermined risk", and decreasing among homosexual/bisexual men in the USA.
- The majority of HIV/AIDS patients attributed to heterosexual transmission, injecting drug use, vertical transmission, and "undetermined risk" are African-American. The majority of all female patients are African-American.
- The CDC hierarchical schema for determining HIV/AIDS exposures should be reviewed by those who interpret surveillance data for the public. The CDC definition for "heterosexual contact" exposure is too restrictive.

The opinion or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army, the Department of Defense, or the Food and Drug Administration.

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(5) AIDS Drug Assistance Programs

The AIDS Drug Assistance Program (ADAP) has become a critical source of prescription drugs for low-income people with HIV/AIDS in the United States who have no or limited prescription drug coverage. In a given year, ADAPs reach approximately 136,000 clients, or about 30 percent of those with HIV/AIDS estimated to be receiving care nationally.

ADAPs, then called "AZT Assistance Programs," began serving clients in 1987 when Congress first appropriated funds ($30 million over two years) to help states purchase AZT, the only FDA-approved antiretroviral drug available to treat HIV-infection at that time.

Today, ADAP funding is nearly $800 million. Yet due to the number of eligible patients and the growing number and cost of AIDS medications, many states have enacted waiting lists and formulary restrictions for those eligible for ADAP coverage.

June 8, 2005

AIDS Drug Assistance Programs (ADAPs) provide life-saving HIV treatments to low income, uninsured, and underinsured individuals living with HIV/AIDS in all 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, the Northern Mariana Islands, American Samoa, and the Republic of the Marshall Islands. Since the advent of highly active antiretroviral therapy (HAART) in 1996, AIDS deaths have declined and the number of people living with HIV/AIDS has increased markedly. ADAPs have played a crucial role in making HAART more widely available. Unfortunately, less than adequate increases in federal funding the past three years threatens to undermine the progress ADAPs have made in expanding access to HAART for those in need. For the current fiscal year (which began April 1, 2005), ADAPs received a $38 million increase in federal appropriations, which is inadequate to provide treatments to all eligible individuals. President Bush's proposed FY2006 budget increases ADAP funding by a mere $10 million, far less than what is required to meet anticipated needs.

On June 23, 2004, President Bush announced immediate availability of $20 million in one-time funding outside of ADAP to provide medications to individuals on ADAP waiting lists in 10 states (registered as of June 21, 2004). Currently 1,438 individuals are enrolled in the program (as of May 12, 2005), which is administered separate from ADAPs in eligible states by BioScrip, Inc. (formerly Chronimed, Inc.). Funding for ADAP in FY2005 did not address continuation of this separate program and it is unclear how participating states will transition clients into their ADAPs when the program expires in September 2005. As a result, states now include these individuals on their ADAP waiting lists since they may lose access to the medications they receive through the President's Initiative unless new resources are made available.

As of May 12, 2005, a total of 1,891 individuals were on ADAP waiting lists in 10 states. As mentioned above, 1,438 of these individuals are currently receiving medications through the President's Initiative, which is set to expire in September 2005. Another 453 individuals on waiting lists in eight states are not covered by the President's Initiative. Eleven ADAPs have instituted capped enrollment and/or other cost-containment measures since April 1, 2004. Eleven ADAPs anticipate the need to implement new or additional cost-containment measures during the current ADAP fiscal year ending March 31, 2006.

ADAPs with Waiting Lists

(1,891 individuals, including 453 not covered by the President's Initiative - as of May 12, 2005)

Alabama: 565 on waiting list (385 PI, 180 regular)*
Alaska: 14 on waiting list (All PI)*
Arkansas: 59 on waiting list
Idaho: 54 on waiting list (41 PI, 13 regular)*
Iowa: 88 on waiting list (33 PI, 55 regular)*
Kentucky: 260 on waiting list (180 PI, 80 regular)*
Montana: 24 on waiting list (20 PI, 4 regular)*
Nebraska: 61 on waiting list
North Carolina: 723 on waiting list (All PI)*
West Virginia: 43 on waiting list (42 PI, 1 regular)*

** President's Initiative (PI) states. Two states originally eligible for the initiative were able to enroll all clients on their waiting lists into their regular ADAP program and thus have no clients participating in the initiative: Colorado enrolled 347 clients and South Dakota enrolled 28 clients.*

June 8, 2005

NASTAD
NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

ADAPs with other cost-containment strategies (instituted since April 1, 2004)

Alabama: Capped enrollment for Fuzeon access with 1 individual on Fuzeon waiting list
Arkansas: Reduced formulary
Georgia: Capped enrollment for Fuzeon access with 40 individuals on Fuzeon waiting list
Louisiana: Capped enrollment for Fuzeon access with 12 individuals on Fuzeon waiting list
Minnesota: Cost sharing between 100%-300% FPL (drug co-pays) and reapplication every six months
Missouri: Reduced formulary
New Hampshire: Medical eligibility and formulary restrictions,
capped enrollment for Fuzeon access with 2 individuals on Fuzeon waiting list
Oklahoma: Annual per capita expenditure limit
South Dakota: Annual per capita expenditure limit, capped enrollment
Texas: Capped enrollment for Fuzeon access with 33 individuals on Fuzeon waiting list
Utah: Reduced formulary and cost sharing

ADAPs anticipating new/additional cost-containment measures (before March 31, 2006**)

Georgia
Kansas
Louisiana
Massachusetts
Mississippi
Missouri
New Hampshire
North Carolina
Oregon
Pennsylvania
Tennessee

*** March 31, 2006 is the end of ADAP fiscal year 2005. ADAP fiscal years begin April 1 and end March 31 each year.*

NASTAD (www.NASTAD.org) is a non-profit national association of state health department HIV/AIDS program directors who have programmatic responsibility for administering HIV/AIDS health care, prevention, education, and supportive services programs funded by state and federal governments. If you would like to receive *The ADAP Watch*, please forward your email address to Natane Singleton at nsingleton@nastad.org.

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Views and Estimates on the Fiscal Year 2005 Budget of the United States

HIV/AIDS Treatment

Domestically, the President's budget request includes a $35 million increase for the AIDS Drug Assistance Program (ADAP), bringing the program's total appropriation to $783 million for fiscal year 2005.

ADAP, funded under Title II of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, is the final safety net for Americans who have no other means of accessing HIV medications and for low-income people with HIV/AIDS who are underinsured or lack adequate prescription coverage. Each year, 127,000 patients are served by ADAP. Many state ADAPs are facing financial constraints and are unable to meet the needs of those who depend on the program. Currently, 15 states are restricting access to treatment, and 791 patients are on ADAP waiting lists. California recently announced plans to restrict access to ADAP as well.

The Committee believes that outdated funding formulas are a significant factor in AIDS treatment funding disparities that are partially responsible for ADAP waiting lists. Current formulas award state and local grants based upon estimated living cases of AIDS, the end stage of HIV infection, rather than the number of patients infected with HIV and eligible for treatment in an area. In 2000, Congress reauthorized the Ryan White CARE Act and directed the Department of Health and Human Services to include all those diagnosed with HIV in CARE Act formulas no earlier than fiscal year 2005 or no later than fiscal year 2007. The Committee urges the inclusion of all those living with HIV in FY 2005 formulas to ensure more equitable funding.

The General Accounting Office (GAO), at the request of the Committee, is examining the Ryan White CARE Act program to identify strategies to more equitably distribute federal grants and to improve access to ADAP.

The Committee supports the President's request for increased funding for ADAP but is concerned that additional funding may be necessary to provide sufficient resources to ensure that all ADAP eligible clients have access to AIDS treatment.

A consultation on Maintaining and Improving Access to HIV-Related Drug Therapies was conducted by the George Washington University School of Public Health and Health Services on behalf of the Health Resources and Services

Administration's (HRSA) HIV/AIDS Bureau on January 23, 2003. The meeting was structured to identify options to improve access to AIDS treatment. The consultation's report suggested "reprioritization of funding to focus on a core or essential set of services," noting "one thing that was clear from the consultation was the increased willingness of grantees to recognize that some of the priorities for services adopted in the earlier years of the epidemic require reconsideration in light of the adoption and success of new treatment patterns."

The Committee supports this suggestion and recommends $131 million in reprioritized offsets be transferred to ADAP from the following sources:

National Institutes of Health.

The Committee supports research and development of improved AIDS treatments and HIV vaccines. The Committee has, however, identified several HIV vaccine related projects by the National Institutes for Health that would be better spent on ADAP. NIH is spending $119 million on an HIV vaccine study in Thailand that analyzes two components that have both failed to protect against HIV infection in previous studies. One of the components of the vaccine called gp120, which has completed phase III trials, "failed completely in providing any degree of protection to HIV infection," according to Dr. Robert W. Doms, chairman of the department of microbiology at the University of Pennsylvania. The other component, called ALVAC, has had unimpressive results in trials, he adds. "Combining something that's failed with something that has not been terribly impressive doesn't seem to provide a good rationale for proceeding with such a large and costly trial," Doms says. Twenty-two leading HIV researchers including Dr. Robert Gallo, the co-discoverer of the AIDS virus, wrote a letter published in the January 16 issue of Science that criticized the funding for this project. In addition, NIH spends more than $1 million every year promoting HIV vaccine "awareness," when no such vaccine even exists of which to be aware. The President's 2005 budget request, in fact, extends the goal of developing an HIV vaccine from 2007 to 2010 "to more realistically reflect the state of the science." The Committee recommends transferring $120 million from these NIH projects to ADAP.

Conferences.

The Department of Health and Human Services (HHS) spent $40 million to fund conferences in 2002. This includes $3.6 million for an AIDS conference held in Barcelona, Spain, to which 236 HHS employees traveled to attend. In September 2003, HHS provided over $300,000 for a single AIDS conference in New Orleans that was noted for its political rather than public health content. At a time of budget restraint in important health care programs, we do not have the luxury for excessive spending on conferences. The Committee recommends transferring $7 million from the conference budgets of HHS and its agencies to ADAP.

HUD AIDS Housing

The President's budget includes $294.8 million for the Housing Opportunities for Persons with AIDS (HOPWA) program administered by the Department of Housing and Urban Development (HUD). This amount represents a $62.8 million, or 27 percent, increase since Fiscal Year 2000 when the program was funded at $232 million. In addition to HOPWA, HUD has other programs that can be used to serve persons living with HIV/AIDS. HUD's Homeless Assistance Programs, Programs for Persons with Disabilities, and HOME Initiatives can be directed to persons living with HIV/AIDS and their families. AIDS housing is also provided under the Ryan White CARE Act. While HOPWA-- available only to patients in select areas-- is important to many living with HIV, it does not have the same impact as providing medication, which really does make the difference between life and death. The Committee recommends transferring $2 million from the HOPWA budget to ADAP.

The Committee believes that reprioritizing funding from these programs in addition to the $35 million increase requested by the President would achieve the goal of ensuring that all Americans living with HIV are guaranteed basic medical care and medication with little or no significant consequence to other programs. This reprioritization recognizes that of the $18 billion spent annually on HIV/AIDS, more funds should be targeted to those services most needed and/or underfunded, which clearly is ADAP.

HIV Prevention

The President's budget request includes $1.143 billion for the CDC's National Center for HIV, STD, and TB Prevention, which is a $1.7 million increase over FY 2004. The President's proposal requests $696 million specifically for HIV/AIDS prevention programs.

Over the past decade, the CDC has spent more than $7.4 billion on HIV prevention programs alone. Despite these significant financial resources, the annual number of new infections did not decline once during this ten-year period. According to the CDC, 40,000 Americans were newly infected with HIV in each of the previous ten years for a grand total of 400,000 Americans newly infected with HIV.

Recognizing these obvious shortcomings of existing HIV prevention programs, the Administration is instituting greater accountability measures to ensure that federally funded HIV prevention programs are indeed preventing HIV. The Committee applauds this effort to increase effectiveness and accountability of HIV prevention programs.

In 2003, the Administration through the CDC launched a new initiative, "Advancing HIV Prevention: New Strategies for a Changing Epidemic." The

Committee supports this effort aimed at reducing barriers to early diagnosis of HIV infection and increasing access to quality medical care, treatment, and ongoing prevention services. The HIV initiative emphasizes the use of proven public health approaches to reducing the incidence and spread of disease. As with other sexually transmitted diseases or any other public health problem, principles commonly applied to prevent disease and its spread will be used, including routine screening, identification of new cases, partner notification, further reductions in perinatal HIV transmission, sustained treatment and prevention services for those infected and availability of a simple, rapid HIV test in unconventional settings. Because this new initiative will most likely identify many more Americans with HIV, the Committee underscores the need to ensure that ADAP is sufficiently funded to ensure that those diagnosed are ensured access to both appropriate prevention and treatment services.

The President's request provides $270 million for federal abstinence program, which doubles the amount appropriated last year. The Committee applauds this proposal, noting that abstinence is an important element of the strategy to prevent HIV, STDs and unwanted pregnancy and that a report issued by the CDC in December found that a majority of high school teens are now practicing abstinence. The President's request provides additional support for this healthy choice.

The Committee applauds the Administration's leadership on domestic HIV prevention.

Minority AIDS Initiative

In 2002, African Americans accounted for over half of the new HIV diagnoses reported in the United States. Sixty-two percent of children born to HIV-infected mothers were African American.

The President's budget provides $52.8 million for the HIV/AIDS in Minority Communities Fund, located in the Public Health and Social Services Fund, which is one component of the Minority HIV/AIDS Initiative. This is an increase of $3.3 million from FY 2004. The HHS Budget in Brief FY2005 states that the money is intended "to support innovative approaches to HIV/AIDS prevention and treatment in communities heavily impacted by this disease."

Data from states with names-based HIV surveillance have indicated for well over a decade that African Americans were increasingly disproportionately impacted by HIV. This data empowered public health officials in these states and at the federal level to better respond with targeted HIV prevention and treatment. The CDC recommended in 1998 that all states conduct names-based HIV surveillance to improve prevention and treatment programs. While most states have followed CDC's recommendations, others have been reluctant to do so.

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Maintaining and Improving Access to HIV-Related Drug Therapies

A Consultation Conducted on Behalf of the

HIV/AIDS Bureau

Health Resources and Services Administration

January 24, 2003

SUMMARY REPORT

Prepared by

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May 1, 2003

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Background:

The consultation on Maintaining and Improving Access to HIV-Related Drug Therapies was conducted by the George Washington University School of Public Health and Health Services on behalf of the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB). Over 30 individuals were invited by HAB to attend this day-long meeting on January 24, 2003. The individuals represented a variety of partners, including Drug Assistance Programs (ADAPs) program administrators, grantees under Titles I, II, III and IV of the Comprehensive AIDS Resources Emergency (CARE) Act, other HRSA grantees providing HIV-related care, pharmaceutical companies, representatives of consumers and national HIV/AIDS organizations, an ethicist, health services researchers, and representatives from various Federal agencies.

The meeting was structured to identify a range of short-term and long-term options that HAB could consider with regard to access to HIV-related drug therapies. The consultation was not designed to achieve a consensus, but rather to give HAB staff the benefit of a broad range of views as it considers its response to this problem.

Context:

The meeting was held at a time when a number of States were reporting that they were facing increasing financial challenges associated with the administration of their ADAPs, which are funded under the Ryan White CARE Act. ADAP is the principal discretionary program supporting access to HIV-related drug therapies (though the Medicaid program is probably a larger purchaser of these drugs since it covers primary health care for more individuals with HIV). An increasing number of States have had to place some kind of restriction (changed eligibility criteria, creation of waiting lists, reduced formularies) on access to their ADAPs as demand for services outpaces financing. This financial pressure on ADAPs is occurring in a larger environment of both dramatic change in the overall health care financing system in the US in general and within the HIV epidemic as well. Some of the essential components of this evolving environment are:

- There is an overall increase in the demand for HIV-related care (and related drug treatments) due to a steady increase of 40,000 new HIV infections a year, more people with HIV learning their status earlier as there is more hope about successful treatment, and those already diagnosed living longer due to the success of new treatments.
- People with HIV are not progressing to disabling conditions as rapidly, if at all. Since disability is the primary route to Medicaid (and Medicare) eligibility, many people with HIV, who in the past would have left the ADAP rolls as they became disabled and eligible for Medicaid, are remaining on the ADAP rolls longer, even as more and more new people with HIV are becoming diagnosed and seeking ADAP benefits.
- High HIV-related prescription drug costs are occurring earlier and lasting longer.
- New HIV drugs tend to be additive and very expensive.
- Co-morbidities (especially HCV) have very costly prescription drug treatments.

- Only three States have successfully met the criteria for a demonstration expansion of their Medicaid program for the non-disabled with HIV.
- Due to budget crises, States are cutting back on eligibility criteria for Medicaid (e.g., more restrictive income standards for the medically needy program, a critical pathway for people with HIV) and are also imposing new restrictions on prescription drug coverage.

All of these factors increase the demand for services under the Ryan White CARE Act, even though it devotes the smallest level of resources to HIV care financing as compared to Medicaid and Medicare[1] and the CARE Act budget has increased only 11% over the last three fiscal years.

Ethical framework:

The attendees at the consultation recognized that at its core, this was a discussion of how best to ration scarce health care resources to assure the broadest possible access to HIV-related drug therapies. This clearly poses ethical dilemmas, in addition to difficult policy and programmatic choices. Nancy Dubler, an ethicist at Montefiore Medical Center, outlined a framework that should drive consideration of any policy options that attempt to ration access to treatments. The core elements of this framework are:

- Society has a hierarchy of obligation to individuals – as a society we owe some people (e.g., those who are poorest) more than we do others.
- Any rationing process should be transparent: the decision to ration and the criteria for rationing should be openly arrived at.
- Existing rights should not be abrogated; for example, those already under treatment should not lose their access to treatment as a result of new rationing policies.
- The ultimate goal should be to treat people fairly and equally.

While these are general principles, and there was insufficient time at the consultation to develop them further, the participants found these to be a useful framework and many expressed a desire (as indicated below) for the provision of ethical consultation to State ADAPs as they wrestle with these challenging policy decisions.

Policy/programmatic options:

The day-long discussion at the consultation generated a significant number of options for consideration by HAB. The following are four short-term and three longer-term options that the Bureau might want to consider in more depth as it moves forward. These options encompass a number of the suggestions made at the consultation and also reflect additional discussion with some of the participants to gain a better understanding of the options.

A. Short-term activities that can be accomplished under existing authority.

[1] In FY 2003, estimated spending for Medicaid is $8.5 billion (combined Federal and State shares), Medicare is $2.4 billion, and the Ryan White CARE Act is $2 billion.

1. Develop a model to estimate the unmet need for HIV-related pharmaceutical assistance. One element clearly missing from the discussion at the consultation was a clear estimation of what the current unmet demand for pharmaceutical assistance is, how it differs from State to State, and how it might increase given improvements in longevity among people living with HIV and changing demographics of those becoming infected with HIV. At the moment, the principal model in use is one developed by the pharmaceutical industry. The results of this model have been met with some skepticism by key policy makers. A model that serves both HAB in its national projections and individual States in their planning could dramatically clarify the extent of unmet need (and associated costs) and the range of options that must be considered to ensure continued access to needed treatments. A model could measure the potential value of certain options (e.g., greater price discounts). Any modeling exercise should include consultation with key policy makers on this issue, including fiscal analysts within HHS, OMB, and State governments, so that there will be a general agreement about what assumptions should go into the model and what outputs are needed from the model.

2. Maximize Medicaid funds for pharmaceuticals (and all other HIV-related primary care). While some States have achieved very close coordination between the two programs, there is considerable variation in the degree to which ADAPs aggressively seek to enroll eligible clients in Medicaid, how frequently eligibility for Medicaid is redetermined by ADAPs, whether ADAPs seek retroactive reimbursement for clients whose Medicaid eligibility is determined retroactively, and other issues. Clarifying guidance (from HAB and, in some cases, CMS), along with targeted technical assistance, could be used to address the following issues:

a. Models for coordination of Medicaid and ADAP eligibility, since many ADAP clients transition between the programs frequently.
b. Standard policies regarding frequency of Medicaid eligibility re-determination.
c. Technical assistance to ADAPs and Medicaid programs wishing to consider administration of ADAP through the Medicaid program, an option that might be of considerable interest to smaller programs without the internal administrative infrastructure to run a separate HIV drug purchasing program.
d. Absent joint administration, standard methods and model memoranda of understanding regarding data sharing between ADAPs and Medicaid agencies to promote eligibility determination, obtain retroactive reimbursement for ADAP clients whose Medicaid eligibility is determined to be retroactive, and coordination of overlapping responsibilities between Medicaid and ADAPs (e.g., coverage by ADAP of prescriptions that exceed the Medicaid maximum per month, including assuring that Medicaid pays for the more expensive prescriptions). The issue of overlapping responsibility is likely to become increasingly important as States modify their Medicaid benefits package for optional populations (including the medically needy) and optional benefits (prescription drugs) under HIFA waivers or if the President's proposal for modernizing Medicaid moves forward.

3. Maximize the buying power of ADAP funds through greater use of the authorities under the 340B program. Clearly, a lower average price paid by all ADAPs could dramatically increase the number of clients who could be served by the program. Among the options to be considered in this area are:

a. Assure the maximization of the use of the 340B program by all CARE Act providers purchasing drugs (including ADAPs, Title I EMAs and Title III programs) and assess what level of additional guidance and technical assistance can be provided to those programs not yet in the 340B program or who are not yet using the prime vendor program. While this is a complex program to understand, TA is available from BPHC to help demystify the program.
b. Provide support to the ADAPs to form a buying network to negotiate 340B prices for all ADAPs. Under the Alternative Method Demonstration Program, the 340B program is entertaining new approaches to using the 340B authority. It is quite possible that such a buying network would be permissible under this demonstration authority. States could still administer their ADAPs individually and could even choose either the discount or rebate approach. While it is not clear how much clout the ADAPs would have to further reduce the best price received under the 340B program (since it might be unethical to remove some drugs from their formularies), this could at least assure that the current best price for each drug would be available to every State. For those States who have not negotiated discounts or rebates, the buying network approach could bring them very significant discounts. Even a 10% reduction in the overall average paid for HIV-related drugs by ADAPs would dramatically increase the buying power of the program. Consideration should also be given to how Title I EMAs, Title III grantees, and Title IV programs purchasing medications might be included in this joint purchasing arrangement.

4. *Provide technical assistance to ADAPs regarding the development of waiting lists and other rationing strategies (e.g., formulary restrictions).* General guidance is needed by grantees to assist them as they make difficult decisions regarding changes in eligibility criteria and/or coverage for ADAPs. Certain overarching principles should be articulated (consistent with some of the concepts outlined by Nancy Dubler at the consultation) that address ethical, public health, medical management, and financial issues that need to be considered when creating waiting lists or making other changes in ADAPs. This might include providing an ethical consultation for ADAPs and other planning bodies as part of the TA provided by HAB to its grantees.

B. **Longer-term activities, including those that require new authority**

1. Revise the formulas to reflect changing treatment patterns. Any change in the formulas for distributing ADAP funds (or any other CARE Act funds) would require new legislative authority. Discussion and modeling of potential changes should begin before the heat of reauthorization discussions. Modeling could determine how important each of these factors might be. The issue receiving the most attention was the use of AIDS case rates as the basis for the formula. At a time when treatment should begin well before an AIDS diagnosis, and successful treatment should significantly delay that diagnosis, providing funding based on AIDS

cases undercuts the incentive to identify clients early and get them into treatment rapidly. Switching to an HIV-based formula poses major challenges, since many jurisdictions have delayed implementation of any form of HIV reporting and other States are using very different (and perhaps not comparable) approaches to case estimation. In fact, there may be other formula-related factors (other than surveillance data) that could reflect changing treatment needs of the population served by the CARE Act. The pending IOM report may help address these issues. Whether or not it does, modeling of options and full discussion with HAB's partners (inside and outside government) is essential.

2. Encourage re-prioritization of funding to focus on a core or essential set of services. One thing that was clear from the consultation was the increased willingness of grantees to recognize that some of the priorities for services adopted in the earlier years of the epidemic require reconsideration in light of the adoption and success of new treatment patterns. In some instances, jurisdictions have already taken on this challenge. In other communities, some encouragement (through guidance and technical assistance) could move this process forward more quickly. This can be accomplished on a case-by-case basis, but some national parameters may be useful in defining a hierarchy of essential services for people with HIV. This strategy needs to be sensitive to the individualized needs of people with HIV and the variation in alternative sources of care support (e.g., varying generosity of Medicaid programs) across jurisdictions.

Reprioritization will take time, because commitments are already made for FY 2003 funding. However, the next six to nine months could be used to begin a dialogue among grantees about the importance of rethinking core services so that more funds could be targeted to those services most needed and/or underfunded. This effort could result in reallocation of base Title II to the ADAP program and/or greater contributions from Title I EMAs to their State's ADAP program.

Two fears about beginning such a process are that definition of a "floor" of services might become seen as a "ceiling," and that what starts as advisory to planning bodies could become a legislative mandate. One way to avoid a legislatively mandated core set of services is to be able to demonstrate over the next year or two how planning bodies have been able to voluntarily shift their spending to reflect the changes in the epidemic when provided appropriate technical assistance. One lesson of this epidemic is that the needs of clients change too dramatically to have overly specific legislation. However, if this voluntary approach does not result in sufficient change, HRSA could seek authority to mandate response to a core set of services developed by HAB and revised as needed.

3. Use the 340B demonstration authority to generate Medicaid savings that would permit budget neutral Medicaid expansions. An interesting option worth developing would be to use the Alternative Method Demonstration authority to allow Medicaid agencies to purchase HIV-related drugs through their State ADAPs at the 340B price. This would be significantly lower than the current Medicaid price. (The ADAP would be the purchasing agent, not the funder.) The savings generated for the Medicaid program could be used to support a budget neutral waiver for expanding Medicaid eligibility for people with HIV who are not yet disabled. (Most

modeling for Medicaid expansion shows that budget neutrality can only be achieved if drug prices are significantly reduced. The District of Columbia, which has one of only three 1115 waivers approved by CMS for HIV expansion, used just this approach when it learned it had special legal authority to purchase HIV drugs for the Medicaid program under the Federal Supply Schedule.) Medicaid expansions are more than likely to reduce the number of poor people with HIV who are dependent on ADAP (and other CARE Act services), thus permitting reduction in costs and/or waiting lists. HAB could work with BPHC and the States to determine the feasibility of this option and then work with CMS to encourage State Medicaid programs to adopt it.

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AIDS Medication Out Of Reach For Many

By Eric Flack

(LOUISVILLE, September 24th, 2003, 7 p.m.) -- Advocates for AIDS patients in Kentucky say people are dying because they can't afford their medication. And they say the state hasn't set aside enough money to help. The state admits the number of people who need medication but can't get it is getting longer.

The House of Ruth in Louisville helps people below the poverty line fight an expensive illness. AIDS treatment costs more than $9,000 a year. It's expensive for Kim Smith, and she has "insurance and a job. And a doctor would take care to make sure I had the best there was available. And when you don't have any means to start with, it seems like quite a big hill to climb."

Al was diagnosed with full-blown AIDS eight months ago. At the time, he thought his diagnosis was a death sentence. "I was thinking there was no hope for me."

But now Al has hope. For now, his medication is working -- drugs paid for in part by the University of Louisville. Still, with $700 a year in co-pays and no job, Al simply says he simply doesn't "have the money."

A program called the Kentucky AIDS Drug Assistance Program, or KADAP, pays for AIDS medication for the uninsured.

Rhiannon was one of the first people participate in the KADAP Program. Rhiannon is one of the lucky ones, and knows it. "There's too many people out there with HIV and AIDS who need the medications," he said. "They need them now. They don't need to wait."

But al is waiting. And he isn't alone. Right now, 169 people in Kentuckiana are on the KADAP waiting list. By December, that number is expected to grow to 200. Already this year, five people have died waiting for medication.

KADAP gets more than $4 million a year from the federal government. The state only puts in $90,000 -- that's enough to pay for medication for nine people a year. But not enough for Al.

"It's hard for me to go to sleep at night," Al says, "because I'm so scared I might close my eyes and not open 'em back. That's the hardest part."

KADAP already stretches its dollars as far as it can. The amount it spends on each patient is one of the lowest in the nation. The coordinator of the KADAP says they plan to ask for more money when budget negotiations start later this year. Whether they get it remains to be seen in these tight budget times. And Kentucky isn't the only state with a problem. Fifteen other states have waiting lists, too.

Online Reporter: Eric Flack

Online Producer: Michael Dever

-----Original Message-----
From: Foster, Roland
Sent: Tuesday, October 14, 2003 10:18 AM
To: 'Lisa.Daniel@mail.state.ky.us'
Subject: AIDS Care and KADAP Issues

October 14, 2003

Ms. Lisa Daniel
KADAP Administrator
HIV-AIDS Program
Department Of Health Services
275 East Main Street
HS2C-A
Frankfort KY 40621-0001

Dear Ms. Daniel,

As you know, Medicaid and the AIDS Drug Assistance Program (ADAP) are the two most important sources of publicly provided health care for Americans with HIV/AIDS. The U.S. federal government will spend about $16.6 billion in FY2003 on AIDS. About $1 billion of this will be spent on ADAP alone. Despite this significant amount of spending on AIDS, hundreds of Americans with HIV will still not be able to access AIDS treatment or care.

The Subcommittee was very concerned to learn that five persons living with HIV in Kentucky passed away this year while awaiting AIDS care. All of these deaths represent tragic shortcomings that deserve thorough review and attention.

Could you provide the Subcommittee with the following information:

(1) How many eligible patients in Kentucky are currently on the ADAP waiting list?

(2) Were any of the patients that passed away while awaiting access to ADAP coverage receiving any HIV treatment or care? What, if anything, does the state do to ensure that those on ADAP waiting lists are otherwise provided care?

(3) Were these-- or any other patients with HIV in Kentucky-- provided AIDS drugs as part of a "compassionate care" program sponsored by any pharmaceutical company? Does the state help facilitate such coverage for needy patients? What drug companies participate?

(4) We understand that Kentucky receives about $4 million a year from the federal government for AIDS drug coverage and the state contributes $90,000. Are these figures accurate? How much more funding is necessary to ensure all those in Kentucky eligible for ADAP receive optimal treatment?

(5) Other than necessary increases in ADAP spending, in your opinion, what changes could be made to federal ADAP funding formulas to ensure that all eligible patients in your state have access to AIDS treatment?

Thanks you for your thoughts and insights on this matter and for all of your efforts to care for those affected by HIV/AIDS.

Roland Foster
Staff Member
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U.S. House of Representatives
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CABINET FOR HEALTH SERVICES
COMMONWEALTH OF KENTUCKY
FRANKFORT 40621-0001

Department for Public Health

October 17, 2003

Roland Foster
Subcommittee on Criminal Justice, Drug Policy and Human Resources
U.S. House of Representatives
B 373 Rayburn HOB
Washington, DC 20515

Dear Mr. Foster:

Thank you for your interest in the Kentucky AIDS Drug Assistance Program (KADAP). The following paragraphs are in response to the questions stated in your letter dated October 14, 2003.

In response to question one, there are currently 150 clients on the KADAP waiting list. KADAP stopped enrolling clients in February 2000 because the program could no longer keep pace with the demand for services and increasing costs of medications. Due to small increases in federal funds in 2001, 2002 and 2003, KADAP has been able to enroll clients intermittently. As a result, the program has seen a significant increase in the number of clients served. In 2002, KADAP served more than 700 clients, an increase of 170 from 2000.

In response to questions two and three, although an additional five Kentuckians have died since June 2002 while waiting for HIV medications from KADAP, all were receiving medical treatment and their medications were available through other sources, including drug manufacturers' patient assistance programs. Clients enrolled on KADAP or the program's waiting list are required by program guidelines to have a case manager through the state's HIV Services Program. These case managers assist clients in applying for patient assistance programs as well as other services such as Medicaid, Medicare, substance abuse/mental health counseling, nutritional counseling, just to name a few.

Question four inquires about funding for the program. The budget breakdown appears as follows:

Federal		
	ADAP Earmark Award	$3,930,770
	Title II Base Award	$100,000
	Supplemental Award	$502,139
	Carryover	$350,000
State		
	General Fund Allocation	$90,000
TOTAL ALLOCATION		**$4,972,909**

Outside of the ADAP Earmark Award and the Title II Base Award, Kentucky receives a supplemental award because it is a state that meets the criteria set forth in the Ryan White CARE Act as a needy state. Additionally, the program received $350,000 in unspent monies

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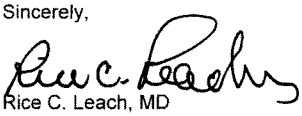
from the 2002 Title II Base Award. The state's general fund allocation has remained level since 1996.

In response to question five, federal funding for the program isn't linked to the number of people living with HIV/AIDS that a state serves. Rather, program funding is based on the number of AIDS cases that are diagnosed in a state. For Kentucky, that is a small number compared to other states. Distribution of federal funds based on need, not formula-based, could potentially be beneficial to the Commonwealth.

Thank you for your time and attention to this information. Should you have questions, please contact Lisa Daniel, Administrator, Kentucky HIV Services Program, at 502-564-6539.

Sincerely,



Rice C. Leach, MD
Commissioner

Washington Blade
May 14, 2004
http://www.washblade.com/2004/5-14/view/columns/wait.cfm

Get tested and wait for meds

President Bush's AIDS plan says 'get tested and get treated,' but the money isn't there for many to get HIV meds.

By DR. JAMES DRISCOLL

Last year the Bush administration launched two breakthrough AIDS initiatives: a $15 billion five-year global program to prevent millions of new infections and bring antiviral treatment to two million AIDS sufferers, and here at home a massive CDC testing outreach utilizing rapid HIV testing and focused on minorities.

Sadly, these initiatives, along with AIDS research, may be jeopardized by inadequate funding for the AIDS Drug Assistance Program. ADAP provides drugs for approximately 100,000 patients without health insurance, which amounts to more than one fourth of all Americans who need HIV medications.

With 1,263 AIDS patients on ADAP waiting lists in nine states and with several other states, including California and Florida, likely to cap or restrict those lists in the next six months, we cannot guarantee treatment for those who test positive in the new CDC HIV/AIDS outreach initiatives.

Where the promise is "get tested and get treated," the reality has too often become "get tested and get on a lengthy ADAP waiting list."

THE DAMAGE GOES beyond treatment delays and disincentives. Cash strapped ADAPs cannot afford to add new, breakthrough AIDS drugs to their formularies.

Fuzeon, arguably the most powerful AIDS drug so far, is a last resort for patients who develop resistance to older medications. For these patients, access to Fuzeon is a matter of life and death. Inadequately

funded ADAPs can pay for Fuzeon only by severely limiting access to it and by curtailing access to other drugs.

While federal ADAP funding has a 5 percent increase for this year, the demand to enroll in ADAP is increasing by up to 10 percent a year. Moreover, patients who progress in the disease need additional drugs and more expensive therapies, like Fuzeon, thereby raising ADAP costs.

If ADAP is not increased enough to pay for additional patients and new drugs, this can only be done by slashing reimbursement on existing drugs.

Because of HIV drug resistance, patients inevitably need new and better drugs. Companies weighing development of novel AIDS compounds will get cold feet when they consider the fate of Fuzeon and the likelihood that ADAPs can add their new drugs only by cannibalizing reimbursement for existing drugs.

Not surprisingly, the number of companies doing HIV research is down 25 percent and the number of new products in the pipeline is down 33 percent over the last five years.

COMBATING AIDS IS a process that begins with basic research and ends with delivering drugs to patients. We waste the taxpayer's money when we fund only the beginning of the process.

Minorities bear the brunt of ADAP funding shortages. One half of new AIDS infections are African American; one fifth are Hispanic.

Unless ADAP is fixed, we may soon be giving AIDS drugs to hundreds of thousands of Africans while failing to provide these life-saving medications to thousands of needy African Americans and Hispanics.

Such neglect is medically and ethically unacceptable. It raises doubt about the president's commitment to fighting AIDS and is likely to undercut congressional and public support for his global AIDS initiative.

How can Health and Human Services insure access to AIDS treatment with limited tax dollars? Most Americans never have enough money to buy all that they want: they must budget. They put everything on the table, separate needs from desires, and set priorities.

The Ryan White Care Act and other federal programs fund a wide array of critical services, everything from AIDS drugs to counseling to housing, to transportation. We also fund AIDS research and prevention efforts that showcase politicians' good intentions but lack scientific promise or proven results.

For example, 22 HIV scientists including Robert Gallo have recently complained that spending $119 million to continue an unpromising AIDS vaccine trial is throwing good money after bad.

In addition to more funding, budgeting for AIDS requires wise prioritizing and tough decisions. The war on AIDS will be set back if we fail to insure that every American who needs HIV medications can obtain them from ADAP.

(6) Advancing HIV Prevention

In 2003, the Centers for Disease Control and Prevention (CDC) unveiled the "Advancing HIV Prevention" strategy in response to the failure to reduce the number of new HIV infections with existing prevention programs.

The new CDC initiative emphasizes traditional proven public health prevention strategies, including early diagnosis and partner notification that have been historically underutilized in HIV prevention efforts.

From the onset of the AIDS epidemic, due to the stigma of the disease and political pressures, barriers were created that discouraged early diagnosis. As a result, many of those who were infected have forgone life saving treatment and unknowingly exposed others to the disease.

CDC estimates that today between 24 and 27 percent of those with HIV are unaware that they are infected. The number is substantially higher among high risk groups, according to studies. A study published in the April 15, 2005 edition of the *Journal of Acquired Immune Deficiency Syndromes* found that 77 percent of men who have sex with men diagnosed with HIV were unaware of their status. An August 23, 2002 study published in the CDC's *Morbidity and Mortality Weekly Report* found that 93 percent of young gay and bisexual black men with HIV were unaware that they were infected.

National Center for HIV, STD and TB Prevention
Divisions of HIV/AIDS Prevention

Advancing HIV Prevention: The Four Strategies

An estimated 40,000 new HIV infections occur in the United States, each year. These new infections include over 300 infants who contract HIV because their mothers are infected. Available evidence suggests that the majority of new infections is caused by persons unaware of their HIV infection, and an estimated one-quarter of those who are infected with HIV do not know they are infected.

CDC's new initiative emphasizes HIV testing, in both medical and non-medical settings, to identify infected persons who are not aware of their own infection and getting them into treatment and prevention services.

Program Outline

1. Incorporate HIV testing as a routine part of care in traditional medical settings. CDC will issue recommendations strongly encouraging all health care providers to include HIV testing, when indicated, as part of routine medical care, like other routine medical tests by:

- Promoting removal of real and perceived barriers to routine testing, including "de-coupling" HIV tests in the medical setting from extensive, pre-test prevention counseling. In some jurisdictions, statutory requirements, e.g. for pretest counseling, can serve as barriers to testing.

- Working with professional medical associations and others to promote adoption of the recommendations. CDC will work with public and private payors to promote appropriate reimbursement incentives.

2. Implement new models for diagnosing HIV infections outside medical settings. Some persons infected with HIV do not have access to traditional medical settings. CDC will create new program models to increase HIV testing in high-prevalence, non-medical settings by:

- Encouraging the use of the HIV rapid test.
- Funding pilot projects in 2003, aimed at identifying the most effective models for HIV diagnosis and referral for medical and preventive care which CDC grantees can employ outside traditional medical settings.
- Taking steps to assure that 2004 funding is used to support such models through CDC grant programs to health departments and community-based organizations.

3. Prevent new infections by working with people diagnosed with HIV and their partners. CDC will promote preventive and treatment services within and outside traditional medical settings by:

- Working with HRSA to reach those who have been diagnosed with HIV but who are not receiving ongoing treatment and preventive care services. CDC in consultation with HRSA will publish and disseminate "Recommendations for Incorporating HIV Prevention into the Medical Care of Persons with HIV Infection" in 2003.
- Conducting demonstration projects through health departments to provide prevention case management and counseling for people living with HIV.

- CDC will standardize new procedures for prevention interventions and evaluation activities to assure that such measures are both appropriate and effective. In accordance with these new procedures, CDC will broadly implement prevention services for people living with HIV through health departments and community-based organizations by refocusing CDC 2004 funding on activities with proven effectiveness.
- CDC will assure that requirements related to partner notification in grant guidance are fully met so that this recognized technique of infection control is optimally employed. Additionally, CDC will pilot new approaches to partner notification, including offering rapid HIV testing to partners and using peers to conduct appropriate partner notification, prevention counseling, and referral.

4. Further decrease mother-to-child HIV transmission. Treatment of pregnant women and their infants can substantially reduce the number of babies born with HIV infection. Such interventions are most effective when the HIV status of the pregnant woman is known as early as possible in pregnancy –and if not known—when the baby can be tested at the time of birth. CDC will:

- Promote screening of every pregnant woman for HIV, using the "opt-out" approach. Make prenatal HIV screening a routine part of medical care.

Promote screening of newborns whose mothers HIV status is not known.

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CDC MMWR

June 24, 2005 / 54(24);597-601

HIV Prevalence, Unrecognized Infection, and HIV Testing Among Men Who Have Sex with Men --- Five U.S. Cities, June 2004--April 2005

Well into the third decade of the human immunodeficiency virus (HIV) epidemic, rates of HIV infection remain high, especially among minority populations. Of newly diagnosed HIV infections in the United States during 2003, CDC estimated that approximately 63% were among men who were infected through sexual contact with other men, 50% were among blacks, 32% were among whites, and 16% were among Hispanics (*1*). Studies of HIV infection among young men who have sex with men (MSM) in the mid to late 1990s revealed high rates of HIV prevalence, incidence, and unrecognized infection, particularly among young black MSM (*2--4*). To reassess those findings and previous HIV testing behaviors among MSM, CDC analyzed data from five of 17 cities participating in the National HIV Behavioral Surveillance (NHBS) system. This report summarizes preliminary findings from the HIV-testing component of NHBS, which indicated that, of MSM surveyed, 25% were infected with HIV, and 48% of those infected were unaware of their infection. To decrease HIV transmission, MSM should be encouraged to receive an HIV test at least annually, and prevention programs should improve means of reaching persons unaware of their HIV status, especially those in populations disproportionately at risk.

NHBS is an ongoing behavioral surveillance system that collects cross-sectional data among populations at high risk for acquiring HIV, including MSM, injection-drug users, and heterosexuals at high risk. Men aged ≥18 years were sampled systematically from randomly selected venues where MSM congregated (e.g., bars/clubs, organizations, and street locations). Formative research was conducted to identify venues and days and times when MSM frequented these venues (*2--4*). Men eligible for the survey were aged

≥18 years and residents of the metropolitan statistical area (MSA). Using a standardized questionnaire, men were interviewed about their sexual and drug-use behaviors, HIV-testing behavior, and use of HIV-prevention services. During June 2004--April 2005, participants in five NHBS cities (Baltimore, Maryland; Los Angeles, California; Miami, Florida; New York, New York; and San Francisco, California) were also tested for HIV infection after informed consent.

The OraQuick® rapid test or an enzyme immunoassay (EIA) was used to screen blood specimens for HIV antibody, and initially reactive specimens were tested by Western blot for confirmation. To estimate HIV incidence, CDC used a serologic testing algorithm for recent HIV seroconversion (STARHS) (*5*). Specimens that were confirmed positive were tested further with the Vironostika-Less Sensitive (LS) EIA, which detects HIV infection approximately 170 days after initial infection by using a 1.0 standard optical density cutoff (95% confidence interval [CI] = 145--200 days) (*6*). A specimen confirmed positive by Western blot and nonreactive on the Vironostika-LS assay was categorized as an incident infection. Persons self-reporting a previous positive test result and HIV-positive participants reporting use of antiretroviral therapy were excluded from the incidence estimate.

Participants were asked about the date and result of their most recent HIV test before having their blood drawn as part of NHBS. Men who had not been tested during the preceding year were asked about their reasons for not being tested. MSM with unrecognized infection were defined as those who reported being HIV negative, indeterminate, or not knowing their HIV status, but who tested HIV positive at the time of their interview. Prevalence ratios and 95% CIs were calculated to evaluate characteristics associated with testing during the preceding year. Differences in reasons for not testing between HIV-negative MSM and MSM with unrecognized infection were assessed by using chi-square tests ($p<0.05$).

In the five cities, 2,261 men sampled from 258 venues participated in NHBS. The participation rate among eligible men was 83% (range by city: 69%--99%). A total of 1,767 (78%) were men who had one or more male sex partners and agreed to the survey, HIV test, and STARHS test (range by city: 222--462). Of these 1,767 participants, the median age was 32 years (range: 18--81 years); 35% were white, 27% Hispanic, 25% black, 7% multiracial/other, and 6% Asian/Pacific Islander. Participants were recruited at bars (30%), street locations (20%), dance clubs (19%), cafes/retail stores (10%), Gay Pride events (6%), social organizations (5%), gyms (5%), sex establishments (3%), and parks (1%).

Of the 1,767 MSM, 450 (25%) tested positive for HIV (range by city: 18%--40%). HIV prevalence was 46% among blacks, 21% among whites, and 17% among Hispanics. A total of 340 (76%) of those who were HIV positive were aged ≥30 years (Table 1). Of the 449 HIV-antibody--positive specimens tested by Vironostika-LS, 80 were nonreactive; of these, 31 were considered incident infections, and 49 were excluded from the incidence estimate. HIV incidence among MSM by city was as follows: Baltimore, 8.0% (95% CI = 4.2%--11.8%); Los Angeles, 1.4% (95% CI = 0.0%--2.9%); Miami, 2.6% (95% CI =

0.0%--5.6%); New York City, 2.3% (95% CI = 0.28%--4.2%); and San Francisco, 1.2% (95% CI = 0.0%--2.6%).

Of the 450 HIV-infected MSM, 217 (48%) were unaware of their HIV infections. The proportion of unrecognized HIV infection was highest among MSM who were aged <30 years, nonwhite, and surveyed in the four cities other than San Francisco (Table 1). Of the 217 MSM with unrecognized HIV infections, 64% were black, 18% Hispanic, 11% white, and 6% multiracial/other. The majority (184 [84%]) of the 217 MSM with unrecognized HIV infection had previously been tested for HIV; 145 (79%) reported that their most recent test result was negative, 33 (18%) were unknown, and six (3%) were indeterminate. Approximately 58% of MSM with unrecognized infections had not been tested during the preceding year. Compared with MSM who were HIV negative, proportionally more MSM with unrecognized infections had not been tested during the preceding year because they were afraid of learning they had HIV (34% versus 68%; $p<0.0001$) and were worried others would find out the result (14% versus 35%; $p<0.0001$) (Figure).

Nearly all participants (92%) reported previously being tested for HIV, and 64% reported being tested during the preceding year. MSM were more likely to have been tested during the preceding year if they had visited a health-care provider and their provider recommended an HIV test (Table 2). Sexual and drug-use behaviors were not associated with testing during the preceding year.

Reported by: *F Sifakis, PhD, Johns Hopkins Bloomberg School of Public Health, Baltimore; CP Flynn, ScM, Maryland Dept of Health and Mental Hygiene. L Metsch, PhD, Univ of Miami; M LaLota, MPH, Florida Dept of Health. C Murrill, PhD, New York City Dept of Health; BA Koblin, PhD, New York Blood Center, New York. T Bingham, MPH, Los Angeles County Dept of Health Svcs; W McFarland, MD, H Raymond, San Francisco Dept of Public Health, California. S Behel, MPH, A Lansky, PhD, B Byers, PhD, D MacKellar, MPH, A Drake, MPH, K Gallagher, DSc, Div of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, CDC.*

Editorial Note:

Consistent with previous studies of young MSM conducted in the same cities using similar sampling methods (*2--4,7,8*), this study revealed that 1) prevalence and incidence of HIV infection in this population were high; 2) many HIV-infected MSM, particularly younger and black MSM, were unaware they were HIV-infected; and 3) among MSM with unrecognized infection, nearly half presumably acquired HIV during the preceding year, and many had not been tested recently because of fears of testing positive. These findings underscore the need to increase testing and improve primary prevention practices for MSM.

Although a majority of MSM had been tested during the preceding year, more than half with unrecognized infections had not had an annual test. The results of this study support CDC guidelines recommending at least annual testing for sexually active MSM (*8*),

especially among younger MSM and minority populations (7).

The findings in this report are subject to at least four limitations. First, the date of a participant's most recent HIV test is self-reported and might be subject to reporting inaccuracies. Second, given the sensitive nature of some questions, HIV status might have been underreported during the interview, thereby inflating estimates of unrecognized infections. Third, these findings are limited to men who frequented MSM-identified venues in the five selected cities during the survey period. Although similar rates of HIV incidence were observed compared with previous surveys (2), the limited number of incident cases prevents comparisons by race and age. Finally, data are preliminary and have not been weighted by venue-selection probability.

The 2004 NHBS system was conducted in 17 MSAs with the highest AIDS prevalence. Although this report focuses on testing results from five selected cities, behavioral data are forthcoming from all participating cities. NHBS is an important tool for monitoring the impact of the HIV epidemic and informing prevention efforts.

HIV incidence and prevalence are high among MSM, and many are unaware they are HIV positive. The high level of unrecognized HIV infections among MSM is a public health concern. Persons aware of their HIV infection often take steps to reduce their risk behaviors, which could reduce HIV transmission (9). To increase the proportion of HIV-positive persons who know they are infected, sexually active MSM should be encouraged to have an HIV test at least annually. Corresponding efforts should be developed to address barriers to testing, particularly those related to fear, and to increase the availability of testing in clinical and nonclinical settings (*10*). Testing programs should target both younger MSM and black MSM to reach populations disproportionately unaware they are HIV positive.

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Table 1

TABLE 1. HIV prevalence and proportion of unrecognized HIV infection among men who have sex with men, by city, age group, and race/ethnicity — five NHBS* cities, June 2004–April 2005

Characteristic	Total tested	HIV prevalence		Unrecognized HIV infection	
		No.	(%)	No.	(%)
City					
Baltimore	462	186	(40)	115	(62)
Los Angeles	382	73	(19)	31	(42)
Miami	222	41	(18)	19	(46)
New York City	336	62	(18)	32	(52)
San Francisco	365	88	(24)	20	(23)
Age group (yrs)					
18–24	410	57	(14)	45	(79)
25–29	303	53	(17)	37	(70)
30–39	585	171	(29)	83	(49)
40–49	367	137	(37)	41	(30)
≥50	102	32	(31)	11	(34)
Race/Ethnicity†					
White, non-Hispanic	616	127	(21)	23	(18)
Black, non-Hispanic	444	206	(46)	139	(67)
Hispanic	466	80	(17)	38	(48)
Multiracial	86	16	(19)	8	(50)
Other§	139	18	(13)	9	(50)
Total	**1,767**	**450**	**(25)**	**217**	**(48)**

* National HIV Behavioral Surveillance.
† Numbers for HIV prevalence do not add to 450 because of missing data in three records.
§ Because of small sample sizes, category includes Asian/Pacific Islander, Native American/Alaska Native, and other.

Table 2

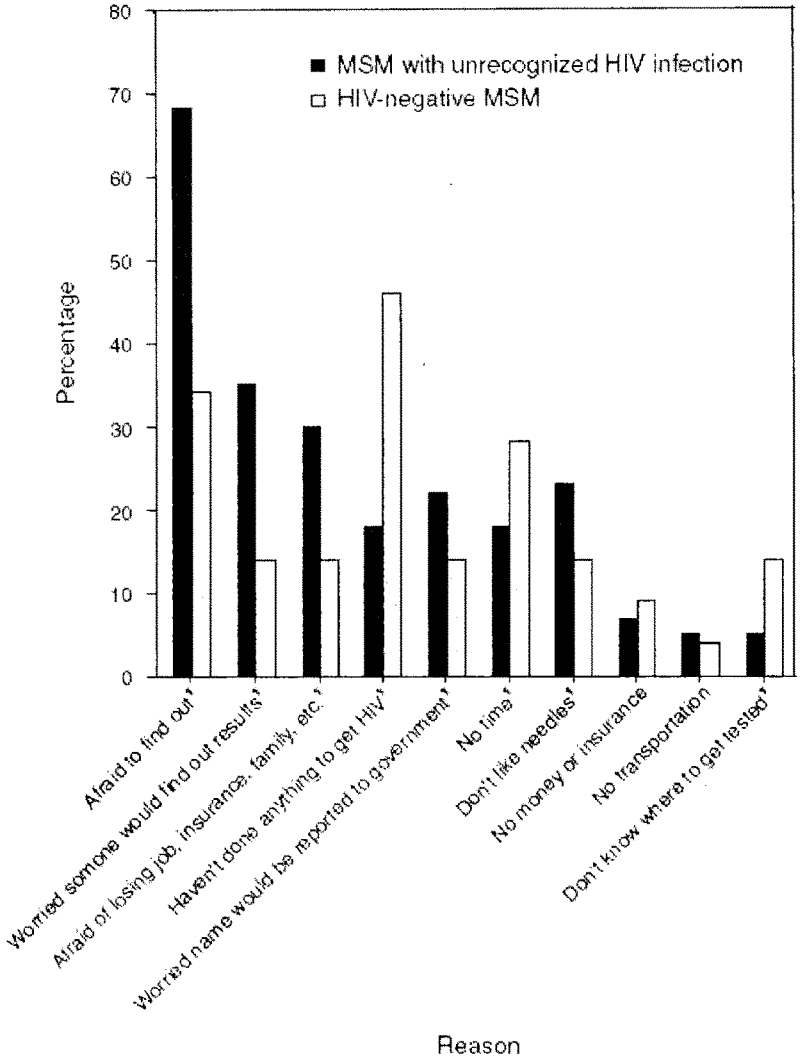
TABLE 2. Prevalence of HIV testing during the preceding year among men who have sex with men, by selected characteristics — five NHBS* cities, June 2004–April 2005

Characteristic	Total previously tested	Last HIV test during preceding year No.	(%)	Prevalence ratio	(95% CI†)
City					
Baltimore	404	260	64	1.00	Referent
Los Angeles	358	231	64	1.00	(0.90–1.11)
Miami	230	136	67	1.04	(0.92–1.17)
New York City	306	202	66	1.03	(0.92–1.14)
San Francisco	351	206	59	0.91	(0.81–1.02)
Age group (yrs)					
18–24	350	285	81	1.00	Referent
25–29	285	200	70	0.86	(0.79–0.94)
30–39	547	330	60	0.74	(0.68–0.81)
40–49	346	180	52	0.64	(0.57–0.72)
≥50	94	40	43	0.52	(0.41–0.66)
Race/Ethnicity					
White, non-Hispanic	589	345	58	1.00	Referent
Black, non-Hispanic	391	254	65	1.11	(1.00–1.23)
Hispanic	422	289	68	1.17	(1.06–1.28)
Asian/Pacific Islander	85	55	65	1.10	(0.93–1.31)
Native American/ Alaska Native	7	6	86	1.46	(1.07–2.00)
Multiracial	79	52	66	1.12	(0.95–1.34)
Other	34	25	74	1.26	(0.36–1.13)
Education					
<High school	142	97	68	1.00	Referent
High school or equivalent	343	227	66	0.97	(0.85–1.11)
>High school	1,135	709	62	0.91	(0.81–1.03)
Sexual identity					
Homosexual	1,256	787	63	1.00	Referent
Bisexual	320	219	68	1.09	(1.00–1.19)
Health-insurance status					
Private physician or HMO§	954	616	65	1.00	Referent
Public	149	91	61	0.95	(0.83–1.08)
None	495	312	63	0.98	(0.90–1.06)
Health-care use					
Visited provider during preceding year					
No	317	156	49	1.00	Referent
Yes	1,305	879	67	1.37	(1.22–1.54)
Provider recommended HIV test¶					
No	809	476	59	1.00	Referent
Yes	496	403	81	1.38	(1.29–1.48)
Most recent HIV test result**					
Negative	1,285	874	68	1.00	Referent
Unknown	95	72	76	0.90	(0.80–1.01)
Total	**1,622**	**1,035**	**64**	—	—

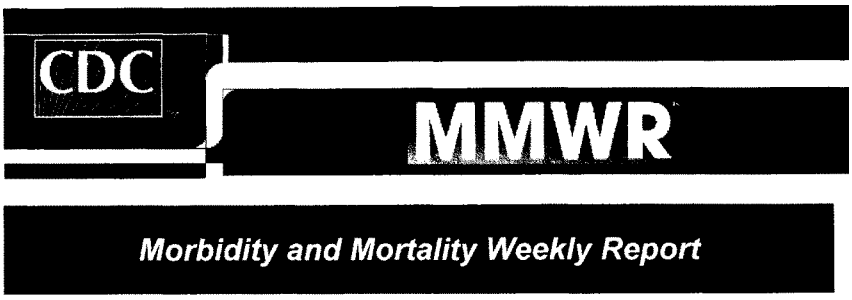
* National HIV Behavioral Surveillance.
† Confidence interval.
§ Health maintenance organization.
¶ Among those who visited a health-care provider during the preceding year.
** Result of last HIV test before participation in NHBS.

Figure

FIGURE. Reasons for not having an HIV test during the preceding 12 months among men who have sex with men (MSM), by HIV-infection status* — five NHBS† cities§, June 2004–April 2005



* HIV-negative MSM (n = 472); MSM with unrecognized infection (n = 119).
† National HIV Behavioral Surveillance.
§ Baltimore, Maryland; Los Angeles, California; Miami, Florida; New York, New York; and San Francisco, California.
¶ $p<0.05$ by Cochran-Mantel-Haenszel chi-square test.



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Unrecognized HIV Infection, Risk Behaviors, and Perceptions of Risk Among Young Black Men Who Have Sex with Men --- Six U.S. Cities, 1994--1998

The incidence of human immunodeficiency virus (HIV) infection among young black men who have sex with men (BMSM) is among the highest of all risk groups in the United States (*1--3*). Two important strategies to reduce HIV transmission among young BMSM are to increase the proportion of men who are aware of their HIV infection and to increase the consistent use of condoms among sexually active men (*4,5*). However, limited information is available to help develop HIV-testing and condom-promotion programs for young BMSM. To address this need, data from CDC's Young Men's Survey (YMS) were used to evaluate the prevalence of unrecognized HIV infection, barriers to testing, and reasons for nonuse of condoms among BMSM aged 15--22 years. This report summarizes the results of the survey, which indicated that of the 16% of young BMSM participants who were infected with HIV, nearly all were unaware of their infection. Few young BMSM reported testing frequently for HIV, and many reported engaging in behaviors that could transmit HIV because they perceived themselves or their partners to be at low risk for infection. These findings underscore the urgency of expanding and improving prevention efforts for young BMSM by increasing the demand for and availability of HIV-testing services and by providing high-quality prevention counseling that includes assessment and clarification of perceived risks for infection.

YMS was a cross-sectional survey conducted during 1994--1998 of males aged 15--22 years who attended MSM-identified venues (e.g., shopping areas, dance clubs, bars, and organizations) in Baltimore, Maryland; Dallas, Texas; Los Angeles, California; Miami, Florida; New York, New York; the San Francisco Bay Area, California; and Seattle, Washington (*1*). Extensive formative research was conducted to construct monthly sampling frames of the days, times, and venues attended by young BMSM. Each month, 12--16 venues and their associated day/time periods were selected randomly and scheduled for sampling. During sampling events, men were approached consecutively to assess their survey eligibility. BMSM eligible for the survey were aged 15--22 years and residents in one or more local counties. Participants were interviewed by using a standard questionnaire, had blood drawn for HIV testing, were given appointments to obtain test results, and were provided HIV-prevention counseling and referral for care when needed.

Specimens were tested for HIV at local laboratories with standard assays. Analyses were restricted to men who reported ever having sex with men and who described their racial background as either being only black or having a mixed background that included being black. Analyses excluded records of duplicate participants, who were identified by using the Miragen antibody profile assay (*6*). Records also were excluded from Seattle because few BMSM had participated in that city.

In the six cities, 920 BMSM participated in YMS (range: 127--202). The participation rate among eligible blacks was 61% (range: 53%--77%). Of the 920 participants, 150 (16%) tested positive for HIV (range: 13%--18%). Of the 150 HIV-infected BMSM, 139 (93%) were unaware of their infection (range: 88%--100%). Of those with unrecognized infection, 99 (71%) reported either that there was no chance, that it was very unlikely, or that it was unlikely that they were infected with HIV; 58 (42%) perceived themselves at low risk for ever becoming infected; and 45 (32%) perceived themselves at low risk both for being and for ever becoming HIV-infected (Table).

During the 6 months preceding the survey, the 920 BMSM reported a median of two male sex partners (interquartile range: one to three), 712 (77%) reported having anal intercourse with another man, and 342 (37%) reported having unprotected anal intercourse (UAI). Of the 79 BMSM with unrecognized HIV infection who had UAI, 41 (52%) reported not using

condoms for one or more of the following reasons: they "knew" they were HIV-negative (24%), they "knew" their partners were HIV-negative (20%), or they thought their partners were at low risk for infection (35%); 34 (43%) also reported not using condoms because none were available (Table).

Of the 920 BMSM, 585 (64%) had ever tested previously for HIV, but few had tested frequently (median number of tests: one; interquartile range: zero to two). Of those who had tested previously, 536 (92%) reported last testing HIV-negative, and of these, 87 (16%) were found to be infected with HIV. The 332 (36%) men who had not tested previously gave the following reasons for not testing (more than one reason could be given): low risk for infection (45%), fear of learning their results (41%), and fear of needles (21%). Of those who had not tested previously, 42 (13%) were HIV-infected. Of the 148 men who had not tested previously because of perceived low risk, 122 (82%) ever had anal intercourse with a man, 99 (67%) had at least three lifetime male partners, and 11 (7%) were HIV-infected.

Compared with their noninfected peers, young BMSM with unrecognized infection were more likely to report engaging in UAI and not testing previously because of fear about learning their results (Table). Noninfected young BMSM were more likely to perceive themselves at low risk for infection and not to have tested previously because of this perception.

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Editorial Note:

The findings in this report are consistent with previous studies suggesting that in several U.S. cities, the majority of young HIV-infected MSM, particularly BMSM, were unaware of their infection (*1,7*). In a preliminary

analysis of 573 HIV-infected MSM aged 16--29 years sampled in six U.S. cities, proportionally more BMSM were unaware of their infection than were white MSM (91% versus 60%) (*7*). However, among all young MSM with unrecognized HIV infection, no racial or ethnic differences were observed among those perceiving themselves at low risk for being infected (66%), engaging in UAI (54%), or not using condoms during anal intercourse because of perceived low personal or partner risks for HIV infection (46%) (*7*). These findings underscore the urgency of improving HIV-prevention efforts for all young MSM by 1) increasing the demand for and availability of HIV-testing services and *2*) providing young MSM with high-quality HIV- and STD-prevention services that include assessment and clarification of personal risks for infection.

In accordance with recently revised guidelines, health-care providers should assess the HIV risks of their patients routinely and encourage all MSM at risk for HIV to test at least annually (*8,9*). Findings from this report indicate that demand for testing by young BMSM might be increased by implementing efforts that increase personal risk perceptions; addressing concerns about testing positive by conveying the benefits of early diagnosis and HIV care; and marketing the availability of oral fluid, urine-based, or finger-stick HIV tests that do not require venipuncture (*9*). Use of testing services also might be increased by offering testing in nonclinical settings that serve or are attended by young BMSM and by providing high-quality partner referral services for all those who test positive (*5,9*).

HIV testing should be accompanied by high-quality prevention counseling that includes an in-depth personalized risk assessment, clarification of risk perceptions, and negotiation of steps to reduce risks (*9*). Because 16% of young BMSM who reported being HIV-negative were found to be HIV-infected, providers should encourage young BMSM to use condoms consistently with all partners, including those who have tested negative previously. In negotiating risk reduction with young BMSM, providers should be prepared to address alcohol, drug, and partner influences on condom use and to help young BMSM cope with emotional responses in high-risk situations. Providers should refer clients who have difficulty in initiating or sustaining safer behavior for more intensive individualized prevention counseling and support services (*9,10*). Finally, managers of prevention programs should consider increasing the availability of condoms in settings where young BMSM are likely to encounter sex partners.

The findings in this report are subject to at least three limitations. First, findings might not be applicable to young BMSM who do not attend MSM-identified venues or reside in the six participating cities. Second, because approximately 39% of eligible young BMSM chose not to participate, selective nonparticipation could have biased reported findings. Finally, data were collected during face-to-face interviews and are subject to disclosure biases. The finding that nearly all HIV-infected young BMSM in this survey were unaware of their infection might be attributed, in part, to one or more of these biases. However, a high proportion of young BMSM who are unaware of their infection is likely given the high HIV incidence and low frequency of testing among young BMSM (2).

In partnership with state and local health departments, nongovernment organizations, community stakeholders, and other federal agencies, CDC is taking steps to reduce HIV transmission and unrecognized infection among young MSM, particularly BMSM. Since September 2001, five national consultations have helped identify current prevention needs of MSM, including young minority MSM. In 2001, additional resources were made available to expand HIV counseling and testing, outreach services, and behavioral risk-reduction interventions for young minority MSM. Ongoing prevention efforts also are being strengthened through capacity development for minority community-based organizations serving young MSM, and through recently released guidelines calling for expanded risk assessment and HIV testing for homosexual and bisexual men (8,9). Finally, new research efforts, including rapid ethnographic assessments, have been initiated to identify additional factors that influence HIV-acquisition risks among young minority MSM. These and similar efforts signal the increased priority at national, state, and local levels to reduce the considerable racial disparities in HIV morbidity and unrecognized infection among young MSM.

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TABLE. Percentage of black men aged 15–22 years who have sex with men who reported low perceived risk for human immunodeficiency virus (HIV) infection, previous HIV testing, and sexual risk behavior, by HIV status — six cities*, United States, 1994–1998

Characteristic	Infected unaware† (n=139) %	Noninfected (n=770) %	p value§
Low perceived risk			
Being HIV-infected¶	71	86	<0.01
Becoming HIV-infected**	42	51	0.06
Being/becoming HIV-infected††	32	47	<0.01
Previous HIV tests			
Ever	70	62	0.07
Last test negative§§	*63*	*58*	*0.34*
Last test unknown or indeterminate	*7*	*4*	*0.06*
Last negative test <1 year before interview	41	41	0.88
≥3 tests	28	21	0.08
Reasons for not testing previously			
(Of nontested men; n=332)	*(n=42)*	*(n=290)*	
Perceived low risk for infection	26	47	<0.01
Scared to learn results	55	39	0.04
Scared of needles	17	22	0.69
Sexual risk behavior¶¶			
≥3 partners	41	37	0.40
Anal intercourse, insertive or receptive	91	75	<0.01
Unprotected anal intercourse (UAI)***	57	34	<0.01
Reasons for nonuse of condoms†††			
(Of men who had UAI; n=338)	*(n=79)*	*(n=259)*	
Participant "knew" he was HIV-negative	24	33	0.11
Participant "knew" his partner was HIV-negative	20	33	0.02
Participant thought his partner was at low risk for HIV	35	36	0.81
Condom was not available	43	37	0.42
Participant was under the influence of alcohol or drugs	27	16	0.06
Participant did not think about it or was too emotionally involved	16	16	0.90
Partner did not like using condoms	23	20	0.69
Participant did not like using condoms	15	14	0.81

* Baltimore, Maryland; Dallas, Texas; Los Angeles, California; Miami, Florida; New York, New York; and the San Francisco Bay Area, California.
† Study participants who tested HIV-positive and who reported not ever testing HIV-positive previously.
§ Cochran-Mantel-Haenszel chi-square comparing infected unaware with noninfected, controlling for city.
¶ Measured by respondent answering "no chance of it," "very unlikely," or "unlikely" to the following question: "Which of the following describes how likely it is that you are infected with HIV today?"
** Measured by respondent agreeing with the following statement: "There is little chance that I could become infected with HIV, or infect others, from what I do sexually."
†† Perceived low risk for both being HIV-infected and ever becoming infected.
§§ Most recent HIV test before study participation.
¶¶ With other men only during the 6-month period preceding the survey.
*** Measured as not always using condoms during insertive or receptive anal intercourse.
††† More than one reason could be given.

CDC MMWR

Morbidity and Mortality Weekly Report

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Voluntary HIV Testing as Part of Routine Medical Care --- Massachusetts, 2002

In 2003, CDC released *Advancing HIV Prevention: New Strategies for a Changing Epidemic*. One of the four strategies of this initiative is to expand routine, voluntary human immunodeficiency virus (HIV) testing (*1*). This report describes the results of a state-funded program in Massachusetts that offered HIV counseling, testing, and referral (HIV CTR) to patients entering one of four hospital-associated urgent care centers. Among the 3,068 patients tested, the program identified an HIV seroprevalence of 2.0%. The findings underscore the effectiveness of routine HIV CTR in HIV case identification.

The Massachusetts Department of Public Health (MDPH) AIDS Bureau identified the 15 cities in Massachusetts with the highest HIV prevalence. On the basis of patient volume and existing HIV primary care services, four hospital-associated urgent care centers in these cities were selected for program implementation. The program, called "Think HIV," was designed to assist centers in routine HIV counseling and testing, facilitate patient follow-up for test results, and promote strategies for linkage to care. Patient privacy and the availability of adequate, expedient HIV care for those who tested positive were essential components of the program.

After registration for urgent care, patients were offered the opportunity to speak with a "health educator," a certified counselor with case-management experience trained specifically in sexually transmitted diseases, hepatitis C, and HIV. Counselors were available weekdays and some weekends. Patients

who agreed to speak with a health educator were told that voluntary, confidential HIV CTR was now offered routinely to urgent care patients. Patients who declined to speak with a health educator were asked about their reasons for refusal, and those who reported they were already known to be HIV-infected were asked if they were receiving HIV care; if not, they were linked to care.

Upon completion of counseling, confidential HIV tests were performed by using the oral swab, OraSure® HIV-1 antibody detection system (Epitope, Inc., Bethlehem, Pennsylvania). Patients were instructed to return to the urgent care center for test results 14 days later, when results were provided and post-test counseling was performed. Substantial efforts, including a minimum of four telephone calls and a follow-up letter, were made to locate all patients testing negative or positive who did not return for results. Additional efforts, including offering transportation vouchers and contacting homeless shelters, were made for persons testing positive who failed to return. At each center, an HIV intake nurse from an HIV outpatient clinic provided assistance to patients during posttest counseling, arranged follow-up HIV clinical care appointments, and often brought patients to their care appointments.

During 2002, the first year of the program, 10,352 patients were offered HIV counseling at the four centers, accounting for approximately 10%--15% of all patients entering these urgent care centers and a percentage determined by counselor capacity. Of the 10,352 patients offered HIV testing, 7,071 (68%) declined testing; 6,291 (89%) of these 7,071 were willing to answer inquiries about their refusal to undergo testing. The reasons given for testing refusal included one or more of the following: 1) did not feel at risk for HIV (2,974 [47%]), 2) tested for HIV before (2,624 [42%]), 3) felt too ill (686 [11%]), 4) testing takes too long (281 [4%]), 5) information too personal (120 [2%]), and 6) already known to be HIV-infected (86 [1%]). Of the 2,573 patients reporting previous HIV testing who also provided the dates of the test, 1,542 (60%) reported their tests were performed in 2002 (Table).

Among the 3,068 patients with completed test results, 60 were HIV-infected (HIV prevalence: 2.0%); of these, 49 (82%) returned for their results. Of the first 42 patients for whom linkage-to-care data were available, all 42 had at least one documented follow-up visit for HIV care. During the interview process, the program also identified six additional patients who reported they were known to be HIV-infected and who described themselves as either not

having a doctor or not being in care. These patients were referred for follow-up HIV care. Four of these six patients had confirmed attendance at their first HIV care appointment.

The program was funded by the MDPH AIDS Bureau. Overall, the cost of the program for the first 12 months was $349,400, which amounted to $7,100 for each of the 49 new HIV-infected patients told of their diagnosis or $5,800 for each of the 60 new cases identified.

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Editorial Note:

This report describes results of the Think HIV program in Massachusetts, which offered voluntary HIV CTR routinely to patients entering four urgent care centers. Because these centers did not previously have routine HIV CTR available, the majority of the 60 newly identified HIV patients likely would not have been identified until later in the course of their disease without the program. Health-care providers often discourage HIV testing in urgent care centers because of concerns regarding adequate training, pre- and post test counseling, and follow-up for patients testing HIV positive (*2*). Because many medically underserved patients at high risk for HIV use urgent care centers and emergency departments for their primary care, repeated opportunities for HIV diagnosis in these patients often are missed (*3*).

Simply making a diagnosis of HIV, however, does not ensure the individual and public health benefits of HIV care. Previous reports have indicated that a mean delay of entry into HIV care of 3 months occurs after HIV diagnosis, with 32% of patients delaying >2 years and 18% delaying >5 years (*4*). To combat this lag to care, the program emphasized a formal linkage-to-care mechanism. An identified intake nurse at each center confirmed that newly HIV-diagnosed patients had rapid, immediate communication with members of their future health-care team. Success with the linkage component of the program is evidenced by a first appointment attendance rate of 100%, compared with 34% in another urgent care routine testing program in

Atlanta (*5*). Results from CDC's Antiretroviral Treatment and Access Study also demonstrated substantial improvements in entry into HIV care with the presence of HIV case-management personnel. Patients who had two to three visits with a case manager during a 3-month period attended more HIV care visits, compared with patients who did not have these encounters (*6*).

HIV testing as part of routine care has been delegated to primary care providers. In a 10- or 15-minute provider visit intended to cover many components of medical care, HIV CTR typically is not performed. By using counselors committed to this effort, the program had an estimated cost per new HIV patient identified of <$6,000, a figure that would be reduced with more streamlined pretest procedures of providing information about HIV testing (as recommended in CDC's *Advancing HIV Prevention* initiative) rather than the previously recommended extensive pretest counseling (*1*). Model-based cost-effectiveness analyses of routine HIV screening in primary care, outpatient, and inpatient settings have projected cost-effectiveness ratios of $22,000--$36,700 per quality-adjusted life year gained, which is more cost-effective than screening for colon cancer (*7--10*).

The findings in this report are subject to at least two limitations. First, although efforts were made to test all patients entering the urgent care centers, access to HIV testing was based on counselor availability. Second, centers with suspected high HIV prevalence were chosen, and results should not be generalized to all urgent care centers throughout the United States.

CDC's initiative *Advancing HIV Prevention: New Strategies for a Changing Epidemic* calls for including HIV testing as a routine part of medical care to increase the number of HIV-infected persons who are aware of their positive serostatus (*1*). The diagnosis of HIV in HIV-infected persons is a priority in the United States. Routine, voluntary HIV screening programs in urgent care centers in areas of high HIV prevalence are feasible and can be successful at diagnosing persons with HIV and linking them to appropriate HIV care. CDC is currently funding such projects in out-patient care clinics and emergency departments in four states. In addition, CDC will be funding community-based organizations and health departments to assist with linkage and referrals in facilities in areas of high HIV prevalence and will evaluate the cost-effectiveness of this strategy.

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Massachusetts Dept of Public Health. National Institute of Allergy and Infectious Diseases, National Institute of Mental Health, National Institutes of Health.

TABLE. Number and percentage of patients* who accepted or declined human immunodeficiency virus (HIV) testing, by selected characteristics and test result — Massachusetts, 2002†

	Tested positive		Tested negative		Not tested	
Characteristic	No.	(%)	No.	(%)	No.	(%)
Sex						
Male	41	(68)	1,684	(56)	3,420	(49)
Female	19	(32)	1,317	(44)	3,626	(51)
Total	60	(100)	3,008	(100)	7,071	(100)
Race/Ethnicity						
White, non-Hispanic	2	(4)	632	(22)	2,160	(35)
Black, non-Hispanic	33	(56)	1,092	(38)	2,033	(33)
Hispanic	12	(20)	794	(28)	1,446	(23)
Haitian	6	(10)	151	(5)	203	(3)
Other	6	(10)	216	(7)	396	(6)
Education						
<High school	22	(37)	772	(26)	1,347	(22)
High school	24	(41)	1,194	(40)	2,447	(39)
>High school	13	(22)	1,029	(34)	2,448	(39)

* A total of 16 (<1%) patients had missing data for age, 32 (<1%) for sex, 957 (9%) for race/ethnicity, and 843 (8%) for education.

† Mean age was 35.5 years among persons testing positive, 33.6 years for those testing negative, and 33.1 years for those not tested.

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Monday, January 14th 2002

Many Young MSM Get HIV After Testing and Counseling

Many young men who have sex with men (MSM) acquire HIV soon after repeated use of HIV counseling and testing services.

Researchers compared the recent risk behaviors and HIV status of young MSM who were first time testers, infrequent testers who had been tested one to two times, and repeat testers who had been tested at least three times.

Providers must strengthen practices to identify, counsel, and test young MSM.

Repeat testers were more likely to acquire HIV and engage in risky behaviors when compared with the infrequent and first time testers (seven percent versus four percent). In addition most repeat testers who acquired HIV -- more than 75 percent of them -- did so within one year of their last test.

These results have implications about the effectiveness of current prevention efforts and testing and counseling services. "Providers must strengthen practices to identify, counsel, and test young MSM and provide enhanced behavioral interventions for those with persistent risks," the study authors write.

There were almost 3,500 participants -- 36 percent tested for the first time, 39 percent were infrequent testers and 26 percent were repeat testers.

First-time testers reported similar use of health care but tended to delay testing for nearly two years after potential risk, compared to repeat testers.

Findings from the study, lead by researchers from the Division of HIV/ AIDS Prevention-Surveillance and Epidemiology of the Centers for Disease Control and Prevention (CDC), were published in the January 1 issue of the Journal of Acquired Immune Deficiency Syndromes.

(7) Baby AIDS

The 1994 AIDS Clinical Trials Group protocol number ACTG076 (076) found that use of the medication zidovudine (ZDV) could dramatically reduce the transmission of HIV infection from an infected mother to her child.

Despite this scientific breakthrough that offered the hope of preventing hundreds of babies a year from becoming infected with HIV, the public health establishment and AIDS community have been slow to embrace universal HIV testing of pregnant women and newborns, which is necessary to identify and treat those at risk.

Both the Centers for Disease Control and Prevention (CDC) and the American Medical Association initially opposed efforts to require routine testing of pregnant women and newborns, only to reverse their position.

CDC did initially fund a national program in which newborns were automatically tested for HIV antibodies, but the results were not disclosed to the children's parents or guardians. The agency discontinued these "blind" tests when Congress sought to require disclosure of positive test results.

More than ten years after 076, CDC estimates that over 300 babies continue to become infected with HIV annually.

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HIV Testing Among Pregnant Women — United States and Canada, 1998–2001

Since 1994, the availability of increasingly effective antiretroviral drugs for both the prevention of perinatal human immunodeficiency virus (HIV) transmission and maternal treatment has resulted in a greater emphasis on prenatal HIV testing and substantial increases in prenatal testing rates. In 2000, preliminary data indicated that 766 (93%) of 824 HIV-infected women in 25 states knew their HIV status before delivery (CDC, unpublished data, 2002). However, an estimated 280–370 perinatal HIV transmissions continue to occur in the United States each year (*1*). The primary strategy to prevent perinatal HIV transmission is to maximize prenatal HIV testing of pregnant women. States and Canadian provinces have implemented three different prenatal HIV-testing approaches. To assess their effectiveness, CDC reviewed prenatal HIV-antibody testing rates associated with these approaches. Medical record data suggest that the "opt-in" voluntary testing approach is associated with lower testing rates than either the "opt-out" voluntary testing approach or the mandatory newborn HIV testing approach.

Under the opt-in approach, women typically are provided pre-HIV test counseling and must consent specifically to an HIV-antibody test. Under the opt-out approach, women are notified that an HIV test will be included in a standard battery of prenatal tests and procedures and that they may refuse testing (*2*). Under mandatory newborn HIV testing, newborns are tested for HIV, with or without the mother's consent, if the mother's HIV status is unknown at delivery.

Three methods were used to estimate prenatal testing rates among all women who delivered, regardless of whether they received prenatal care. First, eight U.S. areas that participated during 1998–1999 in CDC's Active Bacterial Core Surveillance/Emerging Infections Program (ABC) Network assessed HIV testing during prenatal care and ≤2 days before delivery by reviewing a stratified random sample of labor and delivery records and prenatal records forwarded to birthing hospitals (*3*); in collaboration with CDC, network staff received a sample of records from all birthing hospitals in the surveillance areas and weighted testing rates to represent all live-born infants in those areas. Second, public health investigators in each of the five Canadian provinces tallied the number of HIV tests among pregnant women that were submitted to provincial laboratories and divided the total by an estimate of all live and stillborn births in each province during the same year. Third, CDC analyzed weighted data collected in 1999 by interviewers in nine states for CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) (an ongoing, population-based survey conducted in 32 states and New York City among women who have given birth during the preceding 2–6 months [*4*]), who had asked women if they had been tested for HIV during pregnancy. Data on state prenatal HIV-testing policies were obtained from the American College of Obstetricians and Gynecologists (*5*).

HIV-testing rates varied depending on which approach to testing was used. Rates for states using the opt-in approach to prenatal HIV testing included in the ABC Network ranged from 25% to 69% (Table 1), testing rates in Canada ranged from 54% to 83% (Table 2), and rates derived from PRAMS data ranged from 61% to 81% (Table 3). Two U.S. states (Arkansas and Tennessee) and two Canadian provinces (Alberta, and Newfoundland and Labrador) reported using

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an opt-out prenatal HIV-testing policy. ABC Network data indicated that Tennessee had a testing rate of 85% (Table 1). Canada's population-based data indicated a 98% testing rate in Alberta and a 94% testing rate in Newfoundland and Labrador (Table 2). PRAMS interview data indicated a 71% testing rate in Arkansas (Table 3), compared with a 57% testing rate early in 1997 before the law was implemented (Arkansas Department of Health, personal communication, 2002). Two states (New York and Connecticut) require HIV testing of newborns whose mothers were not tested during pregnancy. In New York, an ABC Network review of medical records in seven counties in the Rochester area indicated that the proportion of pregnant women who received a prenatal HIV test increased from 52% of 438 charts during January 1998–July 1999 to 83% of 112 charts during August–December 1999 after New York required that newborn HIV testing results be made available within 48 hours of specimen collection (Table 1). PRAMS data for 1999 indicated that the proportion of women statewide who reported having received an HIV test during pregnancy increased from 69% of 758 women during January–July to 93% of 502 during August–December (Table 3). In separate, statewide analyses of prenatal testing reported on newborn metabolic screening forms from all live-born infants, New York reported prenatal HIV-testing rates of 89% in 2000 and 93% in 2001 (New York State Department of Health, personal communication, 2002). In Connecticut, an ABC Network review of 668 charts indicated a testing rate of 31% during January 1998–September 1999, compared with 81% of 93 charts reviewed during October–December 1999 after enactment of the mandatory newborn testing law (Table 1).

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Editorial Note: Prenatal HIV testing affords the best opportunity for the prevention of perinatal HIV transmission. On the basis of clinical trial data, perinatal HIV-transmission rates among HIV-infected women who begin antiretroviral treatment during pregnancy are as low as ≤2% (*6*), compared with 12%–13% early transmission rates among women who do not begin preventive treatment until labor and delivery or after birth (*7*) and 25% among women who receive no preventive treatment (*8*).

TABLE 1. Number of medical charts reviewed and percentage of charts with a documented prenatal HIV test for pregnant women, by testing approach and area — Active Bacterial Core Surveillance/Emerging Infections Program Network, eight states, 1998–1999

State	Testing approach	No. charts reviewed	% with HIV test*	(95% CI†)
Tennessee (five counties)	Opt-out§	623	85%	(82.1%–88.5%)
New York (seven counties in the Rochester area)	Mandatory newborn testing¶ without expedited testing requirement**	438	52%	(47.3%–57.1%)
	Mandatory newborn testing; results returned within 48 hours††	112	83%	(75.0%–91.5%)
Connecticut	Opt-in§§	668	31%	(27.0%–34.3%)
	Mandatory newborn testing; results within 48 hours¶¶	93	81%	(72.3%–88.7%)
Maryland	Opt-in	665	69%	(65.4%–72.8%)
Georgia (20 counties in the Atlanta area)	Opt-in	866	66%	(61.8%–69.6%)
Minnesota (seven counties in the Minneapolis/St. Paul area)	Opt-in	605	62%	(57.5%–65.8%)
California (three counties in the San Francisco area)	Opt-in	575	39%	(34.5%–42.4%)
Oregon (three counties in the Portland area)	Opt-in	498	25%	(21.5%–29.1%)

* Percentages are weighted to reflect all live-born infants and account for sample weights and design.
† Confidence interval.
§ Pregnant women are informed that a human immunodeficiency virus (HIV) test is being conducted as a standard part of prenatal care and that they may refuse it.
¶ Infants are tested for HIV antibodies if the mother was not tested during prenatal care or at delivery. Mother's consent is not required. Neither Connecticut nor New York have data on numbers of newborn infants tested under these laws.
** Policy in effect until August 1999.
†† Policy in effect beginning August 1999.
§§ Pregnant women are required to consent specifically to an HIV test.
¶¶ Policy in effect beginning October 1999.

TABLE 2. Number of women delivering and percentage receiving prenatal HIV testing, by testing approach, year, and province — Canada, 1999–2001

Province	Year	Testing approach	No.	(%)*
Alberta	2000	Opt-out†	37,963	(98)
Newfoundland and Labrador	2001	Opt-out	4,770	(94)
Quebec	1999	Opt-in§	73,781	(83)
British Columbia	1999	Opt-in	41,739	(80)
Ontario	2001	Opt-in	129,758	(54)

* Canadian prenatal human immunodeficiency virus (HIV) testing rates are based on all live-born infants in each province for the year.
† Pregnant women are informed that an HIV test is being conducted as a standard part of prenatal care and that they may refuse it.
§ Pregnant women are required to consent specifically to an HIV test.

Among the three prenatal HIV testing approaches assessed in this report, opt-out voluntary testing and the mandatory testing of newborns appear to be associated with the highest testing rates. On the basis of the chart-review methodology, prenatal testing rates were higher in Tennessee, which uses the opt-out approach, than rates in states using the opt-in approach and similar to rates achieved with mandatory newborn testing in New York during the same time period. A similar trend was observed among Canadian provinces. In New York and Connecticut, mandatory HIV testing of newborns was associated with increases in prenatal testing rates. On the basis of PRAMS data, three of seven states using the opt-in approach achieved lower prenatal HIV-testing rates than states using the opt-out or mandatory newborn testing approaches.

Increases in prenatal HIV-testing rates were noted in states that shifted from an opt-in approach to either an opt-out or mandatory newborn testing approach and were probably associated with a greater likelihood that woman were offered HIV testing during prenatal care. Data from the Perinatal Guidelines Project indicated that the majority of women will accept HIV testing if it is recommended by their health-care provider (*9*). Perinatal HIV experts and professional organizations have advocated streamlining prenatal HIV pre-test counseling and consent procedures to reduce barriers to the offer of testing by health-care providers (*1,2,10*).

The findings in this report are subject to at least seven limitations. First, testing results for each strategy are for all women, and the proportion of HIV-positive women who accepted testing under each strategy is not known. Second, among women who did not receive prenatal testing, the proportion of women who were not tested because they did not seek prenatal care is unknown. Third, among women who did not receive prenatal testing, the proportion of women who were tested at labor and delivery or whose infants were tested at birth is not known. Fourth, maternal self-reported data from

TABLE 3. Percentage of women who responded that they had, had not, or did not know if they had received an HIV test during their most recent pregnancy, by testing approach and state — Pregnancy Risk Assessment Monitoring Survey, United States, 1999

State	Testing approach	No.	Percentage		
			Yes	No	Don't know
Florida	Opt-in*	1,990	81%	13%	6%
New York†	Mandatory newborn testing (1/99–7/99)	758	69%	28%	3%
	Mandatory newborn testing; results within 48 hours of delivery (8/99–12/99)	502	93%	6%	1%
North Carolina	Opt-in	1,770	75%	20%	5%
Illinois	Opt-in	1,994	72%	17%	10%
Colorado	Opt-in	2,039	72%	21%	8%
Arkansas	Opt-out§	1,892	71%	13%	16%
West Virginia	Opt-in	1,327	67%	22%	11%
Oklahoma	Opt-in	1,980	62%	25%	13%
Ohio	Opt-in	1,589	61%	25%	4%

* Pregnant women are required to consent specifically to a human immunodeficiency virus (HIV) test.
† Excludes New York City.
§ Pregnant women are informed that an HIV test is being conducted as a standard part of prenatal care and that they may refuse it.

PRAMS collected 2–6 months after delivery might be subject to recall bias. Fifth, PRAMS data do not indicate whether a prenatal-care provider was aware of the woman's HIV status. Sixth, among the women interviewed in PRAMS, up to 16% (in Arkansas) indicated they did not know if they had been tested. Finally, chart abstraction can document only prenatal HIV testing recorded in maternal medical records; without such documentation, clinicians might not be aware of the need to offer effective perinatal interventions to infected women and their HIV-exposed infants.

This report emphasizes the need for better data to assess perinatal HIV testing rates in the United States. Ongoing, randomized reviews of prenatal, labor/delivery, and pediatric charts, with a sampling framework ensuring that the sample is representative of the population of women delivering, might provide the most valid approach to assessing a state's progress on perinatal HIV testing and prevention. CDC is working with states with high HIV prevalence rates among women of childbearing age and high numbers of pediatric AIDS cases to ensure standardized monitoring of prenatal testing rates. The data suggest that jurisdictions that use an opt-in approach and that have low prenatal HIV-testing rates should reevaluate their approach.

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Influenza Outbreak — Madagascar, July–August 2002

In mid-July 2002, Madagascar health authorities were notified of a substantial number of deaths attributed to acute respiratory illness (ARI) in the village of Sahafata (population: 2,160), located in the rural highlands of Fianarantsoa Province, southeastern Madagascar (Figure 1). This region is approximately 450 km (280 miles) south of the capital Antananarivo. The Madagascar Ministry of Health (MOH) and the Institut Pasteur, Madagascar (IPM) initiated an investigation, which found an attack rate of 70% for ARI, with 27 deaths in Sahafata. Pharyngeal swab specimens were collected from ill persons for viral culture. Of the four influenza A viruses that were isolated at IPM, two were identified

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Baby AIDS

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Foreward

Perhaps the single, most significant achievement in the battle against HIV/AIDS has been the discovery of medical interventions to nearly eliminate perinatal HIV transmission. Beginning with the 1994 announcement of the AIDS Clinical Trials Group protocol number ACTG 076 (076) that found the use of the AIDS medication zidovudine (ZDV) could dramatically reduce the transmission of HIV from an infected mother to her child, science has made it possible that extremely few babies will ever have to be born with HIV desease. Yet despite this promise, hundreds of babies continue to be infected with HIV every year in the United States. This raises some very important questions. Why is it that so many babies are allowed to have their lives cut short and die from AIDS when perinatal HIV infection can nearly be entirely prevented? What policies could have been – and should be – put in place to take advantage of the medical miracle that is available to save babies from AIDS?

Women and Children Increasingly Impacted by HIV

By the end of 1999, nearly 8,000 perinatally acquired AIDS cases had been recorded in the U.S., the vast majority (84 percent) of which are black and Hispanic children.[1] Most of the AIDS cases resulting from children born with HIV infection since 1997, however, have yet to be diagnosed or reported.[2] An estimated 120,000 to 160,000 HIV-infected women are living in the United States, 80 percent of whom are of childbearing age.[3] Approximately 6,000 to 7,000 HIV-infected women gave birth in the U.S. each

Perhaps the single, most significant achievement in the battle against HIV/AIDS has been the discovery of medical interventions to nearly eliminate perinatal HIV transmission.

year from 1985 to 1995.[4] And as women continue to comprise an increasing proportion of new HIV cases, more and more children are likely to be affected by the disease if no positive action is taken. Likewise more of the children and their mothers continue to disproportionately represent communities of color. African American and Hispanic women accounted for 80 percent of AIDS cases reported in U.S. women in 1999.[5]

During the early 1990s, before perinatal preventative treatments were available, an estimated 1,000 to 2,000 infants were born with HIV infection each year in the United States.[6] The incidence of perinatally acquired AIDS peaked in 1992, and dramatically declined in the aftermath of the 076 study and the subsequent Public Health Service (PHS) recommendations made in 1994 and 1995 for routinely counseling and voluntarily testing pregnant women for HIV, and for offering ZDV to infected women and their infants.[7] Without intervention, the mother-to-infant transmission rate would result in the birth of an estimated 1,750 HIV-infected infants annually in the U.S.[8] Today – despite the fact that perinatal transmission can be nearly eliminated – the Centers for Disease Control and Prevention estimates that 300- 400 babies continue to be born with HIV infection each year in the United States.[9]

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Many Women are Still Not Tested, and Thereby Denied Care for Their Children and Themselves

In response to 076, the Centers for Disease Control and Prevention issued recommendations more than a year later, in 1995, requiring all healthcare providers to counsel pregnant women about HIV and offer voluntary testing with informed consent. The CDC released revised draft recommendations for HIV screening for pregnant women in October 2000 that vary slightly, but maintain the emphasis of the 1994 recommendations. No other prenatal medical screening for any other condition required such extensive pre-test criteria to be performed. Studies and anecdotal reports have found that this "AIDS exceptionalist" approach to perinatal HIV prevention has hindered efforts to effectively identify all affected women and newborns. There is a patchwork of different approaches and results in the various states.

Most HIV-infected pregnant women are still not tested and remain undiagnosed according to the findings of a study that examined a voluntary prenatal HIV testing program in northern California. The voluntary approach only resulted in the diagnosis of 20 percent of the HIV-positive pregnancies between 1994 and 1998. "Our experience," concludes Dr. Edgar J. Schoen and colleagues from Kaiser Permanente Medical Care

Program in Oakland, "confirms the desirability of not depending on voluntary prenatal HIV testing to prevent maternal-fetal HIV transmission."[10]

One in five (19 percent) HIV-positive women were not diagnosed before giving birth in 1996 according to CDC data from studies conducted in Louisiana, Michigan, New Jersey and South Carolina.[11]

A state law adopted by Indiana in 1997, requiring all physicians to counsel and offer every pregnant woman an HIV test, has had little impact with less than half receiving HIV tests.[12] Dr. Martin Kleiman, director of pediatric infectious diseases at the Indiana University School of Medicine said that despite the law, for half of the babies who enter Riley Hospital for Children, there is no record of whether the mother has been tested for HIV.[13]

Tennessee, likewise, enacted a law in 1998, requiring all pregnant women be offered HIV tests. Last year, however, there were roughly 70,000 births statewide, but doctors notified the state of offering HIV tests to only 9,314 women during the first nine months. Of the roughly 15,000 births in Shelby County, Tennessee, doctors reported offering tests to only 1,248 pregnant women.[14]

Only 38 percent of pregnant women enrolled by Anthem Blue Cross and Blue Shield in Kentucky received prenatal HIV testing in the state in 1998, even though the cost of the test is covered by the insurer.[15]

"The median percentage of prenatal patients screened for HIV was only 10 percent," according to a study in Minnesota. Just 43 percent of physicians routinely recommended universal HIV screening for prenatal patients according to the researchers.[16]

Only a third of obstetric practices in Vermont and New Hampshire report testing 95 percent of their pregnant patients for HIV. Thirty-seven percent of these practices had HIV testing rates no higher than 50 percent.[17]

> *"the number of children born with HIV, . . . continues to be far above what is potentially achievable" . . .*

Due to barriers and misperceptions, about 30 percent of women are not tested during pregnancy, according to a study published in the May 2001 issue of the *American Journal of Public Health*. "This study suggests that the U.S. health care system is falling short," according to the authors who note "it supports the need to increase HIV testing if HIV infection is to be eliminated among U.S. children."[18]

In Virginia, over 4,000 pregnant women receiving prenatal care in public health clinics did not receive an HIV test in 1997. This is more than one quarter of the 15,160 who received care in Virginia's 32 health districts.[19]

One in five, or about 2,030, pregnant women in Delaware are not tested for HIV during pregnancy according to Dr. Ulder J. Tillman, the Director of Delaware's Health and Services.[20]

More than one in four (28 percent) pregnant women were not tested for HIV in inner city Chicago. Practitioners did not document whether testing was offered in almost 20 percent of the women. Of those women who were screened, 3.5 percent tested positive for HIV.[21]

Likewise, more than one in four pregnant women (28 percent) were not tested for HIV in a study conducted in San Francisco. Sixty-nine percent of patients, however, said that prenatal testing should be routine. The researchers conclude "proponents of elective testing should re-evaluate the assumption that patients view HIV testing differently from other prenatal tests for which separate written consent is not required."[22]

> *"This study suggests that the U.S. health care system is falling short ... it supports the need to increase HIV testing if HIV infection is to be eliminated among U.S. children."*

According to these studies and anecdotes, between 26 and 62 percent of pregnant women are not being tested for HIV. Most alarmingly, depending which state one looks at, 12 to 80 percent of pregnant women who are HIV-positive are not tested, and therefore go undiagnosed and untreated. This increases the number of children who will become infected during or after birth. The CDC has conceded "the birth of every HIV-infected child is a sentinel health event signaling a missed prevention opportunity."[23] Clearly, far too many women and infants are being denied optimal medical care under the CDC's own recommended approach.

The Institute of Medicine (IOM) has echoed this observation, stating "the number of children born with HIV, however, continues to be far above what is potentially achievable," and "more children than necessary continue to be born with HIV infection."[24]

What Approach Will Save Mothers and Babies?

Few would argue today that relying on voluntary prenatal HIV testing is the answer. This approach has not been an effective policy to identify all women and children who need medical intervention and, therefore, has failed to maximize prevention opportunities.

Of the 449 children identified with perinatally acquired AIDS born in 1995-1997, 35 percent had mothers who were not tested for HIV before birth.[25] Roughly 15 percent of HIV-infected pregnant women receive no prenatal care.[26] And only 47 percent of women with HIV receive "adequate" prenatal care according to researchers.[27]

"Newborn children are routinely tested for errors of inborn metabolism and other problems. Although most of the outcomes are rare, a positive test result triggers interventions that benefit both mother and child, and these efforts have been responsible for substantial improvements in health and well-being," according to the IOM. Furthermore, "these tests are well accepted, and seen to clearly benefit the women and her child."[28]

The IOM outlines five criteria that must be met before newborns are screened for a disease. The disease must be both well defined and severe enough to justify screening in large numbers; the cost of the test must be reasonable; an accurate method of testing must exist; treatment must be available; and medical management facilities capable of confirming diagnosis and providing treatment must exist. Application of these five criteria to HIV leads to a conclusion that universal HIV screening for newborns is justified.[29]

Every state requires newborns to be tested for a number of diseases and conditions. All states have mandatory newborn screening for phenylketonuria (PKU) and hypothyroidism. Most also routinely test for galactosemia, and 41 test for sickle cell disease.[30] None of these are as prevalent or deadly as HIV. Yet only two states—New York and Connecticut—require newborns to be screened for HIV. It would seem logical that babies should also be screened for HIV, particularly if the serostatus of a mother is unknown.

Has Routine HIV Testing Been Successful?

Since February 1997, New York has required HIV testing of all newborns. "Universal newborn HIV testing has resulted in the identification of all HIV-exposed births" in the state according to Dr. Guthrie S. Birkhead, Director of the New York Health Department's AIDS Institute. Furthermore, "newborn testing has allowed hospital and health department staff to ensure that over 98 percent of HIV positive mothers are aware of their HIV status and have their newborn referred for early diagnosis and care of HIV infection. In less than two percent of cases have women not been located to receive newborn HIV test results and have their HIV-exposed newborns tested for HIV infection," according to Dr. Birkhead.[31]

Just under 1,000 HIV-infected New York women gave birth in 1998. Approximately 16 percent of these women did not receive prenatal HIV counseling and testing. Therefore, between 100-160 women may be learning their HIV status for the first time from testing conducted in the delivery setting.

> *. . . depending which state one looks at, 12 to 80 percent of pregnant women who are HIV-positive are not tested, and therefore go undiagnosed and untreated.*

In October 1999, Connecticut enacted a Baby AIDS law requiring universal HIV screening of all pregnant women and newborn HIV testing if no documented HIV test is on file for a woman before delivery.

Two studies presented at the 2001 annual meeting of the American College of Obstetricians and Gynecologists proclaimed the law a success.

Dr. Urania Magriples of Yale University in New Haven, Connecticut, said that since the law was enacted, a much greater percentage of women coming to Yale's high risk pregnancy clinic are getting tested for HIV. Before the law, "only 38.9

percent of [pregnant] women were tested for HIV, but after the law 91 percent of women were tested," she said. "I was originally opposed to this law because I thought it was coercion, but it works," Magriples conceded. The law, she explains, actually "appeals to the maternal instincts in these women to protect their babies."

> *"The birth of every HIV-infected child is a sentinel health event signaling a missed prevention opportunity."*

In the second study, Dr. William Cusick of Stanford Hospital in Connecticut studied the effect of the law during its first 10 months of implementation. Seven women were identified as HIV positive and two additional cases – a husband and a child – were identified after a positive test result. Without the testing requirements, Dr. Cusick acknowledges "we would have missed six of these nine cases." "The results of our study demonstrate that the law is working exactly as intended," he said. "So far all of the children are fine and we've followed them out for 12 months now," Dr. Cusick noted.[32]

Additional Benefits to Newborn HIV Screening

HIV diagnostics today offer noninvasive rapid testing that can help prevent perinatal transmissions. In addition to preventing babies from becoming infected with HIV during delivery, newborn screening offers many other benefits.

In most cases, children born to HIV infected women will not become infected during gestation or delivery, although they will carry detectable antibodies to the virus for some time. Those babies with infected mothers who are fortunate enough to escape HIV before and during delivery are still at risk for HIV if the mother breastfeeds. Studies have reported breast feeding transmission rates of 10 to 20 percent.[33] It is extremely tragic for a baby to escape infection only to become unknowingly infected by a loving, yet unsuspecting, mother via breastfeeding. Yet it continues to occur.

Newborn testing also offers additional hope to those babies who are infected. With knowledge of a child's HIV status, appropriate medical care can protect and enhance the child's health, and thereby prolong and improve life.

Pneumocystis carinii pneunomia (PCP) is the most common opportunistic AIDS related infection. The average survival time of a child who contracts PCP is one month. A study in *The New England Journal of Medicine* showed that two-thirds of children who developed PCP did not receive the disease-preventing prophylaxis because the physicians and families did not know the children were HIV-positive. "If infection is to be prevented, infants exposed to HIV must be identified earlier and prophylaxis must be offered to more children," the researchers stated.[34]

Research reported in the *American Journal of Public Health* showed that Vitamin A supplements alone will help infants with HIV fight off dangerous diarrhea, rashes, respiratory infections and other illnesses that could lead to death. This is a very inexpensive treatment with significant results.[35]

Furthermore, triple combination AIDS therapy, highly active antiretroviral therapy (HAART), can significantly improve the survival of children infected with HIV. The drug "cocktails" have proven to reduce death rates and improve the quality of life of children with HIV. "The effectiveness in infants and children is at least similar, or even greater, than observed in adults," according to researcher Patrizio Pezzotti of the University of Florence in Italy. The risk of death was 23 percent lower in children on monotherapy (one drug), 30 percent lower with double combination drugs and 71 percent down with standard triple drug therapy when compared to children who receive no antiretroviral drugs.[36]

Studies have also concluded that newborn HIV testing saves money. "Annual routine newborn HIV testing would encompass 3.8 million infants, identify 1,061 infected mothers, avoid 266 newborn infections, and would cost $7,000 per life-year gained" in the United States according to a study published in the *Journal of Acquired Immune Deficiency Syndromes*.[37] The average total lifetime charges for care of children with HIV infection is estimated at $491,936.[38] The researchers concluded that routine testing of newborns is, therefore, "cost effective."[39]

A study in Chicago found that the universal HIV testing would result in fewer infected newborns and save the city nearly $270,000 annually.[40]

Newborn HIV Testing is Widely Supported

Newborn testing is supported by the medical community, by the elected branches of the federal government and, overwhelming, by the public.

The American Medical Association, the nation's largest and most respected doctors organization, endorsed mandatory HIV testing of all pregnant women and newborns in 1996. "We have learned enough about the disease to know that the differences in those who are treated versus those who are untreated cuts by two-thirds the risk to the unborn child," said Robert E. McAfee, an AMA trustee and former president.[41] Surgeon

> *"We have learned enough about the disease to know that the differences in those who are treated versus those who are untreated cuts by two-thirds the risk to the unborn child"*

General C. Everett Koop, M.D., stated that "as a former public health officer, I certainly approve of testing of newborns and believe that the information should be available to their parents and caregivers. I think this is the only sensible way to deal with the problem of HIV itself, but also would have the beneficial effect in the further transmission of the disease of AIDS."[42]

In 2000, the Congress passed without dissent, and President Clinton signed into law, the Ryan White CARE Act Amendments which contained a provision encouraging all states to enact newborn testing policies. States which pass such laws would be eligible for up to $4 million in federal funds to support state efforts to reduce perinatal HIV transmission. "This amounts to a federal endorsement of universal HIV newborn testing as

a routine practice," according to Congressman Tom A. Coburn, M.D., the bill's author and a practicing physician who has delivered AIDS babies.[43]

A 1995 poll of New York voters found four out of five respondents saying that mothers should be told the HIV status of their newborns. "The poll shows that the public's attitude is to err on the side of saving as many babies as possible," explained the Times Union newspaper. Support "runs across virtually every subgroup of those polled."[44] Nearly nine in 10 participants in a 1996 *USA Weekend* poll said they favored mandatory HIV testing of all pregnant women.[45] A scientific survey published in the January 2001 issue of *Obstetrics and Gynecology* found that 84.3 percent of women believe all pregnant women should be tested for HIV and three out of five felt such testing should be legally mandated.[46]

Editorial boards across the nation have echoed these same sentiments. *The Washington Post* has editorialized that "while counseling and voluntary testing are fine, all infants whose HIV status is unknown should be tested at birth and the results made known to parents, guardians and primary medical care givers."[47] *The Chicago Tribune* writes that newborn testing "would allow for quick treatment of infected babies. Some political groups have tried to make the testing of women and infants for the AIDS virus a privacy issue, but they are wrong. It is first and foremost a public health issue – one that affects the lives and well-being of the most vulnerable among us."[48] *The New York Times* "has long endorsed mandatory tests for the newborns" because it is "the best solution" to "insuring that all infected babies are identified for monitoring and treatment."[49] "To save the babies we need to know their HIV status at birth, and that of their mothers during pregnancy," writes the *Wall Street Journal*, then asking, "how did the American system arrive at a point where it discovers it can save HIV-infected babies and then decides not to?"[50]

The Arguments Against Newborn Testing

One must wonder why, with the obvious significant benefits and widespread support for newborn testing, such a program has not been recommended by the CDC or implemented nationally.

Over the past decade, newborn testing legislation has been introduced nationally and in numerous states. But, in nearly every case, AIDS activists have successfully derailed or fundamentally altered the underlying proposal with a set of unfounded and unproven claims. These arguments are:

- *Mandatory newborn HIV testing will deter women from seeking prenatal care and thereby, drive the epidemic underground.* "I feel sure we are going to see some women completely freaking out, committing suicide and running away from the whole situation," predicted Terry McGovern of the HIV Law Project.[51] The opposite has been the end result. New York's "Baby AIDS" law has orresponded with an increasing number of pregnant women both receiving prenatal care and HIV testing. A CDC funded study "found higher voluntary prenatal testing rates… after implementation of mandatory newborn HIV testing."[52] "Rates of

participation in prenatal care in New York State… have been increasing gradually over recent years," according to Dr. Birkhead who notes there has been "no [negative] detectable change" in prenatal participation trends "that might be related to the newborn testing program."[53]

- *Testing all newborns would be extremely expensive and would divert scarce resources away from other more effective interventions.* As previously noted, studies have found conclusively that universal newborn testing is the most cost effective intervention. Likewise in Connecticut, HIV testing rates for pregnant women jumped from 38.9 percent before the law to over 90 percent after the law was enacted.[54]
- *There are few health benefits to newborn testing, in effect, it is too little too late.* This could not be further from the truth. With prompt diagnosis and treatment, within 48 hours of birth, HIV infection can be prevented. Other at risk babies can be prevented from unknowingly being infected via breastfeeding. And for those children who are infected, appropriate treatment and proper medical monitoring can prolong and improve health outcomes.
- *Voluntary testing of pregnant women is the best approach to reducing perinatal HIV transmission.* At least 15 percent of HIV-infected pregnant women are not tested. Many do not receive appropriate prenatal care, some receive no prenatal care and others may simply refuse to be tested. It is not an "either/or" proposition, rather both approaches should be utilized. Prenatal screening provides for early intervention and newborn testing ensures that all babies are identified.

> *Clearly, far too many women and infants are being denied optimal medical care.*

- *Testing is unreliable and may result in the treatment of uninfected children with highly toxic medications.* Rapid HIV tests can produce results in an average of 10 to 30 minutes. The sensitivity and specificity of these rapid assays are comparable to other HIV diagnostics. A negative rapid test does not require further testing, and negative results indicate the absence of HIV infection. There is a slim possibility that some tests may produce a "false positive" for HIV. Therefore, a reactive rapid test must be confirmed by a supplemental test. Results from a confirming test to the rapid return may be available within 12 hours of the infants' birth.[55] Studies have yet to show that ZVD has caused any significant adverse health consequence to children. Regardless, a short course of ZVD over several hours is far less dangerous than risking the alternative.
- *Testing a newborn for HIV also reveals the HIV status of the mother, and therefore, violates the mother's privacy, or her "right not to know her HIV*

status." Unfortunately, this is the crux, and underlying agenda of many AIDS activists. The dogma that places privacy over all else, including saving lives of women and babies is based on fear and outdated ideology rather than reality or sound public health. No scientific data indicates that loss of privacy has ever been an outcome of newborn testing policies. Anecdotally, few, if any, mothers have voiced the opinion that protecting the health of their baby jeopardizes their own personal rights. "You can't compare a baby's right to medication against a woman's right to confidentiality," explains Shelly Harrington – an HIV-positive mother of an HIV-positive teenager – who supports HIV testing for both pregnant women and newborns.[56] Hiding behind privacy will not save lives and it will not cure AIDS.

The New York Baby AIDS law, therefore, offers a paradigm that the CDC, other states, and other countries must embrace if perinatal HIV transmission is ever to be eliminated.

These arguments have either been discredited or remain unsubstantiated and run contrary to the existing medical, political, and popular sentiment regarding newborn HIV testing. "With New York clearly demonstrating that mandatory testing of newborns saves lives without endangering women, the argument should have been settled. But opponents are so steeped in ideology that facts don't matter," explains Wesley J. Smith, a well-regarded author on medical ethics.[57]

Conclusion

Unquestionably, the optimal method to prevent perinatal HIV transmission is to identify every infected pregnant woman as early as possible in her pregnancy and provide her with proper prenatal care and prophylaxis. Most women, when offered, will accept an HIV test.[58] Unfortunately, a significant proportion of HIV-infected mothers do not receive appropriate, or any, prenatal care and thereby go undiagnosed and untreated. Routine newborn screening provides a safety net to ensure that no HIV-exposed child is left to slip through the cracks and become needlessly infected. Such a policy also ensures that infected mothers who were previously unaware of their serostatus are given an opportunity to access medical care.

The New York program "has proven to be very effective in increasing prenatal testing rates while providing a safety net to facilitate early treatment for HIV positive newborns and their mothers who were unaware of their serostatus prior to delivery," according to Dr. Antonia C. Novello, New York's Commissioner of Health and former U.S. Surgeon General.[59]

This approach unquestionably has proven to be the single most successful baby AIDS prevention policy. It is more cost effective than other approaches and is the only one to identify all

those who are infected or at risk. The New York Baby AIDS law, therefore, offers a paradigm that the CDC, other states, and other countries must embrace if perinatal HIV transmission is ever to be eliminated.

"The success rate is phenomenal," New York Assemblywoman Nettie Mayersohn, the author of the state's Baby AIDS law proudly proclaims. She believes that "eventually it's going to happen" nationally. "It's just a question of how long it's going to take and how many [babies'] lives we are going to lose before we reach that point."[60]

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Author Affiliation

Roland Foster is a staff member of the U.S. House Subcommittee on Criminal Justice, Drug Policy and Human Resources where he is responsible for the oversight of the federal health agencies. Mr. Foster previously served as Legislative Director for Rep. Tom Coburn, MD, the author of the Ryan White CARE Act Amendments of 2000 and the federal Baby AIDS bill.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
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Atlanta GA 30333

NOV 7 2001

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice, Drug Policy
and Human Resources
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Souder:

This is in response to your letter to Dr. Harold Jaffe inquiring about the Centers for Disease Control and Prevention's (CDC) perinatal HIV prevention efforts. The responses to your questions are enclosed. Please excuse the delay of this response.

CDC appreciates your continued interest in this important public health challenge. An identical letter is being sent to Representative Dave Weldon who cosigned your letter.

Sincerely,

Jeffrey P. Koplan, M.D., M.P.H.
Director

Enclosure

Centers for Disease Control and Prevention's (CDC)
Responses to Questions on Perinatal HIV Prevention
Addressed in Representatives Mark Souder and Dave Weldon's
Letter of August 28, 2001

(1) Do you agree with the AMA and Drs. Koop and Novello that HIV testing of newborns should be a routine medical procedure?

CDC encourages routine, voluntary HIV testing of all pregnant women and the provision of comprehensive care for those women diagnosed as HIV-infected and early determination of their newborn's infection status. Focusing on a strategy of testing newborns offers much less chance of successful perinatal HIV prevention than do efforts to encourage voluntary counseling and testing of women prenatally. When HIV-infected women are identified prenatally, effective antiretrovial and obstetrical interventions can reduce the risk of mother-to-infant transmission to 2 percent or less.

The "Revised Guidelines for HIV Counseling, Testing, and Referral and Revised Recommendations for HIV Screening of Pregnant Women" are scheduled to be published on November 9, 2001, in CDC's *Morbidity and Mortality Weekly Report Recommendations and Reports.* These guidelines replace the 1995 Public Health Service (PHS) guidelines and stress the importance of routinely offering HIV testing to *all* pregnant women in order to offer appropriate treatment to those women identified as HIV-positive and offer interventions to reduce the risk of transmission to their newborns. The guidelines emphasize the importance of reducing barriers to HIV testing in prenatal settings and emphasize HIV testing and treatment at the time of labor/delivery for those women who have not received prenatal care or testing, or for whom HIV status is not known at delivery. The guidelines recommend that women who have not been tested for HIV should be informed that HIV testing is recommended for their newborn and that knowing their newborn's infection status has benefits for their child's health. For infants whose HIV infection status is unknown and who are in foster care, the guidelines recommend that the person legally authorized to provide consent should be informed that HIV testing is recommended for newborns whose biologic mothers have not been tested. Testing should be performed in accordance with the policies of the organization legally responsible for the child and with prevailing legal requirements for HIV testing of children; these legal requirements vary from state-to-state.

(2) Have you reviewed the data of the New York state Baby AIDS program? If so, could you comment on the results?

Based on information from New York State health department officials, the New York State law's major effect appears to be associated with increased efforts by providers in New York to provide voluntary counseling and testing to pregnant women during the prenatal period. HIV-infected women who receive appropriate antiretroviral and obstetrical interventions have an extremely low risk of transmitting the HIV virus to their infants (2 percent or less). Interventions at or following delivery demonstrate substantially higher transmission rates (10-15 percent).

(3) Have you reviewed the studies presented earlier this year at the annual meeting of the American College of Obstetricians and Gynecologists that analyzed the effectiveness of the Connecticut Baby AIDS law? If so, could you comment on the results?

The Connecticut Baby AIDS law, similar to the New York law, appears to be associated with increased efforts by hospitals and providers to offer voluntary counseling and testing to pregnant women during the prenatal period. Other states, such as North Carolina and Florida, have been highly successful in achieving high voluntary testing rates (90.8 percent and 87.0 percent, respectively) without introduction of mandatory newborn testing laws (Royce RA, et al. AJPH, 2001; 91:727-735).

(4) Could you explain why it is useful public health policy to test newborns for syphilis?

The CDC guidelines for treatment of sexually transmitted diseases (STD) do not recommend routine screening of newborns for syphilis infection. Effective prevention and detection of congenital syphilis depends on the identification of syphilis in pregnant women and, therefore, on the routine serologic screening of pregnant women at the first prenatal visit. In communities and populations where the risk of congenital syphilis is high, screening pregnant women should also be done at 28 weeks of gestation and at delivery. The "U.S. Public Health Service Recommendations for HIV Counseling and Voluntary Testing for Pregnant Women" and the STD treatment guidelines are consistent in that both recommend the testing of pregnant women prior to delivery rather than the testing of newborns.

(5) Could you elaborate why, if HIV testing and treatment of HIV-exposed babies can stop infection, the CDC and other federal health entities have not taken advantage of this discovery in the same manner that other infectious diseases--such as [neonatal] syphilis--have been successfully treated to protect newborns' health?

As mentioned in the previous response, testing newborns for syphilis is not recommended. The data are inconclusive regarding the possible effectiveness of zidovudine or AZT treatment of newborns to prevent HIV infection without prior maternal treatment prenatally or at delivery. An *observational* study published in the *New England Journal of Medicine* in 1998 did suggest a protective effect of AZT prophylaxis to the newborn if AZT were administered within the first 48 hours of life. However, subsequent analysis of data from this same study, with larger numbers of study participants, failed to show a statistically significant difference in the risk of transmission for newborns who did not receive AZT compared to newborns who received AZT but whose mothers did not receive antiretrovirals prenatally or at labor/delivery (personal communication, N. Wade, NY DOH, 2001).

With current effective combination antiretroviral interventions during pregnancy, as well as obstetrical interventions such as scheduled cesarean section, perinatal transmission rates of 2 percent or less are being achieved in the United States. These data underscore the importance of offering voluntary counseling and testing during pregnancy to ensure that HIV-infected women receive optimal treatment for their own health and to reduce the risk that their infants will become HIV-infected.

Data from international studies demonstrate that interventions with maternally administered nevirapine and AZT started at labor, with subsequent prophylaxis to the newborn, show significant reductions in transmission risk when compared to no intervention or zidovudine given just at labor and to the newborn. Future clinical trials are being planned that will address whether infant antiretroviral prophylaxis alone given soon after birth can effectively reduce the risk of newborn HIV infection in cases where effective antiretrovirals have not been administered to the mother prenatally or at labor/delivery.

(6) Does the CDC intend to re-examine the need for newborn screening in light of the New York and Connecticut successes and the lackluster results of the current Public Health Service guidelines?

CDC data indicate that there has been a dramatic reduction in HIV transmission from mother to child in the United States (83 percent decrease in new perinatally acquired AIDS cases between 1992 and 1999). These data reflect widespread adoption of the PHS guidelines.

The study cited in your letter, Lansky, et al. (AJPH, 2001), was based on self-reported recall by women over a 12-month period. Findings based on self-reporting over prolonged periods of time (beyond several weeks) may have certain biases that can lead to decreased validity of results. In addition, the specific phrasing of the questions "To your knowledge are you now pregnant?" and "Have you been tested for HIV in the past 12 months?" may lead to different responses than direct questions as to testing during a current pregnancy and during a more recent recall period. Findings from other studies that specifically focused on HIV testing during pregnancy indicate higher rates of testing. For example, recent data (1998) from CDC's multi-state risk assessment morbidity survey indicate that in the general population of women who have given birth, 70-86 percent reported being counseled regarding HIV in pregnancy and 69-85 percent reported having accepted HIV testing. In addition, Royce, et al. (APJH, 2001) interviewed women in hospitals in the immediate post-partum period across four states and found that 89.9 percent of those women reported being offered HIV testing during pregnancy. The infant infection rate was 3 percent overall in this study.

(7) If the CDC does not intend to re-examine its policy to ensure that all HIV-exposed children are identified, could you provide a "ball park" figure of the actual number of children the CDC believes is acceptable to go undiagnosed, untreated and left to become infected with HIV and still consider the existing voluntary testing policy a success?

CDC is committed to reducing the risk of perinatal HIV transmission in the United States and ensuring comprehensive health care for HIV-infected individuals, including HIV-infected pregnant women and their children. The current estimates of perinatally infected infants--83 percent decrease in new perinatally acquired AIDS cases between 1992 and 1999--represent major progress toward this goal.

Based on all available data, we believe the offering of voluntary counseling and HIV-testing to all pregnant women in the United States affords the best opportunity to reduce perinatal HIV transmission. Data presented at the Retrovirology Conference earlier this year indicate that the risk of perinatal transmission can be reduced to 2 percent or less with antiretroviral and obstetrical interventions offered to women identified as HIV-infected prenatally.

CDC will continue to implement a number of key efforts to achieve this goal. The revised recommendations that are scheduled to be published on November 9, 2001, emphasize the need for routine and universal offering of HIV testing during pregnancy and will be widely disseminated to health care providers and State and local public health departments. Social marketing campaigns will also be developed for pregnant women to encourage them to know their HIV status.

In addition, since 1999, CDC has awarded $10 million dollars per year to (1) support programs directed at high-risk pregnant women in states with a high prevalence of HIV and (2) enhance perinatal HIV surveillance efforts. In 2001, CDC awarded additional funds to these states in accordance with the Ryan White Comprehensive AIDS Resources Emergency Act Amendments of 2000. These programs are aimed at promoting and improving the adoption of voluntary HIV counseling and testing in prenatal settings. CDC has also provided funding to national health care organizations to (1) continue training on the prevention of perinatal HIV transmission and about the importance of organization members' offering prenatal HIV testing and (2) develop educational materials for health care workers and pregnant women regarding mother-to-infant transmission of HIV.

Pregnant women who do not have access, or present late, to prenatal care are one of the remaining groups at high risk for transmission of HIV to their infants. International trial data indicate that even among late-presenting pregnant women, there are antiretroviral interventions that can be offered to women identified as HIV-infected around the time of labor and delivery and to their newborns. These interventions can reduce the risk of transmission by about 40 percent.

CDC has also developed and funded the Mother Infant Rapid Intervention at Delivery project to address the feasibility of providing voluntary counseling and testing to pregnant women around the time of labor and delivery, if their HIV status is unknown, in order to provide antiretroviral interventions. However, even with rapid HIV testing around the time of labor/delivery, antiretroviral interventions delivered at this late point will be less successful than interventions begun during the prenatal period, combined with scheduled cesarean section prior to onset of labor. CDC will, therefore, continue to emphasize voluntary HIV counseling and testing during the prenatal period.

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August 28, 2001

Dr. Harold Jaffe
Acting Director - Designate
National Center for HIV, STD and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Atlanta, GA 30333

Dear Dr. Jaffee,

Congratulations on your appointment as Acting Director of CDC's National Center for HIV, STD and TB Prevention. We look forward to working with you to protect the health of all Americans.

Few have been on the frontlines of the battle against HIV/AIDS as long as you have which certainly provides you with a unique perspective and a great opportunity to immediately provide the leadership necessary to combat the epidemic.

As one of the first to recognize that the etiologic agent that caused AIDS could be transferred from an infected mother to her child in 1982, we hope that you will make the elimination of pediatric HIV a priority.

As you know, the AIDS drug ZVD administered to an HIV-positive pregnant woman or to her child within hours of birth can significantly reduce the chance that the child will be infected. This discovery is perhaps the single greatest medical breakthrough in our attempts to combat this devastating disease and to end pediatric AIDS.

There is no question that the optimal medical approach to saving as many babies as possible from HIV is to identify infected women as soon as possible in their pregnancy and provide those who are infected with appropriate medical care. A new study published in the August issue of the American Journal of Public Health found that after five years of promoting voluntary testing among all pregnant women, nearly half are still not screened for HIV. And at least 15 percent of HIV-positive women are not tested for HIV and, therefore, go without proper care or treatment.

If an HIV-exposed child is identified and treatment begins within 48 hours of birth, transmission can still be prevented. Because the window to take advantage of this opportunity is so limited, it is imperative that newborns are screened as soon as possible after delivery. It is equally important that those who escape infection at birth are not cruelly infected later by breastfeeding. Likewise, it is important that those who are infected, both mothers and children, are provided medical treatment to improve and prolong their lives.

Former Surgeon General C. Everett Koop, M.D. has stated, "as a former public health officer, I certainly approve of testing of newborns and believe that the information should be available to their parents and caregivers. I think this is the only sensible way to deal with the problem of HIV itself, but also would have beneficial effects in the further transmission of the disease of AIDS."

Former Surgeon General Antonia C. Novello, M.D., said that the newborn testing program in New York state, where she serves as Commissioner of Health, "has been very effective in increasing prenatal testing rates while providing a safety net to facilitate early treatment for HIV positive newborns and their mothers who were unaware of their status prior to delivery."

The American Medical Association—the Nation's largest doctors' organization--has endorsed mandatory HIV testing of both newborns and pregnant women since 1996.

Yet only two states—New York and Connecticut—have established safety nets to ensure that no baby at risk for HIV is allowed to slip through the cracks and be allowed to die from AIDS. Scientific studies and reported data from both states have shown very significant success towards this end. Sadly, in other states across the Nation, hundreds of babies who could likewise be saved are still allowed to die.

There is no question that leadership is desperately needed to save the lives of these babies that have been abandoned by the CDC's current policy. Consider that in 1995 the U.S. Public Health Service issued national guidelines recommending HIV testing for all pregnant women. Yet, according to Dr. Amy Lansky and colleagues at the CDC, the percentage of pregnant women receiving HIV tests increased only 15 percent--from 41 percent in 1994 to 56 percent in 1999. Obviously this policy alone has failed to maximize the potential that exists to save lives.

As the Nation's leading HIV prevention advocate, we would be interested in hearing your views on this very important issue. Specifically, we would like to know:

(1) Do you agree with the AMA and Drs. Koop and Novello that HIV testing of newborns should be a routine medical procedure?
(2) Have you reviewed the data of the New York state Baby AIDS program? If so, could you comment on the results?

(3) Have you reviewed the studies presented earlier this year at the annual meeting of the American College of Obstetricians and Gynecologists that analyzed the effectiveness of the Connecticut Baby AIDS law? If so, could you comment on the results?

(4) Could you explain why it is useful public health policy to test newborns for syphilis?

(5) Could you elaborate why, if HIV testing and treatment of HIV-exposed babies can stop infection, the CDC and other federal health entities have not taken advantage of this discovery in the same manner that other infectious diseases--such as syphilis—have been successfully treated to protect newborns' health?

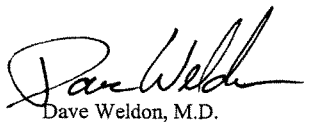
(6) Does the CDC intend to re-examine the need for newborn screening in light of the New York and Connecticut successes and the lackluster results of the current Public Health Service guidelines?

(7) If the CDC does not intend to re-examine its policy to ensure that all HIV-exposed children are identified, could you provide a "ball park" figure of the actual number of children the CDC believes is acceptable to go undiagnosed, untreated and left to become infected with HIV and still consider the existing voluntary testing policy a success?

Thank you for your attention to this issue. We look forward to hearing your thoughts and working with you in the future.

Sincerely,

Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources



Dave Weldon, M.D.
Member of Congress

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CHAIRWOMAN
House Operations Committee

Subcommittee on
Elderly Crime Victims

COMMITTEES
Rules
Health
Labor
Housing
Governmental Operations
Insurance

October 24, 2001

Dr. Jeffery P. Koplan, M.D., M.P.H.
Director
Center for Disease Control and Prevention
1600 Clifton Road, NE.
Atlanta, GA 30333

Dear Dr. Koplan:

Please allow me to introduce myself. I am Assemblywoman Nettie Mayersohn, a 19-year member of the New York State Assembly, and a majority member of its Health Committee. I am also the author of the Baby AIDS and the Partner Notification laws in New York State. I am taking the liberty of responding to your letter of August 16, 2001 to Congressman Mark Souder, of the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Committee on Government, in which you set forth the HIV position and the public health policies of CDC.

I was particularly interested in your response to the following question: "In light of the significant success of the New York State Baby AIDS law in identifying all newborns at risk and providing linkages to care for over 98 percent of those identified while increasing prenatal participation rates, would you agree the universal HIV testing of newborns offers a valuable intervention for HIV prevention and care?"

Regretfully, your response indicated a lack of understanding of the New York program. You stated: "New York law's major effect appears to be associated with increased efforts by providers to offer prenatal voluntary counseling and testing."

While we are indeed achieving remarkable success in prenatal testing – the major reason for our success is that we are able to advise the pregnant woman that her baby will be tested at birth and, at that time, she will be given the baby's HIV test result (and her own HIV status as well). She is then counseled that getting tested during pregnancy gives her the opportunity to prevent the transmission of this deadly virus to her newborn.

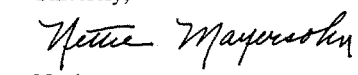
It is a valid, powerful argument and we are getting 93% of pregnant women to agree to testing.

You present your data on HIV testing as a demonstration of the success of your counseling programs – Arkansas 85%, Colorado 79%, and Florida 84%. And these are the states where you feel you have significant success. However, please note that, according to CDC's own data, the national rate of pregnant women being tested for HIV in 1999 was 56%. And, frankly, we don't believe that anything less than the 99.4% success rate in identifying and treating HIV babies that we have achieved in New York, is acceptable. We don't have any magic potion -- no secret formula – we're simply using all of the traditional public health programs that have worked with every other disease. We are counseling mothers during pregnancy to get tested. If they reject testing, the baby is tested at birth and the babies who test positive immediately receive the life-saving treatment to ward off the virus. We do not see this as a choice between counseling pregnant women and testing newborns; we do both – and we have provided a safety net for HIV newborns which allows us to get every baby into treatment.

What we have accomplished in New York can, unquestionably, be done in every state. While too many of our public health agencies have been concerned with doing the politically correct thing, countless HIV babies each year are leaving the hospitals unidentified and untreated; in too many cases, healthy babies are being breastfed and infected by HIV mothers who are not aware of their own infection. And despite all of the arguments set forth by AIDS advocate groups that women will flee the health care system, there is no evidence that this is anything more than a self-serving myth. In fact, the evidence of the New York experience clearly shows that women are accepting the information of their HIV status, and dealing with it as they would deal with any disease which requires the care and treatment of their newborn babies.

You are now in a position to make changes in CDC's policy on HIV/AIDS. There is now treatment available for these babies which can prevent transmission and even reverse the infection in babies who have tested positive. We must begin by acknowledging that our highest priority should be the care and treatment of the HIV newborn; we must acknowledge that we are not dealing with some sacred civil rights issue, but a killer disease that is claiming the lives of the most innocent victims of the epidemic.

Sincerely,



Nettie Mayersohn
Member of Assembly

cc: Honorable Mark E. Souder
Chairman-Subcomm. Criminal Justice, Drug Policy & Human Resources
Honorable David Weldon, MD

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Antonia C. Novello, M.D., M.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

February 3, 2000

Hon. Tom A. Coburn, M.D.
Member of the Congress
U.S. House of Representatives
429 Cannon House Office Building
Washington, DC 20515

Dear Dr. Coburn:

I have been asked to reply to your letter of December 20, 1999, to Commissioner Novello on prevention of perinatal HIV transmission. The perinatal HIV prevention program at the New York State Department of Health is a comprehensive program that seeks to address many of the steps in the chain of events leading to an HIV-infected child, as identified by the Institute of Medicine in their 1998 report, "Reducing the Odds" (Figure I, enclosed).

An important initial prevention step in this chain of events is to ensure that all pregnant women are enrolled in prenatal care in the first trimester and ideally, have received pre-conception care. Significant program resources, including new funding from the Centers for Disease Control and Prevention (CDC) for outreach to high risk women, are directed to this purpose in New York State. In 1997, 10.6% of all women (according to birth certificate data) and about 10% of HIV positive women in New York State (based on chart reviews) received no prenatal care.

The second step in preventing perinatal transmission is to ensure that all women in prenatal care receive HIV counseling and testing according to the U.S. Public Health Service guidelines. In New York State, regulations adopted in 1996 (10 NYCRR sections 98.2(c), 405.21(c), 751.5(a)) require all regulated prenatal care providers (hospitals, clinics, HMO providers) to provide HIV counseling with a clinical recommendation to test, to all prenatal care patients. Such counseling and recommended testing is the standard of medical care in New York State, even for physicians not practicing in regulated settings. The Commissioner has sent a letter to this effect to all prenatal care physicians in the State. The letter was co-signed by the State Medical Society and the State chapters of professional organizations in pediatrics, obstetrics and family practice. The Department also monitors prenatal HIV counseling and testing rates at all regulated health care providers through review of a sample of prenatal care medical records. These data are fed back to providers and technical assistance is provided to improve delivery of these services.

For women who test HIV positive or are known to be HIV positive during pregnancy, the State has developed a network of specialty providers for perinatal HIV medical care. These providers ensure that each HIV positive pregnant woman has a full evaluation for combination

antiretroviral therapy depending on her own health status, prescribe zidovudine (ZDV) according to the PACTG 076 regimen for prevention of perinatal transmission, and make referrals for housing, adherence counseling and other supportive services that these women may need to adhere to therapy. New York Medicaid and the State's AIDS Drug Assistance Program (ADAP) provide reimbursement for pharmaceuticals for women in need so that all women have access to preventive therapy. The Department, with the help of a panel of expert clinicians, publishes detailed clinical treatment guidelines for antiretroviral therapy and prevention of perinatal transmission, and also funds a network of clinical education providers across the state to train clinicians caring for HIV positive patients.

In the area of newborn HIV testing, Public Health Law (PHL) 2500-f, signed into law by Governor Pataki in 1996, created an exception for newborn HIV testing to the informed consent requirements for HIV counseling and testing in the HIV Confidentiality Law, PHL Article 27-F. It also directed the Commissioner to develop a comprehensive program for the testing of newborns for HIV. This program is further defined in State regulations (10 NYCRR Subpart 69-1) and has gone through two phases. During the first phase, beginning on February 1, 1997, the Department's Newborn Screening Laboratory began HIV testing of all newborn filter paper specimens submitted for metabolic screening without removing patient identifiers and returning those test results to the birth hospital for transmittal to the pediatrician of record. Prior to that time, blinded HIV newborn testing had been done for epidemiological purposes since the late 1980's, and mothers had been encouraged to receive a copy of their newborn's HIV test result since May 1996 (over 90% of mothers consented to receive their newborn's HIV test result in that program).

Universal newborn HIV testing has resulted in the identification of all HIV-exposed births. HIV test results from the newborn testing lab are often not available until two weeks after birth. These results are not timely enough to permit administration of ZDV therapy to prevent HIV transmission, but can be used to counsel women to stop breastfeeding which may prevent some cases of transmission. Newborn testing has allowed hospital and health department staff to ensure that over 98% of HIV positive mothers are aware of their HIV status and have their newborns referred for early diagnosis and care of HIV infection. In less than 2% of cases have women not been located to receive newborn HIV test results and have their HIV-exposed newborns tested for HIV infection. The Department is in the process of reviewing all pediatric medical records up to 6 months of age for HIV-exposed infants born starting in 1997 to determine the quality of HIV care they are receiving and to document the perinatal HIV transmission rate.

The second phase of the newborn HIV testing program began on August 1, 1999. It added regulatory amendments to Subpart 69-1 to require expedited HIV testing in the hospital delivery setting in cases where an HIV test result from prenatal care is not available. This addition to the newborn testing program was undertaken because of evidence that perinatal HIV transmission may be reduced by initiating ZDV therapy during labor or soon after delivery, even if ZDV was not taken during prenatal care (NEJM 1998;339:1409-1414). Hospitals now screen all women admitted for delivery for HIV test results from prenatal care. If a prenatal HIV test result is not available, the hospital must provide the woman with HIV counseling and expedited testing if she consents. If the mother does not consent to HIV testing of herself, the hospital

must perform expedited testing on her newborn immediately after birth under the authority of the comprehensive newborn HIV testing law. Expedited tests must be available as soon as possible, but in no case longer than 48 hours. Provisional data from the initial months of the program show that 32 HIV positive women/newborns were identified for the first time by expedited testing at delivery, permitting early initiation of ZDV in most cases; 12 additional positive cases could have been identified if all hospitals had fully implemented the program, and 17 false positive HIV results occurred. False positive preliminary HIV tests occur because Western blot confirmation of preliminary positive results cannot always be obtained in the 48 hour time period. The Department has encouraged the Food and Drug Administration (FDA) to approve additional rapid HIV tests in the near future to alleviate this problem. A significant benefit of the expedited testing program is that delivery hospitals are now working more closely with their prenatal care providers to ensure that HIV counseling and testing is done at the appropriate time during prenatal care and that the test results make it to the delivery hospital.

Rates of participation in prenatal care in New York State are monitored by review of birth certificate data. These rates have been increasing gradually over recent years. Currently about 80-85% of women delivering report first or second trimester prenatal care and about 10.6% of women report no or unknown prenatal care. There has been no detectable change in prenatal participation trends through 1997 that might be related to the newborn testing program. Anecdotally, we have not heard of problems in this regard. The analysis is currently being updated through 1998. Prenatal care for HIV positive women is also being examined through review of prenatal charts. Limited numbers of women whose HIV status was identified by newborn testing are being interviewed to see what the impact of newborn testing has been.

Ultimately, the goals of the perinatal HIV prevention program in New York are to reduce perinatal HIV transmission to the lowest possible level through: ensuring access to prenatal care for all pregnant women; ensuring counseling and testing of all women in prenatal care; ensuring that all HIV positive pregnant women are offered and adhere to ZDV therapy and are evaluated themselves for combination therapy and other care needs; ensuring that HIV test information is transferred in a timely way to the anticipated birth hospital; and, conducting expedited testing in the delivery setting for all women/newborns for whom prenatal HIV test results are not available.

Newborn testing will continue to be conducted at the Department's Newborn Screening Laboratory to ensure that all HIV positive newborns are identified and referred for care. The newborn testing data also provide valuable, timely information to monitor the epidemiology of perinatal HIV and prevention efforts.

Thank you for your interest in our program. Please let me know if I can provide any further information.

Sincerely,

Guthrie Birkhead MD

Guthrie S. Birkhead, M.D., M.P.H.
Director, AIDS Institute

Enclosure

SUMMARY

Reducing the Odds

Preventing Perinatal Transmission of HIV in the United States

Michael A. Stoto, Donna A. Almario, and
Marie C. McCormick, *Editors*

Committee on Perinatal Transmission of HIV

Division of Health Promotion and Disease Prevention

INSTITUTE OF MEDICINE

Board on Children, Youth, and Families

Commission on Behavioral and Social Sciences and Education

NATIONAL RESEARCH COUNCIL
INSTITUTE OF MEDICINE

NATIONAL ACADEMY PRESS
Washington, D.C. 1998

The proportion of women . . .

- who are HIV-infected
  - who become pregnant
    - who do not seek prenatal care
      - who are not offered HIV testing
        - who refuse HIV testing
          - who are not offered the ACTG 076 regimen
            - who refuse the ACTG 076 regimen
              - who do not complete the ACTG 076 regimen
                - whose child is infected despite treatment

FIGURE 1 The chain of events leading to an HIV-infected child.

alpha-fetoprotein), and other conditions (blood type and diabetes). Newborn children are routinely tested for errors of inborn metabolism and other problems. Although most of these outcomes are rare, a positive test result triggers interventions that benefit both mother and child, and these efforts have been responsible for substantial improvements in health and well-being.

As these screening programs have been implemented over the years, a substantial body of experience has been gained. In practice, when screening is conducted in contexts of gender inequality, racial discrimination, sexual taboos, and poverty, these conditions shape the attitudes and beliefs of health system and public health decision makers as well as patients, including those who have lost confidence that the health care system will treat them fairly. Thus, if screening programs are poorly conceived, organized, or implemented, they may lead to interventions of questionable merit and enhance the vulnerability of groups and individuals. Through the experience with public health screening programs, a series of characteristics of well-organized public health screening programs has evolved (Wilson and Jungner, 1968).

The committee's summary of the relevant characteristics is as follows:

1. The goals of the screening program should be clearly specified and shown to be achievable.

2. The natural history of the condition should be adequately understood, and treatment or intervention for those found positive widely accepted by the scientific and medical communities, with evidence that early intervention improves health outcomes.

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

COMMITTEE ON COMMERCE
SUBCOMMITTEES:
HEALTH AND ENVIRONMENT
ENERGY AND POWER

Congress of the United States
House of Representatives
Washington, DC 20515–3602

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December 13, 1999

Antonia C. Novello, M.D., M.P.H.
Commissioner
New York Department of Health
Corning Tower, Empire State Plaza
Albany, NY 12237

Dear Dr. Novello,

As the Health Commissioner of New York state and a former U.S. Surgeon General, you are vested with many valuable and practical insights that are very useful to health care advocates and policy makers around the country. As the state with the highest AIDS case load in the nation, HIV prevention is without a doubt one of the most important issues that you face.

As you may know, I have been an active proponent of early diagnosis and intervention to both prevent infection of those at risk and to provide treatment to those already infected. Perhaps the greatest breakthrough in HIV prevention has been the ability to significantly reduce perinatal HIV transmission if a woman is identified as being infected and provided with proper treatment and counseling. Unfortunately, despite the recommendations of the Institute of Medicine and the American Medical Association, very few states have taken a lead in making HIV tests a routine part of prenatal care.

New York, however, has been a pioneer in protecting newborns from HIV/AIDS. The state's policy advocating prenatal testing and requiring the testing of all newborns ensures that no mothers or children are left to slip through the cracks.. When I proposed a similar federal law several years ago, I was very pleased that Governor Pataki supported my efforts. However, my proposal was aggressively criticized by AIDS activists who claimed such a policy would frighten women away from prenatal care and drive the epidemic underground. As a practicing physician who has cared for pregnant women and children with HIV, I knew that these claims were completely unfounded. Unfortunately, while my proposal passed the House it was watered down in a conference committee with the Senate and never enacted. I can only guess how many children became needlessly infected with this horrible disease and how many families have had to face additional hardships because of this failure.

Could you please provide me a brief overview of the New York law? Specifically, would you deem it a success? Have you been able to identify, diagnosis and provide treatment to every woman and child at risk or do some still slip through the cracks? Has there been any evidence that this law has driven the epidemic underground or discouraged women from seeking prenatal care?

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E-mail: rep.coburn@mail.house.gov
Web site: www.house.gov/coburn

I would also be interested in hearing any additional thoughts your may have on this law and any other insights you may have regarding New York's approach to HIV prevention.

Thank you for taking the time to respond to this inquiry. I truly appreciate your leadership and diligent work and commitment towards HIV prevention.

Sincerely,

Tom

Tom A. Coburn, M.D.
Member of Congress

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
CORDELL HULL BLDG.
425 5TH AVENUE NORTH
NASHVILLE TENNESSEE 37247

DON SUNDQUIST
GOVERNOR

FREDIA S. WADLEY, MD, MSHPA
COMMISSIONER

January 13, 2000

The Honorable Tom A. Coburn, M.D.
United States House of Representatives
429 Cannon House Office Building
Washington, DC 20515

Dear Representative Coburn:

Thank you for your December 13, 1999, letter regarding Tennessee's HIV Pregnancy Screening Act of 1997 and your interest in Tennessee's efforts to reduce perinatal HIV transmission. First, let me point out that this law was enacted to require all providers of health care services who assume responsibility for the prenatal care of pregnant women to counsel them regarding HIV infections and, except where testing is refused, to provide serological testing for HIV, and to provide counseling and treatment for those who are infected. This is not a mandatory testing act, but a statutory requirement for physicians to discuss HIV with their pregnant patients.

As noted in Tennessee statute, counseling consists of the following key points:
1) the nature of the HIV;
2) methods by which HIV can be transmitted;
3) medical treatment that is available to treat HIV infection;
4) reduced rate of transmission of HIV to a fetus if an infected mother is promptly provided proper treatment;
5) advantages of being tested for HIV as early as possible in the course of the pregnancy;
6) reliability of the test; and,
7) confidentiality of test results and the woman's right to refuse HIV testing.

The Department of Health provides educational material and forms for consent or refusal of HIV testing. The health care provider arranges for HIV testing as early as possible in the course of the pregnancy unless the woman has refused testing in writing. If a pregnant woman presents for delivery and has not been tested for HIV, she is counseled and given information as specified above. Unless she refuses in writing after being counseled, she is then tested for HIV as soon as medically appropriate.

All HIV testing is done in a confidential manner and test results are disclosed only as provided by law. After receiving a positive HIV test result, the health care provider arranges for a counselor to be present when disclosing the positive test result to the patient. The counselor explains the meaning and reliability of the test results and the availability of additional or confirmatory testing; counsels the woman to obtain appropriate medical treatment for herself

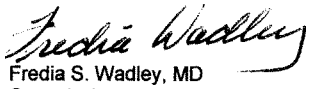
and her baby and informs her of the increased risks to her baby if she fails to obtain appropriate treatment; and, arranges for additional counseling in order to assist the woman in obtaining comprehensive clinical care that can meet her needs.

Attached you will find a copy of the universal consent form that is available to private physicians and utilized within the public health departments. The form used for reporting the weekly activity of providers is also attached. Unfortunately, provider reporting of the number of patients tested has been extremely low. As a result of this low level of reporting, we cannot accurately assess the percentage of pregnant women who are being tested.

We have not seen evidence that this law has had a negative impact on women seeking prenatal care in Tennessee. However, it is important to remember that this is not a mandatory HIV testing law. Women have the right to consent to or refuse HIV testing. Finally in response to your last question, Tennessee is currently not considering expanding the law to require testing of newborns whose mothers have not been tested.

I hope that I have adequately addressed all the issues raised in your letter. If you have further questions, please feel free to contact me.

Sincerely,



Fredia S. Wadley, MD
Commissioner

Attachments

Tennessee Department of Health | HIV ANTIBODY TEST CONSENT | STD/HIV Program

The HIV Antibody Test

I understand:

- HIV stands for Human Immunodeficiency Virus
- HIV is the virus that causes Acquired Immune Deficiency Syndrome (AIDS)
- The presence of HIV antibodies in a person's blood means the person is infected with HIV
- The blood test for HIV is not 100% accurate and may sometimes produce false positive or false negative test results.
- Additional tests will be required to confirm a positive result.
- I can ask questions if I need more information.

Results of the HIV Antibody Test

I understand:

- I must appear in person to receive the results of my HIV antibody test.
- I will be offered counseling to make sure I understand the test results.
- I may need to have additional tests to confirm my results.
- I will receive information on how to prevent spread of the virus.
- I will receive information on health care and support services, if needed.
- If I test positive, I will be asked to assist the Health Department to find individuals who may have exposed me to HIV or that I may have exposed to HIV.
- I will be offered assistance from public health authorities to find and notify individuals whom I may have exposed to HIV.

Confidential Reporting

I understand:

- Tennessee Law requires all HIV positive results to be reported confidentially to the State Health Department, Office of Communicable and Environmental Disease Services, Surveillance Program.
- Only individuals listed in the State Surveillance Policy will know the results of my HIV antibody test unless I direct otherwise.
- I will be provided a copy of the State Surveillance Policy upon request.

Voluntary Testing

I understand:

- My agreement to be tested for HIV antibodies is voluntary.
- If I withhold consent, the HIV antibody test will not be performed.
- I have the right to withdraw this consent at any time prior to the HIV antibody test.

By my signature below, I certify that I have read or had read to me, each item on the above checklist and I authorize my physician or his/her designee to administer the HIV antibody test to me.

Check here if you decline to be tested at this time

Patients Signature _____ Date _____ Witness Signature _____

Patients' Authorized Representative Signature _____ Relationship to Patient _____ Date _____

I wish to obtain the results of my HIV antibody test by telephone. I understand if my test is positive, or if my results indicate a need for additional testing, I agree to return to the Health Department. I also accept responsibility for insuring no one else has access to my code number and my security code.

Patients' Signature _____ Date _____ Security Code _____

Signature of Counselor _____

PH-3296 (rev. 7/98)

RDA 150

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA

COMMITTEE ON COMMERCE
SUBCOMMITTEES:
HEALTH AND ENVIRONMENT
ENERGY AND POWER

Congress of the United States
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December 13, 1999

Dr. Fay W. Boozman, Director
Arkansas Department of Health
4815 W Markham
Little Rock, Arkansas 72205

Dear Dr. Boozman,

As the Health Commissioner of Arkansas, you are vested with many valuable and practical insights that are very useful to health care advocates and policy makers around the country. Because of your unique knowledge and perspective, I am writing to solicit your thoughts and opinions about Arkansas' HIV prevention policy.

As both a practicing physician and a member of Congress, I have been an active proponent of early diagnosis and intervention to both prevent infection of those at risk and to provide treatment to those already infected. Perhaps the greatest breakthrough in HIV prevention has been the ability to significantly reduce perinatal HIV transmission if a woman is identified as being infected and provided with proper treatment and counseling. Unfortunately, despite the recommendations of the Institute of Medicine and the American Medical Association, very few states have taken a lead in making HIV tests a routine part of prenatal care.

Arkansas, however, has been a pioneer in protecting women and newborns from HIV/AIDS. The state's policy requiring routine universal prenatal tests ensures that no mothers or children are left to slip through the cracks.

When I proposed a similar federal law several years ago, it was aggressively criticized by AIDS activists who claimed such a policy would frighten women away from prenatal care and drive the epidemic underground. As a practicing physician who has cared for pregnant women and children with HIV, I knew that these claims were completely unfounded. Unfortunately, while my proposal passed the House it was watered down in a conference committee with the Senate and never enacted. I can only guess how many children became needlessly infected with this horrible disease and how many families have had to face additional hardships because of this failure.

Could you please provide me a brief overview of the Arkansas law? Specifically, would you deem it a success? Have you been able to identify, diagnosis and provide treatment to every woman and child at risk or do some still slip through the cracks? Has there been any evidence that this law has driven the epidemic underground or discouraged women from seeking prenatal care? What percentage of women— if any— refuse to receive an HIV test? Have you considered

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Web site: www.house.gov/coburn

expanding the law to require the testing of newborns whose mothers have not been tested?

I would also be interested in hearing any additional thoughts your may have on this law and any other insights you may have regarding Arkansas' approach to HIV prevention.

Thank you for taking the time to respond to this inquiry. I truly appreciate your leadership and diligent work and commitment towards HIV prevention.

Sincerely,

Tom

Tom A. Coburn, M.D.
Member of Congress

(8) Rapid HIV Tests

In the Ryan White CARE Act Amendments of 2000 (Public Law 106-345), Congress recognized the need for a reliable and effective rapid HIV test by directing the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to make second-generation rapid HIV test available in the United States.

Rapid tests provide a result that indicates the presence or absence of antibodies to HIV onsite within minutes and do not require laboratory review. CDC estimates that barriers to testing have contributed to 280,000 people in the U.S. being unaware they are infected with this deadly virus. CDC further estimates that another 8,000 HIV positive individuals that do not return for their test results would learn their HIV status each year if rapid tests were used. African Americans and other minorities—who are disproportionately affected by HIV/AIDS—would most benefit from rapid testing because they have been less likely to return for test results. All of these Americans are going without appropriate care as a result and may unknowingly be infecting others.

Likewise, pregnant women, newborns, health care professionals and rape survivors could be protected from HIV infection with the availability of a rapid test. Because perinatal HIV transmission can be prevented if AIDS medication is delivered to a women during labor and to her child after delivery, there is also an urgent need to provide timely HIV tests for the estimated 15 to 20 percent of HIV-positive pregnant women whose HIV status is unknown at the time of delivery. Rapid tests are beneficial for deciding whether or not to initiate treatment for health care workers after accidental exposures or to rape victims following sexual assault.

Due to the sluggish response by FDA to approve rapid HIV tests, Congress, the Presidential Advisory Council on HIV and AIDS and the Department of Health and Human Services pressured the agency to adhere to the law and make these diagnostics available.

In November 2002, the FDA approved a rapid finger-prick blood test. In 2003, FDA granted the test a waiver from Clinical Laboratory Improvement Amendments (CLIA) regulations, thereby allowing the test to be more widely used. CLIA-waived tests can be performed and interpreted in a physician's office or other non-traditional medical settings without having to be sent out to a CLIA-certified laboratory. To qualify for a waiver, a test must be simple, accurate and present no reasonable risk of harm.

In March 2004, FDA approved the first oral fluid based HIV rapid test, which is also CLIA waived. Oral fluid rapid HIV1/2 testing appears to offer the greatest hope to scaling up HIV screening due to the simplicity of such tests, patient preference for oral fluid testing, and state laws that create barriers to blood testing.

Despite the progress in developing and approving reliable rapid HIV tests over the past several years, barriers still exist that are hindering the realization of the full benefits offered by this technology.

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BERNARD SANDERS, VERMONT,
INDEPENDENT

April 30, 2002

Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson,

The Subcommittee is disappointed and very concerned about the actions-- or rather lack of action-- taken by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) in making second-generation rapid HIV test available in the United States.

There is a desperate need for these tests, which are widely used in other nations and have been proven to be both safe and effective. These rapid tests provide a result that indicates the presence or absence of antibodies to HIV onsite within minutes and do not require laboratory review. CDC estimates that approximately 8,000 HIV positive individuals that do not return for their test results would learn their HIV status each year if rapid tests were used. African Americans and other minorities—who are disproportionately affected by HIV/AIDS—would most benefit from rapid testing because they have been less likely to return for test results. These 8,000 Americans are going without appropriate care as a result, and may unknowingly be infecting others.

Likewise, pregnant women, newborns, health care professionals and rape survivors could be protected from HIV infection with the availability of a rapid test. Because perinatal HIV transmission can be prevented if AIDS medication is delivered to a women during labor and to her child after delivery, there is also an urgent need to provide timely HIV tests for the estimated 15 to 20 percent of HIV-positive pregnant

women whose HIV status is unknown at the time of delivery. Rapid tests are beneficial for deciding whether or not to initiate treatment for health care workers after accidental exposures or to rape victims following sexual assault.

The availability of a simple HIV rapid test is also a critical component of our Nation's bioterrorism preparedness. In the event of a biological attack, individuals will need to be aware of their HIV status before deciding to be vaccinated with a live virus vaccine that could be as dangerous to them as the biological agent itself. Given the short time frame in which to act, it will be vital for the public health system to already have second-generation HIV rapid tests in their possession in such an event.

Currently, only one rapid test—the complex SUDS test-- is available in the United States, although many simple, second generation tests have been developed and are widely used elsewhere. One company, which has received approval for its rapid HIV test throughout Europe, apparently has decided not to submit an application for approval in the United States because of what they deem unreasonable demands imposed by the FDA, including resistance to allowing these straightforward tests to be eligible for a waiver under CLIA. This is most unfortunate and unacceptable.

Second-generation HIV rapid tests are easy to administer, similar to a home pregnancy test, and do not require a laboratory for results to be interpreted. In addition, HIV testing is highly regulated through guidelines issued by the CDC, state statutes, and both state and local health department regulations, ensuring that counseling and referral accompany each test. Therefore, second-generation rapid tests obviously should qualify for a waiver as described in CLIA.

Secretary Thompson, you have consistently made combating HIV/AIDS at home and abroad a high priority within the Department. The Subcommittee would appreciate any efforts to intervene to promptly make second-generation HIV rapid tests available within the United States and to ensure the ability of our public health providers to use these tests in non-clinical and outreach settings vital to reaching those at highest risk of infection. This means not only expediting the approval process but also allowing second-generation rapid tests to qualify for a waiver under CLIA.

Congress has long recognized the important of rapid HIV tests. The Ryan White CARE Act Amendments of 2000 (Public Law 106-345) required the FDA and CDC to deliver a report to Congress in 2001 to describe the progress made towards, and barriers to, the approval and distribution of rapid HIV tests. This report—required by federal law—is over a year late. And the approval of the rapid HIV tests—despite the fact that they are safe, effective, easy to administer, and widely used elsewhere-- does not appear to be imminent.

The Subcommittee is also interested in receiving answers to the following questions:

(1) How many rapid HIV tests have been submitted to the FDA for approval? How many of these that are not available in the U.S. are currently being used in Europe?

(2) What are the specific reasons for the delay in the approval of these tests? Specifically, have they been found to be either unsafe lacking in either sensitivity or specificity in diagnosing HIV infection?

(3) What is the estimated timetable for approval of these tests?

(4) CLIA lays out clear language on the criteria for a test to receive a waiver and which agency has responsibility for waiver decisions. What agency—including the specific office and staff—is currently making decisions regarding waivers? What criteria are they using to determine whether a test receives a waiver? If the agency making waiver decisions or the guidelines for receiving a waiver differ from what is specified in CLIA, please provide an explanation as to why.

(5) It has been reported that some at the FDA and CDC are resistant to allowing second-generation HIV rapid tests to receive a waiver despite their simplicity and HIV testing being highly regulated. Given the critical public health need, please explain why thus much needed test that does not require a laboratory is being held up by laboratory requirements? Given the negative impact not receiving a waiver will have on the availability of rapid tests, how do FDA and CDC plan to ensure that rapid tests are made available in non-clinical and outreach settings where they will have the most use?

(6) How many HIV-infected Americans that did not return for their HIV test results potentially could have been notified and linked to care if these tests would have been made available at the same time they were approved in Europe?

Thank you again for your leadership in the global fight against HIV/AIDS. The Subcommittee appreciates your intervention into the timely approval of second-generation rapid HIV tests and a prompt reply.

Sincerely,

Mark E. Souder,
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources

Presidential Advisory Council on

HIV/AIDS

Minutes of the 20th Meeting

June 21 - 22, 2002

The Wyndham City Center Hotel
Washington, D.C.

Minutes

Members Present:

Thomas A. Coburn, M.D., Co-Chair
Louis W. Sullivan, M.D., Co-Chair
Stuart C. Burden
Philip P. Burgess, R.Ph., M.B.A.
Joseph A. Cristina
James P. Driscoll
Vera Franklin
Mildred Freeman
John F. Galbraith
Cynthia A. Gomez, Ph.D.
Cheryl-Anne Hall
Karen Ivantic-Doucette, M.S.N., F.N.P., A.C.R.N.
Joseph Jennings
Rashida Jolley
Caya B. Lewis, M.P.H.
Abner Mason
Sandra S. McDonald
Joe S. McIlhaney, M.D.
Hank McKinnell, Ph.D.
Brent Tucker Minor
Dandrick Moton
Nathan M. Nickerson, R.N., M.S.N.
John A. Perez
Debbie Rock
Reverend Edwin Sanders II
Prem Sharma, D.D.S.
Lisa Mai Shoemaker
Anita Smith
M. Monica Sweeney, M.D., M.P.H.

Members Not Present:

The Honorable Ronald V. Dellums
Ingrid M. Duran
Mary Fisher
Katryna Gholston

RAPID TESTING

Dr. Bernard Branson of the National Centers for Disease Control and Prevention spoke first, providing an overview and description of rapid testing, to summarize the public health need, to illustrate difficult concepts regarding the test's predictive value, and to review its current usage.

There are currently an estimated 850,000 to 900,000 HIV-infected persons in the United States, and an estimated 40,000 new infections per year. The CDC estimates that 25 percent of HIV-positive persons do not know they are infected. Standard testing, with centralized labs and complex equipment suitable for high volume testing, is time consuming and technically demanding. After explaining the steps required, Dr. Branson noted that the results from an ELISA (enzyme-linked immunosorbent assay) test may not be known for a few days to even a week or two. By contrast, simple or rapid assays are done at the point of care and allow for same-day results. These tests can be run on small numbers at a time. SUDS, the only current rapid test available, is rapid (about 25 minutes) but not simple and tests serum, which requires a centrifuge. The test also has its shortcomings. The product Oraquick, under FDA review, is done with a finger stick, and the results can be read in 20 minutes. The test produces different results for positive and negative, as well as a separate result if the test was performed incorrectly.

The public health need for rapid testing is dire: the percentages of persons tested but not receiving their results are very high. There are several circumstances in which there is an immediate need (e.g., pregnant women). In addition, it is important to have rapid testing in outreach settings for people who do not typically access the health care system. At publicly funded sites with standard testing, 30 percent of people who test positive and 40 percent of those who test negative fail to return for their results, because it takes 1 to 2 weeks to get the results. In an STD (sexually transmitted disease) clinic, 79 percent of the positives got their results, but only half of these came back on their own; clinic staff had to find the rest.

By comparison, with rapid testing the CDC has found that 93 percent of tested persons received their results the same day. (Some people refuse to wait for even 20 minutes.) Also, 97 percent received preliminary rapid test results and came back for their Western blot results.

Dr. Branson noted graphically how many more people could have known their serostatus and thus represent an increase in individuals who might not have infected others. Given the fallibility of tests, The World Health Organization (WHO) recommends combinations of simple and rapid tests, confirming an initial positive result with a different test. CDC currently supports this globally for both volunteer HIV counseling and testing and to screen pregnant women. Other

examples of where rapid testing makes a difference includes emergency rooms and clinics. Since 1994, emergency room and clinics in high incidence settings recommend screening for all patients. Studies have shown dramatic increases in HIV infection being identified when screening is done in emergency departments. The CDC is doing one other large screening test, in cooperation with the FDA, to screen pregnant women in labor who have not been tested ahead of time.

The CDC considers an increase in serostatus knowledge important; it is the second goal of its 5-year plan to increase from 70 to 95 percent the proportion of HIV-positive persons who know they are infected. Other goals are to increase the motivation of at-risk individuals to know their status, to decrease barriers to testing, and to improve access to voluntary client-centered counseling and testing.

Dr. Edward Baker, the Assistant Surgeon General, spoke on the Clinical Laboratories Improvement Act (CLIA). He noted that the CDC supports rapid testing as a major technological advancement that will save lives, noting that the issue of accuracy must be addressed. While no test is perfect, CLIA tries to improve the accuracy of testing. CLIA works closely with the Centers for Medicare and Medicaid Services (CMS; formerly the Health Care Finances Administration [HCFA]). CLIA's law applies to almost all facets of human testing. The CLIA standard is based on the complexity of the testing; the more complex, the more requirements are in place to ensure accuracy. The guiding principle is to ensure quality testing without interfering with access.

The complexity model is as follows:

- Simple and safe (waived): requires registration, staff must follow manufacturers' testing instructions
- Moderately complex: quality control and quality assurance measures, proficiency testing (PT), limited personnel, requires biennial inspections
- Highly complex: quality control and quality assurance measures, PT, stringent personnel, biennial inspections.

Simplicity is the crux of the issue: How simple does a test have to be? The responsibility for classifying testing protocols has been transferred to the Food and Drug Administration (FDA). In all, 3 percent of tests have been waived; 73 percent are considered moderately complex. If a test is approved by the FDA for home use, it is immediately waived. If DHHS determines that a test is simple and has an insignificant risk of erroneous result it receives a waiver (including those that employ simple, accurate methodologies with a negligible likelihood of erroneous result, or no unreasonable risk of harm to the patients if the result is incorrect).

It is important to think about the total testing process in terms of its simplicity: pre-analytical, analytical, and post-analytical. Limited public health testing is done in the nonprofit; such entities can conduct waived or moderately complex tests at multiple fixed sites (e.g., Michigan) under the oversight of one responsible party. A number of nontraditional sites have been certified for moderately complex testing, including rural clinics, correctional facilities, environmental labs, health fairs, home health agencies, medical foundations, mobile units, nursing homes, physician office labs, schools, and student health services.

Dr. Judith Yost presented some studies from CMS and other sources on waived laboratories. As Dr. Baker stated, the intent of CLIA is to ensure accurate lab testing while maintaining access. There are currently 175,000 labs enrolled. CLIA dictates that waived tests are simple and accurate and have insignificant risks of erroneous results. About 94,000 (54 percent) of CLIA labs do only waived testing. CLIA does not distinguish between screening and diagnostic testing, and does not discriminate by location (the requirements focus only on complexity).

Dr. Yost said CMS is in support of quality, point-of-care rapid testing.

There is no routine oversight of waived tests, but there is a provision in CLIA to initiate oversight if needed. Waived labs have only one basic requirement: to follow the manufacturer's instructions. Therefore, it is important how each lab performs the test and how they ensure it is working properly.

In 1999-2000, pilot studies were performed in 500 waived labs. Approximately 50 percent of the labs had testing problems (e.g., no quality control, not following manufacturer's instructions, etc.). Additionally, based on the pilot studies in Colorado and Ohio, the Office of the Inspector General also did a study, as did the CDC CLIA staff. All studies found similar, problematic results. CMS selected eight additional states in which to visit waived labs to make sure the findings were not an aberration. Quality problems were again found in many of the 270 labs visited, although in Maryland, New York, Pennsylvania, and Idaho-states that have their own state lab licensure programs-the problems were fewer. The problems break down as follows:

The Office of Inspector General (OIG) study had similar findings.

CMS recommendations for improving the system include:

- Institute an education program for waived labs and validate its effectiveness;
- Compile existing education programs into a clearinghouse for the CLIA Web site;

- Survey a percentage of waived labs annually to gather additional data and provide education;
- Develop self-assessment tools for waived labs;
- Provide information on CLIA requirements to newly enrolled labs; and
- Work with testing system manufacturers to clarify instructions and to provide initial training following a sale.

Dr. Yost noted that issues are also exacerbated by turnover in lab personnel.

CLIA-regulated labs demonstrate improved performance over time due to the educational approach and oversight. CMS found that of those regulated labs visited biennially, 35 percent were also not following the most recent manufacturer's instructions. These significant findings have serious implications for patients. For example, in one lab that performed simple occult blood tests, staff were using expired reagents and not performing quality control checks. In one case, a diagnosis of GI cancer was delayed for this reason. Lab experts agree that any incorrectly done tests have the potential for some harm.

Dr. Yost discussed moderately complex tests v. waived tests (myths versus facts).

Quality assurance (QA) is ongoing (continuous quality improvement) to monitor the lab's overall quality of operation. CMS inspects labs routinely every 2 years. CLIA minimum standards provide a low cost and a low burden to laboratories. Technical assistance (TA) is available from CMS and state agencies. Ten years' worth of data shows that CLIA-regulated labs have improved and are doing well. The educational approach has improved performance in labs significantly. The problem rate has dropped from 35 percent to 9 percent. A New York study of HIV-positive patients showed an increased in access and earlier treatment/intervention.

The Blood Products Advisory Committee and one other advisory committee recommended that SUDS not be granted a CLIA waiver. Pre- and post analytical concerns have to be considered, including patient counseling, confirmatory testing, and public health reporting. HIV testing encompasses a broad spectrum of social and legal issues as well as public health issues. The SUDS test does not demonstrate minimal risk of harm; it is not always simple to perform, and it is not always accurate. As findings and concerns show, this is a truly complex issue, and deserves careful consideration.

Dr. Elliot Cowan discussed the FDA review and approval process for rapid HIV testing, including the timeline, the measures that FDA has taken to facilitate approval for new rapid tests, and a report of progress made.

Within FDA, all HIV tests are reviewed in the Center for Biologics and Research's Office of Blood Research and Review. Rapid tests are reviewed as Class III devices. Pre-market review is necessary to provide a reasonable assurance of safety and accuracy.

- The regulatory scheme he discussed was for a rapid HIV test to be used as an aid in diagnosis. Trials are conducted to determine effectiveness; the process requires the filing of an investigational device exemption application (IDE), per 21 CFR 812. Data accumulated in the course of the clinical trials is put into a pre-market approval application (PMA), per 21 CFR 814.

Dr. Cowen discussed the three-part process:

- For the IDE review, the decision must be made by the FDA within 30 calendar days following receipt of the application. If approved, clinical studies can proceed. If the application is deemed "not approvable," a new IDE submission needs to be filed.
- The timeline for approved IDEs is driven by the applicant: once studies are complete, the applicant assembles the study data for submission. FDA encourages pre-PMA meetings to help with this step.
- PMA review: the decision must be made within 180 calendar days of receipt of a completed PMA. There are four possible outcomes for the PMA review: "not approvable," "not approved," "approvable," and "approved." The first three require additional information and/or review.

An inspection of the manufacturer's facility provides evidence that the manufacturer has a quality system for the design, production, packaging, labeling, storage, installation, and servicing of finished medical devices (per 21 CFR 820). Inspection occurs after most review issues are resolved. The FDA determines whether the manufacturer is in compliance with regulations or not. This is a critical part of the process. As desirable as rapid tests are, the FDA and the public need to be assured of a reasonable certainty that the product will remain available as needed.

Dr. Cowen outlined the steps taken by the FDA to facilitate the review process for rapid HIV testing: rational standards for approval, simplified clinical trial requirements, and prioritizing review of rapid HIV test submissions. Since the FDA is prohibited from releasing any information related to test submissions, the discussion was limited to public health information and information authorized for release.

On 1 May, Orasure announced that Oraquick is approvable, but needs to submit product labeling and resolve some review issues.

In closing, Dr. Cowan said the FDA is committed to bringing safe and effective rapid tests to the market as quickly as possible. Through industry contacts, FDA has sought input and solutions regarding perceived barriers to obtaining pre-market approval.

Dr. Frances Pouch Downes, Director of the Public Health Laboratories in Michigan, spoke on the public health impact of rapid testing for infectious diseases. American Public Health Laboratories (APHL) labs have nearly 20 years of experience conducting HIV tests, developing testing guidances, etc. APHL labs have worked with the broader public health community to ensure services are available to the public. An increasing number of rapid care tests (including HIV, influenza, Lime disease, etc.) are being developed for use in emergency settings, physician offices, public health centers, and nontraditional sites. As has been noted, law provides exemptions for simple and safe test products with insignificant risk. When a test is granted a CLIA waiver, it can be performed by anyone in any setting. Proficiency testing, external controls, and oversight are not required. The only regulation is that manufacturer instructions be followed.

In Michigan, Dr. Downes noted, another option is used, a limited public health certificate, ensuring that non-lab professionals working in local health agencies can perform moderately complex and waived testing. The certificate allows for up to 15 waived and/or moderately complex tests to be performed by nurses and medical assistants, while trained professionals review the training and quality control measures. As new testing methods are developed, it is important that an appropriate system is in place to ensure quality. While APHL supports the use of rapid HIV tests and other rapid tests if they ensure reliability, many such tests are not sufficiently accurate. CLIA-waived tests should be sufficiently simple as to require no training, and they should be accurate. HIV and other rapid tests do not fall into this category. By contrast, in Michigan, 10 years of CMS surveys have rarely identified any deficiencies. This points to the need for appropriate training and oversight, reporting practices, etc.

Dr. Downes stated that the nature of rapid HIV testing requires the establishment of quality control and assurance procedures, which regulations for waivers do not include. Only simple, highly accurate tests should be appropriate for a CLIA waiver. APHL believes that rapid HIV tests are moderately complex in nature and should be performed under appropriate CLIA regulations for moderate complexity. High quality tests can be performed in STD clinics, etc., under a CLIA-limited public health testing certificate. Access to testing will not be compromised by using this certificate. APHL recommended that, whatever the complexity, data should be collected to determine how the test is performing and

ask critical questions on access. APHL stands ready to work with leaders to assist with CLIA certificates, TA, and quality assurance.

Dr. Mark Loveless, Medical Epidemiologist and Director of the HIV/STD/TB Program of the Oregon Health Department, addressed the Council representing the National Alliance of State and Territorial AIDS Directors (NASTAD). Dr. Loveless noted he recently found out he is a CLIA-regulated lab director.

- Dr. Loveless spoke in favor of maximum access to HIV rapid tests, and of the critical importance of a CLIA waiver, which NASTAD supports for an extensive list of reasons, inclluding improving testing access and reducing disparities in the test's availability.

Dr. Loveless addressed a number of concerns and misconceptions regarding a CLIA waiver. (1) "HIV is a life-threatening disease that is too significant for a waived test." (the seriousness of the epidemic is the reason for widespread access to testing and other diseases that are life-threatening have waived test status); (2) "A waived test does not mean everybody's going to do it" (Widespread utilization is the goal of the industry); (3) "Too many false positives" (Evolving technology has dramatically reduced false positives); (4) "CLIA offers the only protection against the misuse of HIV rapid tests" (HIV testing is the most regulated and scrutinized medical lab test in use, CLIA is by no means the only HIV test regulatory process, and CLIA has no authority over issues such as the quality of test interpretation and subsequent patient education, counseling, and referral); (5) "There would be no safeguards that persons receive counseling and referral" (CLIA has no authority to ensure this post-test process and therefore does not have relevance); and (6) "There would be no oversight to ensure tests are performed correctly" (Newer technology minimizes the chance for error).

Regarding the "limited public health use" exception Dr. Downes discussed, Dr. Loveless stated this cannot be replicated in Oregon. Such an arrangement would increase the cost and complexity of the testing system without a documented benefit to the patients and testing sites.

In summary: NASTAD strongly supports a CLIA waiver for HIV rapid testing. NASTAD is committed to continuing high quality management of federally-funded HIV counseling and testing systems; they are also committed to working with public health labs and local lab directors to improve the quality and performance of CLIA-waived labs, whether doing HIV testing or not.

Questions and Answers on Rapid Testing and CLIA Requirements

A director of a CLIA-regulated complex lab noted that it is considered a quality problem if the piece of paper that came with the test is not sitting out next to the

test during oversight. She asked what are the consequences of a failure in quality, noting that both waived and nonwaived tests need better oversight in the United States.

Dr. Joe McIlhaney asked Dr. Branson whether the CDC is able to do all the studies they need on rapid testing. Dr. Branson noted that because the test is not currently approved, it has to be treated as highly complex (with respect to sensitivity and specificity). As a result, the CDC cannot gather data on how the rapid test might work in a waived setting.

Rev. Edwin Sanders suggested that today's discussion should move toward specific recommendations, and that questions should be framed appropriately. He suggested one recommendation might be developing uniform guidelines for testing and quality control.

Dr. Monica Sweeney asked whether the push is to have a quick HIV test available at the local pharmacy (like pregnancy tests). Increasing the percentage of people who get HIV test results is important; however, even when somebody gets a negative result they see a counselor for information and interpretation. This service would not be available with a home test kit. Dr. Baker noted there are no applications for home use products at the present time. The distinction to be considered here is whether the CLIA requirements should be waived for lab use, which itself would entail no requirements for counseling and testing. Once the test is waived, it can be done anywhere and by anyone. Dr. Cowan noted that a home collection product is currently available, but the results are read remotely.

Dr. Cynthia Gomez stated that the Council's primary purpose is to increase access. Today's disagreement is about how soon everyone can be comfortable with disseminating rapid testing in the best interest of the people. From all the information presented, Dr. Gomez said, sufficient risk was not demonstrated that would outweigh the benefits of CLIA-waived rapid testing. The risks have been known for a long time. The Council should discuss a timeline by which the country's labs would be comfortable implementing rapid testing safely and accurately. The various parties should work together to improve quality assurance at all times and in all locations. Dr. Downes suggested that the lab community is already in agreement, that rapid testing needs to be implemented now. Nonetheless, rapid testing can and should be done in settings where quality is assured. Dr. Downes said this can be done with many different options in many settings, not just the Michigan model discussed.

Dr. James Driscoll said that a CLIA waiver would considerably expand the market. It is startling, he said, that there are tests available in hundreds of countries but not the United States. With current testing available, everyone will be given other confirmatory tests; indeed, additional tests are in development that will allow two tests at once. Rather than 1 in 1000 false readings, the results

will be closer to 1 in 100,000. He noted there are many places where people cannot afford medical care-underserved populations living at the margins of society. These people are being excluded; it is a barrier to health care.

Lisa Mai Shoemaker asked how hard it would be to ensure that those administering rapid tests would be certified. Dr. Branson responded that each state has its own certification regulations. There is no Federal provision for certifying people, for example, on administering Orasure tests.

Karen Ivantic-Doucette noted that rapid tests still check for the presence of antibodies, so there is still a window of inaccuracy immediately following infection. It is not clear that people understand this point: rapid testing serves no more purpose to the very recently infected than traditional testing. Dr. Coburn stated, however, that testing would be greatly beneficial to health care workers who have had exposure via an HIV-positive patient. He also stated that persons who do counseling and testing are well aware of the window period, and it is a standard part of the counseling technique in delivering negative results.

A council member asked whether any data exist on false negatives (e.g., how rapid tests compare with other tests on this point). Dr. Branson responded that since the CDC has been evaluating tests, some show no false negatives, while others do. An FDA decision will need to be made on this issue. However, Dr. Branson said, difficulty with false negatives arises only in extremely high prevalence populations (much higher than in the United States).

Stuart Burden asked whether the Council is comfortable with safeguards against abuses that can come with HIV positive tests, regarding discrimination in employment, immigration, travel, etc. There are no legal assurances against such discrimination. There is a greater stigma around HIV positivity than around the test itself. While the point was made people can be taught to administer the tests properly, that is very different from providing appropriate counseling. Dr. Baker responded that one consideration CDC gives in waiving a test for any circumstance is to create a series of scenarios in which false results can be used improperly. Secondly, he said, it is important to note that once a test is waived, it is practically unheard of to "unwaive" it.

Debbie Rock said the Council is putting barriers in its own way. A lot of the testing being discussed will be in places where states and community-based organizations (CBOs) are doing collaborative efforts. In Baltimore, for example, Ms. Rock collaborated with Johns Hopkins University (JHU); they took 6 months to train the Department of Social Services on HIV education. This is a point of entry for many at-risk populations. Ms. Rock said this setup has been working well: JHU does the testing and her outreach staff walk the patients through. The point is to get high-risk persons accessing medical care quicker, and working collaboratively can facilitate that goal.

Nathan Nickerson reminded the Council that a CLIA waiver status speaks to who can perform the test and in what settings; it does not refer in any way to the counseling and testing context of the test. If a CLIA waiver is granted, states can still structure their own requirements for counseling and testing. Dr. Baker reinforced the point, noting that if rapid testing were approved as moderately complex, the tester would have to be trained and have a high school education, and there would be quality assurance measures. CLIA-waived rapid testing would be appropriate in a voluntary counseling and testing setting, but there are cost implications for doing this. Basically, performing more testing (and counseling) will require more resources. Dr. Branson said this also affects how results are given out. Very often, the person who administers the test is different from the person who gives the results. In a waived setting, the same person would more often do both.

Dr. Yost noted that not all states have requirements for counseling and testing or oversight. There are about 12 states that have their own lab programs, but many states defer to CLIA or other organizations.

Sandra McDonald suggested the Council should return to the "human" part of HIV. With approximately 950,000 HIV-positive Americans, of which perhaps a third do not know their status, it is imperative, she said, that every tool possible is utilized to access these people, find out their status and refer them for care.

Brent Minor said it is very hard not to be persuaded by rapid testing. It is important, he said, to ensure that counseling and testing is as good and well researched as the test itself. A lot of work has already been done on that side. The benefits include seeing more HIV-negative persons and giving them valuable information as well as to those who are HIV positive. Mr. Minor agreed with Dr. Loveless that "normalizing" HIV testing in society is a great and positive thing; such a stigma exists about getting tested-some people don't even want their clinician to know.

Ms. Shoemaker noted it is important for people to get tested whether they are high-risk or not. The epidemic affects everyone. She said that until improved testing comes, the Council should push on with rapid testing.

Dr. Gomez stated that the main reason for this test is the high percentage of patients who do not get their results. Issues of counseling and testing continue to be important in terms of quality, even under current testing mechanisms; these issues need to be addressed generally, irrespective of any one test's waived status. Of most importance is getting more people to agree to be tested and stay for their results. Dr. Gomez noted that she brings hundred of people into her lab (with the assistance of CBOs) who would not ever go into a clinical care setting. Being able to provide test results before the individual leaves the room is an incredible opportunity.

Philip Burgess noted that pharmacists have been very involved in dealing with HIV infection; they are among the most readily available professionals to assist the community. Pharmacists interact with customers-they know the drugs, the latency periods, etc., and can play a vital role in providing counseling. Mr. Burgess said he strongly supports getting rapid testing fully implemented.

Mr. Burden reiterated that there is potential for misuse and abuse of test results; he recommended that the Council reaffirm its insistence on privacy and confidentiality safeguards. One Council member responded that there are laws in existence in all 50 states that address privacy and confidentiality concerns.

Vera Franklin noted that rapid testing would be extremely beneficial to Native American communities, where social and logistical barriers prevent most people from returning for their HIV test results.

Dr. Sullivan thanked all Council members and guests for their contributions to the discussion.

...

Follow-up Discussion on Rapid Testing

Dr. Coburn called for a Council consensus on rapid testing. He asked whether the Council should formulate this as a recommendation, and if so, how.

Dr. McKinnell noted he does not care whether rapid testing receives a CLIA waiver or is designated moderately complex. The urgent thing is to get it out quickly and widely. Mr. Burgess said that, clearly, allowing rapid testing to be waived will increase access. He recommended waiving it.

Dr. Driscoll noted there is an apparent contradiction for the United States to push for rapid testing throughout the world and denying it to African Americans and other Americans here. When a highly beneficial drug is approved, by comparison, obviously its advocates want it approved for broad usage; the alternative is Viracept approved for last-ditch efforts. Dr. McKinnell countered that the Council should not get bogged down in the process of telling the FDA how to do its job, and recommended letting the President decide on the issue.

Ms. Ware reminded the Council that the FDA representative wanted to make it clear that discussion of the CLIA waiver will not hinder the approval of rapid testing. It was his estimation that it would take no more than 3 weeks after approval to determine whether or not CLIA regulations will be waived. CMS will set regulations for how rapid tests will be used; FDA will then determine whether CLIA will be waived.

Dr. Sweeney noted that the prevention committee met this morning and decided on a recommendation that the full Council urge approval and a CLIA waiver for rapid testing. Rapid testing should be made available as soon as possible, maintaining all confidentiality and counseling and testing guidelines applicable to existing tests. This recommendation was motioned and seconded.

Dr. McKinnell noted there are several FDA advisory committees that have recommended otherwise. He said he would much rather focus on the outcome; working on the details of how to get there leads to a morass that is more appropriate to the President or the Secretary of DHHS. While he agrees that rapid testing should be immediately and broadly accessible, Ms. McKinnell recommends that the Council not urge a CLIA waiver.

Dr. Sweeney noted the prevention committee engaged in extensive discussion this morning and determined that increased availability of rapid testing is a part of the reason for recommending a waiver. Mr. Nickerson agreed that this strategy would provide wide access. It may be the case that a moderately complex rating would not impede access, but that is unclear. Mr. Nickerson said he supports a recommendation to waive CLIA requirements.

Dr. Gomez said that the Council has been given enough information to make an informed decision and assume a position. While the Council has been told the lack of a CLIA waiver will not be a barrier, several of the presenters yesterday disagreed. Dr. Gomez said she feels the Council is meant specifically to recommended "waived" versus "non-waived."

The Council's vote was held momentarily for a process question: will the full Council reconvene following committee meetings this afternoon? The answer was no.

The vote for the proposed recommendation was carried unanimously.

PRESS RELEASE

PUBLIC AFFAIRS DEPARTMENT
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FOR IMMEDIATE RELEASE
25 June 2002

CONTACT: (323) 860-5224
Clint Trout, AHF Associate Director, Government Affairs

US' LARGEST AIDS ORGANIZATION PRAISES PRESIDENT'S ADVISORY COUNCIL ON HIV/AIDS DECISION ON "RAPID" HIV TESTS

AIDS HEALTHCARE FOUNDATION SEES RECENT ACTION URGING FEDERAL AUTHORITIES TO MAKE "RAPID" HIV TESTING WIDELY AVAILABLE AS CRITICAL STEP TOWARD REINVIGORATING HIV PREVENTION

25 June 2002, LOS ANGELES, CA—AIDS Healthcare Foundation (AHF) today praised a recent decision by President Bush's Advisory Council on HIV/AIDS (PACHA) urging federal authorities to make "rapid" HIV testing widely available. "This technology will revolutionize HIV testing in the US," said **Clint Trout**, spokesman for AIDS Healthcare Foundation, the nations' largest AIDS organization. "Instead of being asked to come back in a week for results, you'll know your status in 20 minutes." Trout said that in California alone, over 600 people annually who test positive for HIV fail to come back for results, treatment and counseling.

AIDS advocates have demanded that the federal Food and Drug Administration (FDA) ensure that those at highest risk be able to get their results at community-based anonymous and confidential test sites. Instead, officials testifying at the June council meeting argued against a waiver mechanism that would allow such access.

The council, however, voted unanimously to urge the FDA to immediately make rapid HIV screenings available under a Clinical Laboratory Improvement Act (CLIA) waiver.

AIDS Healthcare Foundation also commended former U.S. Representative Dr. Tom Coburn (R-Oklahoma), council co-chairman, for his leadership on this issue. "While the bureaucracy testified against the waiver, Dr.

Coburn spoke forcefully on the issue and led the council to its unanimous vote," said Trout. "His leadership proved pivotal."

Individuals testing for HIV currently must wait from one to two weeks for their results. This long waiting period is a significant barrier to high-risk individuals returning for their HIV test results or to getting tested at all.

Nationally, one-third of HIV positive individuals do not know that they are positive and 8,000 individuals with positive HIV test results (tested at public testing sites) do not return for their results. **By eliminating the waiting period, rapid screening will greatly increase the number of HIV positive individuals who know their status.** Studies show that HIV positive individuals who know their status are much less likely to pass on the HIV virus to others.

The primary argument *for* CLIA waiver for rapid HIV tests is that a moderate complexity categorization would significantly limit access to rapid HIV testing for populations at highest risk. In California, approximately half of public test sites would *not* be able to access rapid screening without a waiver. Unfortunately, because it is these community sites that serve the majority of our HIV-infected clients, this represents an even larger proportion of our *infected* population who would not have access to rapid screening.

According to Trout, AIDS Healthcare Foundation – which performed over 7,000 HIV tests in 2001 – joins the President's Advisory Council on HIV/AIDS in calling on the FDA to immediately release rapid screening technology under a CLIA waiver.

AIDS Healthcare Foundation is the US' largest provider of specialized HIV/AIDS medical care. AHF serves thousands of patients in California, New York and Florida regardless of their insurance status or ability to pay. In addition, AHF currently operates two free AIDS treatment clinics in Africa: the Ithembalabantu (Zulu for "people's hope") Clinic in KwaZulu Natal, Durban, South Africa & the Uganda Cares Healthcare Center in Masaka, Uganda. www.aidshealth.org.

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AIDS Healthcare Foundation
6255 West Sunset Blvd., 21st Fl., Los Angeles CA 90028 (323) 860-5200

JUL 08 2002

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

JUL – 5 2002

The Honorable Mark E. Souder
Chairman, Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Souder:

Thank you for your letter regarding availability of second-generation rapid HIV tests. I assure you I am committed to HIV/AIDS prevention and treatment and share your concern about people who remain unaware of their HIV-positive status.

The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) are working diligently to ensure the availability of safe and reliable second-generation rapid HIV tests for use in the fight against HIV/AIDS. The importance of these tests in HIV prevention is clearly recognized and referenced in CDC's 5-year HIV Prevention Strategic Plan. Furthermore, FDA and CDC scientists have been working with the manufacturers of rapid HIV tests to clarify regulatory requirements, expedite review performance claims, and assist in field evaluations.

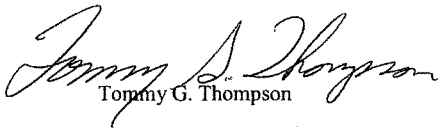
In reference to your comment regarding the report to Congress requested under the Ryan White CARE Act Amendments, the report is being finalized and will provide additional information regarding steps being taken to increase the availability of simple-to-use rapid HIV tests. Additional responses to your questions are enclosed.

We are working hard to ensure a wider range of safe and effective rapid HIV tests to assist in HIV prevention. However, simple tests are not without problems, and monitoring of their performance is critical. For example, a rapid HIV test product produced in the United States and used in Canada was recalled recently due to false-negative results, and the British Columbia Centre for Disease Control issued an advisory to specifically alert those who may have been tested and received a negative test result.

Even in the absence of these new rapid HIV tests, HIV tests are currently being performed expeditiously to meet the needs of potentially unknowing HIV-infected persons such as pregnant women, newborns, health care professionals, and rape survivors.

Please call me if you have any further thoughts or questions. I look forward to working with you on this issue.

Sincerely,



Tommy G. Thompson

Information Regarding Second-Generation Rapid HIV Tests

The Department of Health and Human Services' Responses
to Representative Souder's letter of April 30, 2002

[*Please note that information contained in this response may be considered trade secret and confidential commercial information that is otherwise prohibited from disclosure. Consequently, disclosure of information provided in this response could cause commercial harm to one or more of these manufacturers.*]

Question 1:

How many rapid HIV tests have been submitted to the FDA for approval? How many of these that are not available in the U.S. are currently being used in Europe?

Response:

Number of rapid HIV tests submitted to FDA for approval: Currently, two manufacturers have submitted Pre-Market Approval (PMA) applications to FDA for so-called "second generation" rapid HIV tests. In addition, FDA has six rapid HIV test Investigational Device Exemption (IDE) applications submitted by five sponsors. FDA has worked actively with CDC and various product sponsors to facilitate the design and conduct of clinical trials to validate the performance of candidate rapid HIV tests and to permit expanded access under approved IDEs.

Rapid HIV tests not available in the United States, but currently being used in Europe: Of the rapid HIV tests for which IDE or PMA applications have been submitted to FDA, three are currently being used in Europe. In addition, two are being marketed in Europe on a very limited scale.

Question 2:

What are the specific reasons for the delay in the approval of these tests? Specifically, have they been found to be either unsafe lacking in either sensitivity or specificity in diagnosing HIV infection?

Response:

Performance of tests under review: FDA has determined that both of the tests being reviewed under PMA applications meet the required performance standards if consistency of manufacturing can be assured. Data for one test kit demonstrate that the kit meets the rapid HIV test performance standards when used with serum and plasma specimens; data from the other test kit demonstrate that the kit meets the rapid HIV test performance standards when used with fingerstick whole blood specimens.

Specific reasons that tests under review are not yet approved include the following: In addition to demonstrating the performance characteristics of a rapid HIV test in pre-clinical and clinical studies, the manufacturers must demonstrate to FDA that they are able to produce devices that

are consistently of suitable quality to maintain the level of performance required by FDA and claimed in the product label. However, pre-license inspections of both establishments raised concerns that each of these manufacturers was not operating in such a manner. FDA is actively working with both manufacturers to resolve their respective issues in the shortest possible time through face-to-face meetings, teleconferences, and follow-up inspections.

Question 3:

What is the estimated timetable for approval of these tests?

Response:

The timetable for approval of rapid HIV tests depends upon the ability of each manufacturer to address remaining issues, and consequently, we are unable to estimate when approval will be given.

Question 4:

CLIA lays out clear language on the criteria for a test to receive a waiver and which agency has responsibility for waiver decisions. What agency--including the specific office and staff--is currently making decisions regarding waivers? What criteria are they using to determine whether a test receives a waiver? If the agency making waiver decisions or the guidelines for receiving a waiver differ from what is specified in CLIA, please provide an explanation as to why.

Response:

The Centers for Medicare & Medicaid Services (CMS) has been delegated and retains the authority to interpret Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implement rules, guidance, and policies. The waiver categorization program for commercially marketed tests was transferred from CDC to FDA, pursuant to a Memorandum of Agreement (MOA) with CMS, on February 27, 1999. FDA's Center for Devices and Radiological Health, Division of Clinical Laboratory Devices, administers the program in accordance with the MOA. FDA consults with CMS when there are questions involving the interpretation and application of CLIA's waiver criteria, which are set forth in the statute. Further guidance is contained in a Notice of Proposed Rulemaking published in 1995.

Because none of the second-generation rapid HIV testing products have been cleared by FDA, no waiver determinations have been made for these products; however, two HHS federal advisory committees, including the Clinical Laboratory Improvement Advisory Committee, have advised that simple rapid HIV tests should not be waived.

Question 5:

It has been reported that some at the FDA and CDC are resistant to allowing second-generation HIV rapid tests to receive a waiver despite their simplicity and HIV testing being highly regulated. Given the critical public health need, please explain why [this] much needed

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test that does not require a laboratory is being held up by laboratory requirements? Given the negative impact not receiving a waiver will have on the availability of rapid tests, how do FDA and CDC plan to ensure that rapid tests are made available in non-clinical and outreach settings where they will have the most use?

Response:

CDC and FDA support the development of simple, high-quality rapid HIV tests for use in public health efforts to control the spread of HIV through outreach testing and counseling of individuals at risk of spreading HIV infections. However, because of the critical nature of HIV tests and the potential impact of an erroneous HIV test result, it is essential that the results be accurate to ensure appropriate actions are taken for prevention, intervention, and patient treatment. For example, it is essential that testing not only be accurately performed, but also confirmatory testing and appropriate counseling and other services be provided. Even in the absence of new second-generation rapid HIV tests, HIV tests are currently being performed expeditiously to meet the needs of potentially unknowing HIV-infected persons such as pregnant women, newborns, health care professionals, and rape survivors.

Question 6:

How many HIV-infected Americans that did not return for their HIV test results potentially could have been notified and linked to care if these tests would have been made available at the same time they were approved in Europe?

Response:

CDC's HIV counseling and testing program has data from publicly funded HIV counseling and testing sites, which estimate about how many persons getting tested at those sites are not learning their results. The data from the CDC program have shown that many positive tests do not have documentation of post-test counseling and, therefore, many persons may not receive their results. For example, in 2000, of 15,037 HIV-positive tests (from persons who had not previously tested positive), 4,617 or 31 percent did not have documented return for post-test counseling. Some of those who did not get post-test counseling may get their results through other means, such as follow-up by the health department. However, many do not get their results, and increased use of rapid tests could help to improve this situation. (These data do not include settings outside the publicly funded sites, such as private practitioners and hospitals where people are getting tested and do often learn their test results.)

Foster, Roland

From: Foster, Roland
Sent: Thursday, August 22, 2002 4:43 PM
To: 'JYost@cms.hhs.gov'
Subject: HIV Testing and Lack of Rapid Tests

August 22, 2002

Dear Ms. Yost,

I am forwarding to you a study published today that finds nearly all (93 percent) of young gay black men with HIV are unaware that they are infected. This is despite hundreds of millions of dollars spent by the federal government over two decades to promote HIV testing. Clearly the HIV testing approach as it now exists in the United States has failed this very vulnerable population. Unless these individuals are diagnosed, they will be denied the treatment that can keep them healthy and alive as well as the counseling and education that may help them from unknowingly placing other at risk for HIV.

This study emphasizes that the situation in this regard is not only a problem, it is an emergency, a crisis.

Every day that passes without the approval of a rapid HIV test with a CLIA waiver that enables the test to be taken to the community-- to meet those at risk where they are-- more of these young men will become infected and denied needed medical care. Every day of delay is another lost opportunity to intervene and save lives.

Please share this study with your colleagues that are responsible for making this decision that is the equivalent of life or death for so many.

I look forward to hearing from you as to why these tests should not be approved with a CLIA waiver as recommended by the Presidential Advisory Council on HIV and AIDS, the National Alliance of State and Territorial AIDS Directors and many AIDS advocacy organizations.

Roland Foster
Subcommittee on Criminal Justice, Drug Policy and Human Resources
U.S. House of Representatives
(202) 225-2577

***

"Of young BMSM [study] participants who were infected with HIV, nearly all were unaware of their infection. Few young BMSM reported testing frequently for HIV, and many reported engaging in behaviors that could transmit HIV because they perceived themselves or their partners to be at low risk for infection."

The report notes "The incidence of human immunodeficiency virus (HIV) infection among young black men who have sex with men (BMSM) is among the highest of all risk groups in the United States. ... The findings in this report are consistent with previous studies suggesting that in several U.S. cities, the majority of young HIV-infected MSM, particularly BMSM, were unaware of their infection. In a preliminary analysis of 573 HIV-infected MSM aged 16--29 years sampled in six U.S. cities, proportionally more BMSM were unaware of their infection than were white MSM (91% versus 60%). However, among all young MSM with unrecognized HIV infection, no racial or ethnic differences were observed among those perceiving themselves at low risk for being infected (66%), engaging in UAI (54%), or not using condoms during anal intercourse because of perceived low personal or partner risks for HIV infection (46%). **These findings underscore the urgency of improving HIV-prevention efforts for all young MSM by 1) increasing the demand for and availability of HIV-testing services and 2) providing young MSM with high-quality HIV- and STD-prevention services that include assessment and clarification of personal risks for infection."**

The report is available on-line at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5133a1.htm.

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Blood Test to Detect HIV in 20 Minutes Nears Approval

By CHARLES ORNSTEIN
TIMES STAFF WRITER

September 28 2002

Federal regulators are expected to give final approval soon to an easy-to-use finger-prick blood test that can diagnose HIV infection in 20 minutes. The action will come more than four years after public health officials declared the urgent need for such a tool.

People familiar with the approval process say the Food and Drug Administration has resolved lingering technical and manufacturing issues that have held up approval.

AIDS advocacy groups have accused the FDA of dragging its feet while reviewing tests that have been proved extremely accurate and used in 90 other countries. Some of the proposed blood tests are as easy to use as a home pregnancy test or blood sugar monitors for diabetics.

The test proponents say the delays have endangered the public's health because nearly a third of those who test positive for HIV each year never return to find out their results, which can take as long as two weeks to process. When that happens, infected people go untreated and spread the virus unwittingly to others.

"The potential for saving lives by using this technology, we think, is revolutionary," said Clint Trout, associate director of federal government affairs for Los Angeles-based AIDS Healthcare Foundation. "We think that the rapid test could be for prevention what protease inhibitors have been for treatment."

FDA officials declined to comment on their timeline. The agency granted preliminary approval in May to two rapid HIV tests, pending inspections of manufacturing plants and approval for the products' labeling.

It is not clear when the approval announcement will be made but some people familiar with the process say it could come within the next two weeks.

The first test slated to be approved is OraQuick, manufactured by OraSure Technologies of Bethlehem, Pa., people familiar with the process said.

When the test detects the presence of HIV antibodies, it displays two red bars on a small strip enclosed in plastic. The device is designed for just one use, and the company has not disclosed its price.

With approval near, the debate has shifted to a separate issue that could determine whether the rapid HIV test is widely used.

AIDS activists and public health experts want the federal government to waive requirements that the tests be performed only in technically sophisticated labs.

Though not advocating home use, those advocates say they want the test to provide quick results to sex-club visitors, homeless people at shelters and emergency room patients. Those target populations are among the most likely not to return for their results after they are tested.

Supporters also want to offer rapid tests to late-term pregnant women. If a woman tests positive for HIV before or during delivery, she and her baby can be treated with medications, reducing the chances of transmitting the virus by two-thirds or more.

The military is interested in using rapid HIV tests on the battlefield. When there are many casualties, doctors often request immediate blood donations from fellow soldiers, and there's little time to test for infections.

Despite these arguments, an advisory panel to the FDA has recommended that the government require the tests be performed at sophisticated laboratories. The panel found that untrained personnel often fail to follow manufacturers' test instructions and may lack the skills to interpret the results.

"Until it can be demonstrated that individuals performing this test out on the street have a significantly high degree of accuracy in performing the test, the potential danger to the person being tested is simply too high at this point," said Dr. Jared Schwartz, a pathologist and spokesman for the College of American Pathologists, a medical specialty society that also accredits labs.

Dr. Nelson Michael, a strong backer of rapid tests, disagrees with that reasoning.

"These tests are ridiculously simple," said Michael, chief of molecular diagnostics and pathogenesis at Walter Reed Army Institute of Research. "You basically defeat that ease of testing if you demand that the test be executed in sophisticated laboratories."

The Centers for Disease Control and Prevention has been seeking advice from both sides on ways to allow widespread use of the tests while ensuring accurate results, said Dr. Bernard Branson, a medical epidemiologist with the agency. The agency held a conference in Atlanta earlier this month to discuss the topic.

The stakes are high. Each year, more than 20 million people are tested for HIV, including 2 million in publicly funded clinics. Federal health officials estimate that 40,000 people contract the virus each year, and 900,000 people are living with it.

The standard test for HIV, known as ELISA, takes a minimum of five hours to process, and sometimes as long as overnight. But because the test often is sent to labs--where it is run in batches--results often are not available for days or even weeks.

Both with ELISA and the new rapid test, a person may be infected for several months before producing enough HIV antibodies to show a positive result.

The CDC estimates that about 9,600 HIV-positive people do not return to the publicly funded sites for their test results each year, in addition to about 860,000 people annually who test negative but don't find out. In many cases, test takers are not required to provide their identity or a way to reach them.

"There's a missed opportunity, both in terms of people being aware of their status and informing their partners," said Michael Montgomery, director of the office of AIDS within the California Department of Health Services.

A presidential advisory council and even some members of Congress have grown restless that test approval has taken so long.

"We have an FDA that is a bureaucracy that is totally uncontrolled," said former Rep. Tom Coburn, a physician who chairs the Presidential Advisory Council on HIV/AIDS. "Bureaucrats never take a chance to do something right. They always take a chance to protect their own backside."

Dr. Elliot Cowan, a senior regulatory scientist at the FDA, said his agency is "working on it as fast as we can.... It would be far worse in my mind, at least, to approve a product and then have it fail once it reaches the marketplace," Cowan said.

In their defense, federal officials point to British Columbia, Canada, where rapid testing was halted this April because of concerns that test kits provided negative results to people who actually had HIV.

An official at OraSure said he understood the reasons for the lengthy approval process.

"They have a regulatory protocol that needs to be followed, and they are following that," said Ronald H. Spair, the company's chief financial officer. "I can't characterize anyone as stonewalling this."

Once its OraQuick product is approved, the company wants to conduct studies on a rapid test using oral fluids instead of blood. Other companies want to manufacture rapid tests based on urine.

Technically, OraSure's product won't be the first rapid HIV test in the United States. Since 1993, Abbott Diagnostics has sold a test that can provide HIV results within 20 minutes. But advocates and public health experts say the test isn't very useful because it requires cold storage before use and is labor-intensive to perform.

Abbott has developed an easier-to-use rapid test, called Determine, which is manufactured and widely used outside the United States, but the company has not sought approval to sell it here. It is partnering with OraSure to distribute the OraQuick test here.

MedMira Inc., based in Canada, had expected the go-ahead a year ago. Instead, it received its preliminary approval in May, and officials are still waiting for the green light. The entire research and development staff is now devoted to working with the FDA to answer remaining questions.

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U.S. Food and Drug Administration
FDA News

Department of Health and Human Services

FOR IMMEDIATE RELEASE
P02-49
November 7, 2002

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA APPROVES NEW RAPID HIV TEST KIT

HHS Secretary Tommy G. Thompson today announced that the U.S. Food and Drug Administration has approved a new rapid HIV diagnostic test kit that provides results with 99.6 percent accuracy in as little as 20 minutes.

Using less than a drop of blood collected, this new test can quickly and reliably detect antibodies to HIV-1, the HIV virus that causes infection in most cases in the U.S. Unlike other antibody tests for HIV, this test can be stored at room temperature, requires no specialized equipment, and may be considered for use outside of traditional laboratory or clinical settings. The newly approved HIV test is called The OraQuick Rapid HIV-1 Antibody Test, manufactured by OraSure Technologies, Inc., Bethlehem, Pennsylvania.

"Each year, 8,000 HIV-infected people who come to public clinics for HIV testing do not return a week later to receive their test results," Secretary Thompson said. "With this new test, in less than a half an hour they can learn preliminary information about their HIV status, allowing them to get the care they need to slow the progression of their disease and to take precautionary measures to help prevent the spread of this deadly virus."

To perform the test, a fingerstick sample of blood is collected from an individual and transferred to a vial where it is mixed with a developing solution. The test device, which resembles a dipstick, is then inserted into the vial. In as little as 20 minutes, the test device will indicate if HIV-1 antibodies are present in the solution by displaying two reddish-purple lines in a small window on the device. Although the results of rapid screenings will be reported in point-of-care settings, as with all screening tests for HIV, if the OraQuick test gives a reactive test result, that result must be confirmed with an additional specific test. The OraQuick test has not been approved to screen blood donors.

FDA currently categorizes the OraQuick test as "moderate complexity" under the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Under CLIA, new tests are categorized as either moderate or high complexity. This designation means that the OraQuik test can only be given in CLIA-approved labs by CLIA-certified laboratory technicians or medical staff. If the test manufacturer applies for a CLIA waiver, the FDA can evaluate it for use under less stringent conditions.

"I strongly urge the OraSure company to apply for a CLIA waiver," said Secretary Thompson, "If the FDA finds that the company's data proves that the OraQuick test is both easy and safe to use, it can get a CLIA waiver. Then the test could be given in many more health care settings, perhaps even administered by social workers in HIV counseling

centers. But the process can't begin until OraSure applies for the waiver, so I ask them to please apply now!"

The Centers for Disease Control and Prevention (CDC) has estimated that one fourth of the approximately 900,000 HIV-infected people in the U.S. are not aware that they are infected. Because of the potential public health benefits of rapid HIV testing, the CDC and the Centers for Medicare and Medicaid Services (CMS) are working with state and other health officials to make the test widely available and to offer technical assistance and counseling training for its use.

"This test will be a great help in identifying pregnant HIV-infected women going into labor who were not tested during pregnancy so that precautionary steps can be take to block their newborns from being infected with HIV," said FDA Deputy Commissioner Dr. Lester M. Crawford. "It will also be a critical resource in helping identify HIV infection in health-care and emergency workers who are accidentally exposed to HIV-infected blood while doing their job."

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THE STATE

Implementation of Rapid HIV Test Off to Slow Start

advertisement

Officials blame the state's strict guidelines for delays in switching to the new procedure.

By Daniel Costello
Special to The Times

October 29, 2003

Nearly a year after the Food and Drug Administration approved a highly anticipated rapid HIV test, fewer than a dozen sites in California are offering the screening exam, which offers results in 20 minutes.

AIDS advocacy groups and health officials, who had hoped to have many more test locations running by now, say strict state testing guidelines and confusion about how to implement the test have limited its introduction in California.

The test's slow arrival is frustrating doctors and patients. A major concern is that up to a third of people who undergo traditional HIV tests, which can take up to two weeks to process, never come back for their results and may go on and infect others. The rapid test allows people to learn their HIV status in the same visit and receive counseling and treatment quickly, if needed.

"I think many people had hoped this would go a bit more smoothly, especially considering how long we've waited for this to arrive," Karen Mall, director of prevention services for the AIDS Healthcare Foundation in Los Angeles, said of the new test.

In several instances, officials aren't advertising what sites are conducting the new test for fear of being overrun with patients.

At the heart of the problem, state health officials say, is the fact that California has some of the most stringent regulatory testing guidelines in the country.

Federal regulations require that any site offering blood tests outside of traditional laboratory settings apply for a waiver to U.S. rules. In addition to those federal rules, California requires test givers to have at least a high school diploma and go through more extensive training than the federal government requires.

Many of the people expected to administer the rapid test are now HIV counselors who often have little

or no experience administering blood tests. Most of them have worked with tests that use only an oral swab instead of blood, and haven't had to deal with many of these state and federal rules before.

"It's been a little confusing figuring out how this test fits in with our current system and all the rules that surround it," said Deanna Sykes, who has overseen implementation for the state's Office of AIDS.

The new test, conducted with a relatively easy finger prick, is expected to be available eventually at many local social service organizations, as well as on mobile vans and at sites such as bathhouses frequented by people considered at high risk for contracting HIV.

However, a pilot program the state planned to introduce at 11 sites in late May began at only four locations because the testing sites weren't prepared in time. Officials said the sites that did not make it into the pilot program did not have enough measures in place to guarantee the test's safety and accuracy.

Recently, Los Angeles County's separate proposal for 26 testing sites was held up for several weeks because officials at the state Department of Health Services, which must approve all waivers, said they were unsure if the county's application was technically valid since it lumped together all 26 on one application. After checking with federal officials, the state health department decided it was all right. But it still could be months before counselors at all the Los Angeles-area sites are trained to administer the tests.

State health officials say they are working to ease the initial logjams facing new testing sites. By processing waivers more quickly and offering training seminars, they hope that the rapid test could be available at as many as 700 sites statewide by next summer.

"In the big picture, we're dealing with this as quickly and efficiently as we can," said Paul Kimsey, assistant director of the state health department's laboratory field services office.

Nationally, although California once led the country in the push for the rapid HIV test, state and federal health officials now estimate it is somewhere in the middle of the pack in relation to other states' implementation schedules. New York, for example, began rapid testing in April, and now has it at more than 50 sites throughout the state. Wisconsin has roughly the same number of rapid testing sites up as California, although it has just a seventh the population.

(Some private doctors' offices in many states may be using the rapid test already but health officials are not tracking them.)

Even before the recent delays in California, the rapid HIV test clocked a glacial pace before finally hitting the market last fall.

AIDS advocacy groups protested for years that the federal government was dragging its feet on approving the test. They suggested that was because traditional laboratories are expected to lose significant revenues once rapid tests are more widely available. Several AIDS groups in California have suggested that resistance by labs influenced the state — and its scientists who review test waivers — to go slowly. The department denies that charge.

The rapid HIV test is a cornerstone of the federal government's new AIDS prevention strategy announced by the Centers for Disease Control last spring. The agency estimates that up to a quarter of the nearly 1 million people in the U.S. living with HIV don't know they have the disease.

In California, questions remain about the potentially large costs to train test givers. Those expenses

could be especially hard on small community-based organizations already under budget constraints.

The state Legislature is expected to consider a bill early next year that would condense some of the training into one session as a way to alleviate some of the costs.

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U.S. Food and Drug Administration
Department of Health and Human Services

FDA News

FOR IMMEDIATE RELEASE
P04-36
March 26, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA Approves First Oral Fluid Based Rapid HIV Test Kit

FDA today approved the use of oral fluid samples with a rapid HIV diagnostic test kit that provides screening results with over 99 percent accuracy in as little as 20 minutes. Until now, all rapid HIV tests required the use of blood in order to get such rapid results.

The original version of this rapid test -- the OraQuick Rapid HIV-1/2 Antibody Test, manufactured by OraSure Technologies, Inc., Bethlehem , Pa. -- was approved November 7, 2002 for detection of antibody to HIV-1 in blood. On March 19, 2004 , FDA approved the test for detection of HIV-2 (a variant of HIV that is prevalent in parts of Africa but rarely found in the United States) in blood. Today's approval represents another significant new use for the test. As when used on blood, this test can quickly and reliably detect antibodies to HIV-1 and can be stored at room temperature and requires no specialized equipment.

"Before the approval of this rapid test in November, 2002, many people being tested for HIV in public clinics did not return for the results of standard tests," said HHS Secretary Tommy G. Thompson. "Where the rapid test is available, those tested get their results within minutes. This oral test provides another important option for people who might be afraid of a blood test. It will improve care for these people and improve the public health as well."

To perform the test, the person being tested for HIV-1 takes the device, which has an exposed absorbent pad at one end, and places the pad above the teeth and against the outer gum. The person then gently swabs completely around the outer gums, both upper and lower, one time around. The tester then takes the device and inserts it into a vial containing a solution. In as little as 20 minutes, the test device will indicate if HIV-1 antibodies are present in the solution by displaying two reddish-purple lines in a small window on the device.

Although the results of rapid screenings will be reported in point-of-care settings, as with all screening tests for HIV, if the OraQuick test gives a reactive test result, that result must be confirmed with an additional more specific test. The OraQuick test has not been approved to screen blood donors. Although the test is approved to detect antibodies to HIV-1 and –2 when used on blood, today's approval of the test for use on oral fluid is limited to detection of antibodies to HIV-1.

The OraQuick Rapid HIV-1/2 Antibody test for use on blood was categorized as a waived test under CLIA (Clinical Laboratory Improvements Amendments of 1988) in January, 2003. A waived test system can be given in facilities with any CLIA certificate, rather than only in facilities certified for higher complexity tests. As such, a test categorized as a waived test can be used in many more health care settings by many different health providers.

All new test systems are categorized as high complexity systems until they are submitted for categorization under CLIA.

"I strongly urge the OraSure company to apply for a CLIA waiver for this test using oral fluid samples as well," said Acting FDA Commissioner Lester M. Crawford, D.V.M., Ph.D. "If the FDA finds that the company's data proves that the OraQuick test used with oral fluids is both easy and safe to use in the waived lab setting - as it is with used with blood - then more people will likely be tested for HIV infection. In addition, any risk to healthcare workers of performing the test will be greatly reduced since they will not be exposed to blood."

The Centers for Disease Control and Prevention (CDC) has estimated that one fourth of the approximately 900,000 HIV-infected people in the U.S. are not aware that they are infected. Because of the potential public health benefits of rapid HIV testing, the CDC and the Centers for Medicare and Medicaid Services (CMS) have worked with state and other health officials to make the test widely available and to offer technical assistance and training for its use.

Reuters Health
April 26, 2005

Many HIV-Positive Gay Men Unaware They're Infected

By Amy Norton

A new study found that of approximately 5,600 gay and bisexual men ages 15-29, more than three-quarters of those testing HIV-positive were unaware they were infected. In fact, before testing, a majority of the infected men believed they were at low HIV risk even though half reported having unprotected sex with another man in the previous six months.

Such findings suggest the epidemic "continues unabated" among gay and bisexual men, partly because many are unaware of their infection, said authors.

The high rates of unknown HIV infection, in turn, reflect that many gay and bisexual men were not testing regularly for the virus, said lead author Duncan A. MacKellar of CDC. While many of the men did test, few did so regularly, and only a minority of the newly diagnosed men had tested within the previous year. The reasons why are unclear but may reflect the men's perception that they were at low risk for HIV, he said. Limited health care access and fear of testing positive might also be contributing factors, MacKellar said study findings suggested.

Current guidelines recommend that people at risk of HIV be tested for it and other STDs at least once a year.

The men were from six US cities, recruited for the survey through various venues, including bars, parks, cafes, and shops. A total of 10 percent tested HIV-positive, of whom 77 percent were unaware they were infected. Due to the recruitment method, the figures are probably unrepresentative of US gay and bisexual men. Prior household-based research found lower rates of unrecognized infection.

Nonetheless, the fact that so many of the men did not know they had HIV "underscores the urgency" of increasing HIV testing among young men who have sex with men, said MacKellar.

Study authors recommended expanding rapid HIV testing at venues such as bars and clubs to reach men with undiagnosed HIV infection. In addition, it is key that individual doctors routinely recommend HIV testing to at-risk patients, said MacKellar. "CDC is working with providers to make HIV testing a more routine part of health care," he said.

The full report, "Unrecognized HIV Infection, Risk Behaviors, and Perceptions of Risk Among Young Men Who Have Sex with Men," was published in the Journal of Acquired Immune Deficiency Syndromes (2005;38(5):603-614).

Atlanta Journal-Constitution
Tuesday, June 14, 2005

Quick results up number of people getting HIV test

Patricia Guthrie - Staff

A new quick-response test has more than doubled the number of metro Atlantans testing for the AIDS virus at one of the city's first clinics to offer it.

AID Atlanta, a nonprofit organization based Midtown, says the 20-minute oral test, in use since October, has dramatically increased the number of people wanting to know their HIV status. The older method required drawing blood and took up to two weeks for results.

"Because of the anxiety level and the anticipation of waiting a week, many people didn't want to get tested before, or they didn't show up for results," said Raphael Holloway, prevention programs manager. "We had a huge rate of no-shows before. Now we virtually have no no-shows."

The first rapid test required a finger prick to draw a drop of blood. But last year, a new test using a mouth swab was approved for use. The swab sits in a solution for about 20 minutes and then changes color to indicate a positive or negative result, much like a home pregnancy test. The test indicates antibodies to the AIDS virus. If the result is positive, a second test, called OraSure, is given and sent to a laboratory for confirmation.

The testing also includes extensive counseling on how people can reduce risky behaviors that may lead to AIDS. The Atlanta-based Centers for Disease Control and Prevention is training health professionals and others in how to properly use the rapid test, and it funds many test sites.

The rapid oral HIV test, called OraQuick, is also offered at the AIDS Survival Project, a nonprofit agency near downtown, and at Our Common Welfare, an advocacy health organization in Decatur that is just starting to take the test to the homeless.

County health departments have used the rapid test for several months on a limited basis as their staffs are being trained.

At all sites, test takers can remain anonymous. The test is either free or offered for a small fee.

About one in every four Americans with HIV are unaware that they have the disease --- a longtime statistic that health officials hope to change with rapid testing.

In April, 364 people took the new test at AID Atlanta, compared with the 136 who sought the old test in April 2004. The rate of positive results remained about the same in both years: 4 to 6 percent.

AID Atlanta volunteers have taken the new method of testing on the road. Its convenience, portability and low-tech application make it much easier to offer at health fairs, college campuses and churches, Holloway said.

Greg Smith, director of prevention services at the AIDS Survival Project, said the new test is proving effective in many ways.

"We're reaching the priority groups, African-American men and women," Smith said.

Additionally, the test is attractive to couples. "They show each other their test results in the hallway," Smith said. "Girlfriends and boyfriends, husbands, wives, partners wanting to keep their relationship on the level. There's people taking responsibility. They're taking the test seriously."

Atlanta's experience mirrors data presented Monday at the CDC's 2005 National HIV Prevention Conference, which continues through Wednesday.

In New Jersey, the number of people seeking the rapid test increased 135 percent during a three-month, $2 million publicly funded awareness campaign, said Dr. Sindy Paul, medical director of the New Jersey Department of Health.

In Georgia, 25,548 cases of AIDS have been reported since 1981; 14,921 have died of it.

(9) Hold Harmless

A "hold harmless" provision was created in Title I of the Ryan White CARE Act in 1996 to ensure that eligible metropolitan areas (EMAs) do not experience large decreases in funding from year to year. This hold harmless has largely benefited only one EMA.

During each of the previous two reauthorizations, efforts have been made to address inequities caused by the hold harmless. However, the San Francisco EMA continues to receive nearly twice the amount of CARE Act funding per AIDS case as every other EMA. The amounts used to finance the city's hold harmless funding are siphoned away from supplemental grants intended to assist EMAs that can demonstrate a severe need that requires additional resources.

United States General Accounting Office
Washington, DC 20548

Health, Education, and
Human Services Division

B-286131

August 24, 2000

The Honorable Tom A. Coburn
Vice Chair
Subcommittee on Health and Environment
Committee on Commerce
House of Representatives

Subject: Ryan White CARE Act: Title I Funding for San Francisco

Dear Mr. Coburn:

This letter responds to your request for additional information regarding funding for San Francisco under the Ryan White CARE Act. Specifically, you asked that we compare San Francisco's fiscal year 2000 title I grant award, which was determined using the act's hold-harmless provision,[1] with what the award would have been had deceased AIDS cases been included in the calculation. You also asked how funding for San Francisco that was based on the inclusion of deceased AIDS cases would have compared with the amount San Francisco would have received if the fiscal year 2000 hold-harmless level had been reduced by 25 percent.[2]

In brief, San Francisco's fiscal year 2000 title I grant award would have been 26 percent less had both living and deceased AIDS cases been used to calculate the award instead of the current hold-harmless provision. The reason for this result is the substantial decline in newly reported AIDS cases in San Francisco compared with other eligible metropolitan areas (EMA). Therefore, a 25-percent reduction in the current hold-harmless level would have provided San Francisco with funding comparable to what it would have received if title I grants had been calculated on the basis of both deceased and living cases.

[1]The hold-harmless provision limits the amount that the funding of an eligible metropolitan area may decline from its fiscal year 1995 level. From fiscal year 1996 through fiscal year 2000, eligible metropolitan areas were guaranteed that their funding would not decline more than 5 percent below their fiscal year 1995 level.

[2]Under H.R. 4807, The Ryan White CARE Act Reauthorization Act for 2000, the hold-harmless level would be reduced by 25 percent over 5 years.

This analysis is based on data obtained from the Centers for Disease Control and Prevention and computer models we developed to calculate how funding would change under various formula scenarios. We performed our work in August 2000 according to generally accepted government auditing standards.

BACKGROUND

The Ryan White CARE Act of 1990 provides health care and preventive services to people infected with the human immunodeficiency virus. Prior to the 1996 reauthorization of the act, the number of both living and deceased AIDS cases was used to distribute title I funds among EMAs. Under this practice, areas of the country with the longest experience with the disease had the most deceased cases and therefore received funding disproportionate to their share of living cases in need of care. The 1996 reauthorization eliminated this practice by counting only live AIDS cases.[3] The effect of the change was to shift funding away from EMAs with higher proportions of deceased cases and toward those with newly diagnosed cases. As geographic trends in the disease change, the revised formula automatically realigns funding with the current distribution of the disease.

A hold-harmless provision was also included in the 1996 reauthorization to provide for a gradual transition to new funding levels for those EMAs that would otherwise have experienced substantial funding decreases. This provision allowed grant awards for affected EMAs to decline by no more than 5 percent by fiscal year 2000. In fiscal year 1996, four EMAs benefited from the hold-harmless provision: San Francisco, New York, Houston, and Jersey City. By fiscal year 1999, all but San Francisco had made the transition to the new formula.

Under the current title I formula, EMAs receive grant awards that are proportional to the number of living AIDS cases. In fiscal year 2000, Los Angeles had 6.9 percent of all AIDS cases nationally and received 6.7 percent of title I funding. Similarly, Miami had 4.4 percent of all AIDS cases and received 4.3 percent of title I funding. EMAs received $1,290 in title I funds per AIDS case in fiscal year 2000. However, because of the hold-harmless provision, San Francisco's grant award was substantially higher: it received $2,360 per AIDS case, or 80 percent more than other EMAs. As a consequence, San Francisco received 6.7 percent of title I formula funding even though it had just 3.8 percent of all living AIDS cases.

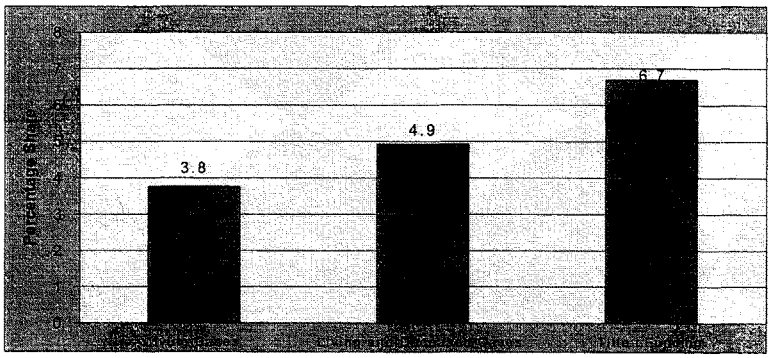
RESULTS OF DIFFERENT FUNDING APPROACHES

If both deceased and living AIDS cases had been used to calculate fiscal year 2000 title I formula grants instead of the hold-harmless provision, San Francisco's grant would have been about 4.9 percent of all title I formula funding, or 26 percent less than it actually was (see fig. 1). Thus, a 25-percent reduction in the current hold-harmless level, as provided for in H.R. 4807, would have an effect on San Francisco's

[3]The 1996 reauthorization also eliminated an AIDS prevalence factor from the calculation of the award. This factor had had the effect of targeting additional aid to EMAs like San Francisco, which had high AIDS prevalence rates as well as large numbers of AIDS cases.

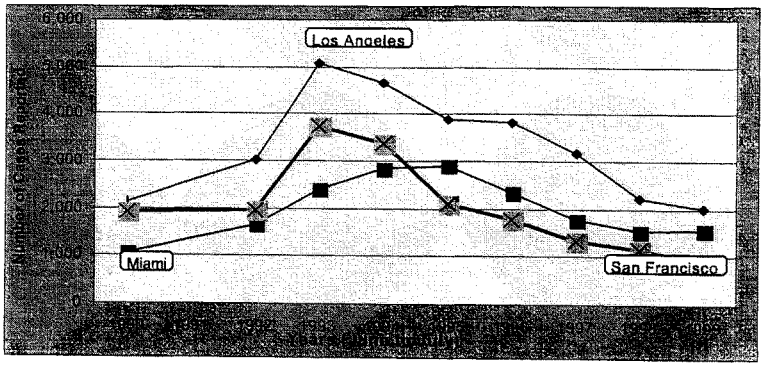
funding similar to that of calculating grant awards on the basis of both deceased and living cases.[4]

Figure 1: San Francisco's Share of AIDS Cases and Its Share of Title I Funding, FY 2000



An important reason that San Francisco's share of living AIDS cases is so much lower than its share of title I formula funding is that the rate of new cases has declined to a much greater extent in San Francisco than in almost any other area of the country. As figure 2 shows, San Francisco's newly reported AIDS cases dropped by over 50 percent between 1990 and 1999, while other EMAs have shown either smaller declines (Los Angeles) or increases (Miami).

Figure 2: Reported AIDS Cases in San Francisco, Los Angeles, and Miami, 1990-99



At the start of the decade, Los Angeles and San Francisco were reporting nearly the same number of new AIDS cases (2,130 in Los Angeles and 1,923 in San Francisco). By the end of the decade, San Francisco was reporting half as many new cases as Los

[4]H.R. 4807 provides for a 25-percent reduction in the hold-harmless level over 5 years.

Angeles (904 compared with 2,027). Similarly, at the start of the decade, Miami was reporting about half as many new AIDS cases as San Francisco (1,076 in Miami compared with 1,923 in San Francisco). By the end of the decade, Miami was reporting about 70 percent more new cases than San Francisco.

We did not obtain comments from other parties because your request pertains to the formula provisions in the law and not to the activities of any agency or organization.

If you have any questions regarding this letter, please contact me at (202) 512-7118 or Jerry Fastrup at (202) 512-7211. Greg Dybalski and Michael Williams made major contributions to this work.

Sincerely yours,

Janet Heinrich
Associate Director, Health Financing and
Public Health Issues

(201097)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

HIV/AIDS Bureau

Rockville MD 20857

SEP 12 2002

The Honorable Mark E. Souder
House of Representatives
Washington, D.C. 20515

Dear Mr. Souder:

This is in response to an August 7 e-mail from Mr. Ronald Foster of your staff on the Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources, to the Division of Service Systems expressing concern about a $1.68 million carry-over request that is forthcoming from the San Francisco Eligible Metropolitan Area (EMA) Title I grantee. In his message he asked why the EMA has this amount available from fiscal year (FY) 2001, given national funding shortfalls in AIDS Drug Assistance Programs (ADAP) and the ongoing housing crises within the San Francisco EMA. He also requested information about the amount of carry-over the EMA has requested in the last three fiscal years.

According to Public Health Service Grants management policy, grantees may request carry-over of funds from a previous fiscal year provided that the funds were not restricted. The grantee must notify the Grants Management Office (GMO) of its intention to carry funds forward to the current budget period and provide documentation of the amount available for carry-over on its current Financial Status Report (FSR). In addition, Title I grantees must provide to the Health Resources and Services Administration (HRSA) a rationale for the request and satisfactory justification for the proposed use of the funds. This justification must explain how the intended use of funds is connected to current service priorities of the EMA. Requests are approved based upon this information, the history of expenditures and carry-over requests, current compliance with conditions of award, and an approval of a final FSR. Funds cannot be used for administrative responsibilities of the grantee.

With regard to the $1.68 million forthcoming carry-over request, HRSA has not received a request from the San Francisco EMA for carry-over for this fiscal year. The GMO has confirmed that the EMA does have approximately $1.68 million available from FY 2001 for carry-over into FY 2002. This amount is approximately 4.7 percent of the San Francisco EMA's FY 2001 total award. Over the past three fiscal years the EMA has requested the following carry-over amounts: FY 98-$1,540,560; FY 99-$643,625; and FY 2000-$885,428.

With regard to the use of carry-over for national ADAP shortfalls, since ADAP is funded under Title II, Title I funds cannot be used for this purpose. With regard to the use of carry-over funds to address the housing crises in the San Francisco EMA, carry-over funds could

be used to cover transitional housing services if there is an identified need for additional funding in this service area.

I hope this information is helpful. If you or Mr. Foster have any further concerns, please contact Mr. Douglas Morgan, Director, Division of Services Systems, HIV/AIDS Bureau, Health Resources and Services Administration, Parklawn Building, Room 7A-55, Rockville, Maryland 20857, (301) 443-6745.

Sincerely,

Deborah L. Parham

Deborah L. Parham, Ph.D., R.N.
Associate Administrator

http://sfgate.com/cgi-bin/article.cgi?file=/c/a/2005/07/20/MNG8CDQMG31.DTL&type=health

San Francisco Chronicle

Wednesday, July 20, 2005

Large drop reported in HIV cases in S.F.
Feared second wave of infections appears to have crested

By Sabin Russell and Ilene Lelchuk

In a rare piece of good news on AIDS, San Francisco health officials may revise downward their estimates of the number of new HIV infections each year after three new analyses suggested that the spread of the virus in the city's gay community has slowed substantially.

Since 2001, the city's highly regarded epidemiology team has held to an estimate that more than 1,000 city residents are newly infected with the AIDS virus each year.

But last month, a federal study of HIV among gay men in five U.S. cities found that new infections in San Francisco were occurring at about half the rate recorded four years ago.

"This one (CDC) study has been quite an eye opener for us," said Dr. Willi McFarland, epidemiologist for the San Francisco Department of Public Health's Office of AIDS.

The study by the national Centers for Disease Control and Prevention used survey methods considered state of the art in disease surveillance. Based on a sample of 365 gay men tested in the city, the study found that men were becoming infected at a rate of 1.2 percent per year.

San Francisco epidemiologists had previously estimated an infection rate of 2.2 percent.

The startling new finding prompted McFarland's office to analyze other sets of data often used by the city to track the course of the epidemic. Two of them -- information collected by the city's Stop AIDS Project, and surveys of infection rates at city clinics -- pointed to a similar downward trend in new HIV cases.

City officials therefore are expected to convene within a month a panel of experts to consider lowering San Francisco's official estimate of annual HIV infections -- which would signal that the feared second wave of the epidemic detected in 2000 has crested without a return to the ghastly infection rates of 8.5 percent in the early 1980s. By 1988, half the city's gay male population was infected.

"HIV incidence among men who have sex with men in San Francisco appears to be decreasing," said city health director Dr. Mitch Katz.

The reasons for the apparent decline in new HIV infections may take years to understand, but Katz said the most likely explanation is that effective AIDS drugs have lowered the level of virus in those men who are HIV-positive and still having unprotected sex. Another possibility is that gay men are increasingly reserving the most risky behaviors, such as anal intercourse without a condom, for partners who are of the same sero-status -- a practice known as "sero-sorting." For example, HIV-positive men who sero-sort would have unprotected sex only with HIV positive partners.

"The message is that, overall, prevention is working," Katz said.

Gauging HIV infection rates is a notoriously difficult task, and since the beginning of the epidemic, scientists have had to pool data from multiple sources to make an educated guess. No single study, such as the CDC survey released last month, will do.

At the forthcoming HIV "consensus conference" in San Francisco, experts will consider at least 11 different indicators that the city regularly uses to track the course of the epidemic.

It was such a consensus conference in 2001 that set the city's estimated HIV rate at 1,048 new infections per year. Prospects now appear good that the estimate will be substantially reduced.

Even if further analysis confirms a lower infection rate, McFarland remains cautious.

"The incidence rate is still too high," he said. "There is a lot more work to be done. It's ground we lost when (HIV) resurged in the first place."

The CDC study, conducted in five major cities, was based on interviews with more than 1,764 men contacted at bars and dance clubs, sex clubs and gyms, and on the streets and in parks and shops. Participants included gay men in San Francisco, Los Angeles, New York, Miami and Baltimore. In addition to volunteering for blood tests, they were asked about their partners, where they met them, their drug usage and other questions.

City health officials were heartened by a finding in the CDC study that among the five cities surveyed, San Francisco had the lowest rate of gay men who were infected but didn't know it at the time of the study.

In Baltimore, for example, a startling 40 percent of men participating in the study tested positive, and 62 percent of them did not know they were infected when they volunteered to be tested. In San Francisco, by contrast, 24 percent of participating men tested positive, and only 23 percent of those did not already know it.

Overall, researchers found that nearly half the men who tested positive in the survey did not know they were infected -- prompting calls for increased efforts to encourage people to get the test.

According to McFarland, the city was due for a new consensus conference anyway, since the last one took place four years ago. Data from the city's sexually transmitted disease clinics, where infection rates are expected to be high and were 5.4 percent in 2000, have fallen to 3.2 percent. At a clinic that provides anonymous testing services, rates have fallen from 3.9 percent to 2.8 percent.

Surveys by the Stop AIDS Project show a significant trend toward greater use of sero-sorting, which reduces but does not eliminate the risk of transmitting or acquiring HIV. Since 2001, the percentage of HIV-positive men reporting having unprotected sex with HIV-negative men, or men whose status is unknown, has fallen to 21 percent from 31 percent. The percentage of HIV- negative men who have had unprotected sex with positive men, or men of unknown sero-status, has fallen to 4 percent from 20 percent.

Stop AIDS spokesman Jason Riggs attributed the apparent decline in HIV infection rates to efforts that focus prevention messages on men who are already positive, encouraging behaviors such as sero-sorting. Programs to discourage use of crystal methamphetamine may also be paying off in San Francisco, he said.

Studies show that men who use the drug are three to four times more likely to become HIV-positive. The drug promotes "disinhibition," causing users to be more likely to engage in risky sex.

"If we can reduce the numbers of men using and abusing crystal methamphetamine, we can reduce the number of new infections significantly," Riggs said.

E-mail the writers at srussell@sfchronicle.com and ilelchuk@sfchronicle.com.

(10) Submitted Testimony

the **Institute** *for* **Youth Development**

August 11, 2005

The Honorable Tom Coburn
United States Senate
172 Russell Senate Office Building
Washington D.C., 20510

Dear Senator Coburn,

Congratulations of having a hearing on the Ryan White Care Act, which clearly pointed out the disparity in distribution of funds and highlighted the need to bring equity to this program so that all who suffer from HIV disease can receive equal care. Having testified before Congress in the past on this issue I thought you might enjoy seeing my testimony from 1995 – over ten years ago – which essentially brings to light the same issues you raised. It is long past time to make the necessary changes to this Act, which have been so desperately needed for so long.

It is refreshing to see someone have the courage finally to do what is right, even though it may still not be politically correct to some in the AIDS establishment. Please feel free to call on us at any time for additional information.

Sincerely,

Shepherd Smith

Shepherd Smith

TESTIMONY
U.S. HOUSE OF REPRESENTATIVES
HEALTH SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
OF THE
COMMITTEE ON COMMERCE

By
W. Shepherd Smith
President
Americans for a Sound AIDS/HIV Policy

April 5, 1995

Thank you, Mr. Chairman and other distinguished members of this Committee, for the opportunity to appear before you once again. I would like to begin by congratulating Congressman Bliley for his efforts to have these hearings before rushing into a re-authorization of this act last year. The pressures on him to move forward quickly in the fall were ill advised and he showed considerable courage in standing up to often times unreasonable, if not unethical, lobbying tactics. The Republicans in the Senate should be congratulated, as well, for their effort to not re-authorize Ryan White in 1994.

The reason that it is critical that this important AIDS care Act be reviewed carefully is that it is fundamentally flawed in its present form. The basic error in the Act is in its formula for distribution of care dollars. It was based on AIDS prevalence, which is an accumulation of all AIDS cases from the beginning of the epidemic. As we know, unfortunately, about 60 percent of those individuals have died. Consequently, a disproportionate share of proceeds went to cities that had the earlier epidemics of HIV and AIDS, and did little for areas with rapidly growing new case loads.

You will hear significant amounts of data from the Government Accounting Office which has done an excellent job in evaluating where monies went under the old formula and what a redistribution of those dollars means to cities and states most impacted today. To illustrate the disparity in distribution of Ryan White dollars under the old formula, a city such as San Francisco received approximately $4,300 per case while an individual in Chicago received approximately $1,600, and some in rural areas of the country as little as $640 apiece. It is fundamentally unfair to have such significant disparities for people who are suffering from this disease since they all face substantial needs.

As the only AIDS organization which openly opposed Ryan White re-authorization in the form that was put forward last year, we would encourage this Committee to look carefully at suggested formulas since nearly anything can be done with numbers. The ideal way to distribute dollars would be to give aid to those people who are either HIV positive or have symptomatic AIDS who need care; i.e., those living with the disease today in need of care. However, that is quite difficult to do since as a nation we have focused very little on HIV disease, rather we've put the bulk of our attention on end-stage symptomatic AIDS. Even there our record keeping is something less than perfect in that

many people, perhaps as many as 10 to 20 percent of AIDS cases, go unreported for a number of reasons; and often where contact is lost with an individual they may have died but are still listed as people living with AIDS. Consequently, you're dealing with an inexact science that requires some healthy repair.

It is our suggestion that dollars be distributed to state public health departments for distribution based on HIV infections and AIDS cases that accurately reflect those people living with this disease today who have medical needs in their jurisdictions. This can be done by greater reporting of HIV and more medical/public health involvement of those suffering. This suggestion, of course, brings with it the combining of Titles I and II. I'd like to articulate now the benefits of combining these Titles and giving State Public Health Directors and their State AIDS Directors more flexibility in responding to this changing epidemic in their respective states.

The AIDS epidemic as we know it is changing dramatically. What was thought to be a disease of predominantly white gay men is rapidly and unfortunately becoming a disease of color. This last year over 55 percent of AIDS cases reported by the CDC were people of color. What is alarming about these numbers is the rapid increase in percentages within various racial and ethnic groups. For example, AIDS cases in 1994 within the African American Community grew by 3 percent of the total AIDS case reported, and now show that community over-represented in the epidemic by three times.

I would like to illustrate the dramatic disparity between the rates of AIDS cases in these two primary communities, the African American and the White community, as reported by the CDC last fall. The attached charts came out of the report that AIDS is now the leading cause of death among all men age 25 to 44. However, it is by far the leading cause of death among Black men and the second leading cause of death among White men in that age group. The graph illustrates a similar dramatic rise among Black women versus White women. I would like to also interject that this issue of dramatic disparity should come as news to no one since military data in the mid '80s, which was focused on HIV infections, showed that these trends would ultimately occur (even though at the time the ratio of Whites to Blacks was significantly greater in AIDS cases).

1985 to 1988 data showed that Black women in the armed forces had higher rates of HIV infection than White men; a time when most people believed this was nearly exclusively a White man's disease. The military data illustrates our need to look more closely at trends in HIV infections, which ultimately result in AIDS cases. By doing this we can plan much more effectively for future resource needs and changes.

The purpose in illustrating the differences in rates and the changing face of this epidemic is to say that within each state needs also change year to year. We are seeing right now, for example, the greatest increases in HIV infected infants occurring in the rural South rather than the Northeastern metropolitan areas. By combining Titles I and II it will allow states to better direct resources in response to the changing dynamics of the epidemics in their respective areas. It could be argued, in fact, that all Ryan White Titles be combined and dollars distributed on cases by state with little federal involvement. However, I think there are reasons why some small portion of dollars should have federal

control; so that efforts can be better coordinated at a national level for what is a series of regional epidemics that affect the entire nation as the epidemic spreads to new areas.

As you move forward in your consideration of Ryan White re-authorization we would encourage you to evaluate this special health issue funding in respect to all other health issues. We have set a precedent with this particular program that may or may not be applicable to long-range health care financing objectives. When the first Commission on HIV issued its report in June of 1988, it raised the question of the challenge posed by HIV in respect to financing. I'd like to include a quote from that valuable document:

> "The Commission believes that the financing issue is one of the most difficult problems of the HIV epidemic. It is not easy to answer the questions about treating AIDS and HIV infection apart from other devastating sicknesses and diseases. If we can make changes in our financing system, do we do it only for those with HIV or do we do it for everyone? Allocating limited healthcare resources when the needs are so great presents a significant challenge."

So we would, therefore, encourage the Committee to look at Ryan White re-authorization in respect to Medicare, Medicaid, Social Security Disability Income and other benefit plans that individual states have set up in respect to caring for those suffering from this disease. While we fully support re-authorization funding levels for this Care Act, we nevertheless feel it is important to evaluate this program in respect to other programs presently in place and those that may be anticipated in the future since this is a five year re-authorization measure. The reality is that there may be ways to enhance benefits for those who suffer from HIV and AIDS through other mechanisms and we would want the Congress to retain flexibility in being able to do that in the future; and to evaluate if this is a good model for other medical conditions, which it may well be.

In respect to funding levels I don't believe anyone in the AIDS community believes we will ever see the unprecedented growth in funding we saw under the Reagan and Bush Administrations. We do expect, however, to see the continued commitment from this Congress and Administration that this issue has received in the past. But funding should be based on realistic needs and should be in perspective to needs of all people with serious illnesses. We, therefore, encourage the Committee to fully fund Ryan White at its present suggested level, but in a way that creates greater equity to all in need and fundamentally embraces our fairness doctrine.

Fairness to Americans for a Sound AIDS/HIV Policy means that those individuals with needs receive benefits equally. This Congress has the opportunity to structure Ryan White re-authorization so that those with the greatest needs today are the primary beneficiaries. And it is a fact that those with the greatest needs today are individuals from communities of color. In respect to how this can best be done, we suggest the following:

(1) Base distribution of dollars by state on numbers of people living with HIV and AIDS who have care needs. This expanded definition to include HIV positive individuals who don't necessarily fit the AIDS case criteria will benefit

women and children who often receive substandard care because they don't meet present case definitions for AIDS. If states are unable to define, because of a lack of HIV reporting, those individuals who presently are living with HIV and AIDS who need care, then we would suggest the formula be based on the last two and on-half years of cumulative AIDS cases. We believe this would be a reflective number of total numbers of people presently living with HIV and AIDS.

(2) We are troubled by the double counting in respect to formulas and feel that by combining Titles I and II we can largely eliminate this measure in present Ryan White formula configurations.

(3) We would hope that dollars are distributed to locations where people are presently living with HIV and AIDS rather than to where they were originally diagnosed, as is part of the present Ryan White formula. As the epidemic changes in focus we may find that more people from city areas move back to their rural homes, particularly in the South, and that the needs would grow significantly there. Such a formula change would then incorporate our concept of fairness.

(4) We hope that added measures of means testing be applied to those receiving benefits. While the present formula does restrict benefits to a large degree, we believe it important that tighter measures be required so that dollars be given to those who truly need them and can't afford such benefits otherwise.

(5) Lastly, the program needs to be evaluated critically in respect to bureaucratic waste. Are there ways to reduce red tape and any excessive program costs so that more dollars can go to those in need and not to a bureaucratic infrastructure?

In conclusion, I would like to share a little from our experience in this epidemic. This past year we helped over 8,400 children and families affected by this disease in some way, making us one of the largest AIDS service organizations in the country, if not the largest. Most of our clients come from underserved communities and the most often heard complaint is that while funds are available to others, they often aren't to them. There is inequity today created by the Ryan White Care Act that must be changed. And we must remember that this epidemic itself is changing rapidly in composition. Any measure this Congress enacts must take into consideration the needs of those truly needy, the needs of those in communities of color, and the needs of women and children.

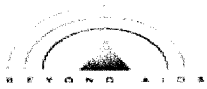
The benefit of our suggested expanded definition of AIDS including HIV positive individuals who have care needs combined with the formula change we hope will result ultimately in a decreasing epidemic. By giving greater focus to HIV rather than just end-stage disease AIDS we will ultimately be able to provide optimal medical care to those who need it and allow those infected to have the opportunity not to infect others. Because of our over focus on AIDS rather than HIV most people in the United States today who carry the virus are totally unaware that they are infected and most often have

no idea they have even been exposed to anyone infected. Consequently, we have an epidemic largely out of control, one which has the potential unfortunately to lead us soon to believe that this is a disease of color. The truth is that this is a sexually transmitted disease that will end up where all STDs end up and that's among sexually active young people of all races, particularly heterosexuals.

As the Committee formulates final language on this Act, I would like you to remember the first point of the Executive Summary of the Presidential Commission on HIV issued in June of 1988:

> "The term 'AIDS' is obsolete. 'HIV infection' more correctly defines the problem. The medical, public health, political, and community leadership must focus on the full course of HIV infection rather than concentrating on later stages of the disease. Continual focus on AIDS rather than the entire spectrum of HIV disease has left our nation unable to deal adequately with the epidemic. Federal and state data collection efforts must now be focused on early HIV reports, while still collecting data on symptomatic disease."

So while you are essentially focusing on care for those in end-stage disease, a careful restructuring of formulas and distribution of dollars will hopefully affect the course of this epidemic so that such funding can ultimately be eliminated entirely when this epidemic is eliminated from our country.
Thank you.



June 12, 2005
Reply to:
Beyond AIDS, Inland Empire
1540 Barton Road #435
Redlands, CA 92373

Honorable Senator Thomas Coburn, MD
United States Senate
Fax: (202) 224-6008
172 Russell Building
Washington, DC 20510

RE: Ryan White CARE Act Renewal: Important Recommendations to Improve the Control of HIV Transmission

Dear Senator Coburn:

We are writing on behalf of the Board of Beyond AIDS, to congratulate you for initiating hearings into how the Ryan White CARE Act can be improved in the 2005 renewal process, and **to provide you with five specific recommendations to Congress**. Beyond AIDS is a national non-partisan organization of health professionals and concerned citizens, dedicated to reversing the course of the HIV epidemic by implementing sound public health policy.

In the 2000 amendments, thanks in large part to your personal leadership, the Ryan White CARE Act incorporated wording that created a strong fiscal incentive to states to adopt HIV reporting that meets federal standards, no later than FY 2007. The only HIV state reporting systems that have been found adequate by the Centers for Disease Control and Prevention (CDC) are those of some 38 states, which use reporting by name. Beyond AIDS strongly supports name-based HIV reporting, not only to obtain accurate, timely, and unduplicated information on the progress of the epidemic, but because **the names reported can be used for life-saving preventive public health measures**.

1) MAINTAINING THE DEADLINE AND CONDITIONS FOR HIV REPORTING SYSTEMS:

It is of the utmost importance that the deadline for adequate HIV reporting be maintained, and that there be no softening of the requirement or the penalty for failure to comply.

During the past few months, Beyond AIDS was involved with a coalition of AIDS and public health agencies (including the California Health Officers Association, the County of Los Angeles, and the AIDS Healthcare Foundation), in a major effort to get an HIV reporting bill passed by the California Legislature. That bill, SB 945, was killed in committee by a handful of powerful state legislators, who challenged the resolve of Congress to maintain the HIV reporting requirement. They vowed not to permit an HIV reporting bill to pass in California unless Congress reaffirms the requirement and deadline of the 2000 amendments. This leaves California with a reporting system for HIV infections that have not progressed to AIDS, which requires secret 17-digit codes, which almost everyone (especially public health departments) admit does not work, and which is a barrier to partner notification and "prevention of positives."

The irony is that over 135,000 AIDS cases have been reported in California without a single breach of patient confidentiality or other problems. The distinction between AIDS and non-AIDS HIV cases in increasingly arbitrary; e.g., a patient with a CD4 count of 201 does not have AIDS, but if the count is 199 (which is within the margin of test error), AIDS is diagnosed.

Many of the AIDS organizations that joined in supporting the California HIV reporting bill did so only to assure continued Ryan White funding, because of the language in the 2000 amendments. They were betting that Congress would maintain its resolve, in contrast to the legislators who were betting against that. **But everyone agrees that California will remain without an adequate HIV reporting system unless the 2005 amendments maintain the requirement related to HIV reporting.**

2) DENIAL OF FUNDING TO ANY STATE THAT PROHIBITS LINKAGE OF REPORTING WITH PARTNER NOTIFICATION:

An alarming possibility developed during the development of the California bill. Until the last minute, the draft for SB 945 included wording that would have prohibited the names of reported HIV-infected persons from being used for any other purpose such as partner notification. No other states have adopted such language, but this type of legal provision could surface again in California or other states, and would be a terrible blow to public health. It would mean that a public health officer would know who was infected, but could not do any outreach or communication to help stop the chain of transmission, or even to refer patients to treatment services. **It is of great importance that this year's Ryan White renewal include a new amendment that denies all funding to any state that makes it illegal to use information from HIV prevention for partner notification or other prevention strategies.**

3) REQUIREMENT FOR CDC GUIDELINES ON LINKAGE OF REPORTING WITH PREVENTION SERVICES:

In addition, we strongly urge CDC be required to develop guidelines, to be issued no later than the beginning of FY 2007, for specifically linking HIV reporting with

contact tracing and partner notification, and with "prevention for positives" efforts such as prevention case management. CDC's guidelines to date have been ambiguous and inconsistent. One draft CDC document actually recommended against such linkage, while another draft document on partner notification agrees that partner notification is an essential activity.

Special CDC funding has been going recently to "prevention for positives" activities, yet CDC has never made it clear that public health departments may confidentially contact persons whose infections have been reported, to recruit them to participate in such activities. In contrast, for tuberculosis and syphilis, CDC has guidelines calling for persons reported as infected to be contacted by public health to identify potential contacts who should be tested, to encourage safe behavior that will not spread the infections, and to refer these persons to necessary services.

4) FUNDING FOR LINKAGE OF REPORTING AND PREVENTION SERVICES:

We also strongly urge that a significant and specific amount of prevention funding be reserved for grants to states and cities, administered through CDC, for developing linkages between HIV reporting and prevention strategies, including but not limited to contact tracing, partner notification, and prevention case management. These grants should be for activities that are consistent with the required guidelines to be developed by CDC, and **issuance should commence during FY 2007** and continue annually thereafter. **Grants for innovative programs and demonstration projects should also be available during FY 2006**, pending the CDC guidelines.

5) RYAN WHITE CASE MANAGEMENT: EXPANSION TO PREVENTION CASE MANAGEMENT:

For many years, the Ryan White CARE Act has funded case management services. Case managers meet with infected persons to discuss housing, sustenance, access to medication, etc. **But funding has not been specifically provided, nor has there been any requirement, for these Ryan White case managers to deal with prevention aspects of case management, e.g., helping infected persons to change unsafe behavior so as to avoid endangering others, and querying them periodically about past or new sexual or needle-sharing contacts who should be notified.** To help slow the development of drug resistance, helping clients to achieve medication regimen adherence should also be a topic of such case management. In many cases, a close rapport and trust develops between clients and case managers, making the latter an ideal group to address ongoing prevention issues. In this role, they would be an adjunct to public health departments, which are in general unfunded for HIV case management and do not have the advantage of the trust and rapport with clients. Contacts elicited by case managers over time could be reported to public health for notification services. Such activities and relationships are being successfully used in some local jurisdictions, and it is time that they the be federally funded and applied nationwide.

We recommend for this year's renewal bill, that Congress authorize the use of case management money to train existing and new case managers to perform contact interviews, to counsel clients on behavior change and avoidance of high-risk behavior that may foster transmission, and to advise clients on methods of enhancing treatment adherence. Guidelines for this should be developed by HHS with CDC participation, during FY 2006. Beginning in FY 2008, prevention case management should be a mandatory component of Ryan White case management.

Thank you for considering our recommendations. They are essential to finally control this epidemic of HIV infections, which far from being controlled, is actually increasing, with more than a million infected persons estimated by CDC as of December 2003. Hundreds of millions of dollars have been spent each year on prevention, with the amount approaching a billion dollars annually, yet we seem to be falling further behind. Clearly, new initiatives and new strategies are essential, yet they must also be evidence-based. The five proposals outlined above are consistent with successful evidence-based strategies used for the control of tuberculosis and syphilis, and programs implementing recommendations 4 and 5 have been successfully utilized for HIV in localized public health programs. Congress should adopt all of them and assure that they are incorporated into the 2005 Ryan White CARE Act renewal

Sincerely,

Cary Savitch M.D.

Cary Savitch, MD, President

Ronald Hattis, MD, MPH

Ronald Hattis, MD, MPH, Secretary

Yvonne W. Pover

Yvonne Pover, RDH

Patrick Monette-Shaw
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August 7, 2005

The Honorable Tom Coburn, MD
Senator
United States Senate
172 Russell
Washington, DC 20510

Re: Testimony Regarding the Ryan White CARE Act Re-authorization 2005

Dear Senator Coburn,

In 2000, you successfully worked in a bipartisan, bicameral way with Congressman Henry Waxman on the Ryan White CARE Act Reauthorization bill while you were both Congressmen, for which I thank you. I am glad to see that you are again, five years later, taking an active role in the Reauthorization of the CARE Act in 2005, this time in the Senate. As a former Democrat, and a current Green Party member, I look forward to your leadership in crafting bipartisan support for the 2005 Reauthorization effort.

As you may know, I am an accountability activist in San Francisco, and have been monitoring the performance of the San Francisco EMA's HIV Health Services Planning Council for the past four years. While our CARE Council's performance has improved, in part due to my reporting on their performance, serious issues regarding conflict of interest remain. One of my chief interests is ensuring that increased accountability provisions, long overdue, are incorporated into the Reauthorization legislation.

I hope you might consider the following concerns as joint conference discussions about the Reauthorization progress:

HIPP

In the mid 1990's, my partner and I lived in Georgia. He had been diagnosed with AIDS, and as his illness progressed he was no longer able to work. He resigned a management position, and elected to continue his health care insurance under COBRA provisions. After a year languishing on a waiting list for the CARE Act Title II's Health Insurance Premium Payment (HIPP) program, a slot for HIPP coverage opened up when another person in the program passed away.

I recommend that the HIPP program under Title II become a central focus of Reauthorization 2005. By transitioning as many people into insurance continuation as possible, we can save both Medicaid (in California, Medi-Cal) and ADAP expenditures by moving clients in need of CARE-funded services into private payors, helping to preserve CARE Act funds as the payor-of-last-resort, utilizing private insurance programs to their fullest capability.

I would like to see a realistic formula introduced into the Title II provisions that would require States to set aside a given percentage of their Title II awards to expand State HIPP programs. I believe strongly that Sates should be required to use this provision as broadly as possible. I believe that relatively small increases in spending on the HIPP program would yield substantially significant savings that could be utilized to fund other HIV/AIDS healthcare services. Whether that involves extending the period of HIPP coverage permissible, or in other ways, the goal of expanding the HIPP program would be to mandate that States first seek to utilize Title II funds to increase the amount of CARE Act funding that could be applied to payor-of-last-resort obligations elsewhere in the system of care.

Payor of Last Resort

Over the past four years, I have repeatedly advocated before our local CARE Council to identify and utilize other payors-of-last resort in order to utilize our CARE Act award more effectively. However, during our annual prioritization and allocation processes, rarely has this council discussed or investigated other payor sources as they make funding allocation decisions. In fact, during the July 25, 2005 meeting of our CARE Council, Russ Zellers, a

budget analyst in the San Francisco Department of Public Health's AIDS Office, made a presentation concerning utilization of our CARE funding during the past fiscal year, and distributed what are called "Summary Sheets" summarizing spending in each category of services prioritized for funding. He stated during that meeting:

> "The payor of last resort data in the Summary Sheets is not complete. We don't have dollar amounts from other funding sources. Maybe in future years we can do a better job of determining other sources of funding coming into our EMA." [or words to that effect]

We have heard this before, and I have repeatedly stressed to our Council members that they have a responsibility to make sure that background research is performed accurately before voting to make prioritization and allocation decisions. But each year, this "homework" never gets done, and it is my belief that our council continues to shirk its duties to fully investigate whether they are in fact using CARE Funds as the payor of last resort.

I believe the CARE Act language should require, in the strongest language possible, that the grant application process require detailed analysis of all funding streams being used in an EMA, and that those funding streams be explicitly detailed in the grant application submission.

Rollover Funds

San Francisco has worked hard at reducing its unspent CARE Act funds. Last year, it reported no unspent funding. However, this was accomplished by re-allocating funding from one budgeted healthcare service to other service categories at the very last minute, and was done in part by decisions made in the AIDS Office, not decisions made by the CARE Council.

I recommend that in order to better utilize unspent, rollover funding into the ADAP program, that tighter controls be placed on how rollover funds can be reallocated. I would like to see a provision that would require any budgeted funds allocated to a major service category that are unspent can only be reallocated within that healthcare service category, and cannot be moved to a completely different category at the last minute. Any funds that could not be reallocated within that service category and spent within the year Congress intended the funding to be spent would have to then be returned to HRSA for reallocation to ADAP. I believe this would force CARE Councils to perform better budgeting decisions at the time they make allocation decisions, and they would be more careful to accurately forecast the need of funding in each category of service.

Audits of HIV/AIDS Caseload Reporting and "Double-Counting"

As you may know, Michelle Cochrane has noted in her book *When AIDS Began: San Francisco and the Making of An Epidemic*, that San Francisco may have over reported by 8 percent its AIDS caseload by including out-of-county residents (page 143). San Francisco's Department of Public Health recently released its annual AIDS epidemiology report for 2004, and acknowledged that it had changed its methodology to no longer include out-of-county cases. When it adjusted its AIDS caseload downward, there was an 11 percent (not 8 percent) decline in the statistics reported. But Dr. Cochrane, a post-graduate fellow at UC-Berkeley, indicates that a second "double-counting" problem involves jurisdictions reporting AIDS cases of its residents who are actually living in other jurisdictions. San Francisco has not yet reported what percentage, if any, of its AIDS caseload involve San Francisco residents who no longer live in the Bay Area.

Therefore, I believe the semi-annual audits of AIDS case registries (databases) be a requirement in the Reauthorization language for 2005, specifically requiring auditors to monitor both out-of-county cases and cases who no longer live in the jurisdiction in which an AIDS case was first diagnosed.

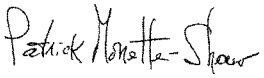
Conflict of Interest

Over the past four years, I have repeatedly advocated that our local council honor conflict of interest ethical provision, to no avail. While our Council now reports potential conflict of interest of all council members, they have not adopted a provision that bars members from voting on allocation or policy decisions for which they may have a conflict of interest. They merely have to acknowledge their conflict, and then are allowed to vote, anyway, if they so choose not to abstain from voting.

Therefore, I would like to see the CARE Act strengthened to prohibit council members from being able to cast votes on matters before them that involve real or perceived conflicts of interest. In those situations, the members should be required to recuse themselves from voting.

Thank you for consideration of this testimony.

Sincerely,



Patrick Monette-Shaw

RESPONSES TO QUESTIONS FROM DR. JANSSEN

1. **In his testimony, Mr. Montgomery stated that because California and a few other states have failed to set up accurate HIV reporting systems that CDC "will need to develop a methodology to estimate HIV cases for these states." As you know, the existing law does not allow for this and requires that only "counted... cases of HIV disease as reported to and confirmed by" the CDC will be acceptable for federal funding. CDC has stated that only name based HIV reporting systems can be confirmed as reliable and accurate. States without names based reporting should be provided official notice that they are at risk of losing significant federal financial support beginning in FY 2007 if they do not quickly develop a names based system. Will CDC issue a statement to those states with non-name-based HIV reporting systems alerting them of the financial risks, as well as the public health deficiencies, they face if they do not revise their HIV surveillance systems?**

   This matter is under discussion. We will be happy to keep you apprized of planned actions.

2. **A CDC evaluation of unique identifiers found that "the UI approach complicates efforts to collect this information and increases the number of lists of HIV-infected persons that could be disclosed in a breach of confidentiality." Could you elaborate on how unique identifiers may actually increase the risk for confidentiality violations?**

   In order to assure that complete information on cases can be obtained by health department personnel, code systems necessitate that providers keep lists connecting codes to patient names in their offices. Providers maintain medical records by patient name and must institute a special system to match codes to patient names. Therefore, coded systems often result in lists of individuals who are HIV infected being maintained by laboratories and health care providers. This provides additional opportunities for compromising confidentiality. For example, anecdotal reports have revealed that lists of

codes are sometimes maintained in insecure locations in health care provider facilities and have titles such as the "HIV Name and Code list."

Health departments have strict confidentiality and security standards and procedures to protect the data they hold; thus, inadvertent breaches in confidentiality by the public health department are unlikely to occur.

3. **In April 2003, CDC launched a new initiative entitled "Advancing HIV Prevention" with four key strategies that emphasize routine HIV testing. Have any states adopted these strategies? What incentives is the CDC providing to states to incorporate these strategies? How much of CDC's $900 million HIV prevention budget is being spent on this new initiative?**

The Advancing HIV Prevention (AHP) initiative is a component of CDC's comprehensive HIV prevention portfolio and supports the prevention work of the past two decades. Two of CDC's main HIV prevention program announcements, one for state and local health departments and one for community-based organizations (CBO) funding, include activities in support of the AHP initiative. For example, CDC requested community planning groups to designate people living with HIV as the highest priority population and to prioritize services for those who are at highest risk for transmitting the virus. In the CBO announcement, several key activities were included to implement AHP strategies. These include: outreach and counseling, testing and referral; prevention with HIV-positive persons; and prevention for very high-risk HIV-negative persons. These activities of our state and community-based organization partners are a key to CDC's support of AHP strategies.

In addition, CDC has supported a number of demonstration projects to adapt and implement the strategies of AHP. CDC will then work to disseminate findings from these projects to its state, local and CBO partners. For instance, just last month, CDC published preliminary findings regarding a demonstration project on the use of social networks to identify persons with undiagnosed HIV infection. The approximate 6% prevalence of HIV infection among those tested in the project was five times the average prevalence reported at publicly funded counseling and testing sites.

In 2005, CDC received $786 million for HIV prevention activities in the National Center for HIV, STD and TB Prevention. Subtracting international funding for the Global AIDS Program and the HHS evaluation assessment, $644 million was available to NCHSTP divisions for domestic program activities. While the fiscal year is not yet over, we estimate that roughly $149 million of this total will be spent on AHP-related activities this year.

4. Are all CDC funded STD clinics now required to conduct routine HIV testing?

Since 1987 CDC has recommended that HIV testing be routinely offered to all persons seeking treatment for sexually transmitted diseases (STD) in all health care settings. More recently, recommendations for routine HIV testing were included in the Advancing HIV Prevention Initiative, and have been

shared with state and local health departments through letters, *Morbidity and Mortality Weekly Report (MMWR)*, and technical guidance provided to grantees.

CDC guidance to STD Programs on the content and quality assurance aspects of clinical services also addresses HIV testing. For instance, CDC's *Program Operating Guidelines for STD Prevention* includes a chapter on "Medical and Laboratory Services." Contained within this chapter is a series of recommendations for STD clinics. The following recommendations are relevant to HIV testing:

- Clinics should provide the basic range of HIV-related services specified in state and federal statutes and, for patient convenience, should offer as many as possible on site (e.g., counseling and testing, partner services).
- Confidential counseling and testing for HIV should be offered at the time of the STD visit so that patients do not have to visit separate clinics or make return visits.
- Confidential counseling and testing for STDs, including HIV, should not be denied because a patient refuses other STD services.
- Anonymous HIV testing should be available on site for patients requesting the service or at community sites convenient to patients.
- Written policy and procedures should be in place for the referral of patients for HIV early intervention services (e.g., continuing medical

evaluation, tuberculosis and immune system testing, treatment, and support group counseling).

CDC also encourages STD and HIV prevention programs to integrate and collaborate in offering counseling, testing, and referral services. Both the STD and HIV program announcements to state and local health departments encourage this integration of services. The STD program announcement also requires recipients to assure that its programs are consistent with CDC's guidelines and recommendations.

Finally, STD clinical services are supported and provided by state, city and county health departments as part of the local contribution to STD Prevention program services. Clinical standards for diagnostic testing are determined at the State level and according to local statutes.

5. About one-in-four of the one million Americans living with HIV are unaware that they are infected according to the CDC. CDC has made routine testing and early diagnosis a priority for "Advancing HIV Prevention." Yet, since the approval of the rapid oral fluid HIV test, the number of tests distributed by the CDC has been remained static at about 200,000 per year. With the overwhelming patient acceptance and preference for oral fluid testing, considerable state regulatory barriers to blood testing, scientific evidence demonstrating the positive impact of rapid testing on prevention and treatment, and Congressional support for scaling up the use of this new technology, it would appear to be imperative that the deployment of these tests should be scaled up. Please provide year by year totals of rapid tests purchased beginning in 2002 until the present. Please discern between oral based and blood based rapid tests. Please also provide the number of HIV tests performed in the U.S. every year, how many locations have access to this new oral fluid technology through the CDC, and how many locations could be provided access to this technology if CDC doubled

its availability? How many new cases of HIV infections could be identified by doubling the availability of the rapid tests?

The rapid HIV test was approved several months before the AHP initiative was launched and gave CDC the impetus to aggressively encourage routine HIV testing. Since September 2003, CDC has purchased over 700,000 OraQuick rapid HIV test kits and distributed them for use by 137 different entities, mostly health departments and community-based organizations seeking to use the test in settings without ready access to clinical laboratory services. CDC's purchases in Fiscal Year (FY) 2003 and FY 2004 totaled $4 million. CDC purchased about 250,000 rapid HIV test kits in FY 2003 and about 279,750 in FY 2004. All of these were blood-based rapid tests. In FY 2005, CDC made a $2.3 million bulk purchase of the OraQuick rapid HIV 1/2 test kits when the OraQuick test was approved for use with oral fluid. These kits were distributed free of charge to CDC-funded AHP demonstration projects. Nearly 210,000 have been purchased in FY 2005. Recipient of CDC HIV funds are also allowed to use HIV prevention funds to purchase rapid tests.

Based on the latest available data in 2002, 10%--12% of persons aged 18-64 years in the United States (an estimated 16 million to 22 million persons), reported being tested for HIV during the preceding 12 months. The estimated number of HIV tests conducted during this time period 22,158,000. This total includes all test performed in public, private and CDC-funded sites.

Approximately 17% of these, or about 3.8 million tests, were performed in CDC-funded sites.

Regarding your question about how many new cases of HIV infection could be identified by doubling the availability of rapid tests, CDC cannot accurately model the number of new cases of infection identified. The yield of new cases depends not only on the number of kits, but also on where they are deployed. We are still evaluating the feasibility and effectiveness of different testing strategies and venues that feature the use of rapid tests.

6. **Is the CDC currently funding or providing assistance to conduct "blind," or seroprevalence, HIV testing in which individuals are tested for HIV without their knowledge and not provided test results?**

Since the Survey of Childbearing Women ended in 1995, CDC no longer includes blind seroprevalence surveys in its surveillance program portfolio. However, in 2004, CDC initiated one specific research study of HIV incidence among men having sex with men (MSM) diagnosed with syphilis using this type of testing. Diagnosis with an STD is a well-established marker for increased risk of infection. Recent outbreaks of syphilis among MSM in a number of major U.S. cities could result in an increase in HIV transmission within this population. The goal of this project is to assess the extent of new HIV transmission in this special population to inform HIV and STD prevention and disease control efforts. Preliminary data from one site suggest a high rate of HIV acquisition among MSM diagnosed with early syphilis. These

results suggest that this testing activity needs to be expanded to other areas experiencing increases of syphilis among MSM to more precisely measure the association between HIV and syphilis in this group. All clients served in these clinics are offered HIV testing and comprehensive STD and HIV prevention services.

7. **Five years ago, a bipartisan group of Congressman took issue with the manner in which CDC classified HIV risk in a category called "No Identifiable Risk," or NIR. At that time, CDC was classifying infected heterosexuals who did not know the HIV status of a current or previous partner as no identifiable risk. This was the case even if the infected person had reported contact with multiple partners exclusively of the opposite sex. Only if an opposite sex partner was known to be infected with HIV, was the source patient categorized as heterosexual risk. CDC pledged to re-examine this unusual system. What has CDC done to clarify this classification bias?**

Identifying risk factors for HIV transmission are critical to monitoring the HIV epidemic. In December 2001 CDC convened a group of public health experts to address the issues related to cases reported without risk factors. The consultants recommended adding a subcategory (presumed heterosexual contact) to the existing transmission category of no identified risk factor (NIR). The consultants believed that the addition of this category would help to classify cases that were recorded as NIR. They also believed that many of these cases at least had information about heterosexual contact as a potential means of exposure.

CDC conducted an analysis in 2003 to assess the relevance of the recommendation, using national HIV/AIDS surveillance data. For this

analysis, CDC classified cases into an NIR subcategory of presumed heterosexual contact, using a standard definition recommended in the consultation summary (Lee LM, et al. Classification of transmission risk in the National HIV/AIDS Surveillance System. *Public Health Rep* 2003;118:400–407.) (Attachment 1) The analysis demonstrated that many reports to CDC did not contain the information necessary to classify the relevant cases into the presumed heterosexual category. The investigators concluded that data collection on risk factors had to improve to better address the problem of no identified risk. Creating new categories alone was not sufficient.

In addition, a CDC-funded project to assess the usefulness of a new protocol for ascertaining risk factors was conducted in 10 areas in 2002 and 2003. Through this project, CDC found that in some areas, including some very high morbidity areas, substantial risk factor information could not be obtained from existing medical documentation, even when intense follow-up was attempted.

Finally, in January 2004, CDC formed a workgroup with state HIV surveillance coordinators to revise HIV/AIDS surveillance technical guidance. The workgroup developed guidelines for risk factor ascertainment, established standard HIV/AIDS risk factor terminology, and developed provider educational materials to assist with risk factor ascertainment.
These guidelines for risk factor ascertainment serve as the basis of an intensified effort to obtain risk factors. Emphasis is placed on educating

providers about their role in collecting risk factor data according to CDC definitions. CDC currently is developing model methods to train and educate providers about the importance of adequately documenting all known patient HIV risk factors. These efforts should decrease the burden of following up on cases with missing or incomplete risk factor information.

CDC is also working with states to create a common definition for a new sub-category "presumed heterosexual contact." In September 2004, CDC funded the Risk Factor Ascertainment Materials Evaluation Project. Three surveillance areas (New York City, Florida and Texas) will evaluate the impact of educational materials developed for providers in collaboration with state health department employees, and test the availability and performance of risk factors for use in defining a "presumed heterosexual contact" transmission category. Some examples of risk factors that need to be evaluated include history of sexually transmitted diseases, multiple sex partners, and non-injection drug use. This assessment should be completed by the end of 2006.

8. **Could you provide the Subcommittee with a full listing of all contractors, grantees, and sub-grantees that received funding from the CDC for HIV and STD prevention in the most recently available fiscal year?**

Attachment 2 is a list of the CDC's grantees and contractors for FY 2004. CDC does not have a fiduciary relationship with subgrantees; thus, we do not maintain a database of subgrantee information. The list represents funding provided by the Division of HIV/AIDS and Prevention and Division of STD

Prevention, National Center for HIV, STD, and TB Prevention (NCHSTP); and the Division of Reproductive Health and Division of Adolescent and School Health, National Center for Chronic Disease Prevention and Health Promotion.

9. What is the total amount spent by CDC on conferences in the most recently available fiscal year?

In FY 2004, CDC spent $1,345,446 in direct conference support for HIV conferences, which amounts to about 2/10ths of 1 percent of the total $644 million HIV prevention budget for the National Center for HIV, STD, and TB Prevention.

This funding was mostly used to support two conferences:

1. The National HIV Prevention Conference held June 12-15, 2005, which is the premier scientific HIV prevention conference in the United States providing participants from government, community-based and other non-governmental organizations, and academia information about effective prevention approaches from a broad array of scientific disciplines and opportunities to strengthen collaborations between practitioners and researchers.

2. The HIV Prevention Leadership Summit to be held July 31-August 3, 2005 is a meeting primarily intended for CDC grantees offers practical opportunities for prevention workers to build skills and to apply science to

their programs. The HPLS targets staff from community-based organizations and health departments, community planning group members, capacity-building and technical assistance providers, national partners, CDC and other federal agencies.

This amount is expected to decrease in 2005 because the amount spent on conferences fluctuates each year based on national conference activities.

RESPONSES TO QUESTIONS FROM MS. HOBSON

U. S. Senate Committee on Homeland Security and Governmental Affairs
Subcommittee on Federal Financial Management, Government Information, and International Security
Hearing on Addressing Disparities in the Federal HIV/AIDS CARE Programs
June 23, 2005

Could you provide the total amount spent by each title of the CARE Act on "planning" activities during the most recently available fiscal year?

Answer: Over the past 2 years (2003-2004) HRSA spent approximately $30 million for planning council support in the Title I program which was a little more than 2% of the Title I appropriation for those years. During those same 2 years, approximately $49 million, a little more than 2% of the total Title II appropriation including ADAP, was spent on grantee planning and evaluation and consortia needs assessment, planning and evaluation activities. Over the last 2 years, just under $300,000 was spent under Title III for 6 planning grants which was less than .075% of the Title III appropriation for the same period.

What is the total amount of unobligated funds currently available in all titles of the CARE Act, broken down by title?

Answer: CARE Act funds are annual appropriations and can only be redistributed in the fiscal year in which the original funds were appropriated. Unobligated funds are returned the Treasury as the respective fiscal year's funds lapse, i.e. five years after the end of the fiscal year. As of September 30, 2005, unobligated CARE Act funds totaling $24,731,905 from Fiscal Year (FY) 2000 will be returned to the Treasury. For Fiscal Years (FYs) 2001 - 2003, the total amount of unobligated CARE Act funds was $104,800,764 of which $73,415,111 will be returned to the Treasury. The following is the breakout of the estimated unobligated funds for these years, by Title:

- Title I:
  - $573,317 for FY 2000 will be returned to the Treasury on September 30, 2005.
  - $8,623,576 for FYs 2001-2003 in unobligated funds of which $4,019,762 is to be returned to the Treasury.
- Title II:
  - $17,645,7576 for FY 2000 will be returned to the Treasury on September 30, 2005.
  - $84,552,735 for FYs 2001-2003 in unobligated funds of which $59,646,241 is to be returned to the Treasury.
- Title III:
  - $4,865,843 for FY 2000 will be returned to the Treasury on September 30, 2005.
  - $8,248,074 for FYs 2001-2003 in unobligated funds of which $7,307,018 is to be returned to the Treasury.

- Title IV:
  - $1,646,989 for FY 2000 will be returned to the Treasury on September 30, 2005.
  - $3,376,379 for FYs 2001-2003 in unobligated funds of which $2,442,090 is to be returned to the Treasury.

The existing law requires HRSA to redistribute unobligated, or unspent, CARE Act funds from one jurisdiction to others. Does HRSA routinely utilize its existing legal authority to recollect unspent funds and redistribute those funds to jurisdictions with financial needs?

Answer: Title XXVI of the PHS Act (RWCA) includes discretionary off-set provisions under Titles I and II providing discretion for the Secretary to adjust grant amounts to reflect unexpended and uncanceled grant funds. These offset provisions apply to the immediate prior year award and must be implemented at the time of the new award. HRSA has opted against using these discretionary provisions. Specifically:

- There are specific hold-harmless provisions for Titles I and II designed to limit reductions in grant levels from one year to the next year. In the case of Title II, even if we were to impose an offset for a particular State, depending on the overall level of the appropriation available compared to the preceding year, there may still be a requirement to make an award to that State at no less than the prior year's amount.
- Amounts used as offsets for one or more grantees must be redistributed, using the same formulas, to all of the grantees, which would result in a percentage of the offset being returned to the same entity against whom it was taken.

While receiving about twice the amount of CARE Act funding per AIDS patient as ever other city, San Francisco amassed $3.7 million in unspent CARE Act funds between 2001 and the end of 2003. In the minutes of the February 15, 2005 city Health Commission Meeting, the chair of the San Francisco HIV Health Services Planning Council stated that "It is important to the Planning Council that the [unobligated CARE Act] money is spent down so that monies are not returned to HRSA." He noted that the expenditure of "rollover funds" had been prioritized on a number of items including clothing. Did HRSA approve the use of CARE funds for the purchase of clothes?

Answer: In FY 2003, San Francisco's Title I allocation was approximately $34 million of which over 60% was spent on core services. Of the almost $12 million spent on support services, approximately $59,000 was allocated to vouchers for food, household goods and transportation which are allowable costs. HRSA never approved any expenditure for clothing.

Would the Administration support better targeting of funding based on need and the creation of a funding "floor" for core medical services to ensure that doctors

visits, medication and other essential health services are prioritized over other programs funded by the CARE Act?

Answer: The President's reauthorization principles include focusing the RWCA resources, up to 75% of the grant award, on life-extending medical care such as antiretroviral medications, doctor visits and laboratory tests.

A number of patients living with HIV on ADAP waiting lists in Kentucky passed away recently despite the fact that the state had hundreds of thousands of dollars in unspent Ryan White CARE Act funds. Why are patients dying on waiting lists when the state they live in is sitting on hundreds of thousands of dollars in unspent federal dollars intended to care for those with HIV?

Answer: HRSA, along with many others, is very concerned about the death of five people waiting enrollment in the Kentucky ADAP program. However, based on information made available to HRSA, all five of the people in question had access to HIV medications through pharmaceutical manufacturers' patient assistance programs and two of the people had advanced HIV disease when they presented for care. The President's reauthorization principles are to make the Ryan White CARE Act more responsive to the needs of the people to ensure that they receive the life-saving medical care needed. One of the principles, increased accountability, and the other four as well, should avoid a reoccurrence of this terrible tragedy.

GAO has found that the "hold harmless" provision of Title I has actually harmed the funding levels of 48 of the 51 EMAs and has largely benefited only one jurisdiction. Would the Administration support a total elimination of the hold harmless?

Answer: Yes, the Administration is aware of the distortions in resource allocation caused by the hold harmless provisions and supports eliminating the hold harmless provisions in the Act.

Do you believe that there are more Americans with HIV who lack treatment access who are not represented on waiting lists because they were deterred from enrolling due to the restrictions?

Answer: We are unaware of any efforts by RWCA grantees to deter eligible persons from enrolling for services. The only waiting lists HRSA is aware of are the ADAP waiting lists.

What is the total amount spent by HRSA on conferences in the most recently available fiscal year?

Answer: In FY 2004, the HRSA spent approximately $950,000 on HIV/AIDS conferences including, but not limited to, the RWCA All Grantee Technical Assistance Meeting and Clinical Update Conference, the National AIDS Update Conference, and the 2005 CDC HIV Prevention Conference.

Responses to questions from Senator Tom Coburn, Chairman, Senate Subcommittee on Federal Financial Management, Government Information, and International Security related to testimony given before the committee on June 23, 2005 by Michael Montgomery, Chief, Office of AIDS, California Department of Health Services.

In your testimony, you stated that because California and a few other states have failed to set up accurate HIV reporting system that CDC "will need to develop a methodology to estimate HIV cases for these states." Does the state of California understand that the law does not allow for this and only "counted....cases of HIV disease as reported to and confirmed by" the CDC, which at this time are limited only to name-based reports, will be acceptable for determining federal funding?

This issue impacts many states regardless of whether their HIV surveillance systems use names, name-to-code, or code based reporting. All surveillance systems regardless of reporting method require several years following implementation to achieve maturity sufficient to provide complete and reliable data. CDC does not include data into its national reports until it deems the data has met standards of completeness and timeliness. In the most recent national surveillance report, year-end 2003, data was included for HIV/AIDS from only 32 states and the Virgin Islands with mature HIV reporting systems (i.e., HIV reporting at least since 1999) to allow for stabilization of data collection and for adjustment of data in order to monitor trends. As noted in the IOM report some HIV surveillance systems were implemented in 2004, and are not fully mature. This inherent limitation needs to be addressed by providing a fair and equitable methodology for integrating HIV and AIDS cases into CARE Act funding formulas in a manner that limits disruption of services to persons with HIV/AIDS in all areas. CDC currently uses estimated living AIDS cases, not counted or reported cases, for formulas used in the CARE Act. This has resulted in an underestimate of California's living AIDS cases by approximately 30 percent. We believe that this must be addressed in the 2005 reauthorization of the CARE Act.

A California Performance Review recently found "the state risks a loss of up to $50 million annually in Ryan White CARE Act funds if the CDC does not confirm California's reported HIV cases for Federal Fiscal Year 2007," noting that "California can prevent this loss if it conforms its HIV reporting system to its name-based AIDS reporting system." Can California afford to abdicate $50 million in federal funds for AIDS care?

In fiscal year 2005, Governor Schwarzenegger and the California Legislature continued their commitment to HIV/AIDS services by providing $111 million in State General Fund even in the face of a significant State budget deficit. Federal funding losses in addition to those resulting from the use of the estimated living AIDS formula which undercounts California's actual living AIDS cases by approximately 30 percent would be very problematic. Sparked by the introduction and subsequent defeat of legislation to establish HIV reporting by name in

the 2005-06 session, a spirited discussion continues between the department, consumers, advocates, and the Legislature regarding HIV names reporting in California.

The names of over 134,000 patients diagnosed with AIDS have been reported to the health department in California over the past two decades. Has there ever been a breach of confidentiality with the reporting of these names? Is there any reason to believe that the state could not protect the names of those diagnosed with HIV who have not progressed to AIDS?

California Department of Health Services, Office of AIDS has never had a breach in confidentiality in over 20 years of name-based AIDS reporting. According to California state law, surveillance data collected will not be made available for civil, criminal, or administrative litigation or to any non-health agency, whether it be a federal, state, or local entity. All staff members with access to confidential HIV/AIDS materials are trained annually in handling sensitive information. Staff members are also required to sign confidentiality agreements and attend annual security and confidentiality trainings to reinforce the security protocols and remind staff of the nature and penalties of security breaches. If California were to adopt a named-based HIV reporting system, cases of HIV infection would be processed using the proven secure practices California currently has in place for collecting AIDS cases by name.

How many diseases or medical conditions does the state of California currently designate as reportable? How many of these are reported by name and how many are reported by unique identifier or code?

Currently, 91 reportable diseases and conditions are listed in Title 17 of the California Code of Regulations. With the exception of HIV, all are reported by name.

Is there a logical reason why the state would report the names of those with AIDS but not HIV?

Current California Health and Safety Code Section 120980(i) excludes HIV from being collected as we currently collect AIDS. The California Department of Health Services, Office of AIDS acknowledges the limitations of a non-name HIV reporting system. The department also recognizes that the non-name solution for HIV case reporting currently in place in California is a burdensome, labor-intensive system that requires the arduous task of investigation and follow-up be performed by local health departments, exhausting their scarce resources.

Has the Office of AIDS conducted any evaluation of its HIV reporting system for accuracy and reliability? How much will it cost California to evaluate the effectiveness of its HIV reporting system? Could this money be better spent on HIV prevention or providing AIDS care?

HIV data submitted to the California Department of Health Services, Office of AIDS are constantly reviewed for completeness. HIV data are routinely examined to detect duplicate cases. Specific evaluation protocols developed by CDC to address performance standards

outlined in the December 10, 1999 Morbidity and Mortality Weekly Report (MMWR) have not been implemented in California due to lack of funding. Implementation of CDC's protocols in representative California counties would cost a minimum of $400,000 per year for at least three years. At this time California cannot divert resources of this magnitude from other HIV/AIDS-related programs to fund such an evaluation. However, accurate and reliable HIV data form a critically important basis for appropriate, targeted allocation of limited resources for HIV prevention and care programs for Californians most affected by HIV disease.

Medical professionals and some AIDS advocates in California believe the code-based system is too cumbersome and that doctors and laboratories are not reporting cases because of the added paperwork and costs. Could you comment on these criticisms?

California's code-based HIV reporting system is more cumbersome and more expensive than a name-based HIV reporting system. Most doctors serving patients with HIV fail to maintain the required cross-reference system because it presents a significant increase in their workload. Doctors find communication with public health staff difficult because public health staff lacks the patient name and doctors do not have the code readily available without the cross-reference system. Even with the difficulties associated with code-based HIV reporting, provider reports continue to be submitted to public health officials. Completeness of laboratory reporting has not been affected by the paperwork and costs associated with code-based HIV reporting.

In the January 11, 2003 edition of the *Los Angeles Times* [it was] reported that "county health officials are being allowed to peruse medical records, complete with patient names" to ensure cases are being reported. Did this in fact occur? If it has, does this not undermine the entire concept that a unique identifier would protect patients' names?

Like any reportable disease, accurate tracking of HIV relies on close monitoring of reporting trends, particularly from key reporting sources. Contacting health care providers to strengthen disease reporting is a core public health activity and often includes providing assistance with reporting of cases, particularly when providers are having difficulty meeting or are not yet familiar with reporting requirements.

When assisting with case reporting, public health staff from local health departments must comply with HIV reporting regulations, which prohibit the reporting of personal identifying information to the health department. HIV/AIDS public health staff may assist health care providers with construction of the non-name code, gathering demographic data and recording patient history and treatment. Patients' names, however, are not recorded and all records containing patient names remain with the health care provider.

Are codes ever linked with patient name or identifiers? If there is no link, how do doctors or public health officials know if a patient has already been reported or not?

Section 2643.5(h) of the California Code of Regulations requires health care providers to maintain a system which cross-references patient data with the non-name code for all HIV-infected patients without an AIDS diagnosis.

This cross-reference system allows for the exchange of case report information with the local health officer and exists for the sole purpose of completing or unduplicating HIV case reports. The provider log is the only linkage between patient names and the non-name code permitted under California's HIV Reporting Regulations.

***The Los Angeles Times* reported that in 2002 Los Angeles health officials received 18 new reports of HIV infections among children, and eight of the children had gone undetected for several years. A pre-teen girl's infection was learned only after her mother began showing symptoms of AIDS. You stated in your testimony that California reported 14 cases of perinatal HIV transmission in 2003. The truth, however as demonstrated by the *Los Angeles Times* article, is that no one knows how many babies became perinatally infected in 2003 or any year because children are not routinely checked for HIV antibodies, correct? Are newborns routinely tested for any diseases or medical conditions in California? Do you think the existing laws in California are sufficient for preventing perinatal transmission or would adopting the CDC's recommendation for universal testing of pregnant women and newborns better enable the state to prevent perinatal HIV transmission?**

It is correct that children are not routinely checked for HIV antibodies. In 2004, Governor Arnold Schwarzenegger signed legislation which required the California Department of Health Services to expand the existing statewide newborn screening program by August 1, 2005. California newborns will now be tested for 75 hereditary and congenital disorders. Previously, California tested for 39 genetic disorders.

California is committed to preventing transmission of HIV and continues to develop innovative strategies and programs addressing perinatal transmission. Currently, California has a statute (Health and Safety Code Section 125092) which requires medical care providers to screen every pregnant woman for HIV as part of the standard prenatal test panel. Additionally, providers are required to explain the purpose of the HIV test and to ensure the right of the woman to refuse the test. The law requires laboratories to report a positive HIV test result to the local health officer and mandate the provider who ordered the test inform the pregnant woman of the test results.

Additionally, the California Department of Health Services, Office of AIDS is developing a rapid HIV testing in Labor and Delivery Program. The program will be offered in hospitals statewide focusing on women who present in labor with unknown/undocumented HIV status. Specifically, the California Department of Health Services, Office of AIDS will be focusing on women with no or limited prenatal care, who were not offered prenatal testing, whose results are unavailable or who declined testing previously.

In your testimony, you noted that "partner notification, a key public health strategy to fight communicable diseases, lies within the authority of health departments as part of their mission to protect public health." For every case of HIV infection diagnosed in California, how many partners would you estimate would be contacted and encouraged to receive HIV testing? Do you believe any legal barriers exist in California that are preventing more effective confidential partner notification?

Testing data from fiscal year 2003-2004 show that of the 67,488 individuals tested in counseling and testing sites across the state, 836 (1.24 percent) tested positive. Based on Partner Counseling and Referral Services demonstration data, it is estimated that 25 percent, or 209 of the 836 newly diagnosed HIV-positive clients would agree to inform at least one partner of their exposure to HIV. With an average of two partners being informed per HIV-positive client, we estimate that in a given year, a potential 418 partners would be informed of their exposure to HIV.

Data indicates that more than half of the partners contacted by field notification will choose to test for HIV, with half of those partners being first-time testers. A final positivity rate for these partners is around 15 percent compared with an average of 1.25 percent for other state-funded counseling and testing venues.

No known legal barriers presently exist in California that are preventing more effective confidential partner notification. A high priority is placed on confidentiality of all sources and anonymity to the HIV-positive client referring partners through third party notification.

Since 1996, the Ryan White CARE Act has required states to confidentially notify current and past spouses of HIV-infected individuals that they may have been exposed to the AIDS virus. How many spouses have been notified in California since this federal requirement for funding was enacted?

The 1996 reauthorization of the Ryan White CARE Act requires states to make "...a good faith effort to notify a spouse of a known HIV-infected patient that they have been exposed to HIV". California addresses this requirement through its Partner Counseling and Referral Services program. The majority of HIV disease burden in California is among men who have sex with men or men who have sex with men who are also injection drug users. These two categories together account for approximately 76 percent of AIDS cases in California. Data from 1999 through 2004 shows that 22 marital spouses of known HIV-infected people were notified through the state administered program. Provider resistance and consumer fears regarding partner notification continue to impact program utilization, and complete and accurate data collection is an on-going challenge. Anecdotal information from service providers indicates that it is likely that more spousal notification is being conducted than is being captured by existing data collection systems. Implementation of more sophisticated, user friendly data collection systems in the next year will improve this situation.

California continues to expand the Partner Counseling and Referral Services program and emphasize it as a component of effective prevention and care programs. The eight largest

local health jurisdictions (in terms of HIV prevalence) in the state recently submitted plans for expansion of Partner Counseling and Referral Services in their jurisdictions. Additionally, the state plans to further emphasize this program by requiring that greater amounts of available prevention funding are targeted to Partner Counseling and Referral Services.

The *Los Angeles Times* reported in October 2003, that nearly a year after the Food and Drug Administration approved the rapid HIV test, which provides results in 20 minutes, fewer than a dozen sites in California were offering the test. The paper stated that "At the heart of the problem, state health officials say, is the fact that California has some of the most stringent regulatory testing guidelines in the country." Have these problems been addressed? How widely available is the rapid test now?

At the time the article was written, those were the facts. However, at that time only a pilot program was in operation and since then California has acted to make sure that rapid HIV testing technology is more widely available throughout the state. Currently in California, 40 local health jurisdictions (including all of the high-prevalence locations) have implemented HIV rapid testing. As of July, 2005, there are approximately 160 Office of AIDS-funded testing sites that offer rapid HIV testing. An initial barrier to implementing rapid HIV testing for local health jurisdictions was the requirement that only a phlebotomy technician could do a finger stick to obtain a blood specimen, which was the only method of sample collection at that time. However, since January 2005, with the availability of the oral version of the rapid HIV test, more sites are implementing a rapid testing program, and additional local health jurisdictions are preparing for rapid testing implementation. Currently there is wide-spread consumer and provider acceptance and support for the new technology. Over 450 test counselors have been trained to perform the rapid HIV test in California. Estimates for 2005, indicate that 40 percent (about 65,000 tests) of all HIV testing in California will be done using this technology, up from five percent two years ago. California has devoted over $1.9 million to the development of materials, purchase of rapid test kits, and sophisticated training of personnel to facilitate the implementation of rapid HIV testing state-wide. With the continued support of CDC, the State anticipates that over 90 percent of all HIV tests will use rapid test technology by the end of 2007.

For non-Office of AIDS-funded testing sites, the major barrier to increased implementation of rapid HIV testing is the State laboratory regulations which require specific approval to perform HIV testing as well as the possession of a site-specific laboratory license. Regulations that act as barriers to wider availability of the rapid test statewide are being addressed by advocacy groups for physicians and consumers working with their state legislators to reduce unnecessary regulatory barriers.

Responses to post-hearing questions from Dr. Marcia Crosse, Director, Health Care, U.S. Government Accountability Office.

1. What percentage of Title I and Title II funds are being spent on primary health care services, such as doctors visits, tests, and medication? What is the total amount for each title that is being spent on other services?

Based on HRSA data for fiscal year 2003, of approximately $600 million provided to support Title I, about 52 percent of these funds were allocated for health care services which includes some funding for medications. The remainder of Title I funds, about $287 million were allocated for other activities, such as case management and support services and administration. For fiscal year 2003, of approximately $1 billion provided to support Title II, about 81 percent was allocated for medications and health care services. The remainder of these funds, a little more than $190 million, was allocated for other activities such as case management and support services and administration.

2. Could increasing funding for ADAP under the existing formulas actually have the unintended end result of creating ADAP surpluses in some states while still not providing sufficient funding in others to ensure that all HIV/AIDS patients have treatment access?

Under the existing formula, an ADAP's base grant amount is determined by its state's proportion of the total number of AIDS cases in all states and territories. In addition to their base grants, some states also receive ADAP Severe Need grants by demonstrating that a severe need prevents them from providing medications to clients in a manner consistent with Public Health Service guidelines and agreeing to match 25 percent of the grant. The amount of each state's Severe Need grant is determined by the state's proportion of the total number of AIDS cases in all states and territories that qualify for the grant. Increasing funding for ADAPs under current formulas would result in increased funds for all ADAPs regardless of their financial situation.

3. In your 2000 report, GAO found that "Historically, the distribution of discretionary grants has generally mirrored the pattern of the formula grants" regardless of need. Congress responded to this finding by requiring discretionary funding to be awarded on the basis of need. How has discretionary funding been altered by the addition of need based criteria?

It is unclear what the impact of the need-based criteria has been on the distribution of the Title I Supplemental Grants (also referred to as discretionary grants) for all eligible metropolitan areas (EMA). For fiscal year 2000 we reported that the Supplemental Grant per AIDS case for the San Francisco EMA was about twice as large as the average for other EMAs. We stated that it appeared that the Supplemental Grants reflected the hold-harmless provision as well as the number of people in need. For fiscal year 2004, we found that it still appeared that the Supplemental Grant for San Francisco reflected the hold-harmless provision and need.

4. In addition to housing services provided by the CARE Act for those with HIV, Congress is appropriating nearly $300 million annually for the Housing Opportunities for Persons with AIDS (HOPWA) program administered by HUD. Could you briefly discuss the trend of amounts spent by HOPWA for direct financial rent assistance versus non-housing costs such as administration and support services?

The data we collected on HOPWA funding are from 1994 through 1998 and for 2003. In our March 2000 report we stated that, between 1994 and 1998, about 64 percent of HOPWA funds was spent for housing assistance and the remaining 36 percent was spent for other activities such as support services and program administration. For fiscal year 2003, about 57 percent of HOPWA funds was spent for housing assistance and the remaining 43 percent was spent for support services and other activities.

5. Mr. Montgomery stated in his testimony that California had 14 cases of perinatal HIV transmission in 2003. Based upon your analysis of state perinatal HIV rates, based upon your research, how verifiable is this claim that there were only 14 cases of perinatal HIV transmission in California in 2003 and is it possible that many more children were infected that have not been identified or treated?

I do not know the source of Mr. Montgomery's data. We requested data from California on the number of newborns tested for HIV, and the number of perinatal transmissions for 1997 and 2002. California officials told us that the reported perinatal transmissions for 1997 were based on AIDS cases only. The state began collecting HIV data in 2002. However, we do not know whether these data represent perinatal transmissions statewide. California officials also told us that the state only collects HIV test data from publicly-funded counseling and testing sites.

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