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CDC's Progress in Reducing Barriers to HIV Testing and Improving Opportunities for Early Diagnosis

Statement of

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Introduction

Good afternoon Mr. Chairman and Members of the Subcommittee. My name is Kevin Fenton and I am the Director of the National Center for HIV, STD, and TB Prevention at the Centers for Disease Control and Prevention (CDC). Thank you for the opportunity to discuss CDC's progress in reducing barriers to HIV testing and improving opportunities for early diagnosis and linkage to care.

Twenty-five years ago, the first cases of AIDS were reported in the United States. Although the struggle to prevent new HIV infections is not over, we have made substantial progress and achieved major successes. For instance, the dramatic decrease in mother-to-child (perinatal) HIV transmission is one of the great success stories of HIV prevention. CDC estimates that between 140 and 230 infants infected with HIV through mother-to-child transmission were born in the United States in 2002 – a substantial reduction from the estimated peak of 1,750 HIV-infected infants born each year during the early to mid-1990's. These declines are due to multiple interventions, including routine voluntary HIV testing of pregnant women, 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 by infants after birth.

We have also seen declines in the number of HIV and AIDS cases attributed to injection drug use. For example, from 2000 to 2004 the number of AIDS cases attributed to injection drug use has declined by about 15%.

Despite these major successes, HIV infection and AIDS remain a leading cause of illness and death in the United States. The numbers are sobering--through December 2004, an estimated total of 944,306 persons have been diagnosed with AIDS and 529,113 (56%) of these persons have died. CDC estimates that currently 1 to 1.2 million people in the United States are infected with HIV, and of these, 252,000-312,000 (roughly a quarter) are undiagnosed and at high risk for transmitting HIV. This undiagnosed group is of great concern to us because they are not able to take advantage of medical treatment and because we believe that infections transmitted by people who are unaware that they are HIV positive account for more than half of new HIV infections each year. 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. For these reasons, efforts to increase HIV testing and diagnosis are an important part of CDC's HIV prevention strategy.

Early Diagnosis Efforts

The advances made in HIV treatment have dramatically improved HIV/AIDS survival rates, especially since 1996, when highly active antiretroviral therapy first became available. However, insufficient progress has been made in effecting earlier diagnosis. In 2004, an estimated 39% of persons diagnosed with AIDS first tested positive for HIV within 1 year of their AIDS diagnosis—a modest improvement—compared with 51% of those diagnosed from 1990 to 1992.

Those who develop AIDS soon after their HIV diagnosis likely have been infected with HIV for years without knowing it and thus have not received the benefits of medical treatment or preventive services. Persons tested late in their infection are more likely to be African-American or Hispanic and to have been exposed through heterosexual contact.

Currently, CDC has a number of efforts underway to encourage early diagnosis of HIV infection. In 2003, CDC launched the Advancing HIV Prevention initiative (AHP), which reinforces CDC's evidence-based approach that routine HIV testing implemented in a variety of settings will reduce barriers to HIV testing, will improve opportunities for early diagnosis and linkage to prevention and care, and will help reduce the number of new infections. CDC also encourages its funded partners—state and local health departments and directly funded community-based organizations—to take HIV testing out into the community by using rapid tests in nontraditional settings and in health care settings that provide episodic care, such as emergency rooms. In addition, CDC is currently updating guidelines for testing in health care settings, making HIV testing more routine. Finally, the President's 2007 budget contains an increase in funding aimed at increasing the number of people who know their HIV serostatus through promoting rapid testing in areas with a high incidence of HIV infection.

Advancing HIV Prevention Initiative

The AHP initiative represents a multi-agency collaboration within the Department of Health and Human Services and consists of four key strategies for HIV prevention: make HIV testing a routine part of medical care; implement new models for diagnosing HIV infections outside medical settings; prevent new infections by working with persons diagnosed with HIV and their partners; and further decrease perinatal HIV transmission.

In 2003, nine health departments and 16 community-based organizations were awarded $23 million for 2-year demonstration projects to develop models for demonstrate effectiveness in implementing the four AHP strategies. One project used social network strategies to reach persons at high risk for HIV infection in communities of color and demonstrated the feasibility of using these social networks to encourage HIV counseling, testing, and referral services. These strategies involve enlisting HIV-infected and high-risk HIV-negative individuals in affected communities to encourage members of their social, sexual, and drug-using networks who may be at risk for HIV to be tested. Of the 3,139 network associates tested though this project, 173 of them tested HIV positive (a positivity rate of 5.5%), which is over 3 times the average prevalence reported by publicly funded counseling, testing, and referral sites. This strategy proved to be successful in reaching persons with undiagnosed HIV infection and to be an efficient and effective route to access HIV-infected persons. As a result in 2005 CDC issued a “Dear Colleague” letter in 2005 that formally encouraged funded grantees to implement the social networks strategy. CDC is currently developing

a social networks toolkit, an implementation manual, and training curriculum that includes technical assistance strategies for CDC grantees targeting women of color and men who have sex with men.

A second AHP demonstration project, the Antiretroviral Treatment Access Study II (ARTAS II), explores the effect of linked case management on getting HIV-infected persons into care. In the linked case management approach, a person who has recently received an HIV diagnosis is assigned a case manager to ensure that he or she accesses HIV primary care.

ARTAS II is a follow-up to the ARTAS I study, which showed that when persons with a recent diagnosis of HIV infection meet up to 5 times in a 3-month period with a case manager, they have a greater chance of being linked to care. In comparison, persons with a recent diagnosis of HIV infection who receive only a passive referral are less likely to be linked to care. ARTAS II will compare linkage rates to HIV care providers before and after instituting linked case management. The study findings will strengthen our understanding of how well linked case management works in HIV program settings in the United States. CDC is also working with the Health Resources and Services Administration (HRSA) to develop additional strategies to link newly diagnosed persons to care and treatment services.

Expanding Rapid HIV Testing

In 2003, access to testing was expanded when the Food and Drug Administration gave HIV rapid tests a Clinical Laboratory Improvement Amendments of 1988 (CLIA) waiver, which allowed HIV rapid testing to be performed outside of traditional laboratory settings. Rapid HIV testing is quickly becoming the accepted standard for HIV screening tests, especially in settings such as emergency departments and STD clinics that deliver mainly episodic care and typically do not establish ongoing relationships with patients. To help promote the use of rapid tests among our partners, CDC purchased $6.4 million worth of rapid HIV test kits between FY 2003 and FY 2005. More than 500,000 rapid HIV tests were distributed to 197 health departments and community-based organizations in 36 states. Heath departments and community-based organizations have used their CDC HIV prevention dollars to purchase tests as well. The President's 2007 budget contains a funding increase to make rapid testing available to several million additional Americans at greatest risk.

Routinizing HIV screening in health-care settings

To reduce barriers to HIV testing and increase the opportunity for early diagnosis, CDC is proposing to revise our guidelines for HIV testing of adults, adolescents, and pregnant women in health care settings. The revised guidelines will focus on increasing routine HIV screening of patients in health care settings; fostering the earlier detection of HIV infection; identifying and counseling persons with unrecognized HIV infection and linking them to clinical

and prevention services; and further reducing perinatal transmission of HIV in the United States.

There are several reasons for the proposed revisions. First, many HIV-infected persons access health care but are not tested for HIV until they become symptomatic (very late in their infection); second, persons testing late in the course of the disease are unable to benefit fully from the effective treatment available; and third, data show that awareness of HIV infection leads to substantial reductions in high-risk sexual behavior.

Many persons with HIV infection visit health care settings in the years before their diagnosis, yet they are infrequently tested for HIV. The changing demographics of the HIV/AIDS epidemic in the United States—with rising proportions of infected persons among youth, women, racial and ethnic populations; persons who reside outside metropolitan areas; and heterosexual men and women—has made it harder for risk behavior-based testing to detect many HIV-infected persons.

Historically, prevention strategies or programs that incorporate universal HIV screening have been highly effective. Screening blood donors for HIV has virtually eliminated transfusion-associated HIV infection in the United States. The incidence of perinatal HIV infection in the United States has also declined

dramatically since the 1990s when prevention strategies began to include specific recommendations for routine HIV testing of pregnant women.

Although the number of new perinatal HIV infections per year is low, transmission continues to occur mostly among women who lack prenatal care or who are not offered voluntary HIV counseling and testing during pregnancy. Even though CDC recommends screening of all pregnant women, studies from a limited number of jurisdictions have shown that such screening is not yet universal. With universal screening of pregnant women in combination with prophylactic administration of antenatal antiretroviral drugs, perinatal transmission rates could be reduced to less than 2%.

Routinizing HIV screening eliminates many significant barriers to HIV testing such as time constraints associated with targeted risk assessments, pre-test HIV counseling, and stigma associated with requesting or consenting to an HIV test. The new guidelines will recommend routine (or opt-out) HIV screening in health care settings. Under this approach, the patient is notified that HIV screening is routine for all patients and has the opportunity to ask questions and decline testing. HIV testing should not take place without a patient's knowledge.

Studies in acute care settings demonstrate that routine HIV screening programs are more effective in identifying HIV-positive persons than are targeted screening programs. For example, in settings such as hospitals and emergency

departments, the percentage of patients with positive tests (2% to 7%) often exceeds that observed nationally in publicly funded HIV counseling and testing sites (1.5%) and sexually transmitted disease (STD) clinics (2.0%) serving high-risk persons. In studies that have examined this issue, patients in acute care settings were rarely seeking testing when screening was offered; therefore, many people were identified earlier than might otherwise have been the case. Routine testing also reduces the stigma associated with having to disclose behavioral risks. More patients accept recommended HIV testing when it is offered routinely to everyone, without a risk assessment.

Data from targeted testing programs in acute-care settings show that nearly two-thirds of patients accept screening, but because risk assessment and prevention counseling (features of targeted testing programs) are resource intensive, only a small number of eligible patients can be tested. Targeted testing on the basis of behavioral risks also fails to identify many HIV-infected persons, as many persons do not perceive their HIV risks or do not disclose them.

Another important feature of the recommendations is that screening may be eligible for third-party reimbursement, analogous to other recommended screening (such as mammography or cholesterol screening). Detecting HIV infection earlier through HIV screening (and optimizing opportunities for effective treatment and prevention) has been shown to be cost-effective, even in settings of low HIV prevalence.

The proposed HIV testing recommendations are intended for providers in all health care settings, including hospital emergency departments, urgent care clinics, inpatient services, STD clinics, correctional health care settings, tuberculosis and other public health clinics, community clinics, and primary care settings. The guidelines only address HIV testing in health care settings; they do not modify existing guidelines on HIV counseling, testing and referral for high-risk persons who seek or receive HIV testing in nonclinical settings (for example, in community based organizations and outreach settings such as testing vans.)

Provision of Counseling in Revised Guidelines

In the proposed guidelines, the provision of counseling at the time of disclosure of results will not change from current practices for persons who test positive for HIV. Furthermore, the guidelines will continue to recommend linking those who test positive to care and prevention services. However, prevention counseling (i.e., pre-test counseling with the development of a risk reduction plan, and post-test counseling for HIV-negative persons) will not be required in conjunction with HIV screening programs in health care settings. Several studies have shown that both patients and providers often perceive prevention counseling as a significant barrier to testing in medical settings. Because of time constraints and other considerations, when conventional counseling and testing are recommended for health care settings, most patients receive neither.

Additionally, data from the National Health Interview Survey indicate that, by the mid-1990s, the U.S. population exhibited high levels of knowledge about HIV, HIV testing, and risk factors for HIV transmission. Emerging data suggest that singling out HIV testing is likely to perpetuate the stigma surrounding HIV testing.

Potential barriers to early diagnosis

Legislative and statutory barriers to early diagnosis exist at the federal, state, and local levels. Some states and local jurisdictions may have statutory or other regulatory impediments prohibiting opt-out screening, or may impose other specific requirements for HIV counseling, written informed consent, confirmatory testing, or method for communicating HIV test results. Current federal law also impacts the way counseling and testing services are delivered in federally funded facilities.

Since the initiation of the AHP Initiative, CDC has recognized the potential for existing state laws to impact the performance of multiple AHP-related activities focused on increasing knowledge of serostatus. Barriers to early diagnosis do currently exist. For example, 40 states currently legislate who can order an HIV test. Some states only allow physicians and nurses to order a test, while other states allow persons from a broad range of disciplines (from midwives to dentists to nursing home administrators) to order an HIV test. About half of the 50 states require informed written consent before an HIV test can be conducted. These legislative provisions often stem from efforts to protect the rights and privacy of

those infected and were often adopted before statutory and regulatory protections were put into place to protect this information.

Many states also promote the use of HIV tests through administrative codes or state public health agency policy. While the majority of states encourage the use of rapid HIV tests, only two states specifically promote the use of rapid HIV tests through legislation. CDC is working with states to resolve barriers that might conflict with CDC's recommendations (both current and proposed).

At the federal level, the Ryan White CARE Act requires counseling before testing of HIV disease. This provision, which was added by the Ryan White Care Act Amendments in 2000, is not consistent with CDC's proposed recommendations for HIV testing in health care settings. While this requirement was consistent with CDC recommendations at the time, qualitative data now show that prevention counseling may not always be appropriate or feasible (such as during episodic or acute care visits) and can serve as a barrier to testing.

President's HIV Testing Initiative

To further support the goal of diagnosing HIV infections earlier and increasing access to care, the President's 2007 budget includes an increase of $93 million for CDC HIV prevention programs. Several components are included in this increase. A testing in Healthcare and Non-Clinical Settings Initiative ($52 million) will support outreach and testing for 2 million individuals in health-care and non-

clinical settings and referral, where appropriate. The initiative is expected to identify approximately 30,000 undiagnosed cases. CDC intends to target resources to areas with the greatest need, including jurisdictions with high HIV/AIDS prevalence among African Americans and areas with emerging epidemics. CDC will work closely with the HRSA to ensure that those identified with HIV infection are linked to appropriate care and treatment.

A Jail Testing Initiative ($20 million) will focus on testing of inmates. With $15 million, CDC will directly facilitate the testing of more than 600,000 incarcerated persons. An additional $5 million will support work with the Department of Justice to develop a model HIV/AIDS policy for corrections agencies that will address testing, prevention education, staff and peer training, and discharge planning programs and procedures as part of a comprehensive community re-entry package. Those programs will link HIV-infected individuals to appropriate community prevention counseling and treatment services when released.

An Injecting Drug User Testing Initiative ($21 million) will test approximately 500,000 injection drug users and is expected to help identify approximately 7,500 undiagnosed cases. CDC will work collaboratively with the Substance Abuse and Mental Health Services Administration on this effort.

Closing

Over the past 25 years, our nation has made progress in preventing morbidity and mortality related to HIV. Beginning in the late 1980s, the number of new HIV infections among men who have sex with men declined dramatically. In the 1990s, improved treatments led to improved longevity and decreased deaths, as well as decreases in perinatal infections. In this, the third decade of the epidemic, we are making progress in increasing early diagnosis, which is key to further reducing incidence, illness, and death from HIV. CDC remains committed to helping people live longer, healthier lives by preventing new HIV infections and protecting the health of those already infected. This includes ensuring fewer barriers to HIV testing, improving opportunities for early diagnosis, and linking HIV-infected persons to prevention services and medical care.

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