Professional Judgment Budget
Requested by Henry A. Waxman, Chairman
U.S. House of Representatives Committee on Oversight and Government Reform

Preventing HIV infection is an important part of CDC's efforts to improve the health of Americans, making the United States a healthier nation. The activities outlined below are consistent with the goals of the Healthiest Nation Alliance. Specifically, preventing HIV is critical to CDC's efforts to: 1) Increase the number of adolescents who are prepared to be healthy, safe, independent, and productive members of society; and 2) Increase the number of adults who are healthy and able to participate fully in life activities and enter their later years with optimum health. This professional judgment budget includes an additional $877 million in FY 2009 and an additional $4.8 billion over 5 years. This response offers the professional judgment of the Centers for Disease Control and Prevention and is provided without regard to the competing priorities that the agency, the President, and their advisors must consider as budget submissions to the Congress are developed.

Too Many Americans Are Still At Risk for HIV
The new HIV incidence estimate shows that HIV infection is taking a more severe toll on the lives of Americans than was previously known. An estimated 56,300 Americans are infected with HIV each year and over 1,000,000 Americans are living with HIV infection. Adolescents and young adults are most affected – with approximately 1/3 of all infections occurring before age 30. Profound disparities exist between racial and ethnic minorities in the U.S. Furthermore, according to the latest estimates by the Joint United Nations Programme on HIV/AIDS (UNAIDS), HIV prevalence in the U.S. is higher than that of Canada, Australia, Japan or any Western European country, except Switzerland, which has the same relatively high HIV prevalence rate of 0.6 percent (among persons 15 – 49 years of age).

Multiple independent reviews have shown that HIV prevention works, however, currently too many people who are living with HIV or are at-risk for HIV infection are not being reached by prevention programs. Data from the Centers for Disease Control and Prevention (CDC) show that 1 in 4 persons who are infected with HIV do not know that they have the virus, and 80 percent of gay and bisexual men have not been reached by individual or group-based HIV prevention programs in the prior year. Additionally, CDC data indicate high levels of coinfection with other infectious diseases, most especially viral hepatitis, STDs, and tuberculosis (TB). We know that, STDs accelerate and facilitate the spread of HIV (referred to as the synergistically interacting epidemics (syndemics) of HIV) and, that STDs viral hepatitis, and TB can increase illness among those infected. We also know that the cost of these diseases is high. The estimated costs of medical care and lost productivity due to early death are over $1 million per HIV infection. Put another way, 56,300 new HIV infections each year may cost the nation over $56 billion in medical care and lost productivity.

HIV Prevention Works When We Apply What We Know
While the new estimates underscore the continued challenges facing HIV prevention programs, they also reveal some encouraging signs of success. For example, reductions in new infections among injecting drug users and heterosexuals are important signs of progress. Dramatic declines

in mother-to-child HIV transmission are one of the great success stories of HIV prevention. Further, the much-welcomed success of HIV treatments means that an increasing number of people are living with HIV than ever before. Although this large number of people means that there are more opportunities for transmission to occur, the overall number of new HIV infections has remained relatively stable, indicating that we have had some success in lowering the HIV transmission rate. A new analysis conducted by researchers at CDC and John Hopkins University indicates that the HIV transmission rate in the U.S. is now approximately 5 for every 100 persons living with HIV, considerably lower than previous rates in the early days of the epidemic, before the widespread availability of HIV testing and effective treatments.

New and Anticipated Research Findings Hold the Potential for Even More Progress
Today, Americans are benefiting from key advances in HIV such as methods to reduce mother to child transmission, effective therapies, effective programs to modify risk behaviors, and improved methods to monitor the epidemic. The new HIV incidence estimates, themselves a culmination of years of research and application, will help us to better focus programming for those populations most at risk for infection. Improvements in surveys of risk behaviors have informed us that differences in disease rates are not always due to differences in risk taking behaviors, thereby causing us to look for other causes of disparities in HIV. Today, research is underway to develop a wider array of intervention programs, including interventions that are designed specifically to address the prevention needs of specific populations highly affected by HIV, such as African American men who have sex with men. New approaches to HIV prevention, such as male circumcision, vaccines, and microbicides are being explored.

One of the most promising approaches being explored is the provision of medications to uninfected persons to help them avoid HIV infection. Pre-exposure prophylaxis (PrEP) has proven effective with other infectious diseases, such as malaria. Use of medications to prevent HIV infection has precedent in efforts to prevent mother to child transmission of HIV and to prevent infection among healthcare workers who were exposed to HIV on the job. Multiple studies of PrEP are currently underway, and interim results are expected from some of the trials as early as next year. CDC is working on several fronts to lead U.S. planning efforts to implement PrEP, if it is shown to be effective. Key challenges include determining the implications of trial results, ensuring that PrEP is implemented as part of a comprehensive program which guards against increases in risk behaviors and minimizes the potential for side effects and resistance, and ensuring that populations at highest risk of infection can benefit from PrEP. Initial estimates indicate that PrEP could be very cost-effective, if targeted to those at highest risk. However, because key questions such as who should receive it, what the recommended regimen should be, and how it should be paid for, have not been answered, CDC has not included a budget estimate for provision of PrEP. Initial estimates suggest that costs could exceed $1.5 billion per year; activities in year 1 would be dominated by implementation planning and research, with costs quickly shifting to actual program delivery in year 2 and beyond.

Prevention Must Play a Central Role in a National Discussion About HIV
More can and should be done to prevent HIV in the United States. There is precedent, not only in our domestic successes but also our global successes. By setting bold targets and fully funding

their implementation, the United States has made great strides in reducing the toll of HIV in other nations. We can do the same at home.

To have the greatest impact in reducing the transmission of HIV and preserving the health of those who are living with HIV/AIDS, HIV prevention efforts, led by CDC, must be implemented in a seamless fashion with activities to prevent the syndemics of STDs, viral hepatitis and TB; HIV treatment efforts; a continued program of basic research; and supportive measures for those infected with and affected by HIV. Such an approach must involve all sectors of society, including not only government agencies, but civic, social and faith-based leaders as well. CDC is poised to provide both support and leadership to such a coordinated response.

The Nation Should Establish and Commit to Bold Targets for Reducing HIV.
CDC is firmly committed to achieving the greatest public health impact possible with the use of its existing HIV resources, budgeted at $753.6 million in FY 2008. **With an additional $877 million in FY 2009 (an additional $4,784 million over 5 years), CDC could greatly expand its efforts, increasing coverage and impact, and could provide leadership to an effective U.S. response to the epidemic at home.** In addition to the life saving results of such prevention efforts, significant cost savings could be achieved. With an estimated lifetime cost of over $1,000,000 per HIV infection, by preventing at least 4,800 new infections over the next 5 years, this effort would be cost-saving to society. This would be achievable and feasible by implementing the strategies outlined in this proposal.

Under such an expanded effort, by 2020 the Nation could:

- Reduce the HIV transmission rate by 50%, from approximately 5 percent to 2.5 percent
- Reduce the proportion of persons who do not know their HIV status by 50%, from approximately 25 percent to 12.5 percent
- Reduce disparities in the Black to white rate ratio of HIV/AIDS diagnoses by 50% from 8.9:1 to 4.5:1
- Reduce disparities in the Hispanic to white rate ratio of HIV/AIDS diagnoses by 50% from 3:5 to 1.8:1

By 2015, the Nation could achieve the following interim goals:

- Reduce by 25% the HIV transmission rate, from approximately 5% to 3.75%
- Reduce by 25% the proportion of persons who do not know their HIV status from approximately 25% to 17.5%
- Reduce disparities in the Black to white rate ratio of HIV/AIDS diagnoses by 25% from 8.9:1 to 6.7:1
- Reduce disparities in the Hispanic to white rate ratio of HIV/AIDS diagnoses by 25% from 3.5:1 to 2.6:1

To accomplish these goals, CDC is proposing 25 specific actions. These proposed actions are broadly grouped under three programmatic priorities: 1) Increase HIV testing and the number of Americans who are reached by effective prevention programs; 2) Develop new tools to fight

HIV; and 3) Improve systems to monitor HIV, and related risk behaviors and evaluate prevention programs. A complete listing of the 25 specific actions is included in the appendix.

***Priority #1* - Increase HIV Testing and the Number of Americans Who Are Reached by Effective HIV Prevention Programs**

FY 2008 estimate: $573M
Increased need, FY 2009 = $743M, 5 year total = $3,986M

Justification:
Existing resources are inadequate to meet the needs of increasingly diverse populations of persons who are at-risk for HIV infection and the growing number of persons who are living with HIV. Approximately 56,300 persons are infected with HIV each year in the United States. This figure is 40 percent higher than prior estimates. Men who have sex with men (MSM) continue to be the group hardest hit by the epidemic and comprised 53 percent of new infections in 2006. While overall rates of HIV infection have been stable in the past decade, steady increases in HIV infections have been occurring among MSM since the early 1990s. While MSM overall still account for the largest percentage of new HIV infections, heterosexually acquired HIV infections represent an important percentage of persons diagnosed with the disease. CDC's 2006 incidence estimates indicate that nearly one-third (31 percent) of new infections were acquired through heterosexual sex.

The epidemic has taken a disproportionate toll on African Americans and Latinos. In 2006, rates of new HIV/AIDS diagnoses were nine times higher among African Americans compared to whites, and were three times higher compared to Latinos. Latinos are also disproportionately affected with rates of HIV/AIDS diagnoses that are over three times higher than those for whites. Women now account for more than one quarter of all new HIV/AIDS diagnoses, and rates among women are especially high among African Americans and Hispanics. Young people, ages 13 to 29, especially racial and ethnic minority MSM, are at significant ongoing risk for HIV infection.

Parallel health disparities exist with TB, viral hepatitis, and bacterial STDs. At least nine percent of TB patients in this country also have HIV, most of whom are African-American or Hispanic. MSM are at particularly high risk for hepatitis B infection. An estimated 300,000 Americans, between one quarter and one third of those infected with HIV, also have the hepatitis C virus (HCV). African-American communities continue to have the highest rates of gonorrhea, chlamydia, and syphilis in the United States. The presence of these bacterial infections makes an individual three to five times more likely to acquire HIV, if exposed. In 2006 Chlamydia rates among African Americans were over eight times higher than those for whites, gonorrhea rates were 18 times higher, and syphilis rates were six times higher. Syphilis, as the sexually transmitted disease that most effectively enhances HIV transmission, is a particular concern because of increasing trends of syphilis among African-American MSM and recent syphilis outbreaks among African-American women.

Taken as a whole, these data underscore the critical need to expand HIV prevention programs and HIV testing, to integrate HIV prevention into programs for other infectious diseases, and to

expand efforts to address common social, environmental, behavioral and biological determinants of these diseases. New generations of young persons who did not personally experience the devastating impact of the early years of the HIV/AIDS epidemic need to be reached by scientifically proven interventions. The fact that 1 in 4 persons with HIV do not know that they are infected means that these persons are at increased risk of unknowingly transmitting HIV to others and for progression to HIV-related illness and death.

Currently, there is a considerable unmet need in prevention program funding for state and local health departments, particularly in areas with newer HIV epidemics. Areas with more recent increases in the number of persons living with HIV, *e.g.*, the South and Southeastern United States, tend to be more severely under funded compared with those areas that were hit earliest by the epidemic. Additional resources would allow CDC to meet the unmet HIV prevention needs in these jurisdictions; expand HIV testing and prevention programs; and integrate HIV prevention with STD, TB, and HCV prevention for those groups most severely impacted by the epidemic.

***Programmatic Priority #2* - Develop New Tools to Fight HIV**

FY 2008 estimate: $61M
Increased need, FY 2009 = $85M, 5 year total = $525M

Justification:
While effective interventions exist to reduce behaviors that place individuals at risk for HIV, new tools are desperately needed to effect major reductions in new infections. Promising research on biomedical interventions for HIV prevention is underway, and needs to be expanded. Testing should be improved, and incidence and drug resistance testing should be refined and expanded. Long-standing gaps in the availability of effective HIV prevention interventions for key populations that are disproportionately affected by HIV continue to limit the success of HIV prevention efforts in the United States. *CDC's Updated Compendium of Evidence-based Interventions* documents a lack or insufficient numbers of proven HIV prevention interventions for persons living with HIV, at-risk African American MSM, at-risk Hispanic MSM, at-risk Hispanic drug users, and at-risk Asian/Pacific Islanders, American Indians, and Alaskan Natives. Additional research is needed to develop new interventions or adapt existing interventions for these populations as well as to develop interventions integrating HIV and STD prevention messages. There is also need for additional research to assess factors that affect the ability of community-based providers to successfully implement scientifically proven interventions and to assess the factors that affect the real-world effectiveness of these interventions. In addition, there is a need for research to develop and test structural interventions to address the effects of social, environmental, and other inequities (such as stigma, poverty, homelessness, racism, and homophobia) that contribute to HIV/AIDS health disparities. Additional resources would allow CDC to meet these research needs.

Programmatic Priority #3 **- Improve Systems to Monitor HIV, and Related Risk Behaviors and Evaluate Prevention Programs**

FY 2008 estimate: $101M
Increased need, FY 2009 = $50M, 5 year total = $281M

Justification:
The ability to monitor the course of the HIV/AIDS epidemic and the implementation and outcomes of prevention efforts is an essential component of an effective HIV /AIDS public health response. In recent years, CDC has implemented new data collection systems (surveillance systems) that monitor the occurrence of new HIV infections in select jurisdictions and the existence of drug-resistant strains of HIV. The new surveillance systems assess risk behavior in at-risk populations and persons receiving clinical care for HIV infection. These systems are in a limited number of states. Together, these data allow CDC to estimate the size and scope of the epidemic at the national level and assess the trends in risk behavior as well as the reach of HIV prevention efforts. Furthermore these data allow CDC to gather information on the utilization of HIV treatment services and antiretroviral medications.

Additional resources for surveillance will enable CDC to improve collection of data about cases of HIV/AIDS and expand surveillance for HIV incidence, related risk behaviors and receipt of care. CDC has been unable to provide needed additional resources to states for collecting data about HIV/AIDS cases. Existing funds are inadequate to support this core surveillance function due to the effects of inflation; the increases in drug-resistant strains of HIV; and the growing number of persons living with HIV. In fact, in FY 2007, states requested $46 million for core surveillance activities but received $36 million. Many states have expressed their inability to meet objectives proposed to CDC in carrying out core activities due to funding constraints. With the requested resources, CDC would restore funds to some states that have lost funding for HIV incidence and resistance surveillance. Additional funding would expand behavioral surveillance beyond the current 24 areas to monitor HIV risk behaviors for three groups at highest risk for acquiring HIV infection: MSM, injection drug users and heterosexuals practicing high-risk behaviors.

Support for Public Health Business Services-
Increased need: 2% of program costs, included in amounts above

Justification:
Commensurate to any increase in program dollars for HIV/AIDS prevention, CDC requests monies to support additional requirements on CDC's business service offices who manage the procurement, financial management, information technology and security for CDC. The business service offices at CDC perform critical functions in managing these proposed additional HIV prevention resources in preparing and executing new contracts and grants and managing the information technology needs for this program. The amount requested represents two percent of the total HIV professional judgment budget.

Conclusion:
The possibility to end the U.S. HIV/AIDS epidemic in our lifetimes is real. By reaching those at risk of infection with effective interventions to prevent the acquisition of HIV, increasing awareness of HIV infection among those who are infected, reaching those infected with HIV with effective prevention and care services, developing new and more effective tools to prevent HIV infection, and increasing our ability to monitor the epidemic and evaluate prevention programs, we can halt HIV transmission in the U.S. But we all must agree that it is possible, firmly commit to making it happen, and work together to transform our collective commitment into reality.

Appendix: HIV Prevention Activities to be Implemented and Expanded

1. Increase HIV Testing and the Number of Americans Reached by Effective HIV Prevention Programs

Additional resources would allow CDC to meet the unmet HIV prevention needs in jurisdictions with newer epidemics; expand HIV testing and prevention programs to reach significantly more infected and at risk persons; and integrate HIV prevention with STD, TB, and HCV prevention for those groups most severely impacted by the epidemic.

FY 2008 estimate: $573M
Requested increase, FY 2009 = $743M, 5 year total = $3,986M

A. Further expand the reach of HIV testing programs, with emphasis on gay and bisexual men of all races/ethnicities, African Americans, and Hispanics, so that more HIV-infected Americans have the opportunity to learn their HIV status. (FY 2009 = $101M, 5 year total = $505M)

B. Ensure that individuals who test HIV-positive not only receive prompt medical care, but also receive proven interventions that reduce risk behavior; partner services to make sure that all partners are aware of their risks; and linkage to substance abuse, mental health and other supportive services if needed. (FY 2009 = $86M, 5 year total = $430M)

C. Promote STD, TB, and viral hepatitis screening and vaccination for individuals with HIV to prevent onward transmission of these infections and to reduce the likelihood of secondary transmission of HIV to partners. (FY 2009 = $50M, 5 year total: $250M)

D. Scale up funding to state and local health departments and community-based organizations so that effective HIV prevention interventions (including the distribution of condoms) are available to more persons who are at-risk of contracting or transmitting HIV. (FY 2009 = $290M, 5 year total = $1,450M).

E. Ensure that persons diagnosed with an STD at publicly funded STD clinics are offered HIV testing, hepatitis testing and vaccination, and receive effective HIV prevention interventions. (FY 2009 = $78M, 5 year total = $390M)

F. Provide incentive grants to areas that demonstrate progress on key markers for successful HIV prevention efforts, such as increasing early diagnosis of HIV. (FY 2009 = $50M, 5 year total: $250M)

G. Eliminate the backlog of more than 2000 organizations that are on waiting lists to receive training in the delivery of scientifically proven interventions to reduce HIV risk. (FY 2009 = $2.0M, 5 year total = $10M)

H. Double the number of proven interventions that are supported by CDC's training and technical assistance programs for health departments and community-based organizations. (FY 2009 = $2M, 5 year total = $70M)

I. In correctional settings, expand screening for HIV, STDs, TB, and viral hepatitis as well as the availability of prevention information and prevention tools, including appropriate vaccinations. (FY 2009 = $21M, 5 year total = $106M)

J. Intensify efforts to mobilize African American leaders, as well as leaders in the Hispanic and gay communities, to take action against HIV/AIDS in their communities. (FY 2009 = $3M, 5 year total = $15M)

K. Due to the known interactions between syphilis and HIV, intensify efforts to reach the targets of the National Syphilis Elimination Effort, especially among African Americans and MSM. (FY 2009 = $15 M, 5 year total = $85M)

L. Research, develop and implement national health communication campaigns, as well as novel communications strategies, to promote HIV prevention and sexual health as well as fight HIV stigma, and address persistent myths, which act as barriers to HIV testing. Addtionally, develop communication to promote access to prevention and medical services. (FY 2009 = $12M, 5 year total = $81M)

M. Expand current school-based HIV prevention programs, work with national youth-serving organizations, and develop information and education campaigns to ensure that young Americans, have the knowledge, skills, and confidence necessary to protect themselves from HIV. (FY 2009 = $18M, 5 year total = $116M)

N. Expand and accelerate the implementation of emerging and new biomedical and behavioral approaches (*e.g.,* pre-exposure prophylaxis, microbicides, male circumcision), as they become available. (FY 2009 = 0, 5 year total $150M)

2. Develop New Tools to Fight HIV

Additional resources would allow CDC to, develop new HIV prevention interventions and adapt existing interventions for populations most in need of them, assess factors that affect the ability of community-based providers to successfully implement scientifically proven interventions and develop and test structural interventions to address the effects of social, environmental, and other inequities (such as stigma, poverty, homelessness, racism, and homophobia) that contribute to HIV/AIDS health disparities. CDC would also expand research on biomedical approaches to HIV prevention and develop new testing technologies for improving efficient diagnosis.

FY 2008 estimate: $61M
Requested increase, FY 2009 = $85M, 5 year total = $525M

A. Rapidly expand research on promising biomedical approaches to HIV prevention such as pre-exposure prophylaxis and antiretroviral microbicides, which use oral and topical versions of HIV treatments to prevent HIV transmission when taken by at-risk uninfected persons. (FY 2009 = $30M, 5 year total = $160M)

B. Conduct research to develop, identify and test effective HIV/STD interventions that do not currently exist in sufficient numbers for highly affected populations, such as people living with HIV, at-risk MSM of all races, drug users, incarcerated individuals, and at-risk African Americans, Hispanics, Asian/Pacific Islanders, American Indians, and Alaskan Natives. (FY 2009 = $8M, 5 year total = $85M)

C. Conduct research and scale up integrated and holistic interventions to promote HIV prevention among women of reproductive age, especially pregnant women. (FY 2009 = $11M, 5 year total = $55M)

D. Expand research on promising lab technologies that can improve our ability to identify new HIV infections at the individual and population levels, identify coinfections with viral hepatitis and other STDs, and monitor drug resistance. (FY 2009 = $5M, 5 year total = $27M)

E. Support research on new testing technologies, testing algorithms and combined tests for other sexually transmitted diseases and viral hepatitis, and field effectiveness of such tests in enhancing early diagnosis, treatment and referral to care. Also implement demonstration projects using new testing technology (Nucleic Acid Amplification Test) that allows for HIV infection to be detected earlier than standard HIV tests and link its use with active partner services to break HIV transmission chains. (FY 2009 = $10M, 5 year total = $64M)

F. Conduct research to better understand and develop solutions to the social and structural determinants of HIV infection such as poverty, homelessness, stigma, racism, and homophobia that perpetuate HIV transmission and limit access to HIV prevention and care. (FY 2009 = $6M, 5 year total = $42M)

G. Implement university-community collaborative evaluation projects that allow 30 locally developed (*i.e.*, "homegrown") interventions for high-priority populations to be rigorously evaluated to determine their effectiveness and suitability for dissemination to other communities. (FY 2009 = $13M, 5 year total = $82M)

3. Improve Systems to Monitor HIV, and Related Risk Behaviors and Evaluate Prevention Programs

Additional resources will enable CDC to improve collection of data about cases of HIV/AIDS and expand surveillance for HIV incidence, related risk behaviors and receipt of care in states and high-morbidity jurisdictions. CDC will also be able to improve monitoring and evaluation of prevention programs in order to ensure that resources are used most effectively and efficiently.

FY 2008 estimate: $101M
Requested increase, FY 2009 = $50M, 5 year total = $281M

A. Increase funding to address the growing needs for monitoring of HIV/AIDS cases; expand HIV incidence monitoring to ensure that state and local jurisdictions that have a high burden of HIV can take advantage of the newly available technology and develop more precise local incidence estimates; and monitor for primary and secondary drug resistance. (FY 2009 = $29M, 5 year total = $161M)

B. Increase funding to strengthen behavioral and clinical surveillance activities in states and cities with high burdens of HIV/AIDS in order to improve the national capacity to develop appropriate HIV prevention strategies and monitor care and treatment. (FY 2009 = $11M, 5 year total = $52M)

C. Further strengthen the capacity of state and local health departments and community-based organizations to collect complete program monitoring and evaluation data to increase accountability, demonstrate effectiveness, and disseminate successful programs nationwide. (FY 2009 = $5M, 5 year total = $25M)

D. Fund demonstration projects to identify promising and best practice models for integrated HIV/STD/viral hepatitis surveillance. Implement findings in core surveillance programs to improve efficiency and effectiveness of integrated approaches to monitor these co-occurring epidemics and the public health response to addressing the problems. (FY 2009 = $4M, 5 year total = $42M)