

October 15, 2010

Howard Koh, MD, MPH
Assistant Secretary for Health
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20500

Dear Dr. Koh,

We write to offer our support to the Department of Health and Human Services (DHHS) as it develops plans for implementation of the National HIV/AIDS Strategy (NHAS). We also offer recommendations to DHHS for addressing the research focused actions set forth in the Federal Implementation Plan, and to identify additional areas of research that we believe will be required to make the goals of the NHAS a reality. We hope that our comments can be incorporated into DHHS's response when it submits operational plans for implementing the NHAS to the Office of National AIDS Policy (ONAP) and the Office of Management and Budget (OMB) on December 9, 2010.

We are member organizations of the Research Working Group of the Federal AIDS Policy Partnership (FAPP). FAPP is a national coalition of approximately 125 organizations committed to federal AIDS policy. FAPP conducts its work mainly through specialized working groups, and the Research Working Group includes approximately 80 individuals representing FAPP members. This letter expresses the perspectives of the FAPP Research Working Group.

The NHAS focused on achieving improved outcomes in three areas: HIV incidence, access to care, and health disparities. Research must be an essential component of the strategy because only through research can we develop, evaluate, and deliver the effective interventions so urgently needed to gain control of the HIV epidemic in America. We have focused our comments directed toward the research related action items identified in Federal Implementation Plan.

The short term research focused elements of the Federal Implementation Plan are unquestionably important, but also modest. The plan directs the National Institutes of Health (NIH) and the Centers for Disease Control (CDC) to: 1) continue testing mathematical models to explore the best combinations of behavioral and biomedical prevention activities; and 2) to develop and implement a plan for evaluating community-generated HIV prevention intervention. The NIH is also directed to continue efforts to investigate new antiretroviral therapies for HIV and for its associated conditions. Three

areas of new research - developing new methods for identifying and reaching newly infected individuals, testing interventions that incorporate sexual networks, income insecurity, and other social factors; and improving methods to prevent HIV infection among women- are unfortunately identified only as research in later years. This research, which is critical to meet the challenging goals of reducing infections by 25% by 2015, should be undertaken immediately.

We believe the research tasks currently identified in the Federal Implementation Plan are necessary, but not sufficient, elements of a supportive NHAS research agenda. We believe that critically important behavioral and social science research is missing from the plan, as is research into new interventions, such as pre-exposure prophylaxis (PrEP) and microbicides. Finally, basic and clinical scientific research on HIV/AIDS will remain essential to developing new approaches to both prevention and treatment.

We believe the following research is essential to achieving the goals of the NHAS. This is not an exhaustive list of items, but reflects the NHAS research priorities identified by the Research Working Group.

Research to evaluate and improve the effectiveness of current strategies

We commend the focus of the NHAS on the evaluation of existing prevention interventions and programs for treatment and care. Targeting limited resources to the most effective tools is an important step in realizing the NHAS's goals. This evaluation will require dedicated research to develop new evaluation tools, to evaluate tools in different settings and different population and to understand their effectiveness after scale-up. Operations research efforts across HHS agencies should be planned to test programs and their effectiveness in achieving the goals of the NHAS.

Research address identified gaps in targeted HIV prevention and linkages to care and treatment.

The Federal Implementation Plans plan prioritizes certain communities for prevention intervention including: Black men and women; Latinos and Latinas; Asian Americans, and Pacific Islanders, American Indian and Alaska Natives; gay men and other men who have sex with men; bisexuals; transgender populations; substance users; and HIV positive pregnant women and women of child bearing age. Additional research is necessary to develop interventions that are specifically addressed to, and do, in fact, engage these communities. Social science-based research is also needed for the development and assessment of prevention interventions to address structural factors associated with vulnerability (and, conversely, resilience) to HIV. In particular, community-based

participatory research (CBPR) is needed to identify barriers to HIV testing and treatment in areas of high HIV prevalence and incidence in the U.S., including CBPR to assess the impact that laws criminalizing HIV exposure and transmission are having on various populations' willingness to get tested for HIV and access HIV care and services.

The Federal Implementation Plan establishes goals of increasing the number of Blacks, Latinos and Gay men with undetectable viral load as a measure of the NHAS goal of reducing health disparities. Research will be needed to develop programs that improve care for these communities so that this goal is achieved.

Research into co-infections, co-morbidities, and HIV and aging.

Improving health outcomes, and reducing health disparities, requires new research to gain improved understanding health of HIV positive individuals. Research is needed to develop new treatments and standards of care to address co-infections, such as hepatitis and TB, and co-morbidities such as cardiovascular disease, diabetes, and HIV related and non- related cancers especially anal and cervical cancer. The effect of HIV and HIV treatment, is an additional area of research that is critical to improving health outcomes, yet is absent from, the Federal Implementation Plan. Finally, inflammation, premature aging in people with HIV and the long-term effect of HIV and HIV treatment (in HIV positive adults and children), are additional areas of research that are critical to improving health outcomes, yet are absent from the Federal Implementation Plan.

Research into an HIV Cure

The prospect of eradicating HIV from latent reservoirs and of preventing immune activation exhaustion currently provide many promising scientific opportunities. Promising cure strategy lines of inquiry should be sustained and funded continually in succeeding years at levels necessary to advance the agenda with the proper stimulus. This research has the potential to serve all three goals of the NHAS by improving health outcomes, reducing health disparities and decreasing infections.

Research to improve HIV testing technologies.

The implementation plan directed the FDA to expedite review of fourth generation HIV tests. On June 18, the FDA approved the first fourth generation HIV test. Although this test will significantly reduce the period for which HIV infection remain undetectable, a window remains. Research into new technologies are needed which are capable of distinguishing the earliest infection.

Research on new potential biomedical HIV prevention approaches

Experimental biomedical prevention approaches such as PrEP, microbicides, vaccines, and “Test, Link, Care” (also referred to as “Test and Treat”) are not mentioned in the Federal Implementation Plan. Results from the first oral PrEP trial will be released sometime in the next few months. The CAPRISA04 trial of tenofovir gel released results showing partial effectiveness for that microbicide in July 2010. The RV144 trial of the ALVAC/AIDSVAX vaccine candidate published promising results in October of 2009. These interventions are not validated or available now, but the time to plan for their contribution is now by incorporating them into the research goals of the Federal Implementation Plan.

We look forward to working with DHHS to create a coordinated, accountable, and outcomes-oriented response to HIV/AIDS at home. Please feel free to contact the co-chairs of the Research Working Group: Kevin Fisher, AVAC, Policy Director, at 212.367.1051, or Coco Jervis, Treatment Action Group, Senior Policy Associate, at 202.904.0290 with any questions or comments about our proposals.

Respectfully submitted by,

The AIDS Institute
AIDS Treatment Activists Coalition
AVAC: Global Advocacy for HIV Prevention
HIV Medicine Association
Treatment Action Group

cc: Ronald Valdiserri, MD, MPH