

September 29, 2010

Secretary Kathleen Sebelius  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Sebelius,

We applaud the Obama Administration's commitment to a more coordinated, accountable and effective response to our nation's HIV/AIDS epidemic through implementation of a National HIV/AIDS Strategy (NHAS). AIDS research across federal agencies will be critically important in achieving the goals set out in the NHAS. Now that the Department of Health and Human Services (HHS) and other agencies are engaged in developing their operational plans to implement the NHAS, we are writing to provide several recommendations about how AIDS research can have maximum impact in NHAS implementation.

As you know, our country's investments in AIDS research have paid enormous dividends in lifesaving treatments and HIV prevention interventions, and have also led to important advances in other areas of health. ***Generation of basic scientific knowledge about HIV/AIDS at NIH will remain essential*** to developing new approaches to HIV prevention and treatment, as well as to ultimately ending the epidemic through development of a cure and a vaccine. This basic knowledge must also include insights from social and behavioral science about individual and contextual factors that influence people's HIV vulnerability and their access to and uptake of HIV testing, prevention, and care services.

If we are to make population-level impact on HIV incidence, care outcomes, and health disparities in the next several years - as called for in the NHAS - ***expanded investment in implementation science research across federal agencies is necessary***. In order to scale up interventions for HIV detection, linkage to and retention in care, and improved health outcomes, multi-level approaches will be needed. We already have a strong literature in many of these areas; now is the time to test combination approaches with NHAS targets in mind. NIH should have a lead role in this important area of science, which should be developed and supported in collaboration with other relevant federal agency partners. Both basic and implementation science knowledge and their application not only will benefit people affected by HIV in the United States but those affected globally as well.

***We urge the Administration to seek significant increases in HIV/AIDS and health research funding across federal agencies.*** When adjusted for inflation, base funding for health research at the NIH has declined since 2004, forcing NIH to not fund an increasing proportion of high quality research proposals. Increased resources, and more strategic use of current resources, will be necessary if we are to accomplish NHAS goals and change the trajectory of the domestic and global epidemics. This investment will pay

dividends in terms of knowledge gained and will also stimulate the economy, create jobs, and advance America's long term competitiveness.

***Improved cross-agency research coordination also is a top priority.*** Structural changes in how HIV/AIDS research is planned, coordinated, and utilized are needed.

Just as many agencies will be involved in NHAS implementation, the complex bio-psycho-social nature of HIV infection requires the collaboration of multiple agencies in the creation of a cross-agency strategic HIV/AIDS research plan. The current lack of cross-agency collaborative planning results in a system in which both time and funds are wasted through cumbersome bureaucracy and duplication of research efforts, leaving some important research areas under-studied.

The unique planning, coordination and evaluation role of the NIH Office of AIDS Research (OAR) is central to NHAS implementation. A cross-agency strategic HIV/AIDS research plan is needed and should be established to ensure the major agencies, including NIH, CDC, FDA, SAMHSA, AHRQ, CMS and HRSA, as well as DOL, DOE, NSF, VA, HUD, DOJ, and DOD, are coordinating efforts.

Some ideas for eliminating impediments to interagency collaboration include:

- Creating trans-disciplinary study sections in both NIH and CDC;
- Developing interagency RFP mechanisms, an investment of resources similar to the recent emphasis on Comparative Effectiveness Research;
- Coordinating the research agenda on complications of HIV disease with research agendas in aging, cancer, cardiovascular disease, diabetes, general medicine, liver disease (including viral hepatitis), mental health, and substance use;
- Providing the Secretary of HHS with the authority to award grants for cross-cutting projects that would be reviewed by an interagency review committee (similar to the cross-agency PEPFAR model); and,
- Requiring an annual report from NIH detailing its efforts, in collaboration with other agencies, to improve coordination of research to better accomplish NHAS goals.

***AIDS research should be planned, and proposals evaluated, with close attention to accomplishing NHAS goals.*** This focus will put a new premium on research that can be readily applied in the field and evaluated for both individual benefit and population-level impact. The NIH research agenda should be closely informed by the needs of implementing agencies at HHS (including CDC, SAMHSA, CMS and HRSA) for interventions that can be delivered at scale. NIH should assess the optimal configuration of study sections to pursue NHAS goals and consider creating study sections dedicated to each of the Strategy's three main areas of focus.

Research review processes at NIH are often structured to reward scientific innovation. While innovation is a primary concern in supporting biomedical and all areas of research, it will often not be the most important characteristic of needed implementation science

and other more applied research areas. Thus, we urge NIH to review the research evaluation process to ensure criteria for selection of proposals best suits the research that is needed to advance progress on NHAS goals.

Finally, it is essential to ***address current gaps in AIDS research***, including delivery of combination interventions at scale in communities hardest hit by the HIV/AIDS epidemic. Additional research is needed on prevention and treatment interventions targeted for African-American men and women (including in the South and in high-prevalence settings); Latinos and Latinas; gay men and other men who have sex with men (MSM) of all ethnicities; bisexuals; and transgender populations. Young gay/MSM, especially those from Black or Latino communities, are among the groups at greatest risk of acquiring HIV, yet there is extremely limited research on sex education, behavioral and social/structural interventions, and other HIV prevention approaches that work for this population. In addition, there is need for implementation research on new “home grown” prevention interventions identified in the NHAS.

As noted earlier, expanded investment in research on social determinants of health and structural prevention and care interventions is also needed. Research must help policy makers and providers better understand how social and economic forces influence vulnerability to infection, health care utilization and health outcomes.

We look forward to working with you to accomplish the worthy goals of the groundbreaking Strategy. We would greatly appreciate the opportunity to review the HHS NHAS operational plan and provide comments. Please direct any response or questions to Chris Collins at [chris.collins@amfar.org](mailto:chris.collins@amfar.org) or by phone at 202.331.8600.

Thank you for your leadership on health reform and for your commitment to the health of all Americans.

Sincerely,

*(Affiliations are listed for identification purposes only)*

Adaora Adimora, UNC School of Medicine, University of North Carolina at Chapel Hill  
Judith Auerbach, San Francisco AIDS Foundation  
Grant Colfax, San Francisco Department of Public Health  
Chris Collins, amfAR, The Foundation for AIDS Research  
Kimberly Crump, HIV Medicine Association  
Lynda Dee, AIDS Action Baltimore  
Dazon Dixon Diallo, SisterLove, Inc.  
Anne Donnelly, Project Inform  
Judith Feinberg, Department of Internal Medicine, Division of Infectious Diseases,  
University of Cincinnati College of Medicine  
Kevin Fisher, AVAC  
Anna Forbes, Consultant  
Robert E. Fullilove, Joseph Mailman School of Public Health, Columbia University

Cynthia A. Gómez, Health Equity Institute for Research, Practice & Policy, San Francisco State University  
Mark Harrington, Treatment Action Group  
Kenneth Hugh Mayer, Brown University School of Medicine  
Nancy Mahon, MAC AIDS Fund  
Vickie M. Mays, UCLA Center on Research, Education, Training and Strategic Communication on Minority Health Disparities  
Steve Morin, University of California at San Francisco  
LaRon Nelson, University of Toronto; Black Gay Research Group  
Elizabeth Penniman, Elizabeth Glaser Pediatric AIDS Foundation  
Sue Perez, Treatment Action Group  
Monica S. Ruiz, Department of Prevention & Community Health, George Washington School of Public Health and Health Services  
Michael Saag, University of Alabama at Birmingham  
Carl Schmid, The AIDS Institute  
Susan Sherman, Johns Hopkins Bloomberg School of Public Health  
Melanie Thompson, AIDS Research Consortium of Atlanta  
Dana van Gorder, Project Inform  
Steven F. Wakefield, HIV Vaccine Trials Network  
Rochelle Walensky, Harvard Medical School  
Mitchell Warren, AVAC  
Andrea Weddle, HIV Medicine Association  
Leo Wilton, Binghamton University; Black Gay Research Group  
Carmen D. Zorrilla, University of Puerto Rico School of Medicine

cc: Jeffrey Crowley, ONAP  
Dr. Anthony Fauci, NIAID  
Keith Fontenot, OMB  
Howard Koh, Assistant Secretary for Health, HHS  
Greg Millett, ONAP  
Ron Valdiserri, Office of the Assistant Secretary for Health, HHS  
Jack Whitescarver, OAR