

January 22, 2010

President Barack Obama  
The White House  
Washington, DC 20500

Dear Mr. President,

We applaud your commitment to developing a National HIV/AIDS Strategy (NHAS) focused on achieving improved outcomes in three areas: HIV incidence, access to care, and health disparities. Research must be an essential component of your 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. *The three central goals of the NHAS should be the guideposts for federal domestic HIV/AIDS-related research planning.* Further, in order to reach these goals it is imperative that the HIV/AIDS research agenda be coordinated across all federal agencies and research disciplines and be designed and prioritized with these goals in mind.

We are a group of 32 individuals who are active in HIV/AIDS and health research, policy, and advocacy who met in November 2009 to discuss how HIV/AIDS-related research efforts can best serve the goals of the NHAS. This independent meeting was sponsored by a number of organizations that are members of the Coalition for a National AIDS Strategy to complement the series of community discussions organized by your Office of National AIDS Policy (ONAP). Similar groups of organizations are sponsoring three other independent consultations on aspects of the Strategy: HIV prevention (held in October), HIV/AIDS care (held in December), and HIV-associated health disparities (held in January). However, this letter, as well as the recommendations generated by each of the independent consultations, expresses the perspectives of the individual signers only, not the Coalition.

We believe the following actions are essential to achieving your vision for the NHAS. This is not an exhaustive list of items, but reflects the NHAS research priorities identified by the undersigned individuals. This list comprises overarching issues, priorities for each of the three Strategy goals, and issues of research management. Those items to which we want to give particular priority are noted with an asterisk (\*).

### **Overarching Issues**

- **Prioritize the design and evaluation of research programs based on NHAS objectives.** Domestic research efforts across agencies should be planned and regularly assessed based on their potential contribution to the primary goals of the Strategy. This focus will put a new premium on research that can be quickly and readily applied in the field and evaluated for both individual benefit and population-level impact. Even so, generation of basic scientific research on HIV/AIDS will remain essential to developing new approaches to both prevention and treatment.

- **\* Increase resources for health research, including HIV/AIDS research.** Health research at the National Institutes of Health (NIH) has been nearly flat funded since 2004, forcing NIH to not fund an increasing proportion of high quality research proposals and to significantly reduce budgets of those projects for which funding is awarded. The rejection rate for proposals that are deemed scientifically meritorious by peer review has increased steadily in recent years and young investigators find it increasingly difficult to pursue their research interests in HIV/AIDS and other health fields. Robust investments in HIV/AIDS and other areas of health research are necessary and long overdue. New investments will strengthen our country's scientific infrastructure and global leadership on health research. We urge you to implement your campaign promise to double overall NIH funding within the next decade, and to ensure that research on HIV/AIDS continues to grow at the same rate as NIH funding overall, at a minimum. Sustained and healthy funding levels will be essential to ensuring that research can fully support the NHAS.
- **Improve effectiveness of research investments.** In addition to new funding, it is important to use research investments effectively and efficiently. A transparent evaluation of current funding that includes the perspectives of diverse stakeholders is needed. We suggest requiring an annual, comprehensive evaluation of HIV research across agencies to determine the extent to which the domestic research portfolio serves to advance the NHAS goals. The comprehensive review should seek to identify and eliminate excessive overlap and identify opportunities for cross fertilization and collaboration among agencies. We urge closer collaboration and joint funding initiatives among NIH, CDC and other agencies, in particular, but not limited to, operations research. We also encourage greater transparency across all HHS offices with respect to allocation of HIV/AIDS research funds.
- **Ensure that research addresses identified gaps in targeted HIV prevention.** There is inadequate attention to the development and testing of prevention and care delivery strategies 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; and victims of violence and trauma. Moreover, 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.
- **\* Ensure that research informs implementation:** We urge your Administration to coordinate research and policymaking in a manner that ensures that the results of U.S. government sponsored HIV research guides evidence-based prevention and treatment policy, practice and funding in the field. Proven-effective interventions should be moved to the field in a timely manner, and experience

with those programs should inform further research. It is the obligation of the research community and research sponsors to advocate for implementation of positive research findings in the field.

- **\* Improve coordination of HIV/AIDS research across agencies.** The unique planning, coordination and evaluation role of the NIH Office of AIDS Research (OAR) is increasingly important as you implement your NHAS. A cross-agency strategic HIV/AIDS research plan is needed and mechanisms should be established to ensure the major research agencies, including NIH, CDC, FDA, SAMHSA, and HRSA, as well as DOL, DOE, NSF, VA, HUD, DOJ, and DOD, are coordinating efforts. The NIH research agenda should be closely informed by the needs of implementing agencies in HHS (including CDC, SAMHSA and HRSA) for interventions that can be delivered in the field. Eliminate impediments to interagency collaboration by:
  - creating trans-disciplinary study sections in both NIH and CDC;
  - developing interagency RFP mechanisms funded with HIV Comparative Effectiveness Research funds;
  - coordinating the research agenda on complications of HIV disease with research agendas in aging, cancer, cardiovascular disease, diabetes, general medicine, and 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.
- **Expand the role of community-driven participatory research.** Research planning should be informed by community-identified needs and priorities. Ensure that communities are involved in planning research from the conception and design stages to implementation, dissemination and translation of results. Promote HIV/AIDS research literacy and education among community members, and promote “community” literacy (i.e. about the needs and values of affected communities) among researchers, funders and policy makers. Foster community-based participatory research (CBPR) approaches by: targeting funding and other resources to promote CBPR training, relationships, and research studies; identifying and addressing logistical barriers to CBPR, and widely disseminating successful strategies and methods; and training academic researchers, community-based providers, government and private funders, and people living with HIV/AIDS on CBPR, to foster greater understanding and appreciation of this approach.
- **\* Expand research on social determinants of health and structural prevention and care interventions.** Research must help policy makers and

providers better understand how social and economic forces influence vulnerability to infection and health care utilization and health outcomes. Structural factors include the physical, social, cultural, organizational, community, economic, legal, or policy features of the environment that affect health outcomes. Structural approaches include policies or programs that aim to change the conditions in which people live. Achieving the Strategy goals will require attention to structural approaches, rather than continuing to address individual-level factors alone. A greater investment is needed in social science-based research along with the development and assessment of interventions to address structural factors associated with vulnerability (and, conversely, resilience) to HIV. Boosting of the evidence base of the effectiveness of structural approaches will require a deliberate effort to invest greater resources in social science studies, much as has been done in the case of clinical trials for new biomedical technologies. Scientists and research networks that focus narrowly on proximate determinants of HIV vulnerability must engage with broader social-science methods to elucidate and assess more distal layers of influence and context. Innovative approaches to studying multiple factors in personal health (not only HIV) need greater support. More program officers at NIH and CDC should have a social science background and the investigator-initiated research portfolio around social sciences should be expanded.

- **Evaluate approaches to addressing stigma and discrimination.** Focus particular attention on the impact of stigma and discrimination on individuals' willingness to accept HIV testing, access to care, retention in care, willingness to take antiretroviral and other necessary medications, HIV disclosure, and adoption of risk-reduction strategies. On the societal level, expand research on the effects of laws, policies and cultural norms that contribute to stigma and discrimination and on efforts to ameliorate them. Evaluate interventions from international settings that have proven effective at reducing stigma and promoting other areas of HIV prevention for possible adaptation to US settings. This may require collaboration with PEPFAR.
- **\* Develop a new applied research paradigm that conceptualizes HIV/AIDS interventions from basic design through Phase IV and operations research.** This may require longer time and funding periods and larger grants than are the current norm for NIH and CDC funded studies. New guidelines and incentives should be created to encourage project investigators to engage in long-term studies. Inclusion of costing, cost-effectiveness, and long-term outcomes assessment should be part of this paradigm.
- **Encourage wider participation in clinical trials.** Mr. President, your personal involvement in encouraging individuals from groups traditionally underrepresented in clinical trials to consider participation in this research would have a profound and positive effect.

## **Research Priorities for NHAS Goals**

Each of the three goals for the NHAS should have a focused research agenda. Research activities may advance more than one objective. For example, HIV testing strategies for reducing new infections also should address access to care issues in order to provide successful follow-up for newly diagnosed HIV-infected individuals. For the sake of simplicity in this document, research priorities are listed under one goal only.

### ***Reducing New HIV Infections***

- **Develop improved HIV testing technologies.** Rapid testing has revolutionized the field of HIV testing; however new technologies are needed which are capable of distinguishing among acute, recent, and chronic infection.
- **Create a “real-time” evidence-based national surveillance system.** This system will geographically locate and track acute, recent, and chronic HIV infections and facilitate targeted local rapid-response interventions. Provide appropriate technology, staff, and training to state and local health departments to assure rapid reporting of infections to the national database and seamless functionality at the local as well as national level.
- **\* Create an interdisciplinary working group (or “think tank”) with a mission to reduce new HIV infections** through novel approaches or combinations of proven strategies implemented in specific settings. The working group should include experts from science and medicine, industry, and media, philanthropy, and community.
  - Fund this entity through contributions from federal agency budgets in order to foster collaboration across agencies.
  - Empower this entity to work with a federal interagency working group to develop and monitor outcome goals for this mission across agencies.
  - Endow this entity with authority to rapidly develop and implement pilot studies and demonstration projects targeted toward the mission.
- **Support studies that examine** overlapping factors such as race/ethnicity, sex/gender and class/socioeconomic status that contribute to HIV risk and vulnerability. (In the social sciences, this is referred to as “intersectionality.”)
- **Examine the continuum of HIV prevention, testing, treatment, and care** through studies that assess:
  - strategies to expand HIV testing and strengthen linkages from testing to care and treatment. Strategies to support people at risk in overcoming individual and community barriers to HIV testing and engagement with care;

- strategies to determine the rate at which continuing to scale up antiretroviral treatment to everyone who needs it can reduce community wide viral load and prevent or reduce HIV transmission
  - strategies to support known HIV infected patients to prevent transmission to others (“Prevention for Positives”)
  - strategies to link those who test HIV negative with appropriate HIV prevention interventions, substance abuse treatment, mental health and other services
- **Encourage innovative research on new behavioral and social/structural interventions to reduce risk of HIV transmission.** The pool of available Effective Behavioral Interventions promoted by CDC are not adequate to address the current epidemic. New interventions should be practical, scalable, and culturally appropriate (including, for example, the use of social media and new communication strategies). Utilize rigorous study designs to assess the effects of community level interventions (e.g. district-level cluster-randomized studies). Convene social and policy researchers and methodologists to design appropriate studies of social/structural interventions.
  - **Encourage and support innovative research on structural interventions to reduce risk of infection.** Housing, for example, has been identified as a key structural factor influencing HIV vulnerability and risk behaviors. Housing availability, affordability and quality are all important factors.
  - **Identify and widely disseminate findings about core principles** that have been found to be important to successful prevention programming in various populations so that these can be used by providers to develop and adapt interventions appropriate for specific settings.
  - **Evaluate best practices for HIV-associated provider education that can be effectively applied in health care settings regarding:**
    - CDC guidelines for routine voluntary HIV testing in care settings such as emergency rooms, hospitals, and community clinics
    - CDC guidelines for HIV prevention in medical care settings, “Prevention for Positives”
    - barriers to providing referrals, support, and counseling for newly diagnosed HIV-infected persons in the primary care setting
  - **Invest in research on new potential biomedical HIV prevention** approaches, including pre-exposure prophylaxis (PrEP), microbicides, vaccines, and “Test, Link, Care” (formerly referred to as “Test and Treat”).
  - **Invest in research on HIV prevention among adolescents and young adults** through studies of sexual, drug use and relationship behaviors. This work should include population based, longitudinal studies such as the National Child Study,

and studies of at-risk youth to identify protective habits for sustained HIV prevention.

- Support research to address barriers to **wider and more consistent use of male and female condoms.**

### *Increasing access to care and optimizing health outcomes for HIV-infected persons*

- **\* Support comparative effectiveness research to evaluate:**
  - strategies for increasing the uptake of HIV testing
  - strategies for improving linkages between prevention and testing programs to care and treatment programs
  - strategies for supporting treatment adherence and retention of people with HIV in comprehensive care programs, including re-establishing care for those who have dropped out
  - new antiretroviral therapies, especially studies exploring new targets;
  - optimal strategies for the use of new and licensed antiretroviral therapy to minimize toxicities, increase adherence, decrease resistance, and increase durability of viral suppression
  - strategies that employ structural approaches such as housing assistance.
- **Evaluate the effectiveness of Health Care Home models for optimization of health outcomes for people with HIV.**
- Improve **standardized data collection in public health HIV care settings.** This will include Ryan White programs as well as Medicare/Medicaid funded facilities, with the goal of developing robust databases to describe current health services coverage and gaps. Data collection should document and evaluate provider adherence to current HIV treatment guidelines. To the degree possible, reporting requirements should be unified across agencies to reduce the burden on providers.
- Develop **innovative mechanisms for supporting long-term research** projects to evaluate issues associated with the chronic nature of HIV disease, such as the effect of the virus and retroviral treatment on the aging process.

### *Eliminating HIV-related health disparities*

- **Evaluate geographic disparities** in access to care and provision of optimal HIV care using Medicare, Medicaid, and Ryan White databases, and incorporating data from large private providers (e.g., Kaiser-Permanente) and public programs such as the Veterans Administration (VA), and federal and state prisons.
- **Evaluate interventions to address the disparate impact of social, economic, and environmental factors** -- including incarceration, lack of stable housing, and

mental health and substance abuse problems -- on HIV outcomes for different populations. Engage the participation of multiple federal agencies, including the Departments of Justice and of Homeland Security, Department of Education, the HHS Administration for Children and Families, and the Department of Housing and Urban Development in this research.

- **\* Evaluate and develop innovative strategies to address the overlap between HIV-associated and other health disparities**, including those related to cardiovascular, renal, and hepatic disease, diabetes, hyperlipidemia, obesity, sexually transmitted diseases, adolescent pregnancy, substance use, mental health issues, and susceptibility to violence.

### **Research Management**

- **Institute more transparent and strategic research planning.** Establish an interagency group with authority and responsibility for planning and implementing cross-agency research. The group should include external reviewers from the scientific research, health care and service provider, and HIV affected communities.
- **Ensure the best configuration of study sections to pursue NHAS goals.** Consider creating study sections dedicated to each of the Strategy goals and reviewing and appropriately refining current practices to support the funding of truly innovative research initiatives. Establish an NIH study section on health disparities research designed to identify behavioral, structural, and policy interventions that can advance progress on the Strategy goal of reducing HIV-associated health disparities. Ensure appropriate personnel to review social science proposals. Ensure reviewers have adequate understanding of emerging research, such as viral persistence and eradication science.
- **Improve federal program evaluation by refining** evaluation methods and metrics to focus on quality and outcomes. Develop new metrics for combination interventions.
- **Increase access to relevant data** by establishing a comprehensive US government-wide public database on HIV-related research, program, funding, and epidemiology information. Review regulations governing privacy and confidentiality controls to inform researchers about current flexibilities in sharing data, and to identify potential changes to regulations that would facilitate additional research while still protecting privacy and confidentiality. Establish effective mechanisms (including funding) to fully mine existing databases. Include sexual orientation and HIV-related variables in federal surveillance and NIH-funded cohort and longitudinal studies.
- **Support greater diversity among HIV/AIDS and health researchers.** Set goals for expanding the pool of researchers from the groups and regions most

heavily affected by the epidemic and currently under-represented among government-funded researchers, including young, Black, and gay/MSM researchers, Latinos and Latinas, Asians, Pacific Islanders, Alaskan and Native Americans, and other diverse groups.

- **Develop a rapid response research program** that can address questions that arise from unanticipated scientific, clinical, and policy developments. Review current agency processes, and remove structural barriers that prevent the rapid development, funding and implementation of such research.

**Mr. President, the National HIV/AIDS Strategy** process is an important opportunity to review the role of health research in responding to the domestic epidemic. We look forward to working with you and your staff to create a coordinated, accountable, and outcomes-oriented response to HIV/AIDS at home. Please feel free to contact Chris Collins, amfAR, Vice President and Director of Public Policy, at 202.331.8600, Sue Perez, Treatment Action Group, Policy Director, at 202.615.8831 or Andrea Weddle, HIV Medicine Association, Executive Director, at 703.299.0915 with any questions or comments about our proposals.

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