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Presidential Advisory Council on
HIV/AIDS

AUG - 8 2011

The Honorable Kathleen Sebelius
Secretary of the Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20101

Dear Madame Secretary:

As members of the Presidential Advisory Council on HIV/AIDS (PACHA), we would like to thank you for this wonderful opportunity to serve the nation in addressing the HIV/AIDS epidemic, and to congratulate you for your outstanding leadership in releasing the National HIV/AIDS Strategy (NHAS) in July 2010. The NHAS has done a great deal to reenergize HIV/AIDS efforts in the U.S., and to promote a shared vision of where the nation needs to be by 2015.

While there is great support of the NHAS goals regarding HIV incidence reduction, treatment access expansion, disparities alleviation, and service coordination improvement, a tremendous amount of work must be done by 2015 to achieve these goals. PACHA respectfully requests that you indulge us an annual letter describing what we see as the major successes over the prior year as well as the major challenges for the upcoming year which must be addressed to make the NHAS goals a reality (we are sending a briefer summary of this letter to President Obama). We also plan a press release every World AIDS Day describing for the American people what we see as the major domestic and global challenges and highlighting how everyone in the U.S. might become more involved.

SITUATIONAL ANALYSIS. Since the beginning of the epidemic and through 2006, HIV prevention efforts have averted at least 350,000 infections in the United States and saved over $129 billion in healthcare costs. In a small number of areas (such as San Francisco), HIV incidence appears to be decreasing. In a given year in the U.S., over 95% of all persons living with HIV do not transmit the virus to anyone else (down from very high transmission rates early in the epidemic), thanks to testing, prevention and treatment efforts. Advances in HIV treatment have resulted in very substantial reductions in death rates, and HIV may now rightly be considered a chronic disease. Further, recent scientific findings have helped us to understand the prevention potential of HIV testing and antiretroviral drugs (and we have long known that HIV drugs can be highly successful in preventing mother to child transmission of HIV). In addition syringe exchange programs and other services for persons who inject drugs have led to substantial reductions in HIV incidence attributed to non-sterile injection practices. According to the National Institutes of Health (NIH), other proven interventions include behavior modification

strategies, condom distribution, blood supply screening, and male circumcision. We recognize and applaud the Administration's very important initial steps to better coordinate and prioritize the diversity of HIV/AIDS efforts across the federal government.

Unfortunately, despite these tremendous successes much work remains to be done, and we must honor the memory of over 617,000 friends, partners, relatives and neighbors who died with an AIDS diagnosis. There are still approximately 50,000 HIV infections per year in the U.S. According to the Centers for Disease Control and Prevention (CDC), there were nearly 1.2 million persons living with HIV as of 2008 (a number that grows daily). Sadly, even now in 2011, there is still a death among persons living with HIV roughly every 33 minutes in the nation. The financial consequences of the epidemic are also daunting as HIV care costs roughly $20,000 to $34,000 per client per year, depending on disease stage and provider.

The HIV-related disparities are stunning for gay men (especially Black gay men), African-American, and Latino/Latina communities profoundly disproportionately shouldering the burden of this epidemic. Many women experience poor health outcomes as a result of delayed entry into care and poor retention once in care, and are less likely to begin antiretroviral therapy due in part to insufficient women-centered services, missed opportunities for linkage between services for sexual and reproductive health and HIV, inadequate supportive services, and socioeconomic barriers to care (such as poverty).

Approximately 20% of persons living with HIV are not aware of their HIV serostatus. Of persons diagnosed with HIV, only 75% are linked to HIV care, and only one-half are retained in care. Therefore, the AIDS Drug Assistance Program (ADAP) waiting lists (which now include over 8,650 people living with HIV) are just a small fraction of the unmet needs for HIV care in the U.S.

Of course, the NHAS does an outstanding job of pointing us in a number of key directions that must be taken to address prevention, care, disparities and program coordination aspects of the epidemic. Below, we recognize recent successes and urge new and greater efforts in the four major areas of the NHAS.

REDUCING NEW INFECTIONS. We applaud the NHAS goals of reducing new HIV infections, decreasing the HIV transmission rate, and promoting awareness of HIV serostatus. To make continued progress toward these goals, we believe that the following points need special attention in the coming year.

Refine Evidence-Based Prevention Programs. First, there must be a continued and ever strengthened commitment to evidence-based prevention programs. Recent, exciting scientific findings have provided further evidence that HIV treatment can have not only a major role in HIV care but also in prevention; the full potential of this important finding must be realized. Unfortunately, too many media outlets incorrectly reported that we now have an "end to AIDS"; we wish this were the case but sadly it is not. Indeed, over one-half million people living with HIV in the U.S. are not in HIV care, and therefore the translation of a finding from a landmark clinical trial on "treatment as prevention" into a population level effect poses substantial operational and resource challenges. We suggest that over the coming year, federal and private

sector partners engage in a vigorous discussion that results in a shared approach to maximize the effect of such findings at the population level, that ensures the optimal array of evidence-based prevention programs [such as HIV counseling and testing, treatment as prevention, condom provision, behavior change services, comprehensive sexual education, and structural interventions such as syringe exchange and housing programs] in the best possible combination prevention package, and that determines the requisite level of human and fiscal resources to make the delivery of such optimized services sufficient to achieve the goals of the NHAS. The adoption of an Implementation Science framework as now employed by PEPFAR offers a promising path forward and is one way that global and domestic HIV prevention efforts can draw the best from each other.

Invest in Prevention as a Cost-Saving Public Health Strategy. Second, we recognize that we live in very difficult fiscal times and that public resources are scarce. But according to the published literature, underinvestment in HIV prevention efforts will actually result in *higher* medical costs for the nation in the long term. To truly bend the HIV care cost curve, we must bend the HIV incidence curve. Fully funding prevention serves not only to save lives but also to save scarce public sector resources, and should rightfully be considered a cost-saving strategy. Indeed, the choice not to fully fund HIV prevention efforts is actually a choice to increase federal costs associated with the care of HIV by billions of dollars in the coming years (it has been estimated that the rate of return for new investments in prevention sufficient to achieve the NHAS goals will be over $8 saved for each dollar spent).

Of course, appropriate levels of prevention and care funding should be aligned with where the epidemic is now and where it is headed in the U.S., and should be subjected to the very highest standards of accountability and transparency. We appreciate CDC's and the Department of Health and Human Services' (HHS') focus on the Twelve Cities project that aimed to determine how to realign and optimize current resources, clearly articulate unmet needs and better coordinate services in a dozen jurisdictions heavily impacted by HIV. We appreciate the fact that HIV prevention base funding was increased by $31 million at CDC in FY11 (a year in which CDC's budget was cut heavily by Congress), and we appreciate the HIV prevention increases proposed in the Administration's FY12 budget. However, even these promising events do not result in a fully funded prevention program sufficient to meet the goals of the NHAS. Further, we are concerned that the core prevention service delivery funding for health departments supported by CDC was cut by $20M in the recent FY12 funding announcement and urge its immediate restoration.

Maximize Accountability and Effectiveness by Overhauling HIV-related Metrics. Third, as PACHA, we have appreciated the federal agencies' willingness to review with us their HIV prevention budgets and the initial steps taken to move toward better coordination of these investments (including HHS' initial attempts at ensuring that HIV prevention resources are congruent with the epidemic and serve populations most in need of services). However, more work remains to be done. For example, the number of reporting requirements for Health Departments now receiving federal HIV/AIDS funding approaches ninety separate requirements, and several hundred variables are tracked. We believe strongly in complete accountability and transparency of the use of public sector HIV prevention resources, but clearly such reporting requirements must be better coordinated and streamlined. Further, they must be better prioritized

as the current myriad of requirements has not yielded a comprehensive "dashboard" by which the epidemic can be thoroughly monitored and "managed." Identifying a smaller number of critical metrics to be collected across agencies will help the nation keep its eyes focused on the central outcomes and impacts identified in the NHAS.

We suggest that metric prioritization would better set the stage for cross-agency and intra-agency reallocation of existing resources to achieve optimal HIV prevention impact, and allow for identification of specific ways in which HIV programs can be strategically coordinated with sexually transmitted infections services, hepatitis programs, and substance abuse treatment interventions. PACHA has already begun a very productive dialogue with the HHS Departmental Working Group on HIV/AIDS Metrics; over the next year, we encourage HHS, Office of National AIDS Policy (ONAP), and other partners (in conjunction with PACHA) to finalize work on a streamlined, practical and prioritized set of HIV/AIDS measures and reporting requirements that will both save administrative resources and also allow for the construction of a highly strategic dashboard that will help the nation make annual mid- course corrections necessary to achieve the goals of the NHAS.

IMPROVING ACCESS TO CARE. Pure and simple (and as noted in the Vision Statement of the NHAS), every American living with HIV should have access to high quality care and treatment, and the resources to make this a reality must be identified. As a starting point, this means fully funding the AIDS Drug Assistance Program to eliminate waiting lists, denials of care, and formulary caps that result in suboptimal care and HIV-related disparities. It also means protecting the Medicaid program from budget cuts given its critical role in meeting the care and treatment needs of low-income people living with HIV and other chronic medical conditions.

Recent science (NIH-sponsored HPTN study #052) confirms what many people living with HIV and their providers long suspected—aggressive HIV medication treatment not only extends the lives of HIV seropositive Americans, it also helps to decrease the transmission of the virus. As the NHAS calls for increased access to care (including medications) and lowering transmission rates, achieving these goals will rely heavily on the nation's public health care systems. In particular, Medicaid and Medicare account for approximately 75% of federal spending on HIV and AIDS-related care; along with Ryan White Programs, Veterans Administration and Indian Health Services, they serve the vast majority of people living with HIV and AIDS in the United States. We believe that the following action steps are necessary in the next year to successfully meet the goals of the NHAS and to make real headway against the HIV epidemic.

Ensuring Successful Integration of HIV Care as the Affordable Care Act is Implemented and Creating a Healthy Bridge to 2014:

Provide all necessary support for a full-time senior-level advisor on HIV at the Centers for Medicare and Medicaid Services (CMS). We appreciate CMS's commitment to increasing access to HIV prevention, care, and treatment by urging state Medicaid Directors to cover routine testing, identifying HIV/AIDS as a chronic condition eligible for the new Medicaid health home benefit, and developing guidance for states to facilitate applications for section 1115 waivers to expand access to "pre-disabled" people living with HIV. However, many states and other federal agencies find it difficult to engage with CMS to respond quickly and effectively to

these opportunities. We appreciate the fact that a senior level advisor has been designated who reports directly to the CMS Administrator, but this advisor has a portfolio of responsibilities broader than this task alone. To facilitate outcome-oriented action on these opportunities and to meet the goals of the NHAS, we recommend that the senior advisor be a full-time appointment with sufficient resources to implement the NHAS-related tasks at hand.

Provide support of state efforts to prepare and submit section 1115 waiver applications. CMS has worked diligently to make the 1115 Medicaid waiver a viable option for states to create a bridge to 2014 for people living with HIV. However, states struggling with understaffed Medicaid offices lack the resources to gather data and conduct budget analyses to develop a successful waiver application. We urge CMS and HHS to develop mechanisms to support states to develop plans that meet budget neutrality requirements and the needs of "pre-disabled" people living with HIV. This includes ensuring that all costs of treating persons living with HIV are considered (including pharmaceutical costs) before transferring eligible persons to local Low Income Health Plans to avoid bankrupting local and State health systems. Finally, CMS must also contribute to the successful implementation of the "12 Cities Initiative," and help meet the immediate goals of the NHAS.

Initiate demonstration projects to evaluate quality and outcomes of the HIV "health home" (Ryan White) care model. The Center for Medicare and Medicaid Innovation should deploy a collaborative CMS/HRSA (Health Resources and Services Administration) pilot project to evaluate the Ryan White Program's (and similar program's) model of comprehensive and coordinated care, treatment, and supportive services, and develop payment mechanisms to support this level of care under Medicaid and Medicare, as called for in the NHAS Implementation Plan.

Ensuring Successful Implementation of the Findings of HPTN 052 and Meeting the Goals of the NHAS:

Ensure adequate resources and guideline development that incorporate the latest scientific breakthroughs. As noted above, the HIV scientific and clinical community view HPTN 052 as a true "game changer"; with full implementation of the lessons learned through this study, we can not only improve the health of all HIV seropositive patients, but also help to prevent the transmission of the virus and lower incidence rates in the U.S.—all goals of NHAS. To ensure comprehensive implementation of these findings, HHS-supported HIV clinical treatment guidelines must be revised to reflect these findings, followed by adequate funding to allow every HIV seropositive American access to these medications (a recommendation already made by the Institute of Medicine in its 2004 report on public financing of HIV care).

Adopt HIV harmonized quality measures that encourage increased HIV testing and access to care. The U.S. Preventive Services Task Force (USPSTF) has already given a rating of A to routine HIV screening done in which any of the following conditions apply: (a) the geographic area is one of high HIV prevalence; (b) the venue is one of high HIV prevalence (even if the geographic area has low prevalence); *or* (c) the presenting client may be at risk of infection regardless of the HIV prevalence in the venue or the geographic area. (It is useful to note that CDC's entire Expanded Testing Initiative to further promote routine testing would meet

the conditions to earn an A recommendation.) We believe that CMS should immediately move to reimburse such routine testing. Further, the USPSTF is presently reviewing its previous HIV testing recommendations for circumstances in which none of the three conditions above are met, and we believe recent scientific data may well support elevation of such HIV testing to an A or B level recommendation even in such circumstances. We believe that quality measures employed by both public and private healthcare institutions should be adopted that measure such testing efforts and an HIV seropositive American's ability to access HIV testing and quality care.

Develop data sharing protocols between federal, state and other jurisdictions to ensure accurate measurement of NHAS progress and to ensure persons living with HIV are getting the care they need. NHAS access to care goals intended to both address unmet need and reduce health disparities must be predicated on an accurate baseline and the ongoing sound measurement of unmet need and health disparities. We recommend the establishment of an HHS-led task force to develop and implement consistent data collection. We also recommend sharing protocols among CMS, HRSA, state Medicaid directors and State and local AIDS Directors, as well as among other stakeholders, so as to establish these baselines and measurement strategies. These actions should serve to improve service delivery as well as achieve the additional goal of reducing the reporting burden on the states, tribal and local jurisdictions.

REDUCING HIV-RELATED DISPARITIES. The NHAS rightly decries the substantial stigma and active discrimination faced by persons living with HIV in the U.S. It is shocking that thirty years into the epidemic, we still see such social injustices in the nation. This section of the NHAS directs attention toward alleviating the disparities in detectability of viral load in men who have sex with men, African Americans, and Latinos/Latinas living with HIV (relative to the broader population of persons living with HIV). There also are disparities in how the government uses the criminal law to target and punish people with HIV for consensual sex or conduct posing no risk of HIV transmission, based in part on outdated beliefs about the routes and actual risks of HIV transmission, and current realities of living with HIV that reinforce stigma and discrimination.

Improve Equity and Impact in Funding Distributions. Consistent with the tenets of the NHAS, we believe that is it critical that federal HIV/AIDS funding be based on living HIV cases in as close to real time as possible. The recent CDC health department prevention funding opportunity announcement takes an important step in this direction. However, it must be recognized that no jurisdiction is seeing a reduction in persons living with HIV, and it must be recognized that HIV prevention services are seriously underfunded in the U.S. overall. This has created a situation in which resources have been reduced in some jurisdictions, thereby disrupting services, in order to shift funds to other jurisdictions (who must be prepared to quickly and strategically invest these new resources so that they maximally contribute to achieving the goals of the NHAS). We believe that managing this very challenging circumstance will require much analysis, evaluation, vigilance, and community engagement in the coming months. PACHA's members have a wide variety of experiences relevant to this situation, we respectfully request the opportunity to engage in ongoing dialogue with HHS to review the myriad issues associated with resource distribution and attainment of the NHAS goals.

In addition, just ensuring that the "money follows the epidemic" is not sufficient; once the resources are allocated, the best possible interventions must be delivered at the appropriate scale so as to maximally impact the epidemic. This means delivering evidence-based interventions that are customized to the particular social circumstances and needs of the clients and communities being served (for instance, ensuring that critical programs serving youth are based on the best evidence available and incorporate an understanding of the challenging life circumstances facing many young people). Further, this means quickly developing the organizational and institutional capacity among populations where HIV is spreading most rapidly and disproportionately; this is especially true of organizations serving Black gay men and those serving poor Black women and men in the South and elsewhere. Additionally, it means directly addressing human and civil rights issues that contribute to the stigmatization and marginalization of some of the most highly impacted populations (such work should lead HHS to even stronger partnerships with the Departments of Justice, Labor and Education). These partnerships should produce government leadership on pressing issues of stigma and discrimination, and should inform efforts to address critical ongoing issues such as state laws that criminalize HIV status. As stated in the NHAS, CDC data and other studies tell us that intentional HIV transmission is atypical and uncommon. This requires clear statements from CDC about the routes and relative risks of HIV transmission, as well as other affirmative leadership. For instance, it also will require the identification and evaluation of best practices to support jurisdictions that have taken constructive steps to alleviate such discrimination from HIV-specific criminal law, and to support the transfer of these findings to other jurisdictions. This is an important area for ongoing dialogue between PACHA and federal partners.

Improve Access to Health Care to Alleviate Health Disparities. As also noted in the care section above, it is urgent and vital that we eliminate the AIDS Drug Assistance Program waiting list through a combination approach, including the implementation of programs through Medicaid to bridge the gap to 2014 and significantly increased federal appropriations to immediately eliminate waiting lists. Additionally, federal standards should be set to prevent exclusionary program thresholds, such as income eligibility levels, and to ensure an acceptable formulary of medications. Further, we must not stop with ADAP waiting lists but must also attempt to address the entire cascade of unmet HIV care needs described above. Moreover, as we look to 2014, it must be acknowledged that a range of Ryan White-funded support services is essential to assure access to care and must be continued.

Expand HHS 12 Cities Project. CDC's Enhanced Comprehensive HIV Prevention Planning (ECHPP) and HHS' Twelve Cities demonstration projects have been outstanding opportunities to re- examine HIV/AIDS efforts at a local level in a number of very disproportionately impacted locales. We applaud these efforts, and call for their expansion with additional funding. In particular, we recommend that the Twelve Cities project be expanded to include areas with high rates of new transmissions, as well as highly impacted rural areas. Through this expansion lessons learned throughout the demonstration project can be appropriately applied to additional areas of rapidly expanding epidemics, smaller cities and to

rural America. Such an expansion might include a mix of replications of the 12 Cities Projects in some jurisdictions, as well as a much broader delivery of technical assistance services across the country (including capacity building services on emerging topics such as resource allocation

COORDINATION. A very important but unsung section of the NHAS rightly calls for increased public/private- sector interface. We applaud the White House for its forum on public/private sector initiatives, and congratulate HHS for its outstanding efforts to bring together federal agencies working on HIV issues in ways never seen before. There is an increase in communication across agencies that can be clearly noticed. However, we believe there are further opportunities in this area.

Coordinate Funding Announcements, Reporting Requirements, and Evaluation. As noted above, Health Departments that are grantees of federal agencies now face dozens of uncoordinated reporting requirements, and must report on hundreds of variables as a condition of funding. It is vital that these requirements and evaluation metrics be streamlined to a small, strategically chosen set that will not only save administrative resources but allow for increased, more targeted, and more effective service delivery to clients. Further, this set of reporting requirements metrics should be directly tied to annual measurement of progress toward the achievement of the goals of the NHAS.

Continue Support of Transfer Authority for Strategy Implementation Funds. We applaud the Administration for including in the FY12 Presidential Budget Request a plan to build a Strategy Implementation Fund to be used by the Secretary to address key unmet needs and that will help garner information and provide analyses to make optimal use of the entirety of federal HIV/AIDS efforts. Such cross-agency reallocation is crucial to improve our response to the epidemic, and in the future, we believe that such a fund must be maintained and potentially even expanded. We support your efforts to obtain the transfer authority necessary to make this critical fund a reality.

DOMESTIC/GLOBAL EPIDEMIC INTERFACE. Although this letter focuses primarily on the NHAS and the epidemic in the U.S., it is important to recognize the much larger global epidemic and consider that the domestic epidemic exists within and interfaces epidemiologically with the global epidemic. There are important lessons to be learned in both directions and key strategies which can be utilized to confront the challenges of the epidemic both at home and abroad. America's efforts to tackle the global AIDS epidemic through PEPFAR and the Global Fund have had profound impact and laid the foundation for the Administration's Global Health Initiative. However, new resources and portfolio realignment are necessary to take advantage of the connection between HIV treatment and prevention and to scale up these proven evidence-based approaches in our international efforts. We therefore urge targeted new resources for the domestic and global AIDS response -- beyond those proposed in your FY12 budget -- that are designed to take advantage of the new opportunities at hand. We have a moral imperative to turn the tide of the AIDS pandemic globally as it devastates individuals, families, communities, and society at large – possibly threatening our national security as 50 million children worldwide could be left parentless by 2020 without bold action.

CONCLUSION. In summary, we find ourselves collectively at the thirtieth anniversary of the HIV epidemic in the U.S., it is clear that progress has been made and it is no longer the same epidemic it was previously. However, as the NHAS rightly points out, this epidemic is far from over in our nation, and much work must be done in the most urgent fashion possible. We have attempted here to highlight some areas that we believe are in need of greatest attention in the coming year. We gratefully point out that in many cases, your teams in the White House and HHS have already anticipated these issues and are working diligently on them. Hence our points may not be unique, but given our charge as PACHA, we felt it was our responsibility to underscore the importance of these key issues so that you would know directly what we collectively felt are some of the most critical activities needing near term attention.

We thank you most sincerely for taking the time to consider our reflections and recommendations, and would be pleased to hear from you on how we might be of continued and optimal service to the Administration. We take very seriously our roles as members of PACHA and are eager to tackle tasks that you would find informative and useful. We all share your intense commitment to addressing the HIV epidemic in the U.S. and across the globe; indeed, we have all devoted our lives to ending this epidemic.

With greatest respect and appreciation,

David Holtgrave, for

Helene Gayle, M.D., M.P.H.
Chairperson
Presidential Council on HIV/AIDS