

**Presidential Advisory Council on HIV/AIDS (PACHA)
61st Meeting**

**Wilbur J. Cohen Building
Snow Room (Conference Room 5051)
330 Independence Avenue, SW
Washington, DC**

March 13, 2017*

Council Members—Present

Darrell Wheeler, Ph.D., M.P.H., ACSW, Vice Chair
Ada A. Adimora, M.D., M.P.H.
Jeffrey S. Akman, M.D.
Oliver Clyde Allen III
Lucy A. Bradley-Springer, Ph.D., R.N., ACRN, FAAN
Gina M. Brown, M.S.W. (*by telephone*)
Ulysses W. Burley III, M.D., M.P.H.
Nicholas Carlisle, J.D.
Cecilia C. Chung
Michelle Collins-Ogle, M.D., FAAP, AAHIVS
Kevin Cranston, M.Div.
Grissel Granados, M.S.W.
Gabriel Maldonado, M.B.A.
Ligia Peralta, M.D., FAAP, FSAHM, AAHIVS
Harlan H. Pruden
Scott A. Schoettes, J.D.
Patrick Sullivan, D.V.M., Ph.D.
Mildred Williamson, Ph.D., M.S.W.

Council Members—Absent

Vignetta Charles, Ph.D.
William H. Collier
Elizabeth Styffe, M.S.N.

Staff

Kaye Hayes, M.P.A., PACHA Executive Director
Caroline Talev, Public Health Analyst

Federal Liaisons

Laura Cheever, M.D., Sc.M., Associate Administrator, HIV/AIDS Bureau (HAB), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS)

* The meeting was scheduled for March 13 and 14. The second day was canceled due to inclement weather.

Richard Wolitski, Ph.D., Director, Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), HHS

Sara Zeigler, M.P.A., Associate Director for Planning and Policy, National Center for HIV/AIDS, Viral Hepatitis, Sexually Transmitted Disease (STD), and Tuberculosis (TB) Prevention, U.S. Centers for Disease Control and Prevention (CDC)

Presenters

Rena Conti, Ph.D., Associate Professor, Departments of Pediatrics Hematology/Oncology and Health Studies, University of Chicago

Victoria G. Hale, Ph.D., Founder, Institute for OneWorld Health; Founder, Medicines360; Adjunct Associate Professor of Bioengineering and Experimental Therapeutics, Institute of Medicine, University of California, San Francisco

H. Irene Hall, Ph.D., FACE, Deputy Director for Surveillance, Epidemiology, and Laboratory Science, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC

Corinna Dan, R.N., M.P.H., Viral Hepatitis Policy Advisor, OHAIDP, HHS

Amy Killelea, J.D., Director, Health Systems Integration Team, National Alliance of State and Territorial AIDS Directors (NASTAD)

Joshua Sharfstein, M.D., Associate Dean, Public Health Practice and Training, Professor of the Practice, Bloomberg School of Public Health, Johns Hopkins University

Don Wright, M.D., M.P.H., Acting Assistant Secretary for Health (ASH), Office of the Assistant Secretary for Health, HHS

Welcome

PACHA Vice Chair Darrell Wheeler, Ph.D., M.P.H., ACSW, called the meeting to order at 9:23 a.m. and welcomed the members of the Council and meeting attendees. He noted that PACHA continues to be responsible for providing the HHS Secretary with advice on the treatment and cure of HIV and AIDS, adding that PACHA remains committed to an AIDS-free generation. He thanked the presenters for attending and especially thanked PACHA staff—Executive Director Kaye Hayes, M.P.A., and Public Health Analyst Caroline Talev—for their work.

Welcome from the Acting ASH and Oath of Office

Don Wright, M.D., M.P.H., Acting ASH, Office of the Assistant Secretary for Health, HHS

Dr. Don Wright expressed profound gratitude for PACHA members' expertise, knowledge, and passion for service and looked forward to their recommendations to HHS Secretary Tom Price. Dr. Wright also leads the Office of Disease Prevention and Health Promotion, which produces Healthy People, an effort to identify national health priorities and set targets to assess progress toward those priorities using evidence-based science. One of the Healthy People goals for this decade is to increase the proportion of people living with HIV (PLHIV) who know their status.

Dr. Wright commented that important progress has been made against HIV but a tremendous amount remains to be done. Early suppression of viral load, prevention of

new exposures, and preexposure prophylaxis (PrEP) to prevent infection are game-changing interventions. The current challenge is to ensure that these and other powerful new tools reach people in high-risk communities. The Ryan White HIV/AIDS Program serves almost half of U.S. PLHIV, and recipients of Ryan White services have high rates of viral suppression. Federal partners released a comprehensive framework to increase access to PrEP, among other HHS initiatives, and have integrated PrEP into core programs.

Recent CDC data show continued improvement across many populations and all states, but they also highlight unevenness across programs. Disparities persist among men who have sex with men (MSM), African American and Latino men, and transgender women. People living in the South are more likely than those in other regions to have HIV, not know their status, and die from HIV or its complications. The opioid epidemic poses another threat to public health and increases the risk of HIV and viral hepatitis from injection drug use (IDU).

Dr. Wright said national HIV goals cannot be achieved without action to address these challenges. Response to HIV must be a national, not Federal, responsibility tackled through a coordinated effort across all sectors. The perspective of PACHA members is crucial to the effort. Dr. Wright thanked the members again on behalf of HHS for their enduring commitment and service to their communities, the nation, and the world.

Dr. Wright administered the oath of office[†] to six PACHA members who are renewing their terms of service as of this meeting: Ada A. Adimora, M.D., M.P.H.; Lucy A. Bradley-Springer, Ph.D., R.N., ACRN, FAAN; Cecilia C. Chung; Ligia Peralta, M.D., FAAP, FSAHM, AAHIVS; Harlan H. Pruden; and Mildred Williamson, Ph.D., M.S.W.

Roll Call

Ms. Hayes called the roll.

Incidence Data Update

H. Irene Hall, Ph.D., FACE, Deputy Director for Surveillance, Epidemiology, and Laboratory Science, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC

Dr. H. Irene Hall explained that CDC is phasing out the surveillance methodology that relies on collecting and testing samples while it ramps up the CD4 model, which is used by other countries. Funding for incidence surveillance will end in 2017; new funding for other types of surveillance will begin in 2018. The CD4 model is suitable for state-level analysis and can be adjusted to ensure complete reporting for a specified period. Dr. Hall outlined the types of HIV surveillance data collected nationally and the flow of data collection and dissemination.

[†] Three others renewing members have since been sworn in: Gina M. Brown, M.S.W.; Vignetta Charles, Ph.D.; and Elizabeth Styffe, M.S.N.

The CD4 model estimates incidence, prevalence, and the percentage of undiagnosed cases of HIV. PACHA members raised concerns that some states have lagged behind in surveillance, and it is not clear that those states will catch up using the new CD4 model. However, it also was noted that the CD4 model relies on standardized testing, reporting, and resources, so it likely will yield better information across the country.

Dr. Hall summarized data from 2008 to 2014 that showed a substantial decrease in HIV diagnoses and incidence among women and slower rates of decline among men overall, but minimal decreases among MSM. In addition, MSM have the highest estimated prevalence of undiagnosed HIV. Incidence was flat for black MSM but increased significantly among Hispanic MSM. Estimates of undiagnosed HIV declined from 2008 to 2014 for all groups, but remained highest for black and Hispanic MSM. In that time, incidence increased for MSM ages 25–34 years. Reinforcing Dr. Wright's comments, Dr. Hall said southern states account for about half of incidence, prevalence, and undiagnosed cases of HIV.

Overall incidence of HIV declined about 18 percent in the period analyzed. That translates to more than 33,000 cases prevented and an estimated savings of \$14.9 billion in medical care. Further decreases rely on continued testing, use of preventive tools (e.g., PrEP, syringe exchange), linking PLHIV to care and retaining them across the continuum of care, and improving surveillance. Better surveillance can identify PLHIV who should be linked to care, reveal transmission networks, and locate those who are unaware of their status or who would benefit from preventive interventions like PrEP.

Discussion

Dr. Hall noted that 2015 data will be available in June, and CDC will release its analysis of the data by the end of 2017. The full impact of PrEP likely will be seen in future years. IDUs are not part of current models but should be considered.

Dr. Hall commented that six states do not have laws in place to facilitate collection of CD4 and viral load data, which poses a major barrier to better state-level surveillance. PACHA could support policymaking in those states and others to ensure that electronic reporting is in place, that laboratories report data, and that standardized reporting practices are followed. Policies also should support states in maximizing their resources and collaborating across diseases to support good reporting. Asked whether states with complete reporting have different disparities outcomes than those with incomplete reporting, Dr. Hall explained how states can use data to look at disparities in care and target initiatives to improve care.

Follow-Up Items

- PACHA staff will follow up with Dr. Hall to identify the six states that do not have laws in place to facilitate HIV data collection for surveillance.
- PACHA staff will follow up with Dr. Hall about how trends in other STDs among MSM compare with those of HIV from 2008 to 2014.

Discussion turned to data collection about transgender men and women; concerns remain that transgender people are misclassified, so data are confusing. Dr. Hall explained that CDC will release data from the Medical Monitoring Project, which conducts interviews and collects better data on transgender people, but some states do not identify transgender people in data collection. Dr. Hall did not have HIV incidence data for American Indians and Alaska Natives; she was not sure CDC has a sufficient amount of data to estimate incidence for those populations. However, recent data are more comprehensive, and the incidence estimates will be updated by the end of the year.

CDC has the capacity to identify clusters of HIV infection and report them to health departments, which can combine the information with their own data to model transmission networks. Such modeling can help health departments identify people at high risk who would benefit from testing and ensure that PLHIV are in care. CDC makes its modeling software available to states so they can identify clusters at the local level.

Dr. Hall acknowledged the ethical concerns around using data to identify and target individuals who have or are at high risk for HIV. She noted the consensus among ethicists and CDC advisory groups that data should be used to improve the care of PLHIV through public health efforts, moving away from policies of “HIV exceptionalism.” Dr. Wheeler concluded the session by noting that efforts need to go beyond analyzing and disseminating data to reaching people affected by HIV.

Welcome Letter to Secretary Price

**Scott Schoettes, J.D., PACHA Disparities Subcommittee Co-Chair, and
Ada Adimora, M.D., M.P.H.**

Mr. Scott Schoettes explained that the letter to Secretary Price originated with the Access to Care Subcommittee; a draft was circulated among PACHA members for review. The letter introduces PACHA and identifies key issues most important in addressing the HIV/AIDS epidemic. The following proposed changes to the letter were accepted:

- Update the data in the letter to reflect the most recent incidence data from CDC.
- Revise the third bullet as follows: “Support the role of Medicaid as a source of health coverage for people with HIV *and other comorbidities*” (emphasis added) to ensure that the letter includes those who require medications or other support not usually available through AIDS Drug Assistance Programs (ADAPs).

Members agreed that including two bullets about global issues is sufficient for now and it is not necessary to add language about international leadership earlier in the letter. Global issues will be addressed in more depth by PACHA in other contexts.

Vote

PACHA members voted unanimously in favor of finalizing the Welcome Letter, with the changes described, and sending it to Secretary Price. (See the appendix for the final version.)

PACHA Subcommittee Reports

Increasing Access to Care Subcommittee

Kevin Cranston, M.Div.

Mr. Kevin Cranston commented that the subcommittee is continuing with the priorities it set for 2016: implementation of the Affordable Care Act (ACA) with particular focus on transparency, cost, and price. In 2017, the subcommittee will factor in new information about Federal health care reform as it evaluates costs and financing. The subcommittee recognizes the need for regulatory reform; for new proposals around transparency and costs, it will evaluate how policies meet the needs of PLHIV. It is likely to recommend implementing Federal regulations that would lock in formularies annually (except for newly improved medications), cover all widely accepted medications, and address coinsurance costs.

The subcommittee continues to assess how the ACA and new health care reforms are integrated with Ryan White services. Successful implementation requires monitoring to assess barriers, facilitating enrollment of PLHIV in insurance plans, ensuring that navigators are able to make good recommendations, and ensuring that qualified plans meet the needs of PLHIV. In 2017, the subcommittee may focus on HIV and aging.

Also, the subcommittee is concerned about coverage restrictions on effective treatments for hepatitis C virus (HCV) that are not based on evidence. Mr. Cranston commented that lessons learned from access to HIV drugs combined with the HIV community's longstanding interest in treating hepatitis coinfection can be helpful in this arena. Like the other PACHA subcommittees, the Access Subcommittee will continue to address social determinants of health (SDH) for PLHIV.

Reducing HIV-Related Disparities Subcommittee

Gabriel Maldonado, M.B.A., and Scott A. Schoettes, J.D., Co-Chairs

Mr. Schoettes noted that the subcommittee focused on stigma reduction throughout 2016, hosting the Stigma Reduction Summit September 20–22. The recommendations resulting from the summit will be discussed later in this meeting. The subcommittee has a working group on SDH and plans to look more closely at disparities in HIV among black gay and bisexual men. Mr. Gabriel Maldonado hoped to address the cost savings realized by early interventions around SDH or other disparities.

Global Agenda Subcommittee

Harlan H. Pruden, Co-Chair

Mr. Harlan Pruden commented that the leadership and advocacy of former PACHA member Yvette Flunder, M.Div., and others will be missed. He explained that the subcommittee frequently discusses the balance between global concerns and the domestic agenda. At the next meeting, members will continue to talk about how to highlight the work of the United States internationally but also discuss what lessons can be applied domestically. Dr. Ligia Peralta added that the group discussed the annual President's Emergency Plan for AIDS Relief (PEPFAR) report to Congress. Richard Wolitski, Ph.D.,

anticipated needing more input from PACHA subcommittees on new data showing increases in new HIV infections among Latino/Hispanic MSM.

Reducing HIV Incidence Subcommittee

Ada Adimora, M.D., M.P.H., and Michelle Collins-Ogle, M.D., FAAP, AAHIVS, Co-Chairs

Dr. Michelle Collins-Ogle noted that the subcommittee still is addressing some of the items from the 2-year work plan it created in 2014, such as collecting and using more data from Native populations. The subcommittee has a subgroup on the topic that is working on convening experts for a PACHA presentation about funding for data collection. The subcommittee is satisfied with the response it received from Eugene McCray, M.D., director of CDC's Division of HIV/AIDS Prevention, about the challenges of timely incidence reporting. In 2017, the subcommittee will create a new work plan. Dr. Ada Adimora added that the subcommittee will monitor coverage and access to care for subpopulations for whom incidence is unclear.

Discussion

Dr. Lucy Bradley-Springer noted that the needs of women as a special population should be considered. Data on women in the South and women of color, especially Hispanic women, are concerning. Ms. Hayes explained that the presentations on women and girls originally scheduled for Day Two of this meeting will be rescheduled.

Stigma Reduction Summit

Gabriel Maldonado, M.B.A., and Scott Schoettes, J.D., Co-Chairs

Mr. Maldonado and Mr. Schoettes explained that the Disparities Subcommittee convened the summit to address stigma as a significant driver of the HIV epidemic. The draft recommendations were presented at the September 2016 PACHA meeting, and comments were incorporated. The final draft describes the key actions needed to reduce and eliminate HIV-related stigma and improve health outcomes.

Discussion

It was noted that indicators are not in place to measure any reduction in stigma that could occur as a result of implementing the suggested actions. However, the framework provided offers ways to address stigma and negative attitudes through, for example, public education. Mr. Schoettes planned to write a brief cover letter to accompany the HIV-Related Stigma Framework that gives some context and background.

Vote

PACHA members voted unanimously to send the HIV-Related Stigma Framework to Secretary Price along with a cover letter by Mr. Schoettes. (See the [PACHA website](#).)

Viral Hepatitis

Update on the National Viral Hepatitis Action Plan: 2017–2020

Richard Wolitski, Ph.D., Director, OHAIDP, HHS, and Corinna Dan, R.N., M.P.H., Viral Hepatitis Policy Advisor, OHAIDP, HHS

Dr. Wolitski commended PACHA for its focus on viral hepatitis given the impact of hepatitis on PLHIV and the parallels between hepatitis and HIV. His office convened stakeholder meetings in 2016 on the costs of treating HCV; summaries of those meetings are available at www.hhs.gov/hepatitis.

Ms. Corinna Dan provided background about viral hepatitis and how it intersects with HIV. Despite effective tools to address hepatitis, deaths from HCV are rising, and the mortality rate has surpassed that of HIV. Most of those who die had been infected for many years, revealing missed opportunities for diagnosis and cure. Only about 33 percent of people with hepatitis B and more than half of those with HCV have been diagnosed, and only 9 percent of those with HCV have received the curative treatment now available. If all those with HCV were treated, 300,000 lives would be saved and health care costs would be averted.

The updated National Viral Hepatitis Action Plan builds on efforts that began in 2011. It reflects contributions from more than 20 Federal partners, coordinating across agencies and departments on strategic planning and implementation, as well as non-Federal stakeholders, including PACHA members. Partners and stakeholders emphasized the importance of taking a bold stand in the plan, encouraging community mobilization on a broad scale, and emphasizing the availability of a cure for HCV (and potentially hepatitis B). They also stressed that the plan should include information on the effectiveness of harm-reduction strategies, such as syringe exchange.

The plan offers a new vision for 2020 of a country where new hepatitis infections are eliminated and those with viral hepatitis know their status, have access to high-quality care and treatment (including curative treatment), and are free from stigma. It anticipates a cure for hepatitis B and more support for fighting stigma. The plan was streamlined by organizing actions under four comprehensive goals, all of which relate to both HCV and hepatitis B. An overview of the four goals, progress indicators, priority strategies, and recommended actions is available at www.hhs.gov/hepatitis.

The plan identifies 11 priority populations that reflect risks based on race/ethnicity, life circumstances, co-occurring disorders, and age. Ms. Dan commented that there are many opportunities to improve outreach and services by building partnerships with organizations that serve these populations. The next step is to raise awareness and get more people engaged. Progress will be monitored and reported annually; the website will be updated regularly with new tools and information. Ms. Dan expressed confidence that the ambitious goals of the plan can be achieved with effective and strategic collaboration.

Eliminating Hepatitis C Coinfection Among Ryan White Patients

Laura Cheever, M.D., Sc.M., Associate Administrator, HAB, HRSA, HHS

Dr. Laura Cheever explained that the Ryan White HIV/AIDS Program serves 500,000 PLHIV; about 25 percent of all PLHIV also have HCV. The Ryan White HIV/AIDS Program is well positioned to care for those with HCV. For example, Dr. Cheever noted, NASTAD successfully negotiated with pharmaceutical makers to provide HIV medications that are not covered under ADAP.

The cost of drugs for HCV is significant, but covering the cost will not be enough to ensure access and use. Dr. Cheever noted that HRSA received funding from the HHS Minority AIDS Initiative (MAI) to build the capacity of providers, educators, and outreach workers to diagnose and treat HCV. It also is working with NASTAD to improve treatment rates. The MAI funding supports technical assistance and capacity building for individual sites, and it also supports development of an evidence-based online curriculum for providers and trainers to increase awareness and ability to treat coinfection.

The Ryan White HIV/AIDS Program has a successful medical home model, and the HAB already has an approach in place to support individuals receiving HCV treatment. In addition, HRSA received funding from the MAI to partner with local health departments to improve care.

Discussion

It was noted that screening for HCV by primary care providers and others remains very low overall. Ms. Dan commented that HHS indicators track screening at the national, but not the state, level. Dr. Cheever added that the Ryan White HIV/AIDS Program collects data from quality improvement efforts, such as chart reviews.

Regarding the large number of priority populations in the National Viral Hepatitis Action Plan, Ms. Dan commented that HHS data show the disparities, but do not provide as much clarity about hepatitis as HIV. Dr. Wolitski noted that not all of the priority populations are at risk for coinfection.

Dr. Cheever stated that the Ryan White HIV/AIDS Program has a very high rate of HCV screening, and she expressed confidence that the approach would translate to community health centers and elsewhere. She acknowledged the challenge of increasing screening among those who do not have HIV. As with HIV and other conditions, learning one's status is an important first step.

Participants discussed the link between increasing opioid use and hepatitis. Data demonstrate that states with the highest hepatitis infection rates are also those hardest hit by opioid abuse. Disease spikes have led some states to identify their vulnerability and work with HRSA and CDC to plan and prepare for outbreaks. The role of the Substance Abuse and Mental Health Services Administration (SAMHSA) in supporting screening and treatment for HIV and HCV should be considered. It is not clear whether the

21st Century Cures Act includes education about HCV screening as part of the waiver requirements that allow more providers to administer buprenorphine to opioid users.

Innovation in Financing and Organization of Access to HIV and Hepatitis C Treatment

Moderator: Ligia Peralta, M.D., FAAP, FSAHM, AAHIVS, PACHA Member

Dr. Peralta noted that this session takes a broader look at the issue of access to medication than all the previous PACHA panels. Given the new administration and proposed changes to the health care system, Dr. Peralta hoped the session would help PACHA move quickly to form recommendations for Secretary Price.

HIV and HCV Medication Access: Priorities for a Changing Coverage Landscape

Amy Killelea, J.D., Director, Health Systems Integration Team, NASTAD

Ms. Amy Killelea explained that the landscape of health insurance coverage is changing daily; the first bill to replace the ACA was introduced in the House on March 6. Because House efforts are taking place under the Congressional budget reconciliation process, the current legislation is limited to funding provisions. The proposed bill, the American Health Care Act, is likely to be accompanied by executive actions and further Congressional actions.

The current bill and other similar proposed legislation all aim to reduce Federal support for Medicaid significantly, weaken protections for people with preexisting conditions, and reduce subsidies for low-income people to purchase insurance. This bill does not remove the essential health benefits requirements for private insurers, but it is anticipated that future legislation would.

Proposed block grants for Medicaid do not provide flexibility to account for increased enrollment or new drugs. Ms. Killelea stressed that threats to Medicaid are most problematic for those with HCV. She also noted that experience with high-risk pools to cover the sickest patients—currently being proposed as a way to lower costs for healthy beneficiaries—results in higher premiums and deductibles and negatively affects access. Proposals to base subsidies on age but not income will mean lower-income and older people will suffer, and PLHIV or those with HCV will get less help. Ms. Killelea added that the current legislation also eliminates actuarial value requirements and caps, so individuals would buy weaker, less regulated insurance products.

Over the past 5 years, ADAP, with HRSA help, has ramped up purchasing capacity and helped more people buy private insurance coverage. If changes decrease access and affordability, many more will rely on ADAP for more expensive medication support. Repeal of the ACA will mean a critical loss of funding for PrEP for uninsured and underinsured people; it is likely that people with HCV also will turn to public providers for treatment.

Ms. Killelea summarized the hallmarks of plans' discriminatory practices around medication access, as well as successes under the ACA in mitigating discrimination and improving access to treatment. She suggested the following steps:

- Push for continued monitoring and enforcement of nondiscrimination and benefits requirements by the Office of Civil Rights and the Center for Consumer Information and Insurance Oversight.
- Monitor and enforce Federal Medicaid laws on prescription drug coverage.
- Meaningfully address drug pricing at the national level.
- Monitor efforts by the National Association of Insurance Commissioners to address discriminatory plan design at the state level.
- Monitor state policies around medication access.

Ms. Killelea concluded that the ACA is built on a three-legged stool of ensuring access for people with preexisting conditions, providing subsidies, and mandating individual coverage. She does not believe a system can stand if the latter two are removed. The upcoming Congressional Budget Office's analysis of the American Health Care Act likely will show that the plan results in millions' losing health insurance coverage.

Public Health and Drug Pricing: Policy Solutions for Population Coverage

Joshua Sharfstein, M.D., Associate Dean, Public Health Practice and Training, Professor of the Practice, Bloomberg School of Public Health, Johns Hopkins University

Dr. Joshua Sharfstein commented that the high cost of HCV medication illustrates the common knowledge that pharmaceutical companies price new drugs for the market knowing that not everyone who needs the drug will be able to buy it—a practice that poses a public health problem that is particularly evident with infectious diseases. He added that the process of pricing drugs should begin with determining the access to treatment needed—that is, tackling the public health barriers by ensuring that people have access to good medical care. By providing treatment at a lower price through public health providers, companies make a small profit in settings in which they had never planned to make any money under their traditional pricing models.

Governments can use such mechanisms as direct purchasing (as with the Federal Vaccines for Children program), guaranteed substantial discounts (e.g., ADAP), and innovative patent use (e.g., government use of patented products at a reasonable rate lower than market price). Drug makers would continue to sell to the large private sector at full price. The public sector would get a lower price in exchange for access to a large market of people who otherwise would not buy the drug. Dr. Sharfstein commented that, ultimately, public health begins with a focus on what is needed to foster a healthier population, and looking at drug pricing alone is too narrow a lens. Considering drug pricing and volume together can break through some of the current gridlock in the United States.

Innovative Financing: Thinking Outside the Box

Victoria G. Hale, Ph.D., Founder, Institute for OneWorld Health; Founder, Medicines360; Adjunct Associate Professor of Bioengineering and Experimental Therapeutics, Institute of Medicine, University of California, San Francisco

Dr. Victoria Hale described mechanisms used to address high drug prices in ways that benefit public health. For example, OneWorld Health looked at old vaccine technology (use of killed virus) that had not been studied for the purpose of making an HIV vaccine. Over decades and with millions of dollars in philanthropic investment, the company created a vaccine that is being used internationally.

Medicines360 used a donor's money to create a less expensive alternative to the hormonal contraceptive intrauterine device known as Mirena. The product was made available to health care organizations through the Federal 340B drug discount program, which drove the cost of Mirena down.

Dr. Hale pointed out that the U.S. government paid \$9.2 billion for HCV drugs in 2015. Instead of continuing to spend billions, efforts could be made to purchase existing lead candidates, develop them further, and eventually market them—pharmaceutical companies often shelve products because similar drugs reached the market first. Such an approach requires an upfront investment—Dr. Hale estimated \$1 billion over 5 years—as well as individuals with both expertise and experience in bringing a product to market.

By establishing a desired efficacy level—for example, 90 percent of the commercial product—the U.S. government could produce a much less expensive product to treat more people sooner, perhaps turning to the more expensive option if the lower-priced one fails. The government has the resources to invest, and the cost of marketing the product to the public health sector would be negligible. In fact, a particularly effective product could be sold on the private market, with the profits going toward repaying the initial investment. Dr. Hale emphasized that nonprofit and hybrid pharmaceutical companies have demonstrated they can make their own drugs, so the U.S. government can as well. In fact, doing so would give the government substantial leverage in negotiating with private pharmaceutical makers.

Dr. Hale also contended that pharmaceutical makers support the mission of public health and want to partner with public health efforts. Developing affordable drugs to treat infectious diseases can be framed as a corporate social responsibility. Dr. Hale concluded that the expertise and technology are available to pursue alternative approaches to drug development; all that is needed is financial investment, courage, and vision.

Ensuring Access to HIV and Hepatitis C Treatment: Economic Challenges and Opportunities

Rena Conti, Ph.D., Associate Professor, Department of Pediatrics, Sections of Hematology/Oncology, and the Department of Health Studies, The University of Chicago

Dr. Rena Conti described three economic challenges to access to medication: (1) Drug innovation is expensive and risky; (2) the societal benefits of treatment are undervalued; and (3) ensuring access for all who are eligible is expensive. She summarized solutions in

place that address pieces of these challenges and outlined the market failures that prevent greater success. For example, the “innovation paradox” posits that the only way to ensure innovation is to allow manufacturers to set prices for new drugs as high as they want. Payment systems are so complex and opaque that drugs are much more expensive than necessary and the price is not related to what insured individuals pay. Manufacturers factor into their prices the amount of drug they anticipate providing free, with rebates, or at a discount under plans such as 340B. Discounts and rebates may reduce the cost to the insurer but not help patients.

Some potential solutions are available. For example, to improve affordability and increase access, states could increase their use of 340B extensions and Medicaid rebates and require that rebates be shared with government payers and patients. Such solutions address patient pricing but do not hamper innovation. Other countries have used purchasing commitments to eradicate HCV. Advance market commitments have worked in the United States to fuel vaccine development. Creative public-private partnerships such as those described by Dr. Hale are worth pursuing.

Dr. Conti suggested that the most salient economic challenge for PACHA and the easiest to address is information asymmetry (i.e., undervaluing treatment). Policies should reward providers for doing the right thing. Dr. Conti pointed out that some of the proposed solutions to the economic challenges circumvent the innovation paradox, which can make the conversation less incendiary.

Discussion

Attendees suggested that PACHA recommendations should speak to politicians’ promises that no one will be financially worse off under a new health care system. PACHA has an obligation to make the voices of public health providers heard in the debate about health care. Also, PACHA should emphasize that “access” to care does not equate to coverage. Meaningful coverage requires more than access to insurance for people with preexisting conditions; it also must be affordable and ensure certain benefits are provided.

PACHA can claim the moral high ground by reminding the country that public health benefits everyone. Dr. Sharfstein noted that individuals have real, personal experience with health care, so PACHA and others have an opportunity to make it clear to people what the proposed changes will mean to them. Dr. Hale added that public health can be bold and negotiate directly with drug makers for lower prices, providing companies with profit where there was none when the drugs were too expensive.

Discussion turned to options under the 340B program. Panelists explained that states have options in place to pursue lower prices for HCV drugs and expand coverage. Medicaid and 340B are not receiving the discounts they should because of certain statutes and practices. The greatest barrier to care is not the cost of drugs, but rather access to screening and linkage to care.

Panelists suggested the following considerations for policy recommendations:

- Counter threats to Medicaid by underscoring the importance of the program for people who have or are at high risk for HIV or HCV.
- Ensure that discounts and rebates flow back to government payers and patients.
- Emphasize the power of states and of state and Federal investigative bodies to enforce requirements and policies.
- Create state policy laboratories to test new approaches to making medications affordable.
- Develop a proposal for pharmaceutical executives that describes the number of patients who need treatment and the price that public health providers want to pay for the treatment and ensure that providers have the capacity to provide treatment.

Regarding intellectual property constraints, Dr. Sharfstein pointed out that the government already has some authority to use patented drugs at lower costs. Patent exclusivity is a separate issue that also can be addressed. Not all approaches require new legislation. PACHA may want to consider how other countries have addressed high drug costs.

All of the panelists agreed with the premise that quality of care and access to care should not be determined by geography. PACHA should support equity.

Some suggestions for addressing rebates and discounts are as follow:

- Expand 340B programs at the state level to extend discounts immediately—for example, to correctional institutions.
- Partner with HRSA to draft guidance for states.
- Allow rebates, discounts, and free goods to flow to individuals, reducing their out-of-pocket costs, which may require rulemaking on the part of the Centers for Medicare & Medicaid Services.
- Create a central Federal entity responsible for drug pricing that brings together all of the available Federal options and resources to help states develop and test solutions (e.g., how to better leverage the 340B program).
- Contact pharmaceutical companies directly with suggestions and illustrate for them what might be possible.
- Shift the public debate to create the expectation that drug makers should do more to address public health.

Public Comment Period

Emily McCloskey advised PACHA of NASTAD's statement affirming conclusive scientific evidence that a person living with HIV who is on antiretroviral therapy (ART) and maintains viral suppression does not sexually transmit HIV. This statement accelerates NASTAD's longstanding work to end HIV and HIV-related stigma and dramatically reduce new HIV infections. The evidence provides an unprecedented

opportunity to improve the lives of PLHIV, improve treatment uptake and adherence, and advocate for expanded access to treatment and care.

This new evidence confirms that treatment is a powerful preventive intervention. It also encourages PLHIV to initiate and adhere to a successful ART regimen, closely monitor their viral load, and stay in regular medical care. NASTAD and its members will widely share this new scientific understanding of the risk of sexual transmission of HIV from virally suppressed PLHIV to both promote optimal health outcomes and reduce stigma. NASTAD will continue to support efforts to examine and support evidence-based public health policies, approaches, and resources to promote and reduce barriers to HIV prevention and care. NASTAD members also will continue to emphasize the importance of providing comprehensive prevention and care services for PLHIV to improve their quality of life and reduce risk of transmission to others. Finally, NASTAD will continue to advocate at the national level to raise awareness about the latest science of HIV transmission risk and implement policies and practices grounded in the best science, void of stigma and discrimination. NASTAD will continue to monitor the scientific landscape for advances that will enhance understanding of how to reduce new HIV infections and optimize the quality of life for PLHIV.

Adjournment

Ms. Hayes thanked the staff and contractors for their work in support of this PACHA meeting. She adjourned the meeting at 3:35 p.m.

Appendix

Welcome Letter to HHS Secretary

Presidential Advisory Council on HIV/AIDS



March 30, 2017

The Honorable Thomas Price, MD
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Price:

The Presidential Advisory Council on HIV/AIDS (PACHA) advises the President and Secretary of Health and Human Services regarding programs, policies, and research priorities to slow – and ultimately, *end* – the HIV/AIDS epidemic. PACHA is comprised of physicians, public health professionals, service providers, and advocates who volunteer their service. We, the members of PACHA, write now to update you on our activities and recommendations.

The new administration assumes the mantle of power at a critical time in the fight against HIV/AIDS. In the United States, approximately 1.1 million people are living with HIV.¹ A 2011 National Institutes of Health (NIH) funded study showed that providing treatment for people living with HIV reduced the risk of transmitting the virus to HIV-negative sexual partners by 96%.² Other government-supported research has shown that medications used to treat people living with HIV can prevent uninfected people from acquiring infection (pre-exposure prophylaxis).³ But despite dramatic research advances, 1 in 7 people living with HIV are unaware of their infection and just over half of those diagnosed with HIV are receiving regular treatment.⁴ Moreover, although new HIV infections decreased 18% overall from 2008 to 2014 and declined within most subgroups, they increased 35% percent among 25- to 34-year-old gay men, went up 20% among Latino gay and bisexual males, and stabilized at unacceptably high rates for Black gay and bisexual men. Furthermore, the opioid epidemic has led to increases in injection

¹ Centers for Disease Control and Prevention (CDC), "HIV Among Gay and Bisexual Men," available at <https://www.cdc.gov/nchstp/newsroom/docs/factsheets/cdc-msm-508.pdf> (last viewed Mar. 28, 2017).

² Cohen MS, Chen YQ, McCauley M, et al., "Antiretroviral Therapy for the Prevention of HIV-1 Transmission," *N Engl J Med* 2016; 375:830-839, September 1, 2016, DOI: 10.1056/NEJMoa1600693, available at <http://www.nejm.org/doi/full/10.1056/NEJMoa1600693#t=article> (last viewed Mar. 28, 2017).

³ See, e.g., Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med* 2010;363(27):2587-99. For links to this and related studies, visit: <https://www.cdc.gov/hiv/research/biomedicalresearch/prep/> (last viewed Mar. 28, 2017).

⁴ CDC, HIV Surveillance Report, Supplemental Report (Vol. 21, No. 4), "Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data, U.S. and Six Dependent Areas, 2014," available at <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-21-4.pdf> (last viewed Mar. 28, 2017).

drug use and viral hepatitis, raising concern that a new wave of HIV infections among people who inject drugs might not be far behind.⁵

HIV prevention and treatment not only saves lives and decreases transmission – but also saves money. Each new infection is associated with an estimated lifetime cost of \$449,000.⁶ The total cost of treating the 37,600 people who were newly infected with HIV in the United States in just one year (2014) is more than \$16.8 billion.

The United States will reap the benefits of its investments in research only if people living with HIV are diagnosed in a timely fashion, have access to medical care, and consistently receive HIV medications and the support necessary to remain adherent to their treatment plan – and people at high risk for HIV can receive prevention services, including pre-exposure prophylaxis.

In order to achieve these goals, PACHA recommends the following:

- Continue implementing the strategy we have developed, which includes roadmaps to: (a) reduce new infections; (b) increase access to care and improve health outcomes for people living with HIV; (c) reduce HIV-related health disparities and inequities; and (d) achieve a more coordinated national response to the HIV epidemic.
- Fully support and fund the highly successful Ryan White HIV/AIDS program, which provides funding and expertise to states, cities, clinics, and local community organizations and has helped ensure that many patients achieve viral suppression.
- Support the role of Medicaid as a source of health coverage for people with HIV, as well as other co-morbidities. Medicaid has played a key role in HIV care for many years. In States that chose to expand Medicaid, many people with HIV now have access to life-saving treatments, which, in turn, decreases the risk of new infections. Contractions in Medicaid may well have the opposite effect.
- Maintain and expand health insurance coverage and ensure that all people have access to affordable, meaningful, and uninterrupted coverage—with strong consumer protections—for inpatient and outpatient care, prescription drugs, preventive services, and other necessary medical care. Health insurance coverage is critical for both prevention and treatment of HIV and for achieving the goals of the National HIV/AIDS Strategy (NHAS).
- Embed quality metrics into HIV care management (<https://www.aids.gov/federal-resources/pacha/meetings/2015/dec-2015-letter-to-president-obama.pdf>).
- Support and improve patient protections for people living with HIV, to enhance access and treatment adherence. Examples of potential actions here include: (a) preventing insurers from denying coverage or charging higher premiums based on an HIV diagnosis or the existence of other health conditions; (b) ensuring that health plans provide access to needed services and treatments; (c) limiting the impact of extremely high co-pays and/or co-

⁵ CDC, “HIV Incidence: Estimated Annual Infections in the U.S., 2008-2014, Overall and by Transmission Route.” (hereinafter “HIV Incidence”), available at https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/hiv-incidence-fact-sheet_508.pdf (last viewed Mar. 28, 2017).

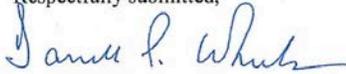
⁶ See Farnham PG et al. Updates of Lifetime Costs of Care and Quality of Life Estimates for HIV-Infected Persons in the United States: Late Versus Early Diagnosis and Entry Into Care. *J Acquir Immune Defic Syndr* 2013; 64: 183-189; CDC, “HIV Cost-Effectiveness,” available at <https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html> (last viewed Mar. 28, 2017)

insurance costs; and (d) maintaining anti-discrimination provisions that prevent insurer discrimination based on race, color, national origin, sex, age, diagnosis, or disability.

- Support federal funding for initiatives that address HIV public health concerns. These include NIH research, Health Resources and Services Administration (HRSA) programs, CDC initiatives (especially HIV and STD prevention programs), HUD housing programs, and Substance Abuse and Mental Health Services Administration (SAMHSA) activities.
- Strengthen and ensure protection from discrimination for gay, lesbian, and transgender individuals.
- Support programs focused on the U.S. Territories and countries around the globe. We recommend implementing the nation's HIV strategy in all U.S. Territories, and we fully support the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) programs for less developed countries struggling with the impact of HIV epidemics.
- Support international efforts to reach clear targets to save lives and decrease new transmissions: 90% of the population diagnosed, 90% in treatment, and 90% virally suppressed, referred to as the "90-90-90" treatment targets.⁷

We look forward to working with you in your efforts to improve the health of Americans and make this country the best that it can be.

Respectfully submitted,



Darrell P. Wheeler, PhD, MPH, ACSW
Vice-Chair
Presidential Advisory Council on HIV/AIDS

cc: Don Wright, MD, MPH, Acting Assistant Secretary for Health, U.S. Department of Health and Human Services

⁷ UNAIDS, "An Ambitious Treatment Target to Help End the AIDS Epidemic," available at <http://www.unaids.org/en/resources/documents/2014/90-90-90> (last viewed Mar. 28, 2017).