Presidential Advisory Council on HIV/AIDS (PACHA)
60th Meeting

Hubert H. Humphrey Building
8th Floor/Penthouse
200 Independence Avenue, S.W.
Washington, DC

September 26–27, 2016

Council Members—Present

Nancy Mahon, J.D., PACHA Chair (*day one*)
Darryl Wheeler, Ph.D., M.P.H., ACSW, PACHA Vice Chair (*day two*)
Ada A. Adimora, M.D., M.P.H.
Gina M. Brown, M.S.W. (*by phone, day one*)
Ulysses W. Burley III, M.D., M.P.H.
Vignetta Charles, Ph.D.
William H. Collier
Michelle Collins-Ogle, M.D., FAAP, AAHIVS
Kevin Cranston, M.Div.
Grissel Granados, M.S.W. (*day one*)
Gabriel Maldonado, M.B.A.
Ligia Peralta, M.D., FAAP, FSAHM, AAHIVS
Scott A. Schoettes, J.D.
Patrick Sullivan, Ph.D., D.V.M.
Mildred Williamson, Ph.D., M.S.W.

Council Members—Absent

Jeffrey S. Akman, M.D.
Oliver Clyde Allen III
Lucy A. Bradley-Springer, Ph.D., R.N., ACRN, FAAN
Nicholas Carlisle, J.D.
Cecilia C. Chung
Yvette Flunder, D.Min.
Harlan H. Pruden
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, Health Resources and Services Administration (HRSA)
Jennifer Kates, Ph.D., Liaison, Centers for Disease Control and Prevention (CDC)/HRSA Advisory Committee on HIV, Viral Hepatitis, and Sexually Transmitted Disease (STD) Prevention and Treatment (CHAC)
Amy Lansky, Ph.D., M.P.H., Acting Director, White House Office of National AIDS Policy (ONAP) (*day one*)
Richard Wolitski, Ph.D., Acting Director, Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS)

Sara Zeigler, M.P.A., Associate Director for Planning and Policy, National Center for HIV/AIDS, Viral Hepatitis, STD, and Tuberculosis Prevention, CDC

Presenters

David Evans, Director of Research Advocacy, Project Inform
Lisa Joldersma, J.D., Vice President, Policy and Research, Pharmaceutical Research and Manufacturers of America (PhRMA)
Joel White, President, Council for Affordable Health Coverage (CAHC)

Day One—September 26, 2016

Welcome

PACHA Chair Nancy Mahon, J.D., called the meeting to order at 1:38 p.m. and welcomed the members of the Council and meeting attendees. (PACHA members had gathered earlier in the day for ethics training and an overview of the Federal Advisory Committee Act.) Ms. Mahon announced that she would be completing her PACHA tenure as of this meeting, and she gave special thanks to PACHA staff and members for their work.

Roll Call

Kaye Hayes, M.P.A., called the roll.

Introductory Remarks

Amy Lansky, Ph.D., M.P.H., Director, ONAP

Amy Lansky, Ph.D., M.P.H., reported that the National HIV/AIDS Strategy (NHAS) is paying off. Although more work must be done, great strides are being made toward the meeting the goals. For example, new diagnoses of HIV are declining, and more people living with HIV (PLHIV) are getting treatment. The goal of 90 percent of PLHIV knowing their status is within reach, she noted, and the focus on HIV testing should continue. Good progress has been made on linkage to care, retention, and viral suppression; but the target numbers for retention and suppression are still some distance away.

Although there is some good news around reducing HIV disparities, more focus is needed on decreasing HIV among young black gay and bisexual men, in particular. Dr. Lansky noted that the Southern States account for about one-third of the U.S. population but about half of new HIV diagnoses. However, disparities are down among black women and girls, and a new NHAS target for that measure will be set later this year. New NHAS indicators for expanding access to pre-exposure prophylactics (PrEP) and ending stigma will be released in December.

Dr. Lansky summarized several policy changes from the past few years that have contributed to progress in addressing HIV/AIDS. Recently, revisions to federal policies

around housing for PLHIV and syringe exchange programs have made an impact. Reaching the goal of ending HIV/AIDS requires cooperation across all levels of government and all sectors of the population. ONAP is collecting input from stakeholders about what they are doing to implement the NHAS.

Discussion

Michelle Collins-Ogle, M.D., commented that a more realistic picture of retention emerges when looking at patients in treatment over the long term—that is, 3 or more years after initial treatment, rather than within 1 year. Dr. Lansky stated that the current indicators look at retention within 1 year, but she appreciated the point.

PACHA Subcommittee Reports

Access to Care Subcommittee

Vignetta Charles, Ph.D.; and William Collier, Co-Chairs

Vignetta Charles, Ph.D., noted that the priorities of the Access to Care Subcommittee are implementation of the Affordable Care Act (ACA) and its integration with the Ryan White HIV/AIDS Program, HIV/hepatitis C virus (HCV) coinfection; monitoring of the quality of HIV information; and social determinants of health (SDH), a topic that is addressed by all the subcommittees. As part of ACA implementation, the Subcommittee is focusing on transparency, cost, and price; on day two of this PACHA meeting, the Subcommittee has arranged the first in a series of panels to discuss drug pricing.

Mr. William Collier pointed out that more organizations are signing on to the 90-90-90 target (by 2020, 90 percent of all PLHIV will know their status, 90 percent will be receiving antiretroviral therapy, and 90 percent will have achieved viral suppression). The Subcommittee suggests scrutinizing the number of city health departments using a 90-90-90 dashboard as an indicator. Another area of Subcommittee interest is "churn," or the movement of individuals into and across insurance plans, which can affect continuity of care. It also is concerned with issues around aging, as more PLHIV live longer and half of PLHIV are older than 50 years of age.

Reducing HIV-Related Disparities Subcommittee

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

Scott Schoettes, J.D., reported that the Reducing HIV-Related Disparities Subcommittee has been focused on the Stigma Reduction Summit, which took place September 20–22. The outcome of the Summit will be discussed later in this meeting. Mr. Schoettes added that the Subcommittee will follow up on its recommendations to standardize metrics around HIV to better ensure better quality across the board, which originated in the Disparities Subcommittee. The Subcommittee also has a working group on SDH. In future efforts, the Subcommittee will look more closely at the huge disparities in HIV among black gay and bisexual men.

Global Agenda Subcommittee

Jennifer Kates, Ph.D., Liaison, CHAC

Jennifer Kates, Ph.D., reported that the Global Agenda Subcommittee has been discussing the International AIDS Conference. The Subcommittee hopes to discuss the connections between domestic and global HIV issues at an upcoming PACHA meeting.

Reducing HIV Incidence Subcommittee

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

Ada Adimora, M.D., M.P.H., noted that the Reducing HIV Incidence Subcommittee identified surveillance, particularly testing, and viral suppression as key concerns a year ago. Those concerns led to recommendations to the HHS Secretary and ONAP to put new quality measures in place, including assessment of the number of people testing positive for HIV who are linked to care within 30 days. Dr. Adimora stated that the Subcommittee will hold a teleconference with CDC about reporting on new infections and that she hoped such calls could occur more frequently.

The Subcommittee created working groups that are addressing data collection in Native American populations and the effect of looser federal funding restrictions on syringe exchange programs. The Subcommittee also is evaluating trends in HIV among young black men who have sex with men and how HHS can raise awareness about the use of PrEP and payment for counseling about PrEP. The Subcommittee will talk with CDC representatives about updated guidelines that better address PrEP.

As a result of the concerns raised at the PACHA question-and-answer session at the U.S. Conference on AIDS (USCA) earlier in September, the Subcommittee hopes to organize a PACHA panel discussion on HIV and HCV among incarcerated populations, including those in juvenile detention. Dr. Adimora asked for input from other PACHA members on next steps for the Subcommittee.

Discussion

Ms. Mahon observed that PACHA is most effective when it makes targeted recommendations; she advised PACHA to prepare a short list of key issues and recommendations for the transition team of the next Administration.

Ligia Peralta, M.D., noted that several issues raised at the USCA revolved around surveillance and data. Participants called for more attention to veterans, which raised the question of how the Department of Veterans Affairs (VA) has addressed HCV and managed high drug prices for HCV treatment. Dr. Collins-Ogle said the VA and others have useful data that are not easily accessible. She is concerned about implementing guidance without data and hoped PACHA would discuss making data more widely available.

Stigma Reduction Summit

Overview

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

Gabriel Maldonado, M.B.A., and Mr. Schoettes explained that the Reducing HIV-Related Disparities Subcommittee conceived the Summit as an opportunity to bring together a broad range of community voices on addressing HIV-related stigma, including researchers, policymakers, advocates, and others. Summit participants divided into three groups to brainstorm about ways to decrease (1) internalized stigma; (2) stigma in accessing care (or clinical stigma); and (3) social/community stigma. Numerous suggestions came from those breakout sessions, which Mr. Maldonado and Mr. Schoettes combined into the recommendations submitted to PACHA on behalf of the Subcommittee.

HIV-Related Stigma and Discrimination: Key Concepts and Terminology

Anne Stangl, Ph.D., Senior Behavioral Scientist, International Center for Research on Women

Anne Stangl, Ph.D., presented definitions of stigma and discrimination, which have evolved and become more nuanced over time. Dr. Stangl explained a framework for thinking about malleable aspects of stigma and potential interventions for eliminating it. Some key targets for interventions are fear of infection from casual contact, lack of knowledge of stigma and its harmful consequences, and stereotypes and prejudicial attitudes. Key manifestations of stigma also can inform interventions:

Manifestation	**Definition**
Anticipated	The fear of negative ramifications if one's HIV status becomes known, should one associate with a PLHIV or should one test positive for HIV
Perceived	Community members' perception of stigma that is directed towards PLHIV by community members
Internalized (self)	PLHIV's application to themselves of negative beliefs and feelings associated with HIV.
Experienced	The experience of discrimination, based on HIV status or association with a PLHIV or other stigmatized group, that falls *outside* legal purview
Discrimination	The experience of discrimination, based on HIV status or association with a PLHIV or other stigmatized group, that falls *inside* legal purview
Resilience	Overcoming and resisting HIV-related stigma experienced

Discussion

Dr. Stangl clarified that the only difference between experienced stigma and discrimination is that the former refers to actions that are not illegal, such as encounters in public spaces, while the latter includes illegal actions, such as decisions made in the workplace. What is legal varies by context and by country, she said. Moreover, the interventions vary—that is, efforts to reduce discrimination often focus on laws and policies, and reducing experienced stigma usually involves raising awareness and training. The purpose of the definitions is to remind advocates and policymakers not to lump all types of stigma together.

Ms. Mahon suggested researchers drill down into one program to illustrate how stigma undermines the program's intentions and use the information as a foundation for concrete suggestions on how to move forward. She further stated that research on the economic effects of stigma, in the context of a single program, could tell a very human story. Patrick Sullivan, Ph.D., D.V.M., strongly agreed that creating an economic model of the effects of stigma could be used to leverage resources and mobilize investment in reducing stigma.

Mildred Williamson, Ph.D., M.S.W., noted that behavioral interventions often are directed to individuals, but stigma is tied to layers beyond the individual. She called for more research on structural drivers of HIV-related stigma and definitions in terms of the historic, cumulative effects of racism, homophobia, and other forms of stigma. Dr. Williamson also hoped to hear more examples of collective human agency to address the structural drivers, which could result in addressing policy and structural conditions while also uplifting individuals who participate. Mr. Maldonado commented that Summit discussions about internalized stigma could not easily separate HIV-related stigma from racism, homophobia, and SDH.

Stigma Reduction Recommendations

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

Mr. Maldonado and Mr. Schoettes summarized a preamble to the recommendations that explains how the HIV-Related Stigma Reduction Summit differed from the White House Stigma Summit and the unique opportunity for significantly diminishing HIV-related stigma. The recommendations are grounded in the goals of the NHAS, yet acknowledge the importance of stigma reduction as a goal unto itself. The preamble (see Appendix A) calls out the importance of other SDH, including related stigmas, and the limited scope of the recommendations. It also calls for continuing meaningful involvement of PLHIV in addressing stigma.

Recommendation 1: Define and disseminate a framework for HIV-related stigma across federal agencies, among HIV-related federally funded entities, and into the wider HIV service community, including integration into the next iteration of NHAS.

- **Develop guides regarding use of this framework** by federal agencies, service providers, and clients.
- **Conduct a self-assessment of HIV stigmatization** embedded in policies, programs, messages, and so forth across federal agencies, including those tasked with addressing HIV/AIDS or public health. This should include an assessment of the stigmatization and marginalization of other traits, activities, or identities shared by the populations most at risk for HIV (including transgender women, sex workers, and injection drug users).

Recommendation 2: Develop HIV prevention messages and materials that are more sex-positive and that fully embrace the current understanding of the HIV risk landscape.

- **Engage in widespread educational outreach about the benefits of treatment as prevention and PrEP** targeted at populations at higher risk for HIV, including the message that medication side effects are minimal and manageable.
- **Develop a strategy that embraces social media** for dissemination of these messages.

Recommendation 3: Use levers of federal government to eliminate HIV-related stigma and discrimination wherever possible.

- **Update outdated regulations, rules, and practices in which HIV-related stigma is embedded**, including the blood donation guidelines, Peace Corps recruitment/retention policies, Department of Defense recruitment/retention policies, and HIV-based prosecutions under the Uniform Code of Military Justice.
- **Incentivize states to dismantle HIV criminalization laws.**
- **Mandate insurance coverage for treatment of lipodystrophy and lipoatrophy** in marketplace plans by leveraging antidiscrimination principles in the ACA.

Recommendation 4: Include a stigma reduction component in all federal HIV funding opportunity announcements and application processes.

- Applicants should be encouraged to consider and address HIV stigma, as well as **related forms of stigma for the populations served, the intersectional nature of such stigmas, and stigma related to comorbidities and other SDH**.
- **Require all federal grant applicants related to health workforce training and service delivery to have a stigma reduction plan** that will be considered in the scoring of the funding application (e.g., training, assessments, monitoring).

Recommendation 5: Monitor and assess the operations/clinical/client experience related to stigma as part of the federal grantee review process, using a "Stigma 360" review that assesses the program at all levels.

- Reviews should include **client-based quality assurance evaluation** and be facilitated by a mechanism through which clients can report experiences related to stigma (i.e., a grievance process).
- **Incorporate metrics related to stigma experienced by clients** along the health care continuum (testing, diagnosis, engagement in care, treatment, and retention) and include metrics to evaluate provider and health facility staff knowledge and mitigation of stigma and related adverse clinical outcome.
- **Develop and disseminate a stigma reduction toolkit** for training staff at care centers receiving federal funding and otherwise **encourage support for technical assistance** that trains and supports grantees on reducing HIV and related forms of stigma; consider **adapting the stigma reduction toolkit for use by communities of faith** and engaging in training and capacity-building for this work with interested groups.

Recommendation 6: Enhance the self-esteem and bolster the resiliency of PLHIV.

- **Connect newly diagnosed individuals to national networks of PLHIV and/or local support groups** by requiring those receiving federal funding for HIV testing to provide such information in counseling after a positive test.
- **Create leadership and professional development training opportunities for PLHIV** who are serving on advisory boards and commissions to help retain them and sustain their ongoing participation.

Recommendation 7: Partner with the U.S. Department of Education to encourage stigma reduction.

- Starting in elementary school, in an anti-bullying framework, **provide guidance on curricula/education that values differences** and serves as a foundation for stigma reduction in later years.
- **Find ways to promote sexual education that is not heteronormative** and not focused solely on reproduction or the cisgender experience, but more generally encompasses sexual health and variations in gender identity.
- **Require training related to HIV-related stigma and other social determinants of health** (e.g., racism, homophobia, transphobia, misogyny, housing insecurity, food insecurity) in accredited curricula for the health care workforce, including interactive learning with people/patients who have personally experienced such forms of stigma.

Discussion

Ms. Mahon thought PACHA should identify the most effective mechanisms for accomplishing the goals described in the recommendations. Dr. Lansky suggested that PACHA think carefully about what aspects are most important to recommend now to capitalize on the current convergence of interests around addressing stigma. She also proposed more discussion with federal representatives about who would implement the recommendations and discussion with federal grantees about minimizing the burden of implementation.

Asked to prioritize the recommendations, Mr. Maldonado indicated that federal investments in stigma research and looking at the ecology of models struck him as being most important. He noted that the self-assessment of stigma in policies and programs and inclusion of stigma reduction in funding mechanisms were highly ranked by Summit participants.

Action Item

Mr. Maldonado and Mr. Schoettes will reevaluate the suggestions from the Summit to determine the highest priorities for action.

PACHA members raised numerous questions about specific details of the proposed recommendations. They emphasized the need to think broadly about the potential effects of the recommendations so as to avoid unintended consequences. All members supported the spirit of the recommendations but requested more time to delve into the details and

develop specific promotion strategies so the recommendations can be implemented effectively.

Public Comment Period

William McColl of AIDS United, who participated in the Stigma Reduction Summit, thanked Mr. Schoettes and Mr. Maldonado for their efforts. The Summit process took advantage of community insight and perspectives. AIDS United is a national organization working on stigma and other issues. Mr. McColl stated that there is a need to take on the charge of treatment as prevention, moving people to adherence and helping them achieve a low viral load. The proposed stigma reduction recommendations are a step forward, and he encouraged PACHA to move toward implementing them.

Recognition of the Outgoing Chair

Ada Adimora, M.D., M.P.H.

Dr. Adimora described Ms. Mahon's many professional roles, including her leadership of PACHA since 2001. In that time, Ms. Mahon has presided over 15 full Council meetings, during which debate has centered on important and sometimes controversial recommendations. Under Ms. Mahon, PACHA provided recommendations to HHS and the White House that have the potential to profoundly affect the lives of PLHIV—covering such topics as comprehensive sex education, HIV disclosure, transgender populations, and two-spirit people. Dr. Adimora described how Ms. Mahon's passion and dedication led to a rapid joint resolution from PACHA and CHAC calling on lawmakers to remove federal restrictions on access to sterile injection equipment. She added that Ms. Mahon is the embodiment of action and works daily to improve the lives of people around the globe.

Closing Remarks

Nancy Mahon, J.D., PACHA Chair

Ms. Mahon commented that it had been an incredible pleasure and learning experience to serve as PACHA chair. She praised PACHA members for their passion and dedication to the Council. Ms. Mahon noted that she appreciated the opportunity to lead PACHA and looks forward to working with the Council in some other capacity in the future. Finally, she thanked PACHA Executive Director Kaye Hayes and Public Health Analyst Caroline Talev for their excellent support. Ms. Mahon adjourned the meeting for the day at 4:33 p.m.

Day Two—September 27, 2016

Welcome

Darrell Wheeler, Ph.D., M.P.H., ACSW, PACHA Vice Chair

Darrell Wheeler, Ph.D., M.P.H., called the meeting to order at 9:24 a.m. He acknowledged the previous day's robust discussion of the draft stigma reduction recommendations. He said such efforts are important, because biomedical interventions will not resolve how people feel or how they demonstrate their bias against PLHIV.

Roll Call

Ms. Hayes called the roll.

Understanding Pharmaceutical Pricing and Potential Actions to Engage and Influence Allies

Moderator: Vignetta Charles, Ph.D., PACHA Access to Care Subcommittee Co-Chair

Dr. Charles noted that the issue of drug pricing has been the subject of Congressional scrutiny and has been mentioned in the Presidential campaign. This panel represents diverse perspectives on the costs of prescription drugs. A future panel will include health economists. The goal of these panels is for PACHA to gather information that will shape its recommendations and to learn how to engage and influence allies.

Prescription Medicines: Costs in Context

Lisa Joldersma, J.D., Vice President, Policy and Research, PhRMA

Lisa Joldersma, J.D., highlighted how prescription drugs have made a significant difference in the health and longevity of people who have HIV, HCV, cancer, and cardiovascular disease. Of 7,000 new medicines in development, 159 address HIV. Since 2008, she noted, the amount spent on prescription drugs, as a proportion of overall health care spending, has been stable. She acknowledged some outliers (EpiPen, HCV drugs). Ms. Joldersma pointed out that when medicines are effective, individuals realize indirect benefits (e.g., staying out of the hospital and continuing to work).

A 10-year projection of health care spending predicts that the cost of prescription drugs will remain stable through 2025, but costs of other health care expenditures, such as procedures, will increase. In addition, the costs of prescription drugs tend to decline over time. For example, when azidothymidine (AZT) was introduced in 1989, alarms were sounded about its high cost, but the drug went to market through the usual process and the price came down. Ms. Joldersma stated that if the government had attempted in 1989 to limit the price of AZT, she is not confident that such HIV regimens as PrEP and highly active antiretroviral therapy would be available now.

Ms. Joldersma acknowledged that despite overall stability in costs and declining costs of most prescription drugs over time, individuals seem to be paying more for their prescriptions, and people are reading about increasing drug costs. The launch prices of new drugs represent a changing market in which the science is harder, riskier, more costly, and more individualized than ever before. New drugs target smaller populations and tougher markets. Ms. Joldersma estimated that the cost to develop a new medicine has doubled over the past decade and now reaches $2.6 billion. Trials have become more complex and the regulatory burden is increased. Research is focusing on areas where the science is difficult and the risk of failure is high. Researchers carry a greater burden to meet payer demands (e.g., narrow protocols and formularies) and face more competition to get to market faster. All of these demands are reasonable, but meeting them is not free, Ms. Joldersma stated. In addition, medication management has been significantly expanded and costs have been shifted by payers and pharmacy benefit managers (PBMs)

through cost-sharing, prior authorization requirements, and step therapy protocols. Pharmaceutical company-sponsored patient assistance for medications also is under scrutiny.

Another significant trend affecting consumers with high-deductible health plans is the inclusion of medications in the plan deductible. As a result, many people pay 100 percent of undiscounted prescription prices for months—even if the insurer receives a rebate that reduces the cost to the insurer. Ms. Joldersma emphasized that PhRMA takes its commitment to patients seriously and sees some solutions that address cost concerns. However, she reiterated, "Where would we be today if the solution for AZT were for the government to cap the price of the drug?"

Prescriptions for Value

Joel White, President, CAHC

Mr. Joel White opened by stating that CAHC is focused on lowering the cost of health care for all Americans. He described trends in health care costs since 1990. For the typical family, spending on health care is increasing dramatically, while spending on food, clothing, transportation, and other essentials is decreasing.

Mr. White used the recent introduction of an HCV drug as an illustration of market competition at work to bring down prices. As more products became available and the value of curative treatment was recognized, insurers and PBMs negotiated discounts of nearly 50 percent. Mr. White emphasized that the invoice price growth of HCV drugs (more than 12 percent since 2011) is much higher than their net price growth (less than 3 percent).

Mr. White presented data estimating that the proportion of health care costs related to drug spending is unlikely to increase dramatically over the next 10 years. He also acknowledged that consumers are feeling the pain of drug prices daily, as they are spending more out of pocket. Effective drugs keep people healthy and out of the hospital, he noted. In fact, increased drug spending translates into decreased hospital spending for several major health conditions.

Mr. White summarized current laws that affect drug costs and coverage, such as the Ryan White HIV/AIDS Program and the 340B Drug Pricing Program. More products on the market means more competition and lower prices, yet the Food and Drug Administration (FDA) has a large backlog of generic drugs waiting for approval. Medicaid requires manufacturers to offer the same discount to all programs, so manufacturers are less likely to offer any. Manufacturers are further challenged by the complex terms and requirements of HHS' value-based purchasing policies, ACA policies, the federal supply schedule, anti-kickback statutes, and Medicare Part D.

CAHC recognizes the concerns about certain drugs, although the causes of price increases vary. Mr. White noted that prices remain high for drugs that treat multiple sclerosis, despite several competing products. The payer practice of including all HIV/AIDS drugs on the most expensive tier of the formulary is discriminatory, he stated,

but it represents an insurer coverage issue. For consumers in the private sector, companies provide tools to identify which drugs are on their plan's formulary and what their cost obligation is, but such tools are not available for those purchasing insurance through ACA exchanges.

CAHC is creating a coalition of payers, manufacturers, consumers, and providers to discuss areas of agreement around four major issues:

- Revising laws and policies to enhance value through increased coordination and better infrastructure
- Improving competition by addressing the FDA backlog and regulations that slow down clinical trials
- Empowering consumers with information and education about covered drugs, cost-sharing, and appeals
- Encouraging dialogue to minimize support for bad ideas—such as importing drugs, price controls, and benefit caps—that create access issues, supply shortages, and safety and efficacy concerns

A Look at Prescription Drug Price Increases

David Evans, Director of Research Advocacy, Project Inform

Mr. David Evans emphasized that the high cost of drugs is a critical issue for PLHIV and people with HCV. Their perspectives are not always represented at the table, and his organization advocates for them. Furthermore, real drug price information is hidden from consumers, which hampers research and advocacy.

Mr. Evans presented data on three HIV drugs that contradicted previous speakers' claims that drug costs are not increasing. Project Inform identified the real price increases paid for each. Mr. Evans noted that the price of AZT came down by 20 percent with community pressure. At that time, the life expectancy for PLHIV was months, not decades. With a specialty drug aimed at a small population for a short period, it could be expected that manufacturers would charge high prices to recapture their development costs. In contrast, HCV affects more than 250,000 people per year, and HCV drugs are not specialty drugs.

Mr. Evans next summarized national efforts to address drug pricing over the years, which have had limited success. He described some "ominous trends" in drug pricing. First, the change in narrative from describing prices in terms of recapturing the cost of research and development (R&D) to prices reflecting "value" is problematic, because patients and their advocates are not at the table to weigh in on what constitutes value. Insurance "churning" also has not been part of the discussion. Generic drugs are unlikely to save PLHIV, said Mr. Evans, as evidenced by huge price hikes for certain drugs. He added that aging PLHIV often are taking multiple medications, thus bearing a higher cost burden.

Some proposals to fix systemic problems call for blowing up the system, Mr. Evans stated. Health care is not a rational market, and asymmetry prevents individuals from

understanding the costs. Without transparency, consumers cannot shop for better services. Alternatives include a single-payer health care system, central government authority to negotiate and set prices, and reduced patent protection. Instead of trying to fix one problem at a time, Mr. Evans suggested dramatic change. The current system financially rewards bad corporate behavior, he suggested.

To transform the system, Mr. Evans recommended increasing transparency of R&D, other costs, and price negotiations; lowering consumer prices when the government pays for critical research; allowing Medicare to negotiate drug prices; better regulating against monopolies by brand-name and generic drug makers; and including all stakeholders in decisions about prices based on value. Finally, Mr. Evans suggested creating a neutral entity to educate consumers about diseases and treatments, reducing bias in marketing and capturing some savings to reduce costs.

Discussion

Asked about the role of public health plans in negotiating drug prices, Mr. White stated that Medicare Part D is working well for beneficiaries as is. If Medicare were allowed to negotiate, it is not clear whose interests would take precedence—those of the beneficiaries, the plans, or the taxpayers. Ms. Joldersma argued against focusing on a single sector of spending. Mr. Evans pointed out that most proposals around negotiation offer attendant policies to help with access and price.

Ms. Joldersma raised the point that ACA's expansion of Medicaid increased the volume of prescription drugs subject to price controls, thus distorting the market. Dr. Adimora responded that such logic is nonsensical for patients and providers who see access to drugs limited by high costs even as they see other countries getting the same drugs at lower costs. Dr. Kates commented that the market is complicated. She also stated that polls show most people favor price negotiation and price controls, do not think the prices they pay are fair, and say they have trouble paying for their medications.

Mr. Evans added that the conversation is further complicated by lumping together all kinds of patients and drugs. The discussion rarely focuses on increasing access to drugs for life-threatening conditions for which there are huge social barriers to getting and staying on drugs. Mr. White agreed that the market is fragmented, and multiple laws serve different populations. Some of the unrest about drug pricing should be directed at insurance coverage policies, he noted.

Dr. Collins-Ogle asked how the costs of advertising affects the price of drugs. She also pointed out that the United States has both the highest drug prices and the highest drug profits in the world. Ms. Joldersma questioned figures purporting that pharmaceutical marketing expenses actually surpass R&D.

Mr. Evans distinguished between marketing that drives a consumer to seek care and efforts to discriminate against drugs. He again recommended that an entity other than drug makers take charge of education to help individuals understand the differences between similar drugs. Mr. White commented that companies advertise to increase their

sales, noting that consumers do not get angry about Ford's advertising or perceive that it adds to the cost of its product. Regarding costs, he suggested that using electronic health records to better match patients to trials could reduce R&D costs.

Several PACHA members took umbrage with Mr. White's analogy, pointing out that drugs are different from trucks. "No one needs a truck to live," stated Dr. Collins-Ogle, and advertising fails to provide consumers with important information about cost and access.

Regarding "churn," Dr. Sullivan indicated that if all carriers agreed to provide treatment, the benefits would accrue across all payers. He asked if payers are discouraged by the fact that Medicare ultimately accrues the benefits of health maintenance and prevention investments in younger consumers. Mr. White stated that the cost of curing HCV is going down, but many people with HCV are covered through the Indian Health Service, VA, or prison health systems.

Turning to the issue of generic drugs, Dr. Peralta noted that even basic medicines for opportunistic infections (e.g., doxycycline) can be unaffordable. Although federally mandated upper limits are applicable in some cases, the states determine their own maximum allowable costs, which should be addressed. Ms. Joldersma responded that PhRMA members recognize the critical role that generic drugs play in access and affordability. She maintained that the market and competition are the solution, not the government.

Mr. White stated that some entities have proposed creating competition among generic drug makers, for example, by setting a floor price to keep more manufacturers in the market or offering priority review vouchers as an incentive. Clearing the current FDA backlog of generics requires some federal funding and more staff. Mr. Evans commented that it is difficult to construct competition artificially. Dr. Peralta cautioned that price spikes are likely for PrEP.

Follow-Up Items

- Mr. White and Ms. Joldersma agreed to send PACHA their organizations' suggestions on how to reduce the costs of R&D.
- Mr. Evans agreed to provide research about the effect of shareholder priorities in drug pricing and the specific benefits of corporate social responsibility.

Stigma Reduction Summit Recommendations, Continued

Dr. Wheeler invited PACHA members to give further input on the recommendations discussed the previous day. Dr. Kates suggested revising the language of the recommendations to align more closely with NHAS so that the two work together to gain more traction.

Gina Brown, M.S.W., sent PACHA members a table on preferred language to avoid stigma against PLHIV, emphasizing that the recommendations should incorporate such language. In a written statement, she reminded PACHA members that PrEP is not being

used by “black and brown” people, and especially black women, at the same rates as it is by their white counterparts. Black women still bear the brunt of this epidemic, compared with Latina and white women, commented Ms. Brown. The data make it clear that not enough is being done to address these disparities.

Mr. Schoettes said that reaching the 2020 NHAS goals is getting more difficult, as efforts increasingly prioritize the hardest-to-reach populations. Reducing stigma is key to closing the gaps.

Action Item

Mr. Maldonado and Mr. Schoettes will further refine the draft recommendations according to the input from PACHA members.

Pharmaceutical Pricing, Continued

Dr. Wheeler invited PACHA members to give their impressions of the panel discussion. Several agreed that the Government has proven essential to increasing access to treatment for PLHIV. Other sources, such as the VA and national health systems in other countries, could provide more insights about cost regulations and controls. It may be helpful to focus further panel discussions on PLHIV, because they face a higher burden than the general population. Because the pharmaceutical industry is highly competitive, more conversation about market incentives is needed.

Recommendation

Before the next pharmaceutical pricing panel, PACHA members should receive the presenters’ materials in advance to enhance the discussion.

Closing Remarks

Darrell Wheeler, Ph.D., M.P.H., ACSW, PACHA Vice Chair

Dr. Wheeler stated that PACHA should address not just the individual experience of stigma but also its underlying issues. He reminded the group that the United States is constantly debating between constitutional and human rights and that the country is still evolving and experimenting with capitalism in a republic structure with a democratic platform. The conversation on drug pricing reminded Dr. Wheeler that each PACHA member brings personal experience and unique perspective to the table. He looks forward to future discussion on the issues.

Adjournment

Dr. Wheeler adjourned the meeting at 11:54 a.m.

Appendix A: Preamble to the Stigma Reduction Draft Recommendations

BACKGROUND

On September 20–22, 2016, a subgroup of the Disparities Committee of the Presidential Advisory Council on HIV/AIDS (PACHA) convened approximately 35 people—academics, researchers, clinicians, educators, advocates, federal partners, and community members living with HIV—for a 2-day summit on HIV-related stigma. In contrast to the White House Stigma Summit held in March 2016, which was more focused on stigma research and the identification of an appropriate metric for assessing HIV-related stigma pursuant to a specific mandate in the National HIV/AIDS Strategy Updated to 2020 (NHAS 2020), the purpose of PACHA's HIV Stigma Reduction Summit was to develop proposals for specific activities that the federal government could immediately undertake to reduce HIV-related stigma and discrimination in the United States. The resulting proposals were presented to the full PACHA at an in-person meeting on September 26, 2016, and as modified and adopted by that body on September 27, 2016, are presented below as PACHA's recommendations for action to reduce HIV-related stigma (the "Recommendations").

PREAMBLE

We are at a pivotal time in the HIV/AIDS epidemic in the United States, particularly with respect to our ability to turn the tide on stigma as a driver of the epidemic. With the availability and growing use of pre-exposure prophylaxis (PrEP) and recent studies concluding that those who have a suppressed viral load are—for all intents and purpose—not infectious, the potential is enormous for greater social acceptance of people living with HIV as sexual beings deserving of the full range of opportunities to lead a healthy, productive, and fulfilling life. These medical breakthroughs, combined with the widespread understanding that successful treatment transforms the once inevitably fatal disease into a chronic but manageable one, make the likelihood of significantly diminishing HIV-related stigma greater than ever.

Like the version updated to 2020, the original National HIV/AIDS Strategy (NHAS) recognized stigma as a primary driver of the epidemic and a serious impediment to the quality of life for people living with the disease. The vision of NHAS is that: "The United States will become a place where new HIV infections are rare, and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity, or socio-economic circumstance, will have access to high-quality, life-extending care, *free from stigma and discrimination*." Not merely a platitude, the goal of addressing and eliminating HIV-related stigma and discrimination is embedded throughout NHAS 2020. The effect stigma reduction will have on the three primary goals of reducing incidence, increasing access to care, and eliminating HIV-related health disparities is described throughout the Strategy (and we have identified below the specific goals of NHAS 2020 that each Recommendation addresses). In addition to the significant, measurable effect that stigma reduction will have on health outcomes across the continuum of care, PACHA embraces stigma reduction as an end in and of itself. We affirm that improving the mental health and well-being of people living with this condition is as worthy an

objective as reaping the benefits in terms of prevention, access to care, and achieving health equity.

PACHA also affirms its commitment to addressing all of the other social determinants of health, of which HIV-related stigma is but one. We recognize that it is impossible to separate HIV-related stigma from the many other forms of stigma connected to populations at higher risk for HIV, including racism, sexism/misogyny, transphobia, homophobia, as well as stigma against sex workers, immigrants, injection drug users, and people who live in poverty. We further recognize that there are multiplying effects for those residing at the intersections and experiencing two or more forms of stigma at the same time, and that, for many, HIV-related stigma by itself may not be the foremost problem they encounter in their everyday lives. Given, however, the enormity and complexity of these multiple and overlapping forms of stigma, PACHA's charge as an advisory body on HIV/AIDS working through the Department of Health and Human Services (HHS), and the finite amount of resources PACHA had to develop these proposals, our Recommendations are focused exclusively on addressing HIV-related stigma. Through other activities and actions, PACHA will continue to address the various other social determinants of health, including the many insidious and overlapping forms of stigma and discrimination that contribute to the dynamics of this epidemic.

We view the meaningful involvement of people living with HIV in this process as absolutely imperative. The Stigma Subgroup of the Disparities Committee strove to obtain—and in fact obtained—input from a diverse group of people living with HIV in the process of developing the proposals that subsequently became these Recommendations. PACHA sincerely believes that such input significantly enhanced the quality and legitimacy of these Recommendations, and we strongly encourage the Secretary to continue to seek input and guidance from a diverse group of people living with HIV as these Recommendations are implemented. To that end, PACHA would be happy to facilitate contact and further consultation opportunities with the group—over half of whom live openly with HIV—that gathered to assist in the production of these Recommendations. We thank them for their service and hereby acknowledge that the participation of each and every one of them was vital to the process.