Use of Generic ARVs for Treatment of HIV in the United States

A Project of the Forum for Collaborative HIV Research, ACRIA, and the HIV Medicine Association

University of California Washington Center
1608 Rhode Island Ave NW
Washington, DC 200036
31 March 2014 9:00 AM - 4:00 PM

AGENDA

8:00 AM	**Continental Breakfast**	
9:00 AM	Welcome & Introductions	John Bartlett, *Johns Hopkins Medical School* Veronica Miller, *HIV Forum*
	Session 1: Setting the Stage	
9:05 AM	History of Generic Drugs	Jeremy Greene, *Johns Hopkins Medical Institute*
9:20 AM	Intellectual Property and Pharmaceutical Patent Law	Jay Thomas, *Georgetown Law Center*
9:35 AM	Regulatory Approval Process for Generic Drugs	Sophie Wang, *FDA/CDER/OGD*
9:50 AM	Q & A and General Discussion	*All*
	Session 2: From Clinical Research to Guidelines - Where Are We?	
10:15 AM	Status of research on adherence benefit of single-tablet regimen • What are the implications of cost-effectiveness and comparative effectiveness research? • What data are needed to support the use of one pill per day vs. two or more pills per day? • What are the advantages and disadvantages for the use of generics in treatment regimens? • What unique, but vital, research questions should be addressed as this natural experiment proceeds to determine the type and level of impact upon treatment adherence, HIV care-seeking, and HIV care?	**Moderator:** Trip Gulick, *Weill Cornell Medical College* **Panelists:** Alice Pau, *NIAID, NIH* Daniel Seekins, *Bristol-Myers Squibb* Kimberly Y. Smith, *ViiV Healthcare* Anil Soni, *Mylan* Rochelle Walensky, *Harvard Medical School/MGH/B&WH*
11:15 AM	**Coffee Break**	
	Session 3: Consumer and Provider Perspectives	
11:25 AM	**Panel 1: Consumer Perspective: Attitudes and Beliefs** • What impact will the use of generics have on treatment decisions and outcomes in disproportionately affected populations, such as racial/ethnic and sexual minorities or those otherwise marginalized in the epidemic? • What, if any, individual-level tradeoffs (e.g., a decrease in Quality Adjusted Life Years [QALYs] or reduced length of life) are acceptable for societal benefit? • How might increased out-of-pocket costs negatively impact treatment choices, treatment adherence or even care-seeking, and if so which patient sub-populations are most impacted? •How do we balance recognition of cost-savings v. preference for innovator drugs? • Need for patient education • Other questions	**Moderators:** Victoria Cargill, *NIH Office of AIDS Research* David Evans, *Project Inform* **Panelists:** Cornelius Baker, *FHI360/NBGMAC* Lynda Dee, *AIDS Action Baltimore* Glen Pietrandoni, *Walgreens* Daniel Seekins, *Bristol-Myers Squibb*
12:15 PM	**Panel 2: Provider Perspective: Attitudes and Beliefs** • What is the role of providers in containing health costs? • What is the role of guidelines and research findings in provider perspective? • How can providers be best informed about the appropriate use of generics for their patients? • One pill per day has been a major advance in treatment of HIV. How will providers deal with the potentially increased complexity of treatment regimens? • Other questions	**Moderator:** John Bartlett, *Johns Hopkins Medical School* **Panelists:** Richard Fons, *AIDS Resource Center of Wisconsin* Peter Kadlecik, *Kaiser Permanente* Kimberly Y. Smith, *ViiV Healthcare* Melanie Thompson, *AIDS Research Consortium of Atlanta*

1:05 PM	**Lunch**	
	Session 4: Financing Considerations in HIV care	
1:55 PM	Drug Pricing Overview	Lanny Cross, *Independent Consultant*
2:10 PM	Changes in the HIV Care Landscape	Jen Kates, *Kaiser Family Foundation*
2:25 PM	**Panel: Financing, payments, and reimbursement considerations in HIV care** • Is guidance likely to be provided to federal grantees or by CMS to state Medicaid programs on this issue? • Do third-party payers see benefits in combination medications? What factors (if any) do third-party payers consider in making the decision to cover a combination medication versus its component parts? Or a newer, more expensive treatment versus a less expensive but still preferred treatment regimen? • Does the trend toward higher cost sharing, which often now requires patients to pay a percentage of the drug cost, influence decisions to break up combinations? Does this decision depend on the payer (e.g., is ADAP different than Medicaid)? • Is cost-sharing considered in selecting a treatment regimen? Are patients informed of what their cost-sharing would be or do providers stay out of those discussions with patients? • Is it realistic to think savings will be reinvested in HIV programs? For third-party payers - what's needed to make that case? • For providers – does utilization management such as prior authorization influence prescribing habits?	**Moderators:** Murray Penner, *NASTAD* Andrea Weddle, *HIV Medicine Association* **Panelists:** Sean Cahill, *Fenway Institute* Lanny Cross, *Independent Consultant* Jerry Ernst, *ACRIA/Amida Care* Joseph Fine, *CMS* Jen Kates, *Kaiser Family Foundation* Donna Sweet, *University of Kansas/American College of Physicians*
	Summary	
3:25 PM	Where do we go from here? Summarize the day's discussions with recommendations for policymakers, guidelines panels, clinical researchers, advocacy groups, etc.	Veronica Miller, *HIV Forum* *Open Discussion*
3:55 PM	Final Comments	John Bartlett, *Johns Hopkins Medical School* Veronica Miller, *HIV Forum*