

enhancing and facilitating HIV research



Forum for Collaborative HIV Research



Located in Washington DC, part of the School of Public Health



SAFETY ISSUES IN PREP

PROPOSALS FOR MANAGEMENT OF SAFETY CONCERNS IN SCALE-UP

**Forum for Collaborative HIV Research
1608 Rhode Island Ave.
Washington DC 20036
August 19 2011**



ACKNOWLEDGMENTS

- PrEP Trialists Working Group
- Panelist, Moderators and Presenters
- Kimberly Struble & Kendall Marcus, FDA
- Forum staff
 - Jur Strobos
 - Ben Hauschild
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- UCDC AV team



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FORUM MISSION & FUNCTION

- To enhance and facilitate HIV research
 - Identify gaps
 - Bring together experts from all stakeholder groups
 - Review, discuss, recommend
- Catalyze stakeholders to act on the recommendations



FORUM EC MEMBERSHIP

- Academia
- Advocacy/community groups
- Foundations
 - BM Gates Foundation, Clinton Foundation, amfAR, EGPAF
- Governmental agencies
 - US HHS (CDC, FDA, HRSA, NIH), State (OGAC, USAID)
 - EMEA
 - ANRS
 - Public Health Agency of Canada
- World Bank
- Industry
 - 22 pharmaceutical, diagnostic companies
- Health Care Insurers



PREP: A NEW “FIRST” IN HIV/AIDS

- An open public meeting convened to address safety and public health concerns associated with the potential approval of ARVs for prevention
- An opportunity for experts from each sector to present PrEP issues from their perspectives
- Joint discussion by all stakeholders
- An opportunity for regulators and other public health leaders to obtain input from all stakeholders



MEETING OBJECTIVES

- To identify safety issues associated with the introduction of PrEP
- To discuss potential remedies to mitigate any safety concerns
- To discuss the public health implications of PrEP scale-up
- To disseminate the discussion to the broadest possible audience



FORUM METHODOLOGY -1

- Background research
- Stakeholder interviews
 - FDA; EMA
 - NIH
 - Public Health Agencies
 - CDC; State and Local
 - PrEP Trialists
 - Community Advocates
 - HIV Medicine Providers
 - Insurers



FORUM METHODOLOGY - 2

- Agenda
 - Consultative process
 - Inclusive
- Process: dialogue between expert stakeholder representatives
 - Everyone brings their expertise to the table
 - Formal presentations limited to background and/or overview topics



TODAY'S EVENT

- As of Thursday August 18:
 - 141 on-site participants
 - 70 web-cast participants
- Meeting is being webcast live via cameras in the meeting room
- Audience (live and on-line) participation:
 - Please submit your questions in writing (notepaper provided) or on-line
 - Moderators will integrate into panel discussions



AGENDA

8:30 AM	Introductory Presentations
9:10 AM	Session 1: What safety issues of concern with pre-exposure prophylaxis?
10:25 AM	BREAK
10:40 AM	Session 2: Remedies and their pros and cons
12:15 PM	LUNCH
1:45 PM	Session 3: Public Health Implications
3:00 PM	BREAK
3:15 PM	Session 4: Next Steps
4:00 PM	Session 5: Summary and Action Items
4:30 PM	ADJOURN



NEXT STEPS

- Webcast available online at www.hivforum.org
- Report summarizing the consensus of participants.
 - Goal: advancing research on PrEP and promoting effective public policy
 - Disseminate to FDA and constituencies - government, industry, patient advocates, healthcare providers, foundations, health insurers and academia
- Future meetings as needed



THE FORUM TEAM

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