

**Designing Economic Incentives for Antimicrobials: Implementation in the U.S. Context**

Hotel Monaco • 700 F St NW, Washington, DC 20004

November 9, 2016

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The number of antimicrobial drug resistant infections has been increasing, and this number will continue to grow if concrete actions are not taken to reduce resistance. Appropriate use, pharmaceutical innovation, improved prevention efforts, and global awareness are all areas of need for combatting antimicrobial resistance, and these issues require a multi-tiered approach to improve outcomes. Antimicrobial development is costly, and following approval, return on investment faces additional challenges, as increasing stewardship efforts hinder sales volume. In order to promote continuous development of these life-saving drugs, while also ensuring appropriate use, new economic incentives need to be enacted.

The Duke-Margolis Center for Health Policy is focused on the development of policy approaches that will improve the innovation of novel antimicrobial drugs and support stewardship by focusing on incentives that reward successful development. In July 2016, the Center convened an expert workshop to explore the practical implementation of proposed antimicrobial economic incentives within the U.S. This workshop included a broad range of stakeholders, including antimicrobial developers, infectious disease physicians, and payers, to better understand the advantages and drawbacks of each incentive option. Following this workshop, more research was conducted to build a pathway to value-based reimbursement for innovative antimicrobial products. The purpose of this public meeting is to share the research findings and preliminary policy recommendations with the broader community, and to evaluate challenges to implementation.

**8:30 a.m. Registration**

**9:00 a.m. Welcome**

*Mark McClellan, Duke-Margolis Center for Health Policy*

**9:10 a.m. Impact of Antimicrobial Resistance on Society**

*Tatiana Chiprez Vargas*

**9:30 a.m. Setting the Scene**

*Gregory Daniel, Duke-Margolis Center for Health Policy*

**9:45 a.m. Session I: Application of Transferable Exclusivity Vouchers to the Antimicrobial Market**

- Overview, advantages, and limitations
    - *Amanda Jezek, Infectious Diseases Society of America (15 minutes)*
  - Moderated discussion (45 minutes)
    - *Moderator: Mark McClellan, Duke-Margolis Center for Health Policy*
- Reaction Panelists -
- *Robert Guidos, U.S. Food and Drug Administration*



- *Brad Spellberg*, Los Angeles County-University of Southern California Medical Center
- *Barrett Thornhill*, Antibiotic Innovation Alliance

Q&A/Attendee feedback (15 minutes)

**11:00 a.m. Break**

**11:15 a.m. Session II: Market Entry Reward for High Priority Antimicrobial Drugs**

- Overview, advantages, and limitations
    - *Kevin Outterson*, Boston University, CARB-X (15 minutes)
  - Moderated discussion (45 minutes)
    - Moderator: *Gregory Daniel*, Duke-Margolis Center for Health Policy
- Reaction Panelists -
- *Jason Brown*, U.S. Department of the Treasury
  - *Vikas Goyal*, SR One
  - *Manos Perros*, Entasis Therapeutics
  - *John Rex*, Formerly AstraZeneca; CARB-X

Q&A/Attendee feedback (15 minutes)

**12:30 p.m. Lunch**

**1:15 p.m. Session III: A Sustainable Path to Value-Based Reimbursement**

- Overview, advantages, and challenges
    - *Gregory Daniel*, Duke-Margolis Center for Health Policy (20 minutes)
  - Moderated discussion (55 minutes)
    - Moderator: *Mark McClellan*, Duke-Margolis Center for Health Policy
- Reaction Panelists -
- *Andrea Gelzer*, AmeriHealth Caritas
  - *Amber Jessup*, U.S. Department of Health and Human Services
  - *Shari Ling*, Centers for Medicare and Medicaid Services
  - *Evan Loh*, Paratek Pharmaceuticals
  - *Lynn Marks*, GlaxoSmithKline
  - *Kevin Ronneberg*, HealthPartners
  - *Edward Septimus*, Hospital Corporation of America; Texas A&M College of Medicine

Q&A/Attendee feedback (30 minutes)

**3:00 p.m. Closing Remarks**  
*Mark McClellan*, Duke-Margolis Center for Health Policy

**3:15 p.m. Adjournment**

