Duke UNIVERSITY | Duke-Margolis Center *for* Health Policy

Exploring Practical Implementation of Economic Incentives for Antimicrobial Development in the U.S.

Marriott Marquis • 901 Massachusetts Ave NW, Washington, DC 20001

July 20, 2016

Antibacterial drug resistance is a global public health threat poised to worsen due to the inappropriate use of existing drugs and a marked decline in innovative antibacterial drug development. There is a great need to stimulate the development of antibacterial drugs to address this growing resistance, while also ensuring that all antibacterial products are used prudently in order to preserve their utility. The goal of this meeting is to explore the role of economic incentives in drug development and evaluate potential reimbursement models such as "de-linkage" that could support both stewardship and expanded development for antimicrobial drug products, with the following objectives: 1) ensure that all stakeholders are aligned on the issue and agree to focus on areas that will yield the highest potential impact; 2) review the lessons learned from Europe and discuss viable, foundational proposals that could be feasible in U.S.; 3) identify potential implementation challenges, additional opportunities, and ideas that could be ripe for a pilot; and lastly 4) explore additional areas that are critical for successful and practical implementation of these models in the U.S. healthcare system.

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

9:00 a.m. **Welcome and Introduction**
Mark McClellan, Director, Duke-Margolis Center for Health Policy
Greg Daniel, Deputy Director, Duke-Margolis Center for Health Policy

9:15 a.m. ***Session I: Highlighting potential incentives to invigorate discovery and development, particularly for current unmet medical needs***

Objective: The level of difficulty of developing antibacterial drugs depends on a number of factors including the characteristics of the drug and the types of infection being studied. Many incentives encourage research and development of antimicrobial drugs without consideration of unmet medical need. This session will discuss what policies could be used to best encourage development in areas that pose the greatest public health threat.

Moderator: Mark McClellan, Director, Duke-Margolis Center for Health Policy

Opening presentations:

- Arjun Srinivasan, Associate Director, Healthcare Associated Infection Prevention Programs, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention (CDC)
- Ed Cox, Director, Office of Antimicrobial Products, Center for Drug Evaluation Research, U.S. Food and Drug Administration (FDA)
- Joe Larsen, Acting Deputy Director, Biomedical Advanced Research Development Authority (BARDA)
- Prabhavati Fernandes, Founder, President and CEO, Cempra

Q&A (15-20 min)

Questions for discussion:

- *How should an unmet medical need be defined in the context of AMR?*
- *What are the advantages/disadvantages of explicitly incentivizing therapeutics for pathogens considered to be an area of unmet medical need?*
- *What incentives would yield the most development in areas of unmet medical need?*
- *How can good stewardship practices be incorporated into incentives for addressing unmet medical need?*
- *What policies will allow for flexibility as urgency of threats changes?*

10:45 a.m. **Break**

11:00 a.m. ***Session II: Evaluating the most promising pull incentives - with a particular focus on de-linkage models***

Objective: In order to address the dual issues of innovation and stewardship, antimicrobial policy proposals need to not only spur research and development, but they also need to alter the current volume-based payment paradigm. This session will explore antimicrobial incentive models that have been proposed or implemented in Europe and other de-linkage models and approaches that shift the reward from volume to value.

Moderator: Mark McClellan, Director, Duke-Margolis Center for Health Policy

Opening presentations:

- Joe Larsen, Acting Deputy Director, Biomedical Advanced Research Development Authority (BARDA)
- Anthony McDonnell, Head of Economic Research, UK Review on Antimicrobial Resistance
- Ursula Theuretzbacher, Principal, Centre for Anti-Infectives
- Kevin Outterson, Professor of Law, Boston University
- John Rex, Senior VP and Chief Strategy Officer, Infection Business Unit, AstraZeneca
- Patrick Holmes, Strategic Policy Development Lead, Global Policy and International Public Affairs, Pfizer
- Helen Boucher, Attending Physician; Director, Infectious Diseases Fellowship Program; Associate Professor, Tufts

Q&A (15-20 min)

Questions for discussion:

- *Which models have gained the most traction in Europe, and can those models work in the U.S.?*
- *What measures can be taken to ensure that economic and societal value are aligned for all stakeholders?*
- *What applicable models best ensure stewardship and accessibility?*
- *How can these models be combined with "push" mechanisms to support R&D?*
- *How can the U.S. partner internationally to enact these models?*

12:15 p.m. **LUNCH**

1:00 p.m. ***Session III: Implementing economic incentives in the U.S. to stimulate antimicrobial development: perspective of manufacturers, payers, and providers***

Objective: Manufacturers, regulators, providers, and payers have unique perspectives on what could be the most viable models and approaches to stimulate drug development while ensuring proper utilization. This moderated discussion will explore and evaluate economic incentive models that could be implemented in US.

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Panelists:

- Eugene Sun, CEO, Melinta Therapeutics
- Lynn Marks, SVP, Senior Clinical Advisor, Infectious Diseases, GSK
- Shari Ling, Deputy Chief Medical Officer, Centers for Medicare and Medicaid Services
- Edmund Pezalla, National Medical Director for Pharmaceutical Policy and Strategy, Aetna
- Patrick Courneya, Executive Vice President and Chief Medical Officer, Hospitals, Quality and Care Delivery Excellence, Kaiser Permanente
- Jason Brown, Director, Office of Microeconomic Analysis, U.S. Treasury Department
- Adam Kroetsch, Policy and Informatics Advisor, U.S. Food and Drug Administration

Q&A (15-20 min)

Questions for discussion:

- *What are the most divisive issues? What can be agreed upon?*
- *Which incentives best meet the economic needs of small companies? Of large companies?*
- *Which models are most applicable to the current U.S. healthcare system?*

- *What implementation challenges are unique to the U.S.?*
- *Are there regulatory challenges to the de-linkage models? Can these challenges be addressed within the system, or will new legislation be necessary?*
- *How will new antimicrobials be distributed/paid for under de-linkage models?*
- *Who will pay for the de-linkage models and how can it be sustainable?*
- *How can any de-linkage model be best integrated within new Alternative Payment Models in the U.S.?*

2:45 p.m. **Break**

3:10 p.m. ***Session IV: Discussing scientific and economic challenges that hinder development and market-entry of rapid diagnostics***

Objective: Antimicrobial development and use is impacted by the ability to properly and quickly diagnose an infection and drug susceptibility. Several recent reports have incorporated rapid, point-of-care diagnostics into use and efficacy recommendations because diagnostic tools affect the ability of providers to appropriately utilize drugs and promote the shift to pathogen-specific drugs. This session will consider how antimicrobial policies may be affected by diagnostic development issues and what actions can be taken to mitigate potential scientific and economic obstacles.

Moderator: Mark McClellan, Duke-Margolis Center for Health Policy

Opening presentations:

- Angela Caliendo, Professor of Medicine, Brown
- Sara Cosgrove, Director, Antimicrobial Stewardship Program; Professor of Medicine and Epidemiology, Johns Hopkins School of Medicine
- Sam Bozzette, Vice President Medical Affairs, bioMerieux
- Steven Gitterman, Deputy Director, Division of Microbiology Devices, Center for Devices and Radiological Health, U.S. Food and Drug Administration

Q&A (15-20 min)

Questions for discussion:

- *What are the biggest hurdles for diagnostic development?*
- *How can drug and diagnostic developers coordinate? What regulatory hurdles would need to be cleared to use both diagnostic and drug during clinical trials?*
- *Are de-linkage strategies appropriate for diagnostic development?*
- *What incentives can be used to encourage providers and payers to use microbial diagnostics more frequently?*

- *How can use of diagnostics ensure that the right drugs are used for the right infection?*
- *How can diagnostics be leveraged to enhance de-linkage models?*

4:15 p.m. **Next Steps and Closing Remarks**

4:30 p.m. **Adjournment**