Duke | Robert J. Margolis, MD Center for Health Policy

Assessing Strategies to Improve the Market for Rapid Diagnostics for Bacterial Diseases

1100 New York Ave, NW, Room 3DE, Washington, DC 20005

April 18, 2017

Meeting objective: A number of factors diminish the success of rapid diagnostics for bacterial diseases, including technical challenges with developing devices that are rapid, sensitive, and specific; high costs of clinical trials; complexities of hospital adoption; and uncertain coverage and reimbursement. This meeting will explore some of the challenges associated with bringing a rapid diagnostic device for bacterial disease to market, and will identify steps that can be taken to improve the viability of these products.

8:30am	**Registration**
9:00am	**Welcome and overview** *Mark McClellan, Robert J. Margolis, MD, Center for Health Policy, Duke University* *Gregory Daniel, Robert J. Margolis, MD, Center for Health Policy, Duke University*
9:15am	**FDA opening remarks** *Ed Cox, Office of Antimicrobial Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA)*
9:20am	**Session I: Defining the needs of users of diagnostic results** Presenters: • *Ephraim Tsalik, Duke University and Durham VA Medical Center* • *Angela Caliendo, Alpert Medical School of Brown University and Rhode Island Hospital* • *Nicholas Anderson, Polarity TE (formerly Intermountain Healthcare)* Moderator: *Mark McClellan, Duke-Margolis Center for Health Policy*
10:30am	**Break**
10:45am	**Session II: Overcoming the challenges associated with the clinical development of a rapid diagnostic for bacterial diseases** Opening presentation: • *Vance Fowler, Duke University Medical Center* Moderator: *Gregory Daniel, Duke-Margolis Center for Health Policy* Panelists: • *Vance Fowler, Duke University Medical Center* • *Jorge Villacian, Janssen* • *Sheila Farnham, bioMerieux* • *Chris Bernhard, Curetis, Inc* • *Tobi Karchmer, BD*
12:00pm	**Lunch** (Off-site)

1:00pm **Session III: Balancing risk and uncertainty in the development and use of diagnostics**

Opening presentation:

- *Steve Gitterman, Division of Microbiology, Center for Devices and Radiological Health, FDA*
- *Fred Tenover, Cepheid*

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

Panelists:

- *Steve Gitterman, FDA*
- *Fred Tenover, Cepheid*
- *Ed Cox, FDA*
- *Evan Jones, OpGen and jVen Capital, LLC*

2:00pm **Session IV: Addressing the post-market economic challenges to diagnostics development**

Opening presentation:

- *Hui-Hsing Wong, Office of the Assistant Secretary for Planning and Evaluation (ASPE)*
- *Andrew Fish, AdvaMedDX*

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

Panelists:

- *Hui-Hsing Wong, ASPE*
- *Andrew Fish, AdvaMedDX*
- *Louis Jacques, ADVI*

3:15pm **Break**

3:30pm **Session V: Prioritizing actions to incentivize the development of rapid diagnostics for bacterial infection**

Panelists:

- *Angela Caliendo, Alpert Medical School of Brown University*
- *Ed Cox, FDA*
- *Steve Gitterman, FDA*
- *John McInnes, Division of Outpatient Care, Hospital and Ambulatory Policy Group, Center for Medicare, Centers for Medicare and Medicaid Services*

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

4:20 – 4:30pm **Next steps and closing remarks**

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