AGENDA

January 31, 2013
The Pew Charitable Trusts
901 E Street NW, 10th Floor
Carolinas Room
Washington, DC 20004

8:00–8:30 a.m. **Registration and continental breakfast**

8:30–8:45 a.m. **Welcome and introduction**
Moderator: Allan Coukell, Deputy Director, Medical Programs, The Pew Charitable Trusts

Session #1: Defining the Limited Population Regulatory Pathway: What It Is, What It Does, and Why It Is Needed

8:45–9:45 a.m. **Presentations**

- **Robert Guidos**, J.D., Vice President, Public Policy and Government Relations, Infectious Diseases Society of America
- **Edward Cox**, M.D., M.P.H., Director, Office of Antimicrobial Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
- **Nicole Mahoney,** Ph.D., Senior Officer, Antibiotics and Innovation Project, The Pew Charitable Trusts
- **John H. Rex**, M.D., FIDSA, FACP, Infection Clinical Vice President, Infection Therapy Area, AstraZeneca Pharmaceuticals LP
- **Michael N. Dudley**, Pharm.D., FIDSA, Senior Vice President, Research and Development and Chief Scientific Officer, Rempex Pharmaceuticals
- **Christine Welch**, M.S., RAC, Vice President, Regulatory Affairs, Achaogen, Inc.

9:45–10:25 a.m. **Expert roundtable discussion** *(moderated)*

Discussion questions

- What is the limited population regulatory pathway?
- Why is this pathway needed from the regulator's perspective?
- What types of antibiotics may be approved under this pathway, and what would the drug labels indicate?
- What are the benefits and risks to a limited drug development pathway from a business perspective?
- How would antibiotics approved under this pathway be priced to make this a viable business model?
- How might this pathway impact business decisions and investments in antibiotic development?
- Would companies have an incentive to study limited population antibiotics for expanded indications when appropriate to do so from a public health perspective?
- Would limited population antibiotics differ from traditional approvals regarding marketing and promotion?
- How could drugs approved under this pathway be monitored to ensure they are being used in a manner consistent with the approved indication?

10:25 a.m.–10:45 a.m. **Q & A** *(audience)*

10:45–11:00 a.m. **Coffee break**

Session #2: **Forging a Societal Compact: Perspectives on How to Ensure Antibiotics Approved under this Pathway Are Used in a Limited Population**

Part One: **Role of Health Care Providers and Institutions in Use of Limited Population Antibiotics**

11:00–11:40 a.m. **Presentations**

- **Matthew Bidwell Goetz**, M.D., Chief of Infectious Diseases, Veterans Affairs Greater Los Angeles Healthcare System; Professor of Clinical Medicine, David Geffen School of Medicine at UCLA
- **Steven C. Ebert**, Pharm.D., FCCP, FIDSA, Clinical Pharmacy Specialist, Clinical Supervisor, Meriter Hospital; Clinical Professor of Pharmacy, University of Wisconsin, Madison
- **Kavita K. Trivedi**, M.D., Medical Epidemiologist and Lead, California Antimicrobial Stewardship Program Initiative, Healthcare Associated Infections Program, California Department of Public Health
- **Pranita Tamma**, M.D., M.H.S., Director of Pediatric Antimicrobial Stewardship, Johns Hopkins Hospital

11:40 a.m.–12:20 p.m. **Expert roundtable discussion** *(moderated)*

Discussion questions

- To what extent does the FDA-approved indication guide how a drug is used clinically? Would prescribers treat limited population antibiotic differently than other drugs?
- What factors would influence the availability and use of limited population antibiotics from the clinician and hospital perspective?
- Under what circumstances would limited population antibiotics be used? For example, would diagnostics be required, or would these drugs be used after other treatments fail?
- What impact would this regulatory pathway have on special populations such as children?
- Limited population antibiotics may command premium pricing. What are the potential price sensitivities, if any, for hospital formularies, and what level of evidence may be required for adoption and use of these products?
- How could drugs approved under this pathway be monitored to ensure that they are being used in a manner consistent with the approved indication?
- What remedies could be instituted to curtail inappropriate use if necessary?

12:20–12:40 p.m. **Q & A** *(audience)*

12:40–1:40 p.m. **Lunch, Café 9, 9th Floor** *(provided)*

Part Two: **Role of Payors in Use of Limited Population Antibiotics**

1:40–2:10 p.m. **Presentations**

- **Jim Scott**, J.D., President and CEO, Applied Policy
- **Saira A. Jan**, M.S., Pharm.D., Director of Clinical Pharmacy Management, Horizon Blue Cross Blue Shield of New Jersey; Clinical Professor, Ernest Mario School of Pharmacy, Rutgers State University of New Jersey
- **H. Eric Cannon**, Pharm.D., FAMCP, Chief of Pharmacy, SelectHealth; Director, Academy of Managed Care Pharmacy

2:10–2:50 p.m. **Expert Roundtable Discussion** *(moderated)*

Discussion Questions

- Could insurers (e.g., via reimbursement policies) influence the use of limited population drugs? If so, how?
- Limited population antibiotics may command premium pricing. What are the potential price sensitivities, if any, and what level of evidence would insurers

require to reimburse for the use of these products? Would they require diagnostics? Would they require evidence that limited population antibiotics are used only after other treatments have failed?
- How would the price, reimbursement and access to limited population antibiotics change if indications were expanded?
- What remedies could be instituted to curtail inappropriate use if necessary?

2:50–3:10 p.m. **Q & A** *(audience)*

3:10–3:20 p.m. **Coffee Break**

Session #3: Lessons Learned, Unanswered Questions and Charting the Path Forward

3:20–4:20 p.m. **Rapporteur summaries**
- **Nicole Mahoney,** Ph.D., Senior Officer, Antibiotics and Innovation Project, The Pew Charitable Trusts
- **John Powers**, M.D., FACP, FIDSA, Associate Clinical Professor of Medicine, George Washington University School of Medicine and University of Maryland School of Medicine
- **David M. Shlaes**, M.D., Ph.D., Owner, Anti-Infectives Consulting

4:20–4:30 p.m. **Wrap-up**

4:30–6:30 p.m. **Reception, Café 9, 9th Floor**