



**Economic Research Service**

***Incentives and Disincentives for Research and Development of  
New Antimicrobial Drugs and Alternatives to Antibiotics for  
Use in Food Animals\****

**March 17-18, 2016**

**Auditorium at Patriots Plaza III, 355 E St. SW, Washington, D.C.**

***Agenda 3-7-16***

**Thursday, March 17**

**8:30 a.m. Continental breakfast**

**9:00 a.m. Welcome: Stacy Sneeringer, Economic Research Service, USDA**

**9:15 a.m. Keynote address: Catherine Woteki, USDA Undersecretary for Research, Education and Economics**

**9:30 a.m. Session 1: Why Do We Need New Antimicrobials or Novel Products For Use in Food Producing Animals?**

Moderator: Cyril Gay, Agricultural Research Service, USDA

Panelists:

*The Yin and Yang of Innovation for Food Animal Disease Interventions*

Tom Shryock, Antimicrobial Consultants, LLC

*Antibiotics, Alternatives, Incentives: What's All the Hubbub?*

Tom Campi, Senior Research Advisor, External Innovation and Funding,

Elanco Animal Health

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

**11:00 a.m. Session 2: Regulatory Review Processes of New Drugs and Novel Products**  
Moderator: Neena Anandaraman, Office of the Secretary of Agriculture, USDA  
Panelists:

*Regulatory Review Processes of Antimicrobials and Alternatives to Antimicrobials*

Cindy Burnsteel, Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA)

*General Licensing Requirements and Regulatory Considerations*

Byron Rippke, Center for Veterinary Biologics, Animal and Plant Health Inspection Service, USDA

*Regulatory Review Processes of New Products: 2015 Global Regulatory Review and Global Harmonization*

Carel du Marchie Sarvaas, Health for Animals

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

**1:30 p.m. Concurrent sessions:**

**Session 3A: Animal Diseases, Antibiotic Use and Resistance in Animals**

Moderator: Chase Crawford, Association of American Veterinary Medical Colleges

Panelists:

*Antimicrobial Resistance in Bovine Respiratory Disease*

Brian Lubbers, Kansas State University

*Diseases of U.S. Livestock Requiring Antimicrobials, USDA APHIS National Animal Health Monitoring System*

Kathe Bjork, Animal and Plant Health Inspection Service, USDA

*Perspectives on Needs for Therapeutics for Animal Health and Safe Food*

M. Terry Coffey, Smithfield Hog Production Division

**Session 3B: Animal Health Industry: Basic Research, Development, Testing and Marketing**

Moderator: Ron Phillips, Animal Health Institute

Panelists:

*Animal Health Products: What Does Our World Look Like?*

Rob Hunter, Provetica Animal Health

*The Landscape of Animal Health Innovation*

Grady Bishop, Elanco Animal Health

*The Sequence of Success: New Product Development from the Startup Perspective*

Lucia Mokres, EpiBiome, Inc.

**3:00 p.m. Break**

**3:15 p.m. Concurrent Sessions**

**Session 4A: Connecting Human and Animal Pharma Development**

Moderator: Gail Hansen, Hansen Consulting

Panelists:

*Discovery and Development of Veterinary Antibacterials*

Jeffrey Watts, Zoetis

*BARDA's Role in Combating Antibiotic Resistance*

Joe Larsen, Biomedical Advanced Research & Development Authority (BARDA), U.S. Department of Health and Human Services (HSS)

*A One Health Perspective on Antimicrobial Drug Development*

Laura Kahn, Princeton University

**Session 4B: Challenges to Research, Development & Commercialization of Non-Antibiotic Products**

Moderator: Karin Hoelzer, Pew Charitable Trusts

Panelists:

*Bringing an Animal Product from the Petri Dish to the Market*

Cindy Burnsteel, Center for Veterinary Medicine, FDA

*Alternatives to Antibiotics: Challenges and Opportunities for Combating Antimicrobial Resistance*

Cyril Gay, Agricultural Research Service, USDA

*Success and Impact of Alternative Approaches on Antibiotic Resistance Mitigation*

Hua Wang, Ohio State University

**4:45 p.m. Re-cap, and Overview of Day 2**

**5:00 p.m. Adjourn**

**5:30-7 p.m. Reception**

**Friday, March 18**

**8:30 a.m. Continental breakfast**

**9:00 a.m. Session 5: Incentives and Disincentives to Developing New Antibiotics and Novel Products for Use in the Livestock Sector**

Moderator: Stacy Sneeringer, Economic Research Service, USDA

Panelists:

*Antibiotic Discovery and Development in Animal Health: A Landscape of  
Conflicting Business Signals*

Rick Sibbel, Merck

*Project Funding Roulette--Where Should the Bet Be Placed?*

Tom Overbay, Expedite Animal Health

*Observations from an Academic Entrepreneur*

Mark Cook, University of Wisconsin

*Phage Endolysins as Alternative Antimicrobials: From Protecting Ethanol  
Fermentation to Treatment for Drug-Resistant and Intracellular Staphylococcus  
Aureus*

David Donovan, Agricultural Research Service, USDA

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

**11:00 a.m. Session 6: Government Dollars, Government Levers and Public-Private Partnerships**

Moderator: James MacDonald, Economic Research Service, USDA

Panelists:

*The Economics of Incentivizing Innovation*

Matt Clancy, Economic Research Service, USDA

*Fighting Resistance: How Can Government Incentives Stimulate New  
Antibiotics for Animal Health?*

Andrew Toole, U.S. Patent and Trademark Office

*USDA's Extramural Investments in Sciences Supporting Development of  
Alternatives to Antimicrobials for Livestock*

Gary Sherman, National Institute of Food and Agriculture, USDA

*Developing Partnerships to Commercialize USDA-ARS Research*

Rob Griesbach, Office of Technology Transfer, Agricultural Research Service,  
USDA

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

**1:30 p.m. Concurrent Sessions:**

**Session 7A: Solutions: Private Sector and Federal Agencies**

Moderator: Stacy Sneeringer, Economic Research Service, USDA

Panelists:

Tom Shryock, Antimicrobial Consultants, LLC

Tom Overbay, Expedite  
Cindy Burnsteel, Center for Veterinary Medicine, FDA  
Rick Sibbel, Merck  
Joe Larsen, BARDA

**Session 7B: Solutions: From Basic Science to Commercial Application**

Moderator: Maria Bowman, Economic Research Service, USDA

Panel:

Mark Cook, University of Wisconsin  
Hua Wang, Ohio State University  
Dave Donovan, Agricultural Research Service, USDA  
Lucia Mokres, EpiBiome

**2:45 p.m.    Wrap-up**

**3:00 p.m.    Adjourn**

*\*Since “novel products” is a large umbrella, this workshop focuses on antimicrobial activity targeting multi-resistant animal pathogens, such as: bacteriophage and bacteriophage gene products, essential oils, immune enhancers, innate defense molecules, naturally-occurring antibacterial lytic enzymes, organic acids, phytochemicals, prebiotics, probiotics, small interfering RNAs, therapeutic antibodies, lytic enzymes, cytokines, and vaccines.*

*A note on language: In the policy sphere, the phrase “alternatives to antibiotics” is used to refer to many products, the use of which may lessen the need for traditional antibiotics. However, depending on a number of features, these products may not be marketed as drugs, and therefore do not go through the same regulatory review as drugs. Hence marketers of these products do not refer to them as “alternatives to antibiotics,” since that would be a claim that they have drug-like properties. While the use of the term “alternatives to antibiotics” is in the title of the workshop, we want to be clear that participation in the workshop does not indicate that a participant’s company is making any drug claims about its marketed products.”*

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