

Agricultural Outlook Forum

Smart Agriculture in the 21st C

Session 14: Antimicrobial Resistance

Moderator

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Presentation Topics

Topic 1: Agricultural Perspectives

Crops, livestock and soils all impact and are impacted by the microbial world.

Dr. Charles Rice from Kansas State University will discuss both the effects of antimicrobial resistance on them as well as the role they play in addressing antimicrobial resistance.

Presentation Topics

Topic 2: Agriculture - Public Health Interface with Infectious Diseases, Human Health and Agriculture

A recent report of the President's Council of Advisors on Science and Technology provides an overview of the human and agriculture implications of antimicrobial resistance and sets out a national strategic plan.

Dr. Lonnie King from Ohio State University will provide an overview of this approach and the research, policy and educational roles for agriculture, medicine and government.

Presentation Topics

Topic 3: Responding to Antimicrobial Resistance

Actions and initiatives by the White House and USDA are beginning to address the broad needs for research, education, and surveillance with regard to the use and stewardship of antimicrobials and for addressing the development and spread of resistance.

Dr. Steven Kappes from the USDA will provide an overview of those activities as well as set out developing actions in research and education.

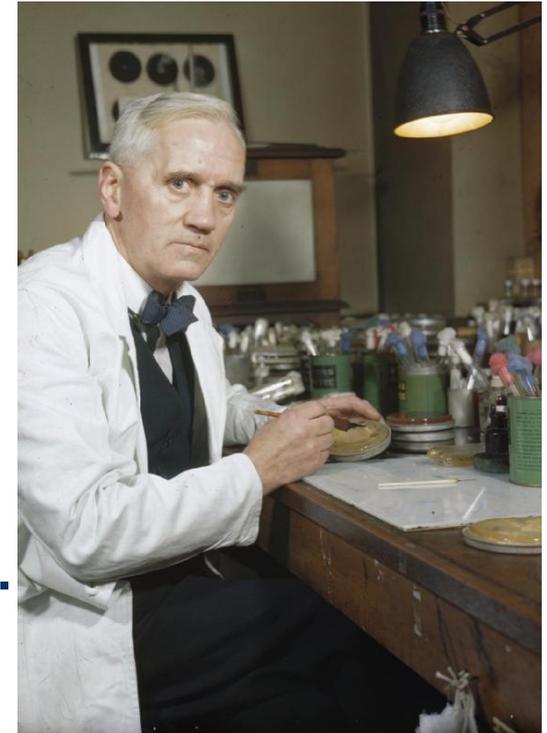
Session 14: Antimicrobial Resistance

- All speaker biographies are available online.
- All speeches and power-point presentations will be posted on the USDA Web site at:
<http://www.usda.gov/oce/forum>



The discovery of penicillin...

- Sir Alexander Fleming
 - 1928 discovered penicillin
 - 1944 knighted
 - 1945 awarded the Nobel Prize
- Cautioned that: Resistance is a natural counterpart to antibiotics.



National Strategy for Combating Antibiotic-Resistant Bacteria (CARB)

The National Strategy outlines 5 Goals:

1. Slow the emergence of resistant bacteria and prevent the spread of resistant infections.
2. Strengthen National One-Health surveillance efforts to combat resistance.
3. Advance development and use of rapid diagnostic tests for identification and characterization of resistant bacteria.
4. Accelerate basic and applied research and development for new antibiotic, other therapeutics and vaccines.
5. Improve international collaboration and capacities for antibiotic resistance prevention, surveillance, control, and antibiotic research and development.

One Health

As we face the complex challenges of the 21st Century, **One Health** is the collaborative efforts of multiple disciplines working locally, nationally, and globally to attain optimal health for people, animals, plants and our environment.

Between animal and human medicine there are no dividing lines--nor should there be."

Rudolf Virchow, MD

Previous Measures to Address Antimicrobial Resistance Risks

- Since late **1980's** – All “new” antibiotics have required veterinary oversight.
- **1996** – National Antimicrobial Resistance Monitoring System (NARMS) established.
- **1997** – Extralabel use of fluoroquinolones and glycopeptides prohibited.
- **2003** – FDA established framework for assessing antimicrobial resistance risks as part of drug approval (Guidance #152).
- **2005** – Withdrawal of enrofloxacin in poultry.
- **2010** – Initiated “judicious use” effort with draft Guidance #209.
- **2012** – Prohibited certain extralabel uses of cephalosporins.

Principles of FDA's Guidances #209 and #213

Principle 1: *The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health and not for production purposes such as growth promotion.*

Principle 2: *The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.*

Guidance 213: Affected Drugs

- 7 Classes (with some examples):
 - Aminoglycosides (streptomycin, spectinomycin)
 - Lincosamides (lincomycin)
 - Macrolides (tylosin, erythromycin)
 - Penicillins (penicillin G procaine)
 - Streptogramins (virginiamycin)
 - Sulfonamides (sulfamethazine)
 - Tetracyclines (chlortetracycline, oxytetracycline)

Implementing Guidance #213

FDA will accomplish these objectives by working with the 26 drug sponsors of affected medically important antibiotics to complete the following by 12-12-2016:

- Change marketing status from over-the-counter (OTC) to either prescription (water products) or veterinary feed directive (medicated feeds).
- Withdraw any approved production indications.
- Indicate the role for veterinary oversight.

Time Frame for Implementation

Industry
Engagement
(December 2013
– June 2014)

Assessing
Impacts of
Product Changes
(December 2016
– Beyond)

Aligning Affected
Products
(June 2014 -
December 2016)

Guidance #213: Next Steps

I. **Implement Changes**

- Change labels (remove production claims, require vet oversight)
- Finalize VFD rule (Spring 2015)

II. **Apprise public of progress**

- Periodic progress reports (every 6 months)
- Evaluation at end of 3-year implementation period (December 2016)

III. **Assess Impacts**

- Continue collecting data (sales and resistance)
- Collect additional data (on-farm use and resistance)

IV. **Reinforce Stewardship**

- Perform training/outreach to support new VFD rule
- Promote judicious use principles

National Strategy – Objectives related to FDA Guidances #209 and #213

Includes objectives that are aligned with ongoing efforts to implement Guidance #213 and to enhance data collection:

Objective 1.2 - Eliminate the use of medically important antibiotics for growth promotion in animals and bring other in-feed uses of antibiotics, for treatment and disease control and prevention of disease, under veterinary oversight

Objective 2.4 - Enhance monitoring of antibiotic-resistance patterns, as well as antibiotic sales, usage, and management practices, at multiple points in the production chain from food-animals on-farm, through processing, and retail meat.

Fostering Stewardship

As part of its overall strategy, FDA is identifying additional measures to foster stewardship of antibiotics in animals:

- National Strategy Objective 1.3 identifies stewardship.
- Includes working with USDA, veterinarians, and producers to develop alternative approaches to meeting animal health needs.
- Includes identifying alternative management practices that would reduce reliance on use of antibiotics to prevent disease.

Collaborative Programs

- National Antimicrobial Resistance Monitoring System (NARMS) – FDA, CDC, USDA
- WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR)
- Global Health Security Agenda (GHSA)
- Trans Atlantic Task Force on Antimicrobial Resistance (TATFAR)

Thank You

