“Improving Antimicrobial Use in Food Animal Production: Alternatives, Options and Incentives”

APUA-sponsored National Stakeholder Meeting
May 6-7, 2012, Omni Shoreham Hotel, Washington, DC

The U.S. Regulatory Framework

2nd presentation
William T. Flynn, DVM, MS

FDA’s Strategy for Promoting Judicious Use of Medically Important Antimicrobials in Food Producing Animals

Dr. Flynn's objective is to present components of strategy to move forward. Three documents: Guidance 209, Draft Guidance 213 and the Veterinary Feed Directive (VFD).

Guidance 209
- Draft Guidance #209 issued in 2010 and finalized in 2012 -- policy statement that relates to concerns about antibiotic use today.
- Underlying principles- Using drugs in both humans and animals contribute to antimicrobial resistance. The focus today is on use in animals. Try to use drugs more judiciously and minimize resistance
- Two key principles: limit use of medically important (in humans) antimicrobials to uses deemed necessary- such as treatment/therapy and increase veterinary oversight.

Draft Guidance 213 – out for comment until July 12
- Offers details on implementation of Guidance 209- directed to the pharm. industry on how to align with guidance
- How to update product label – updating improved use
- Specifies data requirement for new therapeutic uses
- Timeline: drug sponsors to reply within 3 months after finalization of 213; phase in changes within 3 years of finalizing the guidance
- Proposed (expanded) definition of medically important drugs: all drugs listed in Guidance 152 (Appendix A) and include the following drugs used as AGPs: penicillins, tetracyclines, macrolides, lincosamides, streptogramins and aminoglycosides
- Potential new therapeutic indications when AGPs are withdrawn for treatment, control (signs of disease), and prevention (at risk for disease, no clinical signs evident)
  - Data required for approval of new uses
  - Requirements for prevention use: defined daily dose/duration, specific target(s), veterinary oversight

Veterinary Feed Directive
- Drug marketing status changed from OTC to Rx or VFD – to include veterinary oversight – not require direct vet. involvement in drug administration
- Changes planned to streamline process involving record keeping & transmission of VFD form
- FDA has a concern on assuring that veterinary services reach those producers in remote/underserved locations
3rd presentation

**Thomas R. Shryock, PhD**  
**Regulatory Approach for Veterinarian Directed Medicine**

Need antibiotics because we need healthy animals to enter the food chain –100% more food will be needed in 50 years time and 70% of this food must come from efficiency improving technology. Veterinary oversight of antibiotic use is consistent with AVMA objectives. Approved antibiotic label indications: therapeutic – treatment, control and prevention. Production uses are non-judicious. Need to think of population medicine. Timing of administration is a key difference between individual vs. group treatment. Tom advised against using terms he considers undefined: overuse, misuse, inappropriate use, sub-therapeutic use, non-therapeutic use, routine use which are “value judgment terms”. Regulatory actions focus on a subset of food-borne bacteria (salmonella, campylobacter) that may become resistant to antibiotics and will affect people through the food chain and cites NARMS data.

**ASM 2008 Colloquium Report:**
- Prudent use to prevent development of new forms of resistance
- Find a way to co-exist with antimicrobial resistance: develop strategies to prevent new resistance
  - Effectively treat patients with resistant infections
  - Manage resistant strains in environmental reservoirs

Summary
- Disease prevention – primary goal –“with judicious use of antibiotics only when necessary, is best way for animal producers and vets to co-exist with resistance”.

4th presentation

**Chandler Goule**  
**The National Farmers’ Union Perspective(s) on Current Legislative Activity**

The National Farmers Union (NFU), founded in 1902, represents 250,000 family farmers, ranchers, and fisherman in 50 states (2nd largest farm organization in the US)—grassroots organization. NFU policy on antibiotic use:
- Use antibiotics for treatment of disease and for disease prevention during periods of stress; unless FDA proves that the product is unsafe
- Supports producers’ rights to treat animals with antibiotics to address herd health concerns
- Calls for more research and evidence-based legislation (although he incorrectly cited Danish evidence); production systems not comparable between US and Denmark;
- Asks that legislation target specific antibiotics-not entire classes knocks Slaughter’s legislation

Conclusion
Organic production is one way to address the problem but it is not affordable for all consumers & even animals raised organically get sick. Chandler recommends judicious use; follow on-label use; strike a balance between organic and conventional production

5th presentation

**Katherine Feldman, DVM, MPH, DACVPM**  
**The AAPHV: Challenges Representing the Diversity of Perspectives of Public Health Veterinarians**

Dr. Feldman came to the meeting today to learn more about the issue. She is the immediate past president of AAPHV – an umbrella for any veterinarian, who is interested in public health can join. The organization was started in the mid-1940. In 2008, AAPHV revised its priorities:
- Promote science & practice of public health, epidemiology and preventive medicine
- Provide an expert forum for discussion of important public health issues in the veterinary profession and develop recommendations and health resolutions
- Advise Board of Directors & respond to policy inquiries; develop a pathway for policy development; solicit priorities to publish one position statement annually --Policy work group
- Continue to grow, n=229; diverse membership- a strength but a challenge to create a unified policy statement.