Antimicrobial Resistance and the FDA’s Veterinary Feed Directive: Implications for Livestock Producers

Extension/Outreach Presentation

Interview for Cooperative Extension Specialist Position in Livestock and Rangeland Economics
University of California, Davis

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Extension/Outreach Presentation

Overview

• **Issue:** The Food and Drug Administration (FDA) has imposed new regulations that will change/limit producers’ ability to use certain antibiotics in food-producing animals

• **Audience:** Beef producers and farm advisors
  • Presentation could also be tailored for an audiences of dairy, sheep, or goat producers

• **Importance:**
  • Low level of awareness
  • “There is a low level of awareness of the impending regulatory changes—particularly among livestock producers with small-to-medium-sized operations. Many veterinarians are not aware of the impending changes.” – Farm Foundation Roundtable
  • Cost implications

• **Other Materials/Resources:** Handout and website
Background

- Increased scrutiny of antimicrobial drugs used for humans and animals
  - Increasing bacterial resistance to certain drugs
  - Concern about overlap of drugs used for humans and animals

- Antibiotics are widely used in food-producing animals
  - Research suggests that this may contribute to antibiotic-resistant infections in humans

“The FDA believes that human exposure through the ingestion of antimicrobial resistant bacteria from animal-derived foods represents the most significant pathway for human exposure to bacteria that have emerged or been selected as a consequence of antimicrobial drug use in animals.” – FDA, GFI #152
Regulations

• Animal Drug Availability Act (ADAA) 1996
  • Introduced the option of approval under a Veterinary Feed Directive (VFD)
    • When enacted the only antimicrobials under VFD were tilmicosin (e.g., Pulmotil®) and florfenicol

• FDA amended ADAA with revised VFD regulations
  • Published June 3, 2015 (21 CFR 558.6)
  • Rule goes into effect 120 days after publication (October 15, 2015)
  • Full regulatory authority is phased in, culminating Jan 1, 2017
  • New regulations prohibit specific drugs from being used in sub-therapeutic settings (e.g., growth promotion)
**California’s Antimicrobial Regulations**

- **October 10, 2015** the Governor signed Senate Bill 27
  - Will take effect January 1, 2018

- **How is it the same as the FDA regulations?**
  - “Medically important” antimicrobials in CA are defined the same as FDA (FDA GFI #213)
  - Medically important antimicrobials in feed will be regulated with VFD
  - Prohibits the use of medically important antibiotics for sub-therapeutic uses

- **How is it different?**
  - Injectable medically important antimicrobials will become prescription
  - Cannot be administered in a “pattern” (i.e., stricter limits on disease “prevention”)
  - Data collection (sales and usage)
What Products Are Affected?

- Antimicrobial drugs that are classified as “medically important”
  - FDA defines medically important to be those drugs that are used on humans
  - Currently 97% of medically important antibiotics are sold over the counter (OTC)

- Medically important antibiotics in feed:
  - Can no longer be used for growth promotion
  - Can only be used to treat, prevent, or control disease with a VFD under the supervision of a licensed veterinarian

- Water-soluble medically important antibiotics:
  - Will transition from over-the-counter to prescription
  - Prescription uses do not include sub-therapeutic applications
## Examples of Antimicrobials That Will No Longer Be Over The Counter

<table>
<thead>
<tr>
<th>Antimicrobial Class</th>
<th>Specific Drug Examples (Beef)</th>
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<tbody>
<tr>
<td>Aminoglycosides</td>
<td>Neomycin (e.g., Neo-Oxy 50/50)</td>
</tr>
<tr>
<td>Macrolides</td>
<td>Tylosin (e.g., Tylan)</td>
</tr>
<tr>
<td>Streptogramins</td>
<td>Virginianycin (e.g., V-Max)</td>
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<tr>
<td>Tetracycline</td>
<td>Chlortetracycline (e.g., Aureomycin, Aureo S 700) Oxytetracycline (e.g., Terramycin)</td>
</tr>
<tr>
<td>Sulfas</td>
<td>Sulfamethazine (e.g., Aureo S 700)</td>
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</table>
What Products Are Not Affected?

- **Ionophores** – classified as antibiotics but are not “medically important” (e.g., Rumensin, Bovatec)
- **Bambermycins** (e.g., Gainpro)
- **Beta agonists** – not antimicrobial (e.g., Optaflexx, Actogain 45)
- **Other drugs that are not antimicrobials** (e.g., coccidiostats like Corid)
How Can You Prepare for the New Regulations?
Steps to Prepare

1. Establish or strengthen an on-going relationship with a veterinarian to ensure you have a valid veterinary-client-patient relationship;

2. Contact your feed supplier to ensure they are informed about the VFD rule changes and that they will be a VFD feed distributor;

3. Review your operation’s current health protocols and feeds to identify products/procedures that will be affected by the new regulations; and

4. Review your overall health program to determine if there are changes that can be made to reduce the need for antibiotics.
How will the Regulations Affect Producer Costs?
Producer Costs of Compliance

- Veterinary costs will increase given that a VFD will be required for medicated feeds
  - These costs will likely be higher on a per-unit basis for small producers/operations
  - Accessing necessary veterinary services in a timely manner may be problematic for isolated ranches

- Feed costs will likely rise since feed mills will be required to mix and distribute medicated feeds according to specific VFD stipulations

- Lower feed efficiency for some operations

- Higher costs due to treatment of sick animals and potential increases in mortality
Will the Regulations Affect Prices?
Price Impact

- Higher production costs will, over time, reduce supplies and raise prices
  - But, this price increase will likely not fully compensate for higher producer costs in the near term
- Industry groups need to consider promoting producers’ participation in the effort to reduce antibiotic use in the food chain
  - Demand may increase if consumers perceive beef to be a healthier product and an industry that is sustainable and socially responsible
    - Beef Quality Assurance – manual on judicious use of antimicrobials
Compliance Strategies
Compliance Strategies

- Adopt on-going health and vaccination programs
  - Healthier, well-managed animals will have less need for antimicrobials
  - Evidence suggests that these programs earn producers price premiums
    - Premiums may decline over time as more producers adopt these practices
  - Cost savings associated with reduced illness will increase under the VFD regulations
Compliance Strategies Cont.

- Consider cooperatives or LLCs to share access to veterinary services and feed procurement
  - Small-scale producers could work together to secure lower prices
- Consider niche markets
  - Producers can receive premiums for cattle raised with “antibiotic free” and “natural”
  - Need to be able to connect with downstream buyers who want to supply targeted niche
Summary
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• These regulatory changes are fast approaching
  • Planning and preparation is necessary keep your operation functioning efficiently

• VFD regulations will likely increase your costs
  • Participation in value-added management practices and/or niche market programs may offset cost increases

• More information on the regulations and how you can prepare is available at:
  
  https://are.ucdavis.edu/en/people/researchers/tina-saitone/vfd/