The Future of Antibiotic Alternatives

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#feedthe9
The Global Landscape
our WHY
Today’s 3 Food Security Realities…
The Protein Gap

Projected Vs Actual Protein Demand

- Reality #1: 60% protein increase
- Reality vs Expected
- Protein Gap

Demand for bridge protein exceeding projections by about 7%.

Sources: FAO, 2012, World Agriculture Towards 2030/2050, Tables 3.4 & 3.5, pp. 74-75
The impact of moving productivity

Global Average vs Best in Class
Protein production index globally

Milk: 2 gallons vs 8 gallons

Beef: 2 years vs 5 years to maturity

Pork: 40 more lbs in 70 less days

Chicken: 2.2 lbs. in half the time

Eggs: 185/hen/yr vs. 270/hen/yr

We can feed significantly more people with less animals by increasing the global average.
The Dairy Gap

What We Have

What We Need

We have 1 glass a day.
Everyone deserves 2 servings a day
Why We Need 2 Glasses

The Importance of Meat, Milk and Eggs
(Over 5 School Terms)

When diets are supplemented with meat or milk, learning and test scores improve. Quality of nutrients versus just quantity of calories matter.

Vision for a food secure world
The consumer landscape
Objective consumer data is consistent: taste, price, nutrition are top concerns.
The Challenge

There is an **increasing chorus** of voices working hard to increase concern

![Factory Farm Nation](image1.png)

![meat on drugs](image2.png)

![PROP 2 PASSES!](image3.png)

![Prop 37: Your right to know.](image4.png)

1. Percentage of consumers associating livestock production with factory farming

<table>
<thead>
<tr>
<th>Livestock Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chickens</td>
<td>80%</td>
</tr>
<tr>
<td>Beef cattle</td>
<td>60%</td>
</tr>
<tr>
<td>Dairy cattle</td>
<td>40%</td>
</tr>
<tr>
<td>Beef &amp; dairy cattle</td>
<td>20%</td>
</tr>
<tr>
<td>Hogs</td>
<td>10%</td>
</tr>
<tr>
<td>Other livestock</td>
<td>0%</td>
</tr>
</tbody>
</table>
What’s Happened

“food science” yesterday

“food science” today
Consumer Attitudes

- Antibiotic use is a public health issue
- Important for animal agriculture to:
  - Be proactive & take a leading role
  - Maintain confidence in food supply
  - Build consumer trust

<table>
<thead>
<tr>
<th>Consumer attitudes*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>48%</strong> Feel <em>uncomfortable</em> about antibiotic use in animal production</td>
</tr>
<tr>
<td><strong>71%</strong> Have “<em>serious or some concerns</em>” about conventional methods</td>
</tr>
<tr>
<td><strong>53%</strong> Frequently <em>wonder</em> if the food they buy is safe</td>
</tr>
</tbody>
</table>

* Source: ml&p research for USFRA, 10/11, n=1,400.
Millennials: changing the landscape of food
Impacts of the millennial consumer on food decision makers

• More willing to pay for ‘socially responsible’
• Increasingly concerned about health and food safety
• More skeptical than previous generations of ‘big’ institutions (FDA, big ag, big food, etc.)
• More demanding of transparency and shared values
• Expect information to be readily available and easily digestible
• With social media, they have an amplified voice
Shaping the conversation: Subway Case Study

SUBWAY® Restaurants Elevates Current Antibiotic-Free Policy

U.S. Restaurants Will Only Serve Animal Proteins That Have Never Been Treated With Antibiotics
Regulatory Landscape
the game is changing
Access to Antibiotics

• A public health issue
• Access to effective antibiotics:

Critical for public health
Vital for livestock & poultry production
Essential for animal well-being
Access to Antibiotics

• U.S. Food and Drug Administration:
  – Concerned overuse in animals may reduce effectiveness in humans
  – Is making important changes to antibiotic use in animals
  – Goal is to promote judicious use of antibiotics, protect public health, and help curb the development of antimicrobial resistance
Access to Antibiotics

• FDA issues 3 documents proposing to modify use of medically important antibiotics in food-producing animals

Guidance for Industry (GFI) #209

Guidance for Industry (GFI) #213

CFR 558
Guidance for Industry #209

• The “what” component

• Establishes “judicious use” principle
  – Limits shared-class antibiotics to therapeutic purposes

• Key: Use of **medically important** antimicrobial drugs in food-producing animals should be limited to:

  **1. Uses necessary to assure animal health**
  - Prevention
  - Control
  - Treatment

  **2. Uses that include veterinary oversight**
  - **Feed:** OTC to VFD
  - **Water:** Rx (specified in GFI #213)
Performance Indications (GFI #209)

• Phases out performance indications for certain antibiotics

**Therapeutic uses (still allowed)**

**Disease treatment**
Administration of an antimicrobial to an animal or group of animals that exhibit clinical disease

**Disease control**
Administration of an antimicrobial to an animal or group of animals in which morbidity or mortality has exceeded baselines

**Disease prevention**
Administration of an antimicrobial to an animal or group of animals that are considered to be at risk, but prior to onset of clinical disease

**Performance uses (prohibited)**

Growth, nutrition, health maintenance
Administration of an antimicrobial to an animal or group of animals that results in improved performance, e.g., weight gain or feed conversion
**Products Affected vs. Unaffected as Defined by FDA Guidance 152**

<table>
<thead>
<tr>
<th>Unaffected</th>
<th>Affected</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-Medically Important</strong>&lt;br&gt;Products used exclusively in animals:&lt;br&gt;- Ionophores (Rumensin®)&lt;br&gt;- Polypeptides&lt;br&gt;- Carbadox&lt;br&gt;- Bambermycin&lt;br&gt;- Pleuromutilin</td>
<td><strong>Medically Important</strong>&lt;br&gt;Products deemed “important for human medicine” &amp; used by both animals &amp; humans, such as:&lt;br&gt;- Penicillins&lt;br&gt;- Cephalosporins&lt;br&gt;- Quinolones&lt;br&gt;- Fluoroquinolones&lt;br&gt;- Tetracyclines&lt;br&gt;- Macrolides&lt;br&gt;- Sulfas&lt;br&gt;- Glycopeptides&lt;br&gt;- Others</td>
</tr>
</tbody>
</table>

**Therapeutic uses** — still allowed under veterinary supervision<br>- Treat animals diagnosed with an illness<br>- Control the spread of illness in a herd<br>- Prevent illness in healthy animals when exposure is likely

**Production uses** — Still allowed<br>Enhance growth or improve feed efficiency

**Production uses** — No longer allowed<br>Enhance growth or improve feed efficiency
Antibiotics Affected (from GFI #152)

- “Medically important” for human use

<table>
<thead>
<tr>
<th>Antibiotics</th>
<th>Affected</th>
<th>Blue</th>
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</thead>
<tbody>
<tr>
<td>Penicillins</td>
<td>Tetracyclines</td>
<td></td>
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<tr>
<td>- Penicillin G</td>
<td>- Oxytetracyclines</td>
<td></td>
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<tr>
<td>- Penicillin V</td>
<td>- Chlortetracycline (CTC)</td>
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<tr>
<td></td>
<td>- Aureomycin®</td>
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<tr>
<td>Cephalosporins</td>
<td>Trimethoprim/sulfamethoxazole</td>
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<tr>
<td>Carbapenems</td>
<td>Sulfas</td>
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<td></td>
<td>- Sulmet</td>
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<td></td>
<td>- ASP, CSP 250</td>
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<tr>
<td>Monobactams</td>
<td>Pyrazinamide</td>
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<tr>
<td>Quinolones</td>
<td>Glycopeptides</td>
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<tr>
<td>Fluoroquinolones</td>
<td>Oxazolidinones</td>
<td></td>
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<tr>
<td>Aminoglycosides</td>
<td>Streptogramins</td>
<td></td>
</tr>
<tr>
<td>- Neomix®</td>
<td>- Stafac®</td>
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<tr>
<td></td>
<td>Clindamycin (Lincosamide class)</td>
<td></td>
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<tr>
<td></td>
<td>- Lincomix®</td>
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<tr>
<td></td>
<td>Polymyxin B</td>
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<tr>
<td></td>
<td>Chloramphenicol</td>
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<td></td>
<td>Metronidazole</td>
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<tr>
<td></td>
<td>Rifamycins</td>
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<tr>
<td></td>
<td>Isoniazid</td>
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<tr>
<td></td>
<td>Macrolides</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Tylan® (tylosin)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Pulmotil® (tilmicosin)</td>
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Blue = shared feed and/or water
Implications

• Food producers aren’t losing all feed-grade antibiotics
• The way they’re used will change
• Key phrase is “medically important”
  – Refers to drugs important for therapeutic use in humans
Guidance for Industry #213

• The “how” component

• Recommendations for voluntarily aligning products with GFI #209

• Advises companies on how to revise:
  – Labeling
  – Promotion

• 2 options to change product labels
  – Voluntarily remove production indications
  – Seek new therapeutic indications at current doses

• Provides 3 years to comply (Dec. 2016)
21 CFR 558

• Proposes changes to VFD process
  – Strives toward less burdensome process
  – Provides greater flexibility for veterinarians to exercise professional training
  – Streamlines FDA administrative procedures
Human vs Animal Antibiotic Sales are Relatively Different in US

Tetracyclines: 41.06% vs 3.9%

ANIMALS
- 1.56%, Aminoglycosides
- 0.19%, Cephalosporins
- 12.45%, Other
- 30%, Ionophores

HUMANS
- 0.2%, Aminoglycosides
- 14.9%, Other

NEVER used in humans

Penicillins: 6.4% vs. 43.9%

FAIR SHARE?
10 billion animals vs. 300 million people

ANTIBIOTICS
Pound for pound, humans and their pets use 10 times the amount of antibiotics than what is used in food animal production.

VFD Resources

• Veterinarian relationship
  – Establish now

• GlobalVetLINK
  – Offers electronic VFD
  – One-stop solution
  – Sales team: (515) 817-5703
  – Technical support: (515) 817-5704
  – www.globalvetlink.com

• VFD Central
  – Provides veterinarians, feed suppliers & producers with the most pertinent information in a one-stop online resource center

• Collaboration with all stakeholders
Compliance Timeline

- FDA pursuing voluntary compliance
- FDA to evaluate progress 3 years after final publication
  - Guidance for Industry #213 finalized Dec. 2013
  - FDA will consider “further actions” as warranted
Compliance Timeline

• Voluntary approach:
  – Enables companies to efficiently make transitions
  – Provides time to understand policies
  – Enables companies to vary their own timelines
  – Acknowledges a significant undertaking by affected parties

• Approach **not voluntary** for producers or feed manufacturing once labels have been transitioned
Challenges for antibiotic alternatives
The case for alternatives

Global Animal Health is Dynamic

- Constant Health Challenge
  - 3 in 4 cattle fight respiratory disease
  - 1 in 6 dairy cows face mastitis

- Emerging Diseases
  - 6 global emerging diseases

- New Threats
  - Climate volatility is increasing animal disease challenges

9 in 10 chickens exposed to coccidiosis
1 in 3 pig herds experience ileitis

Caution: Prevention and Therapeutic Needs Critical. Don’t set dates to remove solutions without alternatives.
Invest in Innovation

- Pursue advances & treatments that lessen reliance on antibiotics
- Seek new therapeutic indications for treatment, control & prevention of diseases
- Support use of antimicrobials used only in animals for growth & performance (where permitted)
- Provide services that help verify & validate responsible product use
Invest in Innovation

Pursue advances & treatments that lessen reliance on antibiotics

Seek new therapeutic indications for treatment, control & prevention of diseases

Support use of antimicrobials used only in animals for growth & performance (where permitted)

Provide services that help verify & validate responsible product use
The bar for alternatives is higher today…

**Science**
Outcomes must be science-based

**Economics**
Shared opportunity for all players

**Consumers**
Keeping the consumer interest in focus

**Sustainability**
Limited or no negative impacts

**Animal Well-being**
Considering the well-being of the animal

**Ethical**
The right thing to do in food & agriculture
The bar for communicating is higher today

<table>
<thead>
<tr>
<th>You say</th>
<th>They hear</th>
</tr>
</thead>
<tbody>
<tr>
<td>We use antibiotics to be more efficient</td>
<td>Because you only care about making money</td>
</tr>
<tr>
<td>We use antibiotics to keep animals healthy</td>
<td>You HAVE to use antibiotics because animals are kept in poor conditions</td>
</tr>
<tr>
<td>Regulatory agency reviews have approved antibiotics as safe after rigorous review process</td>
<td>We don’t know if it’s safe for the long term. They’ve been wrong before.</td>
</tr>
<tr>
<td>There are rules that dictate maximum residue limits allowed in animals</td>
<td>How can we be sure ANY residue is safe?</td>
</tr>
<tr>
<td>There is no evidence that use of antibiotics in animals causes resistance in humans</td>
<td>Yeah, right. We’re using so many, that has to be part of the reason.</td>
</tr>
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