The current options to control infectious diseases in livestock and the stimulation of innovation to develop new treatments

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A Bacterial World

• More bacteria in the *colon alone* than cells in the *entire* human body
• Neutral or beneficial
• Pathogenic (causing disease) or opportunistic
The Nexus Between Humans and Animals

- Approximately 64% of the 1400 human pathogens are zoonotic
- Twelve of the last 13 significant human epidemics (since 1993) are the result of zoonotic disease
- Animals act as principal reservoir of pathogens
- Disease transmission from animal-derived food to people is an ancient occurrence
Globalization of the Food Supply

As the food supply has become globalized, so have the bacteria that are associated with that food.

It is possible for food that was produced in Guatemala, Honduras, Asia, and Africa to be on your plate within 48 hours of harvest.
Factors in Livestock Production Efficiencies

- Genetics
  - Breeding stock
  - Peri- and neo-natal
  - Nursery
  - Growers/finishers

- Nutrition
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- Animal health products/disease control programs
  - Antibiotics
  - Parasiticides
  - Vaccines
  - Probiotics

- Management
  - Intensive
  - Extensive

- Grain yields; Pasture use; Feed costs
  - Reproduction aids
  - Estrus regulators
  - Nutriceuticals
  - Enzymes

↑ Animal Production
Animals Get Sick Like People

– Regardless of the production system
– Regardless of the level of management
– Regardless of the species
– Regardless of the geographical location

– Therefore, animals [will always] need infectious disease treatment and prevention
Controlling infectious disease: the toolkit

• Management: housing, nutrition, “all in:all out, all clean in between”
• Biosecurity (shower in/shower out, traffic flow on/off farm, closed herds)
• Vaccines
  – Viral: but viruses mutate and change
  – Bacterial: especially the challenges with bacterial vaccines
    • Efficacy is variable, limited for some infections, injection site reactions, modified live vs. killed vaccines
• Probiotics/direct fed microbials
• Treatment of bacterial infections
• Natural Products (oils, plants, minerals, etc.)
  – Unproven
  – Unintended consequences (eg, environmental, palatability, etc.)
Getting Novel Compounds to the Marketplace

Developing Novel Products

• Commercial accessibility of novel compounds depends on
  – Successful new molecule/antigen discovery
  – Advancement of the drug candidate through safety and clinical development
  – Formulation and chemistry
  – Validation of a commercial-scale manufacturing process
  – Efficient regulatory review and final approval by the regulatory agency
  – Timely access to the market to meet the needs
Human and Animal Health R&D Processes

**Human Health Discovery**
- First in Man Studies (Requires IND or Equivalent)
  - 12–15 years
  - 0.5–1.0B Euros

- First Target Animal Studies (Does not require INAD)

**Animal Health Discovery**
- 8–12 years
- 80–100M Euros

**Product Profile**
- Target ID
- Lead ID
- Candidate ID
- Preclinical Data
- Phase I
- Phase II
- Phase III
- Approval
Disease control: The Innovation Paradox

• Animals will continue to get sick, even with optimal use of the tools in the kit
• Antibiotics and vaccines are product categories where constant updates and innovations are indispensable
• Responsibly developing new antibiotics and alternatives to antimicrobials is important to both human and animal health and the regulatory pathway needs to remain predictable, transparent and science based
• Otherwise, industry will invest R&D in other areas with the consequence that veterinarians will have even fewer treatment options available in the future – jeopardizing our one health
Getting Novel Compounds to the Marketplace

Intellectual Property Protection

- Patent lifecycle is critical to return on R&D investment
- Recouping investment more difficult for smaller market products of animal health
- Maximization of IP protection hinges on efficient development, predictable regulatory review, and expedient access to the market
What can policymakers do to foster innovation?

Recognize the need for innovation

Inform and educate consumers about value of innovation

Embrace innovation – the status quo will lead to undesirable outcomes

Streamline approval process: predictable, science-based regulation

Extend exclusivity – payback on investment

Think long-term … act with urgency