THE VISION FOR THE FUTURE

Dr. Matthew Lucia, DVM
Center for Veterinary Medicine

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Protect human and animal health in a global community
Protect human and animal health in a global community

- One Health
- Support veterinary medicine
- Enhance food security
One Health

• Judicious use of antimicrobials in animals
  – Five-Year Plan for Supporting Antimicrobial Stewardship in Veterinary Settings
  – Clarification of approved uses
  – Outreach

• Products for zoonotic disease

• Human-animal bond

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Future of Biologic Products

• Shorter times to market authorization
  – Better vaccine matches for contemporary strains

• Customized products
  – Better product matches for the needs of animals

• Global regulatory efficiencies
  – Harmonization, mutual recognition
Enhance Food Security

- Increasing global population
- Land and water availability
- Environmental sustainability

Support increased production of safe animal protein with fewer resources
Support veterinary medicine

- Leverage information technology
- Enhance product availability
- Increase global focus
Technology for veterinary information management

- Real-time diagnostic source data
- Access to specialized veterinary expertise
- Experiential information sharing
- Tools for client interaction
- Apps for veterinary support
- Remote diagnosis and support
- Information management
**Enhance Global Product Availability**

**Goal**: Minimize impact of drug shortages

**How might we get there?**
- Early notification
- Global response
- Collaboration to address challenges
Enhance Global Product Availability

Goal

Novel therapeutic approaches to address unmet global medical demands

How might we get there?

- Drug-device delivery systems
- New approaches for disease resistance
- Conditional approval approach
- Biotechnology and gene editing for disease resistance
Enhance Global Product Availability

Goal

Novel approaches to leverage available information

How might we get there?

Real-time data and telemetry

Innovative or alternative study designs

Biomarkers and in-vitro models

Pre-approval use of real-world evidence
Enhance Global Product Availability

Goal

Enhance drug availability through “concurrent” global approval processes

How might we get there?

- Expansion of included regulatory bodies
- Increased coordination of regulatory bodies
- Parallel data review and application of individual standards
Enhance Global Product Availability

Goal

Increased harmonization of processes and standards

How might we get there?

- Leverage information technology for collaboration
- Increased transparency of regulatory bodies
- Real-time communication
- Increased accessibility
### Final Vision

**Goal**
- Global approach to enhance access to veterinary drugs

**How might we get there?**
- Minimize impact of drug shortages
- Novel approaches to leverage available information
- “Concurrent” global approval processes
- Novel therapeutic approaches to address unmet global medical demands
- Increased harmonization of processes and standards

**Vision**
- Global label
- Global indication(s)
- Pre-approval testing in emerging markets

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