

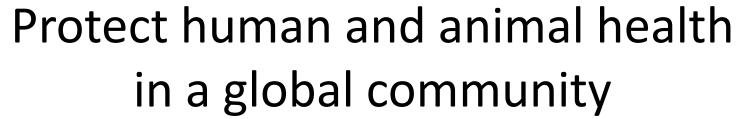


VICH 6 Public Conference

February 28, 2019

THE VISION FOR THE FUTURE

Dr. Matthew Lucia, DVM Center for Veterinary Medicine

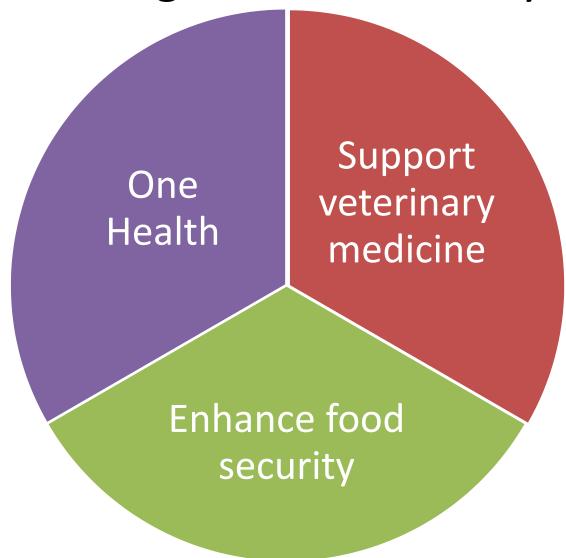






Protect human and animal health in a global community









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





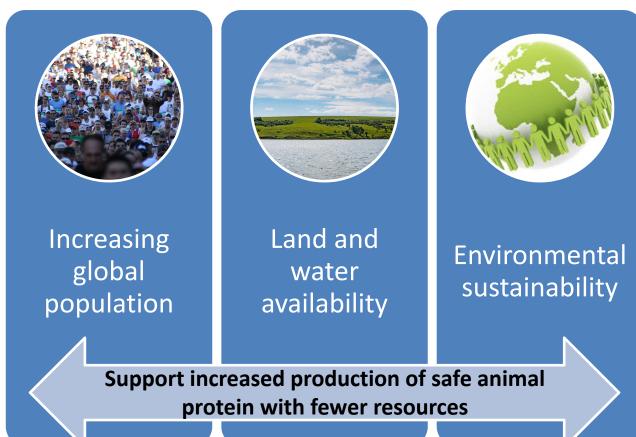
Future of Biologic Products

- 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







Support veterinary medicine



Enhance product availability







Technology for veterinary information management







Goal

Minimize impact of drug shortages

How might we get there?

Early notification

Global response

Collaboration to address challenges





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





Goal

Novel approaches to leverage available information

How might we get there?

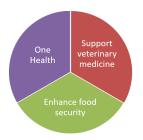
Real-time data and telemetry

Innovative or alternative study designs

Biomarkers and invitro models

Pre-approval use of real-world evidence





Goal

Enhance drug availability through "concurrent" global approval processes

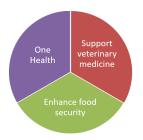
How might we get there?

Expansion of included regulatory bodies

Increased coordination of regulatory bodies

Parallel data review and application of individual standards





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

www.fda.gov

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Protect human and animal health in a global community





