

# AHI Updates

USAHA 2025 –Subcommittee on Pharmaceutical Issues

Sunday, November 2, 10 am MT

Denver, CO

Dr. MJ McNamee, Dir. of Scientific & Regulatory Affairs



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# Martha Scott Poindexter, President & Chief Executive Officer



# Animal Health Market



# Global Initiatives



## VICH International Cooperation on Harmonization of Requirements for Registration of Veterinary Medicinal Products



# Current U.S. Priorities

Regulatory  
Reform

Tariffs

New World  
Screwworm

Ongoing:

Advocate for a fully funded and supported regulatory agency

# Regulatory Reform – Global & Domestic Needs

- **Efficiency** — position the U.S. as the best market in the world to bring new products to market.
  - Science-based risk assessments
  - Predictable timelines
  - Reduction of duplicate studies
  - Aligned PV systems
- **Modernization & Innovation** — more pathways fit to new technologies
- **Access** — fill the unmet medical needs
  - 1500 FDA approved animal therapies vs. more than 20,000 for humans

# Regulatory Reform Priorities: FDA-CVM

- 1 Risk-benefit assessment framework
- 2 Protocol concurrent and well-defined endpoints
- 3 Reduce burden of data requirements
- 4 “Stop-the-Clock”
- 5 Additional outcome-driven metrics

# Tariffs That Could Impact Animal Health

## 1. Reciprocal Tariffs — Announced April 2

- President declared economic emergency under International Emergency Economic Powers Act. This authority is being challenged in court.
- Intended to force countries to negotiate trade deals
- Exempted pharmaceuticals because of inclusion in...

# Tariffs That Could Impact Animal Health

## 2. Section 232 Investigation on Pharmaceuticals

- Authority under the Trade Protection Act; to protect national security
- AH products inadvertently caught up because HTS codes are embedded into human HTS codes
- AHI has conducted extensive lobbying campaign asking the Administration to be sure AH products are not covered by any results tariffs
  - Animal health did not have product shortages during pandemic
  - We have no third-party payers
  - We have diverse supply chains not overly dependent on any single market.  
According to FDA, only 6 percent of AH products sold in the U.S. are imported

# Tariffs That Could Impact Animal Health

## **3. New Section 232 Investigation on Supplies and Devices**

- PPE
- Consumables
- Devices

Dept. of Commerce investigation is on going.

# New World Screwworm

- Threat has arisen after decades of eradication
- HHS announced a health emergency which allows more flexibility in approving products
  - FDA CVM
    - Asking companies to bring applications, focus on currently approved products that need a NWS label, or on NWS products approved in other countries
    - Two approvals to date, one for cattle, one for dogs
    - New labeling guidance
  - EPA and USDA
    - Working together to identify potential Sec 18 Emergency Exemptions for certain products

# Other Challenges

- **Pressure on Animal Testing**

- Stated goal of Trump Administration to reduce animal testing
- We generally agree, but need regulators to work with us on adopting alternatives (NAMs)
- State bills go much further and call for elimination

- **Vaccine Debate**

- Societal pushback: NYT articles last week about spillover effect on vaccine hesitancy as a result of COVID
- All animal vaccines, with new pressure on mRNA: This year, 18 states had bills that would ban, limit or require labeling for animals treated with mRNA vaccines.
- NOTE: There are currently no approved mRNA vaccines for animals

# Thank you.

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