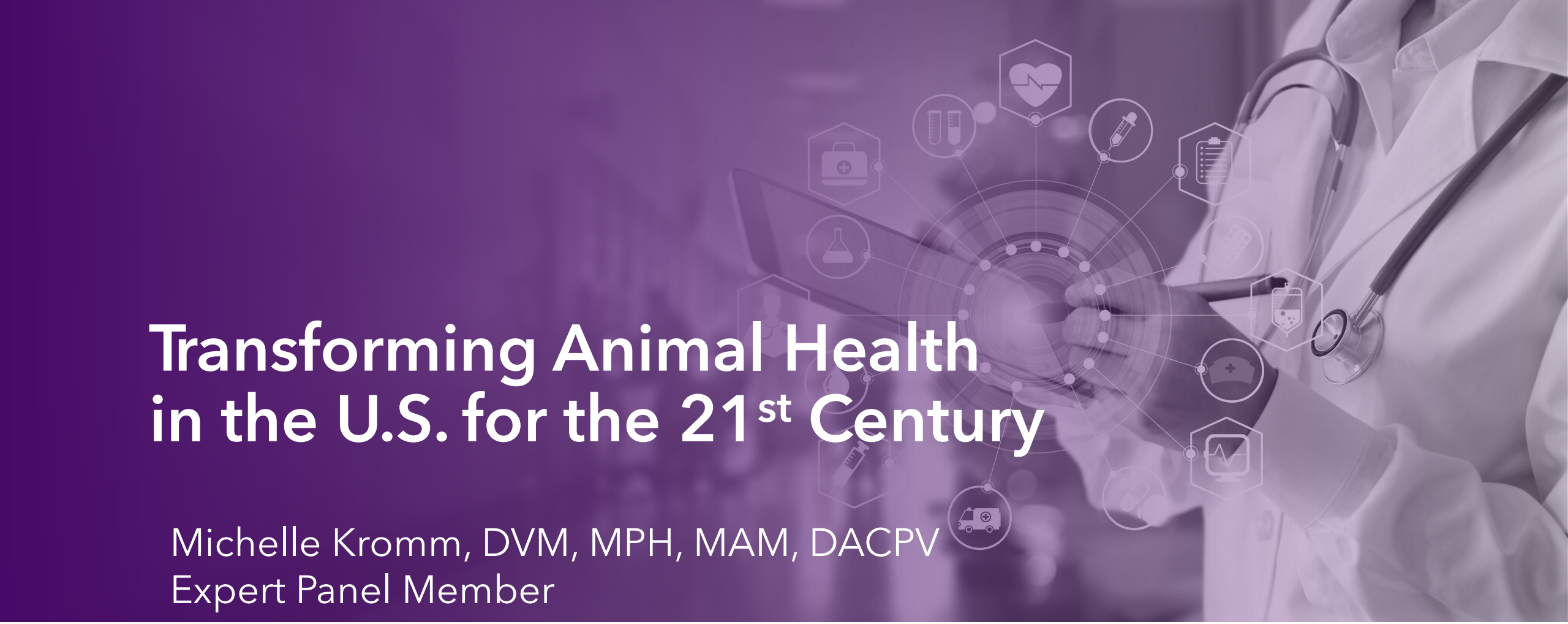

Transforming Animal Health in the U.S. for the 21st Century

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Expert Panel Member

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REAGAN-UDALL FOUNDATION FOR THE FDA

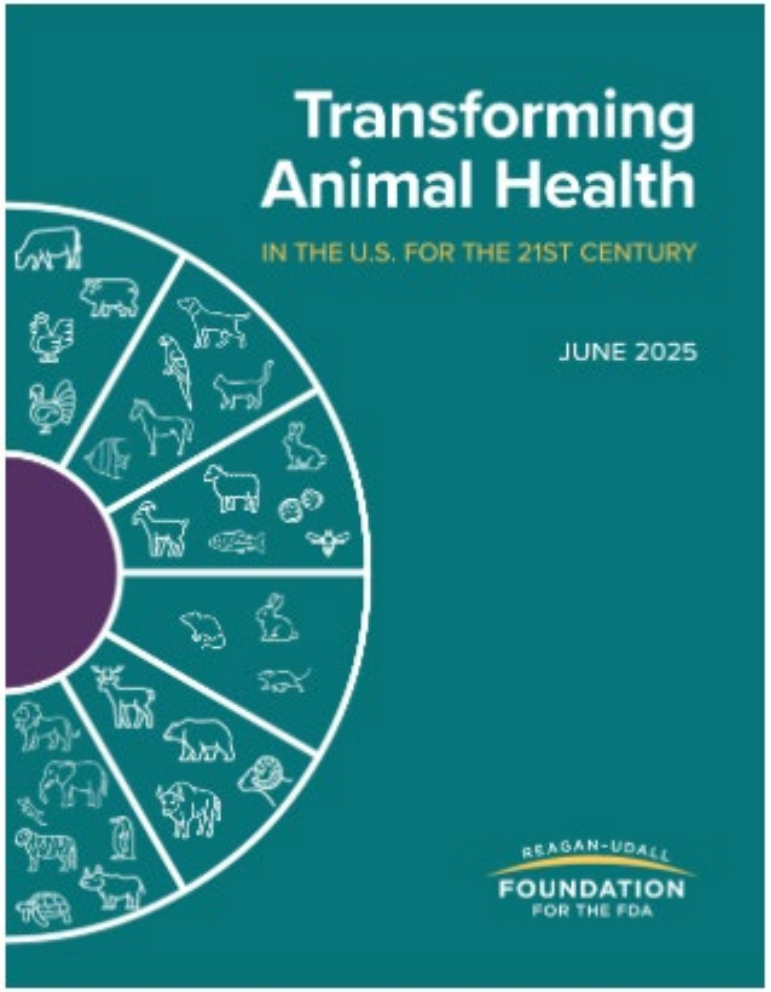
About the Reagan-Udall Foundation

The Reagan-Udall Foundation for the FDA was created by Congress in 2007 as an independent 501(c)3 charitable organization to help the FDA advance its mission.

The Foundation manages a suite of programs that the assist the FDA in engaging with external stakeholders to facilitate evidence generation, improve public understanding of the FDA, and deliver more accessible health information to the public.

Introduction

In 2024, the Center for Veterinary Medicine, U.S. Food and Drug Administration, requested that the Foundation research, survey, and analyze areas of unmet needs or weaknesses within the animal health and animal food ingredient industries.



Process

The Foundation convened a panel of experts to identify the challenges and unmet needs of the animal and veterinary sectors (including animal food ingredients) and recommend approaches to address them.

https://reaganudall.org/projects/addressing-unmet-need-within-animal-and-veterinary-industries

Expert Roundtable Discussions

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The Expert Panel heard candid input from stakeholders in the various sectors, including:

- Aquaculture
- Beef and Dairy Cattle
- Companion Animals
- Equine
- Minor Food Species
- Poultry
- Swine
- Wildlife, Zoo, & Laboratory Animals
- Biotechnology and Pharmaceuticals

Discussion Questions

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1. What are two things going well in your sector?
2. What are the top 3-4 challenges/barriers your sector is experiencing?
3. What are the top 2-3 diseases/threats over the next 5 years?
4. What are the top 2-3 new technologies/practices that are most promising for improving animal production/health over the next 5 years?
5. What are One Health concerns, if any?

What we heard

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Current regulations governing animal health need modernizing

New animal drug review system is perceived as slow and costly for innovators; regulatory options for animal feed needs to be expanded

Minor species, particularly minor food species, have inadequate access to approved medicine

U.S. farmers and food animal producers are disadvantaged in U.S. and global markets when compared to their foreign competition

Recommendations

https://reaganudall.org/publications/transforming-animal-health-us-21st-century

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Authorities: Defining Animal Drugs and Animal Food

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- Modernize the regulatory pathways for animal health products.
- Take a "21st Century Cures Act" approach addressing:
  - Minor Use/Minor Species (MUMS) modernization
  - Biotechnology (e.g., gene-editing, cellular therapies)
  - Food additives and zootechnical animal food substances (ZAFS)
  - Consideration of regulatory data and approvals from nations with trusted regulatory systems
- Provide FDA with more flexibility to interpret the definitions of a drug and food to keep pace with scientific advancements.

FDA-CVM Product Oversight and the Review Process: Animal Drugs

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- A structured risk-benefit assessment framework
- Clear thresholds for achieving protocol concurrence and well-defined endpoints
- Reduce data burden requirements
- “Stop-the-Clock” program modeled after the European Union
- Better tracking and metrics for animal drug reviews
- Utilize non-agency experts, mathematical modeling and simulations in review process
- Improve tracking of adverse events

FDA-CVM Product Oversight and the Review Process: Animal Feed

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- Create new regulatory pathways for zootechnical animal food substances
- Allow manufacturers to claim verified health benefits for certain feed formulations
- Hire experts to review novel food ingredients and provide better guidance to applicants
- Harmonize state requirements for labeling and ingredient safety reviews
- Continue working with global harmonization efforts like Codex Alimentarius and the World Organisation for Animal Health

FDA-CVM Product Oversight and the Review Process: Biotech, GM, etc.

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- Develop fit-for-purpose pathways for biotechnology products
- Provide a clearer entry point for developers of biotechnology products, in coordination with USDA and EPA

Minor Uses & Minor Species

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- Provide stable funding for the Food Animal Residue Avoidance Databank (FARAD)
- Bring the drug review and approval process for minor species under jurisdiction of the Office of Minor Uses and Minor Species.
- Accept data packages that have been prepared for equivalent global regulator review processes
- Allow for the use of related species tolerances or maximum residue limits (MRLs) in establishing withdrawal intervals for minor food animal species products following extra-label drug use
- Amend the definition of minor use to address animal sectors in need

One Health

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- Increase investments to prepare for and respond to emerging zoonotic diseases.
- Continue efforts to estimate antibiotic usage in all animal sectors

Global Competition and Trade Impacts

- Allow the use of foreign studies and aggregate data to support the approval of products
- Address the inequalities between imported and domestic animal products with respect to residue limits
- Industry and regulators should collaborate to conduct thorough risk assessments of supply chains for feed ingredients and pharmaceutical manufacturing

Emergency Preparedness and Emergency Use Authorization (EUA)

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- Streamline, clarify, and expedite EUA and Public Health Emergency declaration processes in its application to animals
- In emergencies, allow veterinarians access to drugs, vaccines, and diagnostics approved in other countries

Communication and Collaboration Across Key Agencies and Other Stakeholders

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- FDA, USDA, and EPA should establish an interagency group to address areas of confusion.
- FDA, USDA, and EPA should use standard terminology consistent with what is being used throughout the animal health ecosystem
- FDA, the veterinary profession, animal sector organizations, industry sponsors, and allied industries should remain engaged on threats, therapy challenges, and other mutual concerns

Enforcement Gaps and Resulting Market Disincentives

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- Ensure the availability of FDA-reviewed products for animal sectors that have relied on compounded products
- Enforce priorities for compounded drugs and update and clarify priorities for unapproved drugs

Workforce Considerations

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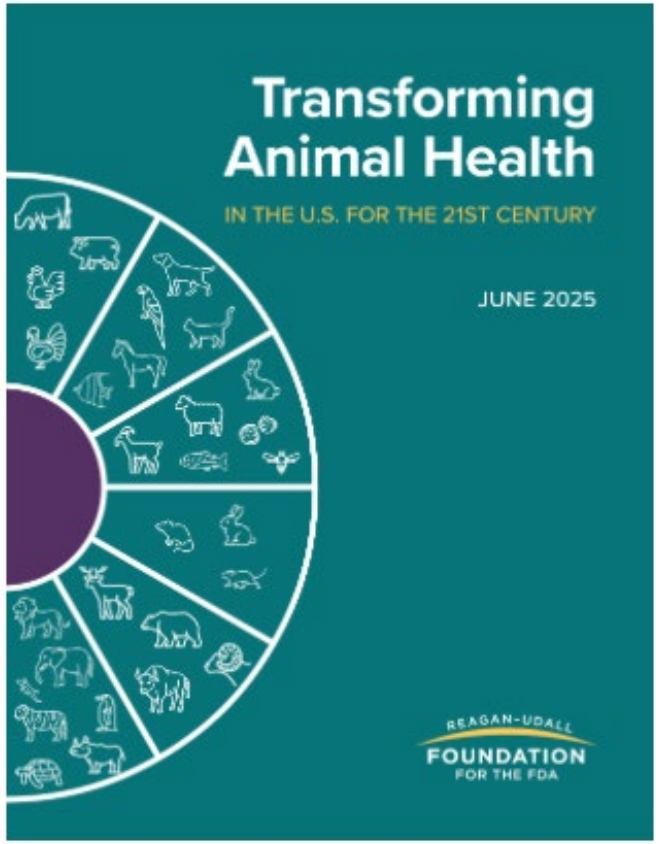
- Utilize the 21st Century Cures Act to increase efficiency and decrease timelines in hiring
- Provide opportunities for FDA staff to gain exposure in the field
- Strengthen the Veterinary Medicine Loan Repayment Program and funding for training in animal handling, husbandry, and biosecurity
- Improve recruiting, training, and retaining of animal health workers
- States should harmonize veterinarian and veterinary technician licensing reciprocity

Report Available:

https://reaganudall.org/publications



Thank You/Questions

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