Animal Health Industry – Challenges & Opportunities to Increase Tools for Minor Species

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Today's Discussion

- Introduction to AHI and the animal health industry
- Review of the regulatory approval process
- Availability of medicines
  - Encouraging innovation
  - Navigating current stewardship efforts
  - Keeping existing products on the market

Introduction to AHI and the Animal Health Industry

About of AHI

- The Animal Health Institute (AHI) is a membership organization that represents pioneer companies that manufacture animal medicines.
- AHI members make medicines that are approved by regulatory agencies, including the FDA (pharmaceuticals), the USDA (biologics/vaccines) and the EPA (insecticides/flea and tick).

ANIMAL HEALTH INSTITUTE

Since 1941, AHI has helped create an environment that fosters robust research and development of innovative and needed veterinary medicines.

Animal Health Industry: What Do We Do?

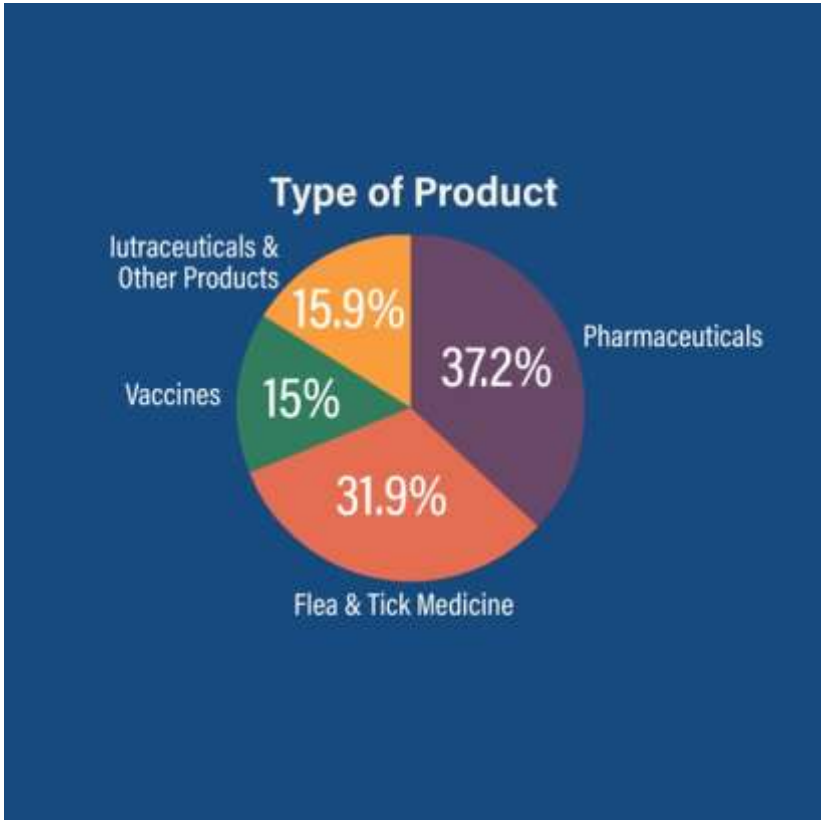
The goal of industry is to improve the health and well-being of animals, which in turn protects and improves the health and well-being of people

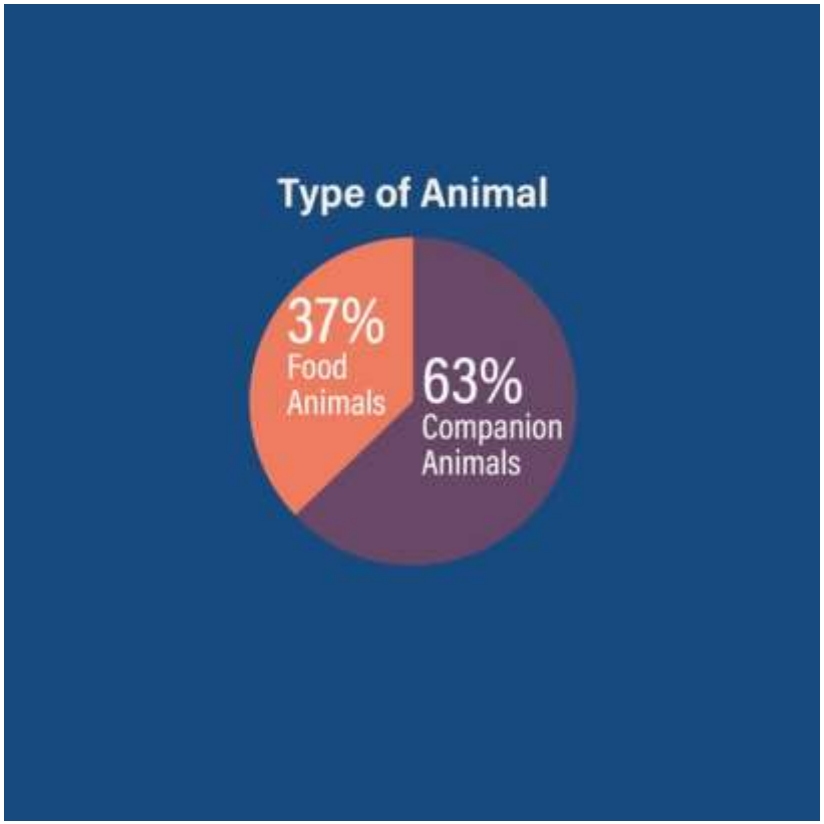
Animal Health Institute Licensed Members

Animal Health Institute Affiliate Members

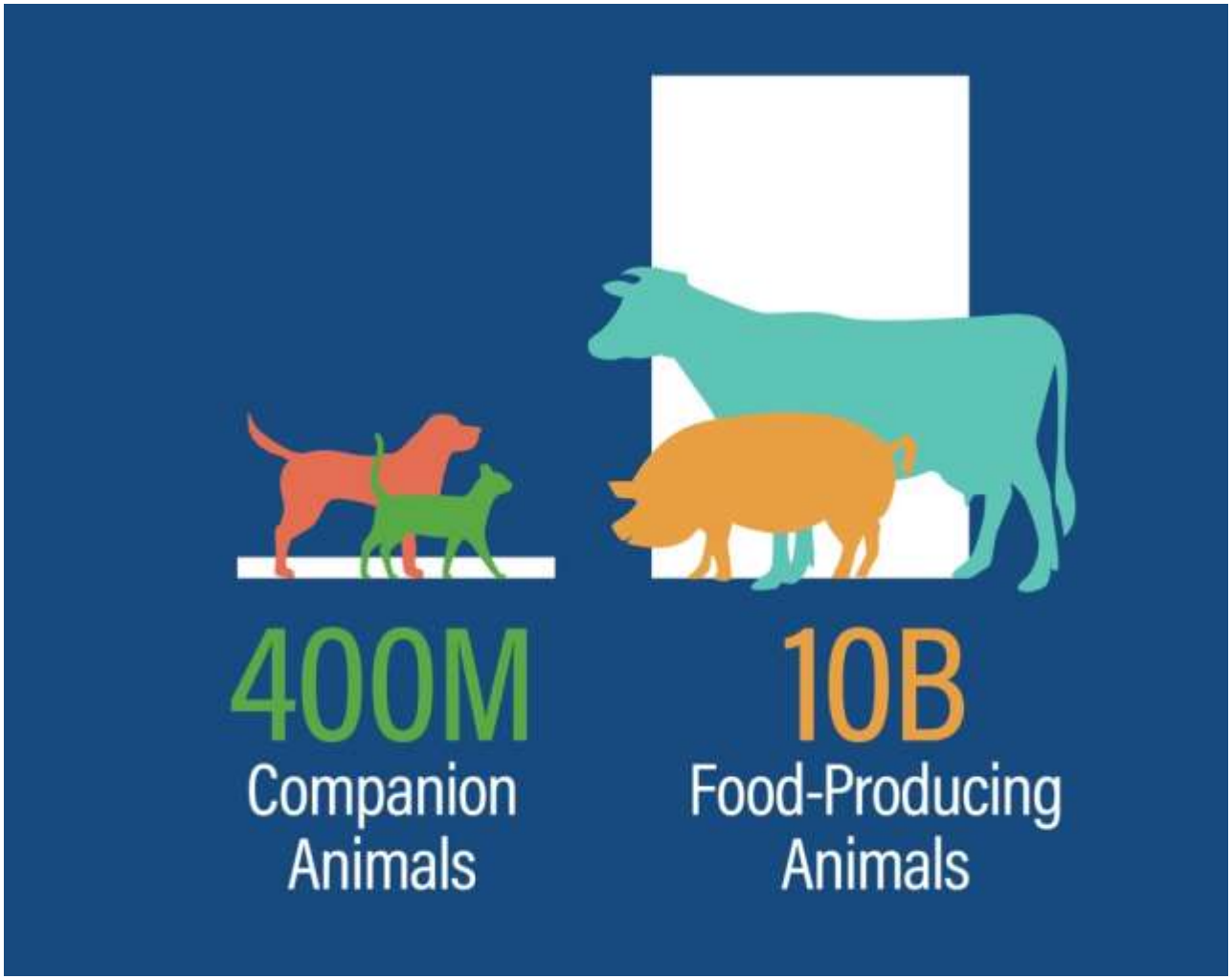
Animal Health Market

Animal Medicines Protect Public Health & the Food Supply





Our Products Support Companion Animals & Food-Producing Animals



Direct Economic Impact

Industries Supported by Healthy Animals

Supported Industries

Dollars in millions	Output	Jobs	Wages
Veterinary Services	$50,998.0	439,211	$21,089.5
Animal Production	$198,952.0	263,408	$11,714.6
Meat & Dairy Production	$338.406.0	673,968	$36,214
Pet Services	$5,961.0	144,251	$3,871.9
Total	**$594.317.0**	**1,520,838**	**$72,889.9**

Review of the Regulatory Approval Process

Animal Health vs. Human Health Industry

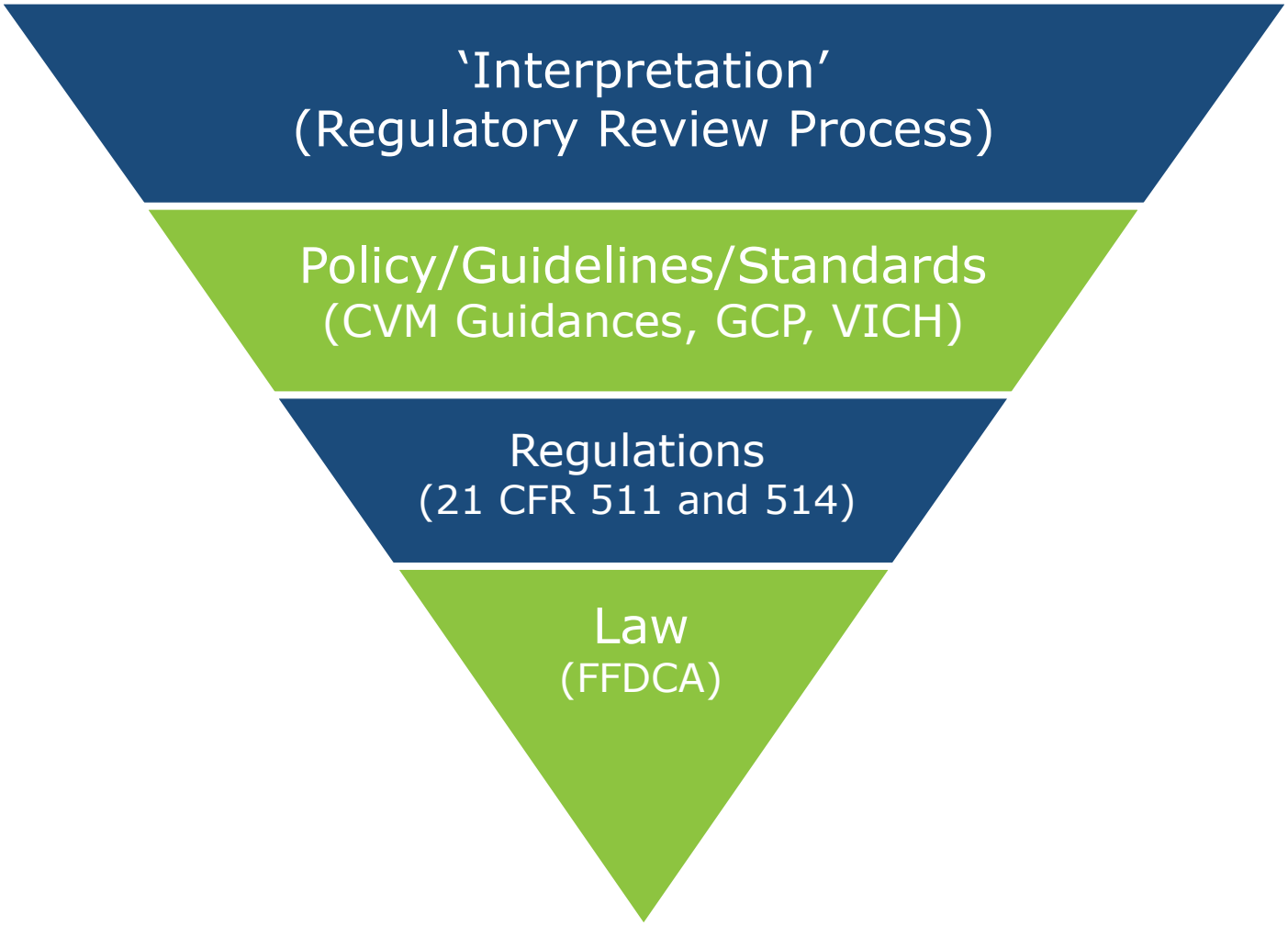
EPA

FDA

USDA

FDA

Pharmaceutical Drug Approval



Animal health is Heavily Regulated

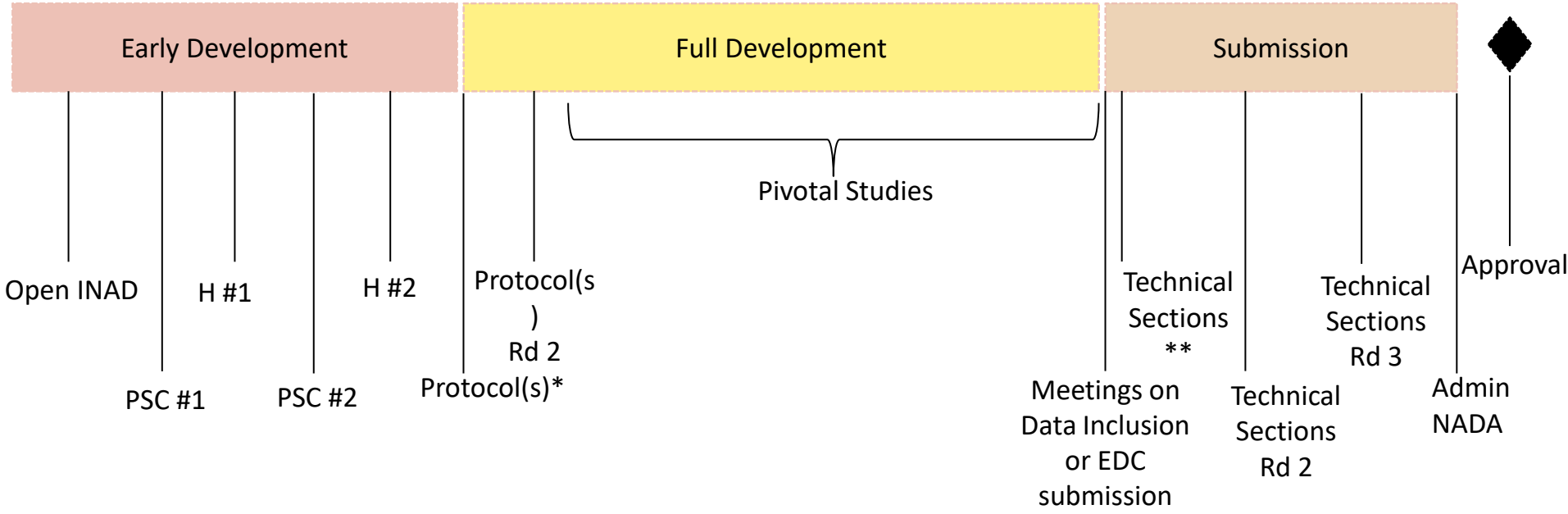
Safe

- Human Food Safety
- Target Animal Safety
- Environment Safety
- Product Safety
  - Chemistry, Manufacturing and Control

Effective

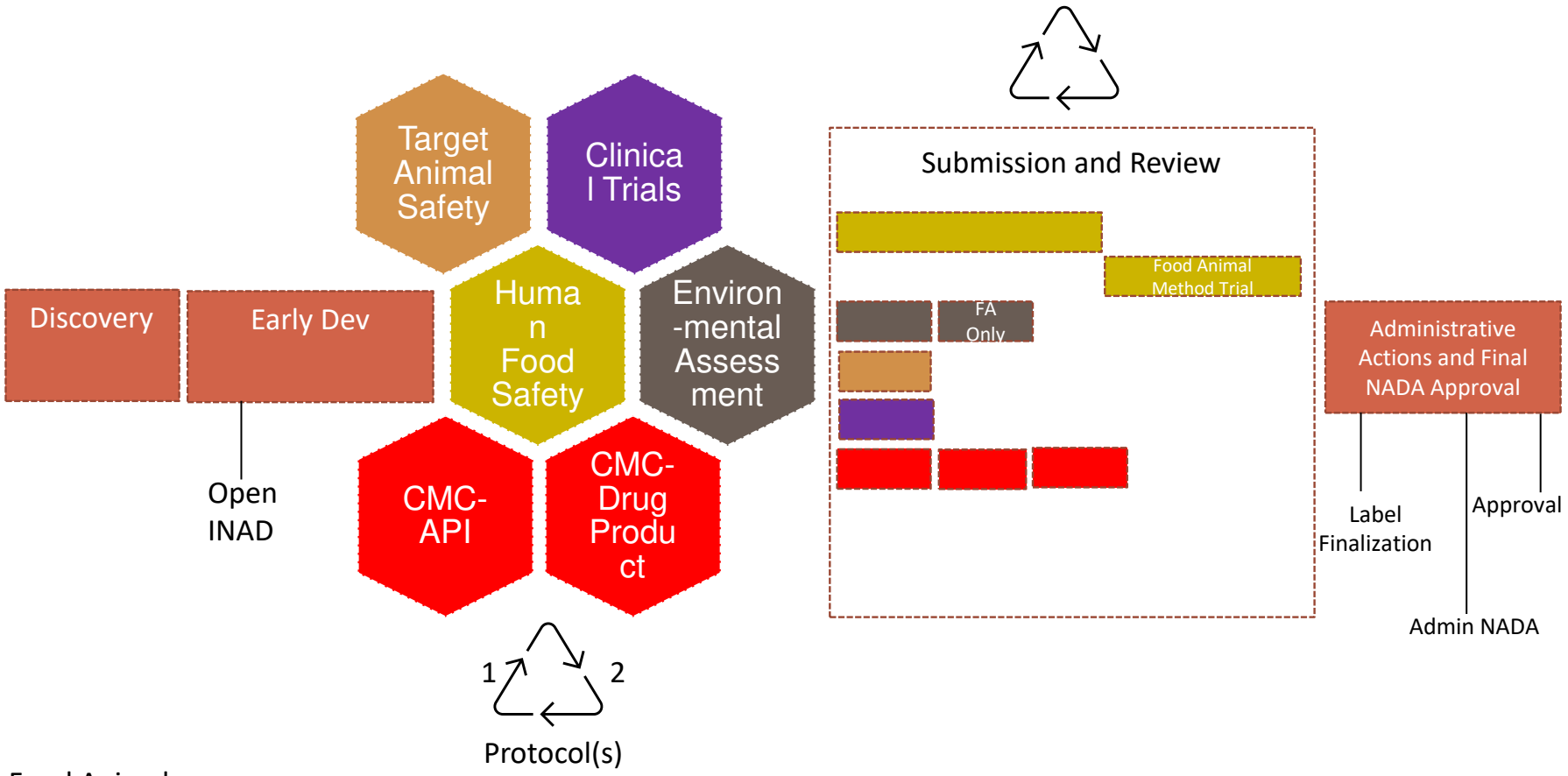
- Target Animal

Development Stages



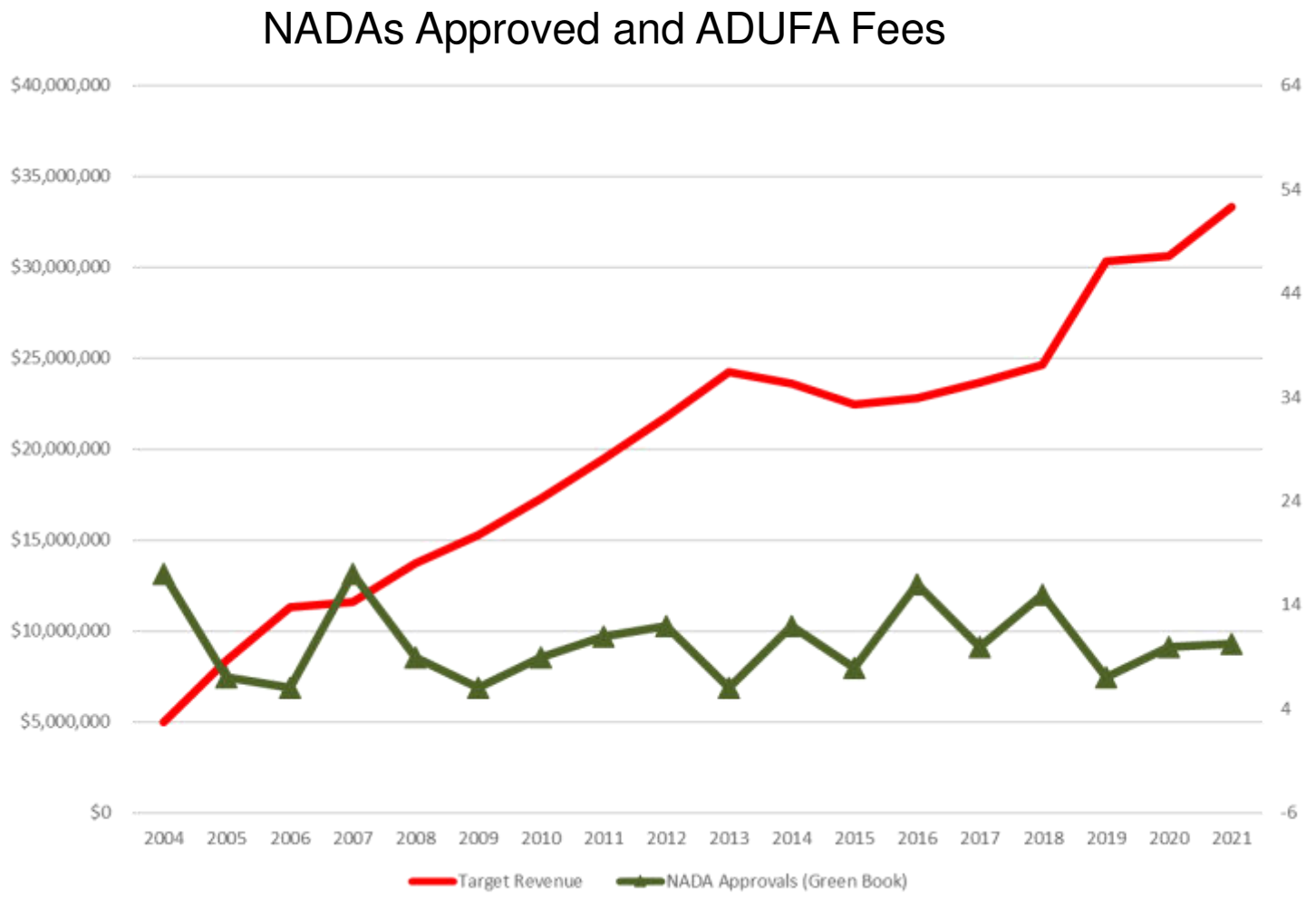
*A typical companion animal project will at have least 2 protocols reviewed but could be much higher depending on therapeutic area or compound class. A typical food animal project will contain at least 4 but could be much higher depending on compound.
**There are 5 major technical sections that must be completed: Effectiveness, Safety, Environmental, Human Food Safety (Food Animal Only) and CMC. AHI sponsors report mutli-cycle reviews are common for 3/5 major technical sections.

Time to Approval



Food Animal	1-2 years	1-3 years	2-4 years	2-3 years	4-6 months	6-12 years
Companion Animal	1-2 years	1-3 years	1.5-3 years	1-2 years	4-6 months	5-10 years

ADUFA has not Increased Approvals



Sources Fees: Annual ADUFA fee setting Federal Register notices
Approvals: Green Book

Availability of Medicines – Encouraging Innovation

Strategies to Foster Innovation

- Regulatory Solutions
  - Conditional Approval – Expanded Conditional Approval or MUMS
  - Clarity of technical requirement
  - Global harmonization of regulatory data requirements
- Business solutions
  - Ability to run studies
    - Availability of CROs
    - Availability of veterinary clinics to participate in clinical trials
  - Data to support that something is a disease and provide data to support MUMS application

Strategies to Foster Innovation – continued

- Incentivizing targeted innovation
  - Funded research
  - Tax incentives for R&D or adoption of new manufacturing processes
- Market Solutions
  - Data protections and exclusivity
  - Patent extension

Availability of Medicines – Navigating Current Stewardship Efforts

Existing Policies Affecting Use of Existing Products

Under the FDA's Guidance For Industry (GFI) #263, by June 10, 2023, all medically important antibiotics that were previously available over-the-counter will require a prescription from a veterinarian for legal use in animals.

CVM has posted a list of affected applications on its website as well as a Farmer and Rancher Q&A

Antiparasitic Resistance

- In 2014, CVM hosted a meeting focused on anthelmintic resistance and has continued to provide information via website
- In 2018, CVM requested language be added to anthelmintics for grazing animals (horses, small ruminants, pigs, and poultry).
- WOAH's Responsible and Prudent Use of Anthelmintic Chemicals to Help Control Anthelmintic Resistance in Grazing Livestock Species

Availability of Medicines – Keeping Existing Products on the Market

Strategies to Maintain Existing Products on the Market

- Protection from illegal compounding copying approved products
- Protecting against hazard-based policies
  - Growing post approval demands
  - Threats of trade barriers
  - Bans based on perceived environmental issues
    - PFAs
    - Extended producer responsibility and packaging issues
    - Antimicrobial Stewardship efforts moving all medically important antimicrobials to Rx

Example – Trade Barrier

- Section in the EU vet medicines legislation that prohibits the use of certain antimicrobials in food animal production exported to the EU.
- New delegated act sets out the conditions under which animals and products of animal origin can enter the EU. These are:
  a) they come from a country that is on an EU list of approved countries, **and**
  b) they have an official certificate stating compliance with EU rules

Reasons for Concern:

- Reduce food/meal/milk/fish/egg exports to the EU
- Hinder access to medicine by preventing veterinarians using products approved by the FDA
- Sets a negative precedence
- Not WTO Compliant and under WTO rules unnecessary

Discussion Questions

- What disease or conditions are small ruminant farmers most in need of innovation?
  - What infectious diseases are most in need of prevention?
- What policies/practices are making it difficult to effectively utilize existing medical tools?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