IOWA STATE UNIVERSITY

Office of the Vice President for Research

Development of New Animal Vaccines and Understanding Federal Regulations

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Base Scenario – Animal Health Considerations

Primary Pathogen IAV

- Swine Clinical Disease
- Human-Animal Transfer with IAV is not uncommon
- IAV can infect dogs, horses, and wildlife via lagoons and fecal spread

Secondary Issues

- **Bacterial Secondary Infect**
  - P. multocida
  - S. suis
  - G. parasuis
  - B. bronchiseptica
- **Animal Welfare**
- **Labor availability to raise and process**

USDA – Animal Health Regulatory Process

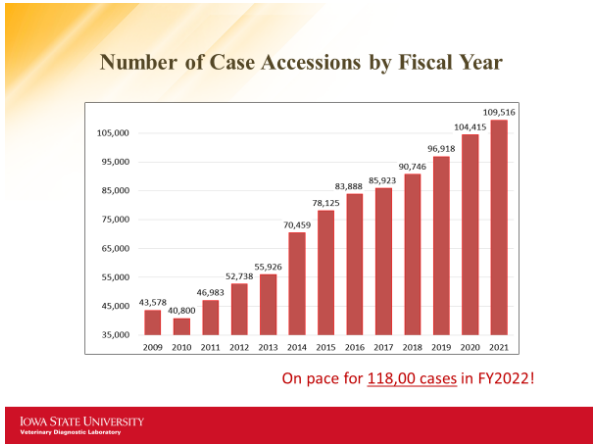
- USDA regulates animal vaccines
- 9CFR Code of Regulation
- Full License Focus
  - Master Seed Concept
  - Safety
  - Efficacy
  - Purity
  - Potency
- "Typical Development Cycles"
  - Killed/inactivated vaccine – 2-3 yr
  - Attenuated Live (non GMO) -2-4 yr
  - GMO – 3-5 Yr

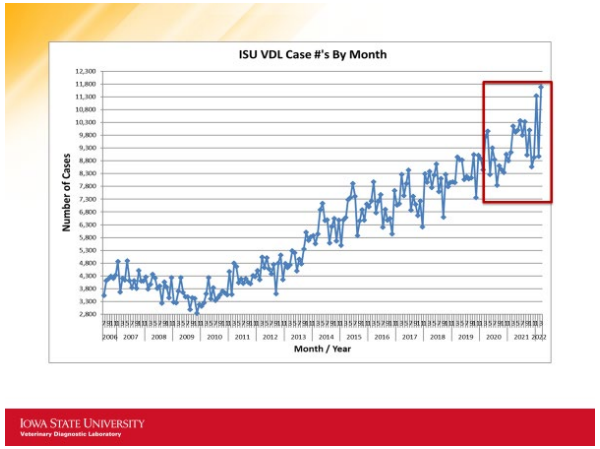
Types of Products Available in AH

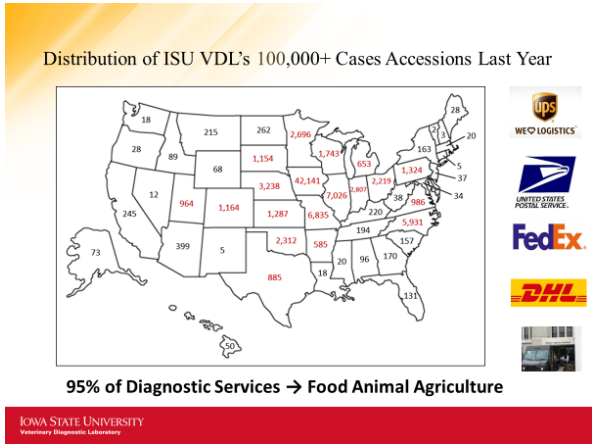
- Fully USDA licensed (most)
- Conditional license
  - Emergency, local situation, or special circum.
  - "reasonable efficacy" and fully validated potency not required
  - Same safety and purity as full license
- Autogenous
  - Farm specific/inactivated
  - 8-12 weeks to product
  - Not tested efficacy or potency
- Prescription
  - Vet-Client Relationship required
  - Uses a USDA licensed non-replicating PLATFORM
  - 10-16 weeks to produce
  - Requires Dx sequence and relevant clinical case/GOI
  - Not tested efficacy and safety limited by Platform license.

IAV Pandemic – Dx and Detection

- NVSL (Federal)
- State Laboratories with swine focus
  - Iowa State University, Kansas State University, University of Minnesota, South Dakota State University, North Carolina
  - Molecular detection – PCR/WGS = fast.
  - Serology – intermediate/cross reactivity??
  - Rapid molecular automated testing
- Swine Health Information Center (SHIC) – shared Dx data and reporting between state labs
- Track Record!! – AIV, PRRS, PEDV







IAV Pandemic – Animal Health Options to Respond (Product level 1)

- Licensed Products – for IAV
  - Fastest Option - may provide some minor cross protection
  - Swine - Flusure (Zoetis (4)), Maxivac (Merck (5)), Pneumostar (Novartis (2)), MERCK RNA (1)
  - Canine – Vangaurd (2) and Nobivac (2)
  - Equine – Fluvac, Prestige, Calvenza, Vetera
  - Relative to IAV specifically – USDA has been open to "isolate swap" which could be significant benefit and provide a strain matched option in an accelerated way.

- Conditional License – based on new pandemic isolate/strain
  - Full license path except "reasonable efficacy" and no validated potency required
  - 12-18 months.

IAV Pandemic – Animal Health Options to Respond (Product level 2 – strain specific)

- USDA Autogenous
  - Lab isolation and purification of field isolates (4-8 wk)
  - Farm specific / inactivated
  - manufacture of vaccines (8-12 wk)
  - Active companies - Medgene, Cambridge, Vaxxinova, ARKO
- USDA Prescription Vaccine
  - Requires Vet-Client Relationship
  - Dx sequence of relevant GOI – HA
  - Cloning of GOI into licensed non-replicating Platform (Baculo, Equine Enceph Virus/RNA)
  - Manufacture – 10-16 wk
  - Active companies – Medgene, MERCK (Boehringer/Huvepharma have a USDA license but not commercially active)

Pandemic response to bacterial pathogens

- **Fully Licensed Products**
  - Pasteurella - Rhini Shield
  - Bordetella – Maxi guard
  - G parasuis – Parasail, Ingelvac HP, Parashield
  - S. suis – None
- **Autogenous**
  - Primary tool for used today for bacteria listed in the scenario.
  - Numerous small/mid sized producers – Arko, Medgene, Phibro, Cambridge

Pandemic Response to Bacterial Diseases

- PRDC (PCV, PRRS, Mhyo) would be a major challenge beyond the bacteria listed in the scenario but good commercial products exist here (Product level 1).
- The efficacy provided by autogenous would be limited and antibiotic usage would be desired by producers (Product level 2)

Opportunities to Increase Speed of Response

- Prioritization of “pandemic” solutions by CVB over other efforts (other vaccines/other policy)
- Remove or don’t enforce – “farm specific” for USDA autogenous
- Remove or don’t enforce – Vet-Client relationship for prescription.
- Allow use of prescription platforms across species without safety data
- Adapt an emergency/concurrent registration process like FDA (COVID) in which safety and efficacy could be assessed concurrently rather than in a linear approval process typically used.
- Presently, the technology for PRESCRIPTION mainly addresses viral disease
  - There is currently not a bacterial specific platform/prescription license
  - It is a challenge to provide significant efficacy with single or cloned protein solutions with complex bacterial pathogens – technical limitation

Opportunities to Increase Speed

- ONE HEALTH – Harmonized FDA/USDA approach
  - Shared database on pathogen sequence/epidem.
  - FDA approved products granted use in An. Health
    - Anti-virals
    - Vaccine technology
  - Leverage DX competency – Test/Removal
  - Regional Control programs