

# VETERINARIAN COMPOUNDING ISSUES IN KENTUCKY

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# Equine Industry 2013

- 23,000 foals in North America
- 7338 registered thoroughbred foals in Kentucky approximately 35% of the U.S. foal crop
- Average sale price is \$85,477
- Total sales of \$328,956,116

# Recent Issues with Veterinary Compounding

- Wickliffe Pharmacy
- Weatherford Compounding  
Pharmacy

# Wickliffe Pharmacy

- Dispensing 100% to animals
- 99% of the prescriptions dispensed are either compounded sterile product or compounded non-sterile product
- approximately 25% are compounded sterile products, all being high-risk
- Approximately 75% are compounded non-sterile products

# Wickliffe Pharmacy

- Wickliffe has 4975 compounding formulas
- The majority of prescriptions are equine
- Daily volume ranges from approximately 400 per day in November and December, to 700 per day the rest of the year
- Wickliffe is permitted in 46 states and Washington DC with 3 states not requiring a permit (North Carolina is the only state in which they are not licensed)

# Wickliffe Pharmacy

- Is an active case in litigation with the Board.
  - Direct Supervision
    - Verbal orders
    - Active Pharmaceutical Ingredient (API) selection and weighing
    - Formula calculations and record keeping
    - Four pharmacists supervising thirty-five technicians

# Wickliffe Pharmacy

- Compounding Issues
  - extends the BUD on CSP past the USP <797> beyond use dates based solely on sterility data without having stability documentation to validate the extended dating
  - extends the BUD on CNSP past the USP <795> beyond use dates without having stability documentation to validate the extended dating

# Wickliffe Pharmacy

- Example of <795> violation
  - toltrazuril/pyrimethamine 416mg/17mg/ml paste contains water
  - For water containing oral formulations, the BUD is not more than 14 days when stored at controlled room temperatures
  - The pharmacy was assigning a BUD of 6 months at room temperature
  - This formula was tested by the FDA laboratory and found to be sub-potent.



# Wickliffe Pharmacy

- Active Pharmaceutical Ingredient (API)
  - Most of the APIs used by Wickliffe are purchased from FDA-approved facilities
  - On November 5, 2014, there was at least one product, aminophylline, purchased from PharmRite in China, which was not USP grade

# Wickliffe Pharmacy

- Potency testing
- Hazardous Drug Storage
- Nonhazardous Drug Storage
- Quarantine Area
- Compounding worksheets
- Prescription labeling, i.e. Veterinarian calls in an order, places one horse's name on Rx, ships to farm for use on multiple animals

# Wickliffe Pharmacy

- Wickliffe received a 483 followed by a warning letter after a joint inspection by FDA Inspector and Board of Pharmacy Inspector.
- Board action is pending.....

# Weatherford Compounding Pharmacy

- Texas licensed pharmacy
- November 8, 2012 a Board Inspector removed from G.L.E. Veterinary Clinic in Louisville, KY, several compounded drugs that were shipped to the clinic as samples
- Weather Compounding Pharmacy was not licensed to ship into Kentucky
- Board issued a cease and desist order

# Weatherford Compounding Pharmacy



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# Weatherford Compounding Pharmacy





# Questions?

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