

# UNAPPROVED DRUGS



**Dr. Lynne White-Shim**

**Assistant Director  
Scientific Activities  
American Veterinary Medical  
Association (AVMA)**

# Preferred Real-World Scenario

Drug Approvals  
Novel Approaches  
Diminished Shortages

Unapproved Drugs  
Reliance on Enforcement  
Discretion



# Drug Approvals

- Continued availability is **critical**
- Many species and conditions
- Reliance on federal and state rules
  - Prescription drugs
  - FDA extralabel drug use rules



# Drug Approvals

- Relevant AVMA policy
  - *Funding of the New Animal Drug Application Approval Process*



# Drug Shortages - Effects

- Human and veterinary drugs affected
- Compounding from bulk – reported impact on return of approved drug to market



# Addressing Drug Shortages

- Frequent status updates needed
- Reduce number of shortages
- (Ideal) No shortages



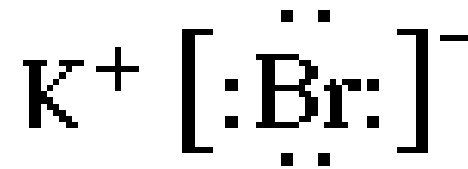
# Medically legitimate unapproved drugs

- Including but not limited to...
  - Injectable vitamins
  - Electrolytes
  - Fluids
  - Topical treatments



# Potassium Bromide

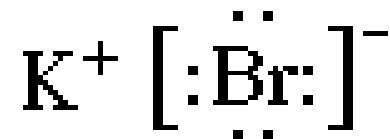
- Anticonvulsant
- Indications:
  - Refractory epilepsy
  - Refractory seizures
  - May be used alone or in combination with other Rx





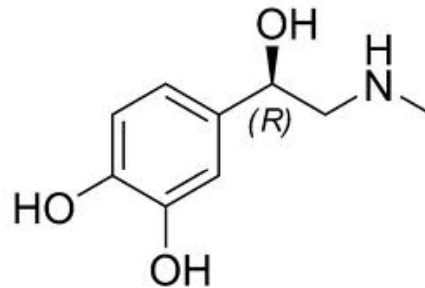
# Potassium Bromide

- No FDA approved formulation
- Unapproved form
- Only other option:
  - compounded formulas



# Epinephrine

- Hormone, neurotransmitter
- Indications:
  - Cardiopulmonary resuscitation
  - Anaphylactic reactions



# Epinephrine

- No currently approved veterinary product
- Only FDA-approved products: single dose autoinjectors dispensing 0.3 mg
- **34** autoinjectors required to give a single treatment to an average size horse



# Continued Availability

- Drugs that should have continued availability have:
  - Minimum to zero food residue risk  
or
  - Manufacturing under GMPs or relevant international standards  
and/or
  - Other federal standards (such as EPA)



# Active Enforcement Needed

- Large-scale manufacturing of mimics
- Circumvention of NADA process
- Questionable safety and efficacy
- Diverts resources away from FDA-approved drugs

*Applicable to both unapproved drugs and unapproved drugs marketed as devices*



# Other ideas

- Labeling of drugs
  - Approved
  - Legally marketed
  - Unapproved
- Readily identifiable
- Indexed drugs
  - “Not approved by FDA” — could be misconstrued



# Summary

- Important topic
- Sometimes medically necessary
- Ideally:
  - Increased approvals
  - Decreased shortages
  - Adequate enforcement
  - Access to needed unapproved drugs
- Further dialog needed

