



ARKO  
Laboratories

---



# Efficacy of Veterinary Biologics

Hans Koehnke, DVM

---



# “Law of Efficacy”

---

$$E = C / R$$



# “Law of Efficacy”

---

$$\text{Efficacy} = \frac{\text{Competition}}{\text{Regulation}}$$



$$E = C/R$$

- 
- Regulation cannot go to 0!
    - The market needs safe, pure and effective vaccines
    - Animal health is economically important – shouldn't be making vaccines in a garage
    - Consumer must have confidence in the product
    - U.S. regulation of biologics is appropriate compared to other countries
  - Competition cannot be infinite – but....
    - Maintenance of a large, segmented market (domestic and exports)
    - Strong support network of Veterinary Services / Diagnostic Services / Nutrition / etc.
    - Competition and Regulation are not mutually exclusive
  - The sweet spot is in-between



# “Law of Efficacy”

---

$$\text{Efficacy} = \frac{\text{Competition}}{\text{Regulation}}$$



# Regulatory Considerations

---

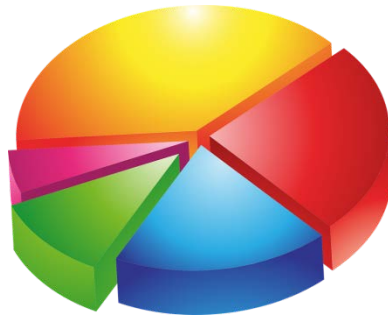
- U.S. regs are very flexible and allow for innovation
- Are general enough to cover both large and small firms
- USDA does a great job listening to stakeholders
- We should be very careful and thoughtful about increasing regulations on biologics
- Some regs are needed to protect the industry



# Regulatory Considerations

---

- Some regs are misguided and decrease competition by tying up precious resources
  - E.g. Single Tier Labeling
  - AVMA driven initiative
  - The ultimate value of a product will still be determined in the field and through human communication
  - Will this increase competition? Maybe (Unlikely)
  - Will this decrease competition? Probably - will slow licensing due to misdirected resources







# Conclusion

---

- Regulation is Necessary
- Our USDA and CVB do a great job balancing the need for regulation in a competitive market.
- Resources are scarce, we can't take our eye off the ball if we want increased efficacy and innovation.



Thanks!

---