

**American Veterinary Medical  
Association (AVMA)  
Council on Biologics and  
Therapeutic Agents (COBTA)**

**Don Reynolds DVM, Ph.D.**

**COBTA Member**

**College of Veterinary Medicine**

**Iowa State University**

**Ames, Iowa**

# COBTA Members

Dr. Fairfield T. Bain, representing Equine Practice

Dr. Shawn Blood, representing Food Animal Practice

Dr. Dawn M. Boothe, representing Pharmacology, **Chair**

Dr. David R. Hustead, Member-at-Large

Dr. David L. Huxsoll, representing Microbiology

Dr. Donald J. Klingborg, Member-at-Large

Dr. James S. Reid, representing Small Animal Practice

Dr. Don Reynolds, representing Microbiology, Vice Chair

Dr. M. Gatz Riddell, Jr., Member-at-Large

Dr. Charles R. Short, representing Pharmacology

# Clinical Practice Advisory Committee (CPAC)

- Formerly Drug Advisory Committee (DAC)
- Members of CPAC/DAC
  - Dr. Lisa J. Becton (guest), American Association of Swine Veterinarians
  - Dr. Richard R. Brown, American Association of Feline Practitioners
  - Dr. Florian Ledermann, American Association of Bovine Practitioners
  - Dr. Thomas F. Meyer, American Association of Equine Practitioners
  - Dr. Gareth A. Moore, American Association of Small Ruminant Practitioners
  - Dr. Michael A. Paul, American Animal Hospital Association

# COBTA Issues / Tasks

- Follow-up On Past Biologic Issues
  - Vaccination Guidelines
    - Published in JAVMA
  - Position statements regarding autogenous biologics
    - Reviewed, edited, amended, etc., previous (AVMA) position statements
  - Vaccine and Pharmacovigilance
    - Working group has been established

# Issues Related to Therapeutics

- Issues of Prescribing and Dispensing
  - (Violations of) Laws, Ethics & Enforcement
    - Abuse of VCPR
    - Internet Pharmacies
    - Kickback Programs
    - Changes in Scripts
    - Etc...
- Other Issues
  - Compounding, Drug Availability, Dietary Supplements, MUMS, AVMA Position Statements, Antimicrobial Resistance, Etc...

# Internet Pharmacies

Date: Sun, 17 Mar 2002 00:43:14 -0600  
Reply-To: <Ken87535621266852@bigpond.com.au>  
From: <Ken87535621266852@bigpond.com.au>  
To:  
Subject: Prescription Weight-Loss and Viagra (8584gRSR645ygtP@16)  
X-Mailer: Microsoft Outlook IMO, Build 9.0.2416 (9.0.2910.0)  
Importance: Normal

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- Save on Refills (No Doctor Consultation Fee on Refills!)
- Please Note that there are No Returns on Prescription Medicine
- We are sorry but any Over Seas orders seized by customs are non-refundable

# Biologic Issues

- Principles of Vaccination
  - Client Brochure
  - Veterinarian Educational Materials
  - Serology Testing

# Biologic Issues

- Biologic Labeling
  - Working Group Established
    - Model of Industry, Government & Profession is successful and synergistic
    - AVMA is pro for science-based labeling
    - Adverse reporting system that serves best patient care is needed
  - Working Group – Current Activities
    - True vs. Tradename
    - Precautionary Statements
    - Required use Instructions

# Vaccine and Pharmacovigilance

- COBTA *approved a motion* to establish a Working Group on Adverse Event Reporting to determine what system is needed to best serve animal health (last year)
  - Algorithm on AE reporting
  - Reporting of AE as part of Vet Med Ethics
  - Establish Website
  - Educ. Inst., Vet Med Assocs., Specialty Boards, etc. to encourage AE reporting
  - Inst. VTHs, et al to serve as “sentinels” for AE reporting
  - EPA for pesticide AE reporting
  - Etc.

Questions????

Answers????

Dr. Elizabeth Curry-Galvin, AVMA Staff