



ISSUES IN EQUINE LAW

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FARRIS LAW FIRM, L.L.C.

NATRC NATIONAL CONVENTION
FEBRUARY 20 – 22, 2015
HOLIDAY INN PLAZA – KANSAS CITY, MISSOURI

EQUINE LAW: WHAT?

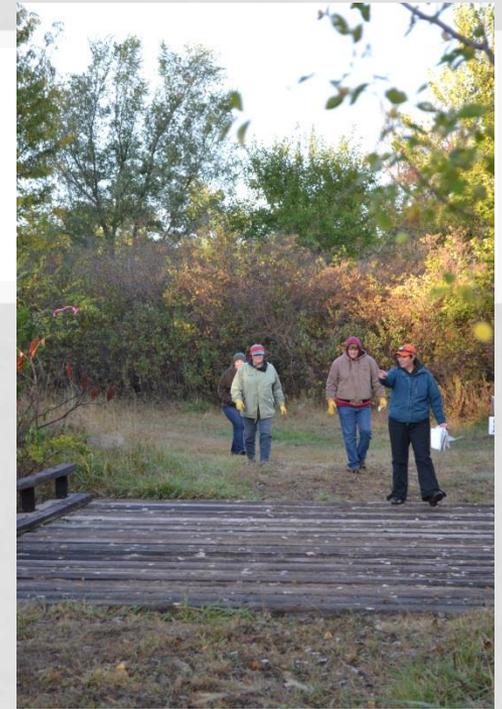
- EALA compliance
- Administrative procedures re: association rules and regulations
- Collection procedures through state agister lien laws and UCC security filings
- Equine contracts (Liability waivers, contracts for boarding, breeding, training, lessons, pony rides, hay rides, trail rides, leasing, in-utero purchases; breeding syndication, employment contracts, etc.)
- Veterinary and Farrier Malpractice
- Workmen's Compensation & American with Disability Acts (Anti-Discrimination Statute) compliance
- Immigration (use of foreign employees as grooms or trainers)
- Land Use and Zoning
- Trespass and Attractive Nuisance
- Agency Law
- Products Liability (Drugs, Tack, Vehicles, etc)
- Tort and Insurance Practice (Personal injury, Insurance Defense)
- Tax planning: Sales and Use Taxes or Estate Planning
- Corporate formations & transactional agreements
- Real Estate Law: Zoning, Land trusts
- Environmental: Manure, carcass disposal,
- Lobbying: Multi User Trail access; EALA laws
- Regulatory (Racing)



OVERVIEW

- **Topics**

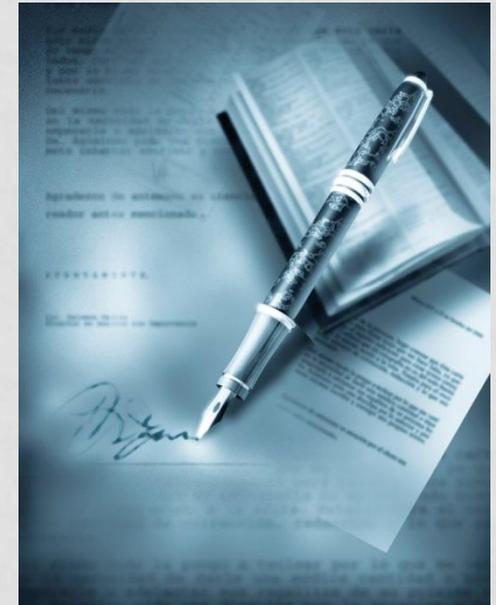
- ABC's of Equine Contracts
 - Buy/Sell Agreements
 - Disclosure of Agent Commissions
 - Sale on Consignment/Terms
 - Leases
 - Liability Waivers
 - Contracting with Minors
- Trespassers, Invitees, Licensees and Kids
- Recreational Land Use Statutes
- Volunteer Protection Act
- Drug Compounding vs FDA/Generic/Compounding
- Trending issues



I. ABC'S OF CONTRACTING - GENERAL

- **CONTRACTING REQUIREMENTS**

- “A” – Applicable
 - Right parties: If an company, use legal name
For Waivers, name Company, Premise Owners, Trainers
 - Correct legal names: ie Prairie Wind Farms **LLC**
 - Correct subject matter: Keep contracts current
 - Covers the relevant points: Each form is different
- “B” – Binding
 - Legal: Age and UCC Compliance:
 - 18 or older
 - UCC: Horse sales exceeding \$500 value must be in writing to be enforceable
 - Mental: Must have legal capacity to comprehend
- “C” – Conforming
 - Contains legal requirements:
EALA Statutory Language
Agent Sales Commissions
 - Contains Case Law compliance element
Liability Waivers: Must include language releasing parties even from instances of their own alleged negligence



I. ABC'S OF EQUINE CONTRACTS

- **APPLICABLE**

- **Buy/Sell Agreements**

- Is a written contract necessary?
 - What constitutes a “written contract”?
 - Buyer, Seller, Sales Item with Specificity, Cost, Date and signature of all parties to be bound
 - What terms/conditions do I want to include / exclude if I'm a:
 - Seller?
 - Selling horse “as is” with buyer opportunity vet exam
 - Seller with consignment purchase?
 - Mortality/Major medical insurance and seller's right to reenter and reclaim horse for breach
 - Buyer? Express warranties and fitness for particular purpose
 - Buyer with consignment purchase? Who covers medical costs and conditions to return; alternatively conditions to secure registration papers on completion
 - **Leases**
 - Is a written contract necessary? Yes, if lease is: year or more, or \$500 or more
 - What terms/conditions apply to a lease situation? Address worse case in lease
 - What about “loaning” a horse or “leasing” a horse for a single competition? Same



1. ABC'S OF EQUINE CONTRACTS

- **BINDING**

- Legal capacity to enter into a contract
- Age capacity to enter into a contract
- Mental capacity to enter into a contract
- Signed by all parties to be bound
 - What constitutes a “signature”
 - Check endorsement: if memo sufficiently identifies subject matter
 - Letterhead or other business identification
 - Mark sufficiently unique to signer as to be identifiable, & witnessed.



I. ABCS OF CONTRACTING (CONT'D.)

- **Binding: Special Issues Related to Minors**

- Cannot legally contract under the age of 18
 - May be modified based on:
 - Close to age of majority
 - Evidence of emancipation
- Cannot waive personal injury claims
 - Open ended exposure for personal injury to minor
 - Based on State Personal Injury Statute of Limitations
 - Minor always retains right to sue when reaching age 18
 - Statute of Limitations commences at Age 18
 - Example: 12 year old injured in Missouri in 2007. Minor turns 18 on 11/14/2013. Minor has until 11/14/2018 to bring suit for injury damages received in 2007.
 - Importance of Insurance:
 - Claims Made: Insurance coverage must be in place when claim is made
 - Occurrence: Insurance coverage must be in place when accident occurred



I. ABC'S OF CONTRACTING (CONT'D.)

• CONFORMING

- UCC Statute of Frauds:
- Terms contained within “four corners”
 - OR: Attachments identified and “incorporated by reference” within “four corners”
- Clear and Unambiguous
- Contains EALA statutory warning
- Contains Case Law liability waiver language
 - Clearly identifies risk
 - Clearly identifies participant's assumption of that risk
 - Clearly waives participant's right to claim for damages for injury or death, “even if allegedly caused by the released parties' negligence”
 - Discuss when Liability Waivers should be used



DISPUTE DIAGRAM: ABC OF WAIVERS



Leases
To:

**HORSES R US
LLC:
Trainer**

Employs:

**Independent
Contractors**

Lessons to Child



Drinking
Dad

And



Minor
Child
Age: 11



Liability Waiver:

1. Releases Horses R Us and Trainer
2. Signed by Drinking Dad



WHAT HAPPENS?

- Minor child falls; seriously injured; sues Barn, Horses R Us and Independent Contractor
- Who is named in the waiver?
- Who is covered and who can be sued?
 - Premise Owners & Independent Contractors can be sued
- Who signed the waiver? Dad only.
- Did he have legal capacity to sign?
 - Was obviously drinking; maybe yes maybe no. Issue of fact for jury.
- If Dad signed but Mother did not, can Mother sue?
 - Yes
- How long does Minor Child have to bring suit?
 - Age 11, statute of limitations doesn't run till she's 18. In Missouri (5 year SOL), 12 more years to file suit. In Kansas (2 years SOL), 9 years.

EQUINE SALES CONTRACTS

- **Must be in writing**

- Values over \$500
- Performance outside 1 year
- Rescission as a remedy: Status before Contract

- **Commissions/dual agency must be disclosed**

- Amount
- When due
- Who pays whom
- Some states mandate disclosure via statute (CA, FL, KY)

- **Cannot lie, deceive or mislead a buyer**

- Caveat Emptor – Buyer Beware or duty of buyer to inquire
- More communication re: specific purpose suitability, higher the burden to disclose
- Special rules for auctions; typically limited disclosure unless written representations made.

- **Contract must be specific but may contain warranty exclusions**

- Fitness for a particular purpose, breeding or performance capability; title or health warranties

- **Consignment contracts require special considerations**

- Insurance coverage and “additional insured” clauses; commencement dates
- Notice and consent re: horse location at all times
- Rights upon default; right to enter and repossess and related costs
- Who holds the registration papers and when are they transferred



I. ABC'S OF CONTRACTING (CONT'D).



- **Case Study: Applicable and Binding**

- Competitor 1 in NATRC receives a letter

Identifying a verbal agreement to use Competitor 2's spare horse during the Region 6 competition season for a flat fee of \$500 and board. The first horse becomes injured at the first ride of the season through no obvious fault of any party. Who is responsible for vet costs and subsequent rehab care? Who is responsible for board?

(Depends on what's in the contract; lacking contract, person "most responsible for horse at time of injury" most likely responsible)

- Competitor 2 then provides Competitor 1 another horse to use for the rest of the season. Nothing in writing is issued. Are terms within that first letter automatically applicable to the replacement horse?

- (No)

1. ABCS OF EQUINE CONTRACTS

- At rider orientation both parties sit together and decide how Competitor 1 will use the second horse for this season and also the next (ie 2 year period).
- The agreement is verbal. Enforceable?

(Depends. If value exceed \$500 or performance for a year or more, not enforceable per UCC Statute of Frauds; requires a written contract)

- Both riders use a napkin to draft out terms and conditions for Horse 2. It shows both of their first names, the horse's name, when the horse will be used and returned, and the \$300 fee for the remainder of the season & \$500 for Season 2. Both parties initial the napkin. Is this a binding contract?
 - Most likely. Includes date, parties names, subject matter, value, time of performance and signature of both parties.

SALES AGREEMENTS: CASE STUDY

Email:

"5/3/2013. I, Denise Farris of 20355 Nall, Stilwell KS do purchase from Ed Buckley of Kansas City, MO a 5 year old quarter horse age 5 for \$2500 cash, to be delivered no cost to my residence on 5/5/2015. If horse does not pass vet check on arrival, I can return horse with my costs reimbursed. On delivery, Agent receives sales commission."

Horse fails vet check.

- What issues?
 - Can buyer return horse and get money back?
 - What are "costs"?
 - Was the "horse" sufficiently identified if Seller has several horses?
- Does "Agent" get commission?
 - Probably where commission conditioned on "delivery" and not "passing vet exam"
- How could you "fix" this Email to plug in the holes?



EXAMPLE: WARNING OF RISKS

- "I HAVE READ the rules, conditions, and regulations of the event and will comply with them. I AGREE to abide by the rules of the and the aforementioned ride. I UNDERSTAND that ... riding is a high risk activity, which involves being in remote areas for extended periods of time, far from communications, transportation, and medical facilities; that these areas have many natural and/or man made hazards which ride management cannot anticipate, identify, modify, or eliminate; that horses can be excitable, difficult to control and unpredictable; that personal belongings can be damaged, lost, or stolen, and that accidents can happen to anyone at any time.
- Is this a sufficient warning of potential risks to be assumed?

EXAMPLE: WAIVER OF LIABILITY

- **I AGREE to assume all risks associated with my participation in this activity, and I accept full responsibility for myself and the animal I am riding. As a condition precedent to my being allowed to participate in this activity, I agree that I WILL NOT SUE OR BRING ANY CLAIM AGAINST THE, ITS DIRECTORS AND/OR OFFICERS, RIDE MANAGEMENT, RIDE PERSONNEL, VOLUNTEERS, PROPERTY OWNERS WHERE EVENT TAKES PLACE, AND/OR ANY OTHER INDIVIDUAL MEMBERS THEREOF, (HEREAFTER REFERRED TO AS “THE RELEASED PARTIES”) FOR ANY INJURY, ACCIDENT, DEATH AND/OR LOSS OF ANY KIND WHICH ARISES OUT OF THIS EVENT, AND WILL INDEMNIFY AND HOLD HARMLESS THE RELEASED PARTIES FROM ALL LIABILITY FOR SUCH INJURY, ACCIDENT, DEATH OR LOSS, EVEN IF SUCH INJURY, ACCIDENT, DEATH AND/OR LOSS ARISES FROM THE ALLEGED NEGLIGENCE OF THE RELEASED PARTIES. I FURTHER ACKNOWLEDGE THAT I HAVE READ AND UNDERSTAND THIS STATE’S EQUINE ACTIVITY LIABILITY ACT WARNING (IF APPLICABLE), A COPY OF WHICH IS ATTACHED HERETO AND INCORPORATED BY REFERENCE HEREIN. I HEREBY CERTIFY THAT MY HORSE IS NOT UNDER THE INFLUENCE OF MEDICATION AND WILL NOT BE TREATED WITH OR GIVEN ANY MEDICATION PROHIBITED BY RULES. I HEREBY GIVE PERMISSION TO THE OR THEIR DULY APPOINTED AGENT, TO TAKE ANY APPROPRIATE ACTION DEEMED NECESSARY TO CHECK FOR POSSIBLE ADMINISTRATION OF DRUGS TO MY HORSE.**
- **Will this waiver be legally enforceable?**
- Most likely; warns of risks, contains express assumption of those risks, and waives liability of Released Parties even for their own “alleged negligence”

EXAMPLE: USE A VENUE, FEES, & ARBITRATION CLAUSE IN CONTRACT

- To the extent any dispute arises out of this agreement, the parties agree to submit said dispute to binding arbitration before a neutral arbitrator mutually selected by the parties, said arbitration to be conducted in accordance with the Rules of the American Arbitration Association. All such arbitrations shall be held in the county or district where National headquarters are located. If the prevailing party, shall be allowed to recover all costs and expenses incurred, including reasonable attorneys fees and costs.
- **"MY SIGNATURE BELOW CONSTITUTES ACCEPTANCE OF THE ABOVE TERMS AND CONDITIONS. I HAVE READ AND UNDERSTOOD THIS LIABILITY RELEASE AND BINDING ARBITRATION CLAUSE."**

ARBITRATION

- Pros
 - Quick and efficient
 - Enables parties to select arbitrator familiar with the equine industry and its practices
 - Confidential
 - Binding
 - Significant cost savings
- Cons
 - Parties do not receive written explanation of decision unless expressly requested
 - No right to appeal if you lose

II. WHO'S ON YOUR PROPERTY?

- Duty to Trespassers
 - Def: On your property without permission
 - Limited Duty to warn/protect
 - But **ONLY IF**:
 - Trespassers presence is known, &
 - Owner has knowledge of specific danger not patently obvious
- Duty to Invitees
 - Def: On your property through invitation
 - Owner has average duty to provide reasonable protection against known exposures
- Licensees
 - Def: On your property for business purposes
 - Owner bears highest duty to inspect premises and protect from known or "should be known" hazards
- Minors – Attractive Nuisance theory
 - High duty to take precautions to protect minors



II. WHO'S ON YOUR PROPERTY?



- **Recreational Land Use Statutes**

- Exists in all 50 states
- Designed to encourage private land owners to “share” property
- Limits liability against property owner for injuries incurred on property IF:
 - No charge for use of land
 - Use is for a “recreational” and non-commercial purpose
 - Owner did not make any safety assurances; i.e. public’s use of property is deemed “use at your own risk”
 - No special conditions exist which create “special risks” and duty to warn (ie old well covers, concealed barb wire, extreme erosion, prairie dog fields, etc. Use warning sign or yellow caution tape or signs)

Mo. Rev. Stat. § 537.346; Kan. Stat. Ann. § 58-3203; Kan. Stat. Ann. § 58-3206.

II. WHERE'S MY HORSE?



- **Laws vary state to state**
- **Missouri:** Mo. Rev. Stat. § 270.010.
 - Horse owners may not allow animals to “run at large”
 - Will be liable for maintenance costs to anyone who catches/cares for a loose horse
 - Will NOT be liable for personal injuries road or vehicle collision **IF** horse strayed through no fault or negligence of owner
- **Kansas.** Ks. Stat. Ann. § 47-122
 - Horse owners may not allow animals to “run at large”
 - Owner will be liable to “any injured party for all damages related to the loose equine”
 - Any injured person shall have a lien on the equine for the amount of the damages caused by the equine that is not paid by the owner.
 - Any person who is injured by a strayed equine may retain the equine until the owner reimburses that person for all of the damages and costs incurred by the strayed equine.
 - *BUT SEE: Abbott v. Howard (1950):* Plaintiff must prove horse was “unattended upon the highway because its owner had failed to exercise due care in enclosing it
 - I.E. liability requires evidence that horse was loose due to fault or negligence of owner

Gate accidentally left open: Most likely fault will be attributed

Tree falls and breaks fence. Unless it was known tree was unstable, no fault will be attributed.

III. VOLUNTEER PROTECTION ACT



- **1997 Federal Volunteer Protection Act**
- Similar Statutes in all 50 states
- **Provides immunity to volunteers working with non-profits for actions occurring in their volunteer capacity.**
- Work must be for a “qualifying organization”; i.e.:
 - A certified nonprofit organization “organized and conducted for public benefit and operated primarily for charitable, civic, educational, religious, welfare or health purposes”; or
 - Any organization exempt from taxation under Sections 501 (a) and 501 (c)(3) of the Internal Revenue Code; or
 - A state or its subdivisions.
- The party must qualify as a “volunteer”, i.e.
 - Can't be compensated for services but CAN
 - Be reimbursed for actual reasonable expenses
 - Receive thank you gifts valued under \$500

III. VOLUNTEER PROTECTION ACTS

Volunteer's actions must be within scope of volunteer's duty

- Volunteer must be properly licensed or certified, where the activity causing the injury required such license or certification (i.e. veterinarian);
- Volunteer can't engage in willful or criminal misconduct, gross negligence, reckless misconduct, or conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer; or
- Volunteer can't cause the injury while the volunteer operates a motor vehicle, vessel, aircraft or other vehicle requiring a license.

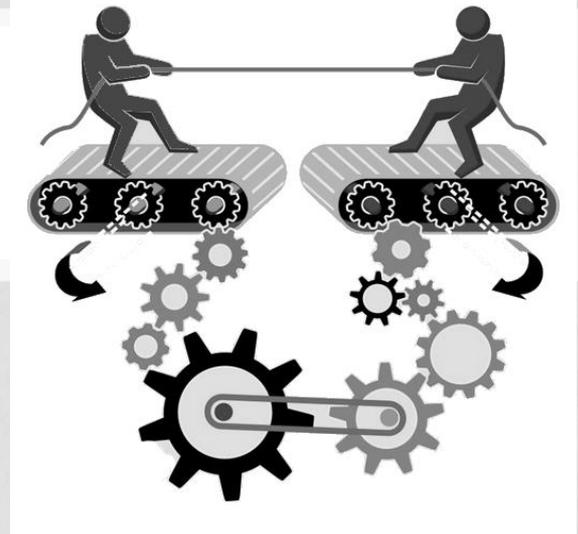


IV. DRUG COMPOUNDING

- **Do YOU Know What You're Giving Your Horses?**
- **Compounding- NON FDA APPROVED Rx**
 - The origin of pharmacology practice before 1938
 - 1938: Passage of FDCA: Human Drugs
 - 1994: Passage of AMDUCA: Animal Drugs
 - Both acts require use of FDA approved drugs to treat specific conditions in humans or animals
 - Both Acts permit limited use of compounded drugs (not applicable to vitamins or supplements, liniments)
 - Use of compounded drugs requires
 - Specific patient/Unique needs/Under Dr. or Vet care; no other FDA drug available



IV. COMPOUNDING



- Historical Discussion
- Origin of Compounding
- Origin of FDA
- Importance of “Measure of Scale” versus “Potential Harm to General Public”
- Importance of Data Capture to Address Harm to General Public issue
 - R & D costs
 - Economic viability to recapture R & D
 - Incentives to continue R&D development of new drugs
 - Vs Need for quick action in unique circumstances

IV. COMPOUNDING

- **Is my supplement a “drug” under FDCA definitions?**
 - Does it contain an active pharmaceutical ingredient?
 - Does it purport to “treat” or “remedy” a condition?
 - Does it require specific dosage, administration, storage or shelf life instructions or considerations?
 - Does it present potential adverse reactions?
- If so, then its most likely a “drug” under FDCA definitions



ONGOING CONFUSION

- **Public Does Not Understand Distinctions**
- **FDA & GENERIC DRUGS**
 - Both subject to
 - FDA oversight and approval
 - Stringent R&D requirements
 - Established Quality Assurance processes in manufacturing
 - Established statistical proof of efficacy, potency, shelf life and potential adverse reactions captured over large universe of users
- **COMPOUNDED PRODUCTS**
 - Not FDA tested, approved or monitored
 - Not subject to manufacturing oversight re: purity, integrity, consistency or safe application
 - No warning label requirements
 - No collected marketing data
 - No collected adverse or alternative “no reaction” data



UNREGULATED COMPOUNDING DISASTERS



- **May 2014: 4 Thoroughbred deaths; 6 more ill**
 - Wickliffe Pharmacy Compounded EPM Treatments using Pyrimethamine/toltrazuril
 - Owner litigation commenced June 2014
 - FDA investigation
 - BAPI 13 times higher than approved level in tested product
- **October 2012: Human Fungal Meningitis Outbreak thru Epidural Steroid Injections**
 - New England Compounding Center (NECC)
 - 3 lots distributed to 75 medical facilities in 23 states; given to 14,000 people
 - 48 deaths, 720 ongoing treatments for persistent fungal infections
- **April 2009: 21 Polo Pony Deaths**
 - Francks Pharmacy, compounded injectable supplement for muscle recovery
 - Containing selenium, vitamin B-12, potassium, and magnesium
 - Selenium levels toxic at 20 times the recommended amount
- **March 2007: Melamine Poisoning in Chinese manufactured pet food**
 - ▶ 100 deaths; 500 cases of treatment for kidney failure
- **“Compounding pharmacies have been linked to deaths, illnesses for years” Washington Post, 2/7/13**
 - http://www.washingtonpost.com/national/health-science/compounding-pharmacies-have-been-linked-to-deaths-illnesses-for-years/2013/02/07/5ba90132-6b19-11e2-ada3-d86a4806d5ee_story.html

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DO YOU USE COMPOUNDED PRODUCTS?

- 48 Phenylbutazones FDA approved; all others are compounds
 - <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm186621.htm>
- Ulcer Treatments: Ulcergard™ Gastrogard™ FDA approved; all others are compounds
- Banamine: Merck/Intervet products only FDA approved; all others are compounds
- Foal formulas?
- Supplements?
- Joint injections? Legend™, Adequan™ Vetalog™ FDA approved; all others are most likely compounds
- Hormones?
- Tranquilizers?
- **How do you know if its' FDA approved or a compound?**
 - All FDA approved products MUST HAVE a label with:
 - 6 digit NADA number on label, and/or
 - "Approved by FDA" statement on label
- **Is it a compound? Look up your product on www.EquineDrugFacts.com**

FDA NADA Label in lower right side (See White Date Circle Below)

Veterinarian's imprint here

Important directions for use

- To ensure adequate absorption, always administer SENTINEL® (milbemycin oxime/lufenuron) Flavor Tabs® to dogs immediately after or in conjunction with a normal meal.
- SENTINEL Flavor Tabs have no effect on adult fleas, but control flea populations by breaking the flea cycle at the egg stage.
- To speed control, products that kill adult fleas like CAPSTAR® (nitenpyram) Tablets, may be used temporarily with SENTINEL Flavor Tabs, depending on the severity of the infestation.
- Treatment may begin at any time of the year. In geographic areas where fleas and mosquitoes are seasonal, treatment should begin several weeks prior to the expected onset and should continue until the end of the flea and mosquito season. In areas with year-round infestations, treatment should continue the entire year without interruption.
- It is important to treat all dogs in the household for fleas. Cats in the same household should be treated with approved products like lufenuron.
- SENTINEL Flavor Tabs must be administered monthly, preferably on the same date each month.
- For full product information, see enclosed inserts.
- If you have any questions concerning the use of this product, contact your veterinarian, who is your pet's healthcare expert.

For technical assistance call 1-800-332-2761.

www.petwellness.com

Manufactured for: Novartis Animal Health
 US, Inc. Greensboro, NC 27408, USA.
 Storage conditions: Store in a dry place at controlled room temperature, between 59° and 77°F (15-25°C).

Dogs



sentinel flavor tabs®
 (milbemycin oxime • lufenuron)

NOVARTIS
 ANIMAL HEALTH
 NAN/SEN-FT/115-230/102/2
 2003351

Recommended for dogs and puppies
26-50lbs

sentinel flavor tabs®
 (milbemycin oxime • lufenuron)

6
 PACK

Recommended for dogs and puppies

26-50lbs

NOVARTIS
 ANIMAL HEALTH

sentinel flavor tabs®
 (milbemycin oxime • lufenuron)

Once-a-month flavored tablets

Recommended for dogs and puppies
26-50lbs

sentinel flavor tabs®
 (milbemycin oxime • lufenuron)

6
 PACK

6
 PACK

Prevents Heartworm Disease and Flea Populations in Dogs and Puppies

Also controls flea populations, adult hookworm infections, removes and controls adult roundworm and whipworm infections in dogs and puppies.

Keep this and all drugs out of the reach of children.

Net contents: 6 tablets, 11.5 mg milbemycin oxime and 230 mg lufenuron each.



Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Product # 52231 NADA # 141-084
 Approved by FDA



SAMPLE ADVERTISING- COMPOUNDED BANAMINE NO FDA NOTATION, NO NADA NO.

- Flunixin (Banamine) Powder 500mg / Teaspoon, 15g Jar
- [Email to a Friend](#)
- **\$100.00**
- Buy 2 for **\$85.00** each and **save 15%**
- Buy 4 for **\$75.00** each and **save 25%**
- Qty: Add to Cart
- **OR** [Add to Saved Items](#)
- [Add to Compare](#)
- **Description**
- Flunixin (Banamine) is a potent non-narcotic, non-steroidal analgesic agent with anti-inflammatory and fever-reducing activity. Flunixin (Banamine) is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in horses. Each teaspoon of Flunixin powder contains 500mg of Flunixin Meglumine. The 30g jar is contains the same amount of Flunixin Meglumine as 20 Banamine syringes. Flunixin powder is apple-flavored and expires 180 days after it is compounded.
- **[RX - Prescription Required](#)**
- Source: <http://www.thrivingvets.com>

BUT IT SAYS “PRESCRIPTION REQUIRED”

- If my vet prescribes it, isn't it “legal”?
 - Not necessarily
 - Discuss with your vet why a compounded product is being used when an FDA approved product is available and required by law
 - If cost savings are identified, ask vet about performance stability of the compound versus the FDA approved product and what data is available?
 - Ask if there have been any adverse issues related to bad batches, unsterile delivery vehicles, etc.
 - Understand if there's a bad reaction, your vet's liability insurance will most likely not cover your claim
 - Use of the compounded product in lieu of FDA approved, for cost savings only, is legally prohibited and thus not an “insured occurrence”.

CAUTION



- Compounded Product
 - Might be cheaper due to lack of RD and FDA regulatory compliance costs, BUT
 - No FDA oversight for
 - Purity of bulk active ingredients
 - Good manufacturing procedures
 - Purity
 - Efficacy
 - Stability
 - Shelf Life
 - Adverse Consequences
 - Is either overly potent or under potent

PERGOLIDE V PRASCEND™ STUDY

- Treatment Cushings Disease
- UC Davis – Dr. Scott Stanley
- Study Goal:
 - Assess potency and stability of various formulations.
 - Liquid, powder, and capsules in common use by practitioners (major compounders.)
 - Stability of the compound was determined at 15, 30, 45 and 60 days post receipt of the drug stored at room temperature and under refrigeration.

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Comparison of Pharmaceutical Equivalence for Compounded Preparations of Pergolide Mesylate

Scott D. Stanley, Ph.D. and Heather DiMaio Knych, DVM, Ph.D.

K.L. Maddy Equine Analytical Chemistry Laboratory, School of Veterinary Medicine, University of California-Davis, Davis, CA 95617; e-mail: sdstanley@ucdavis.edu

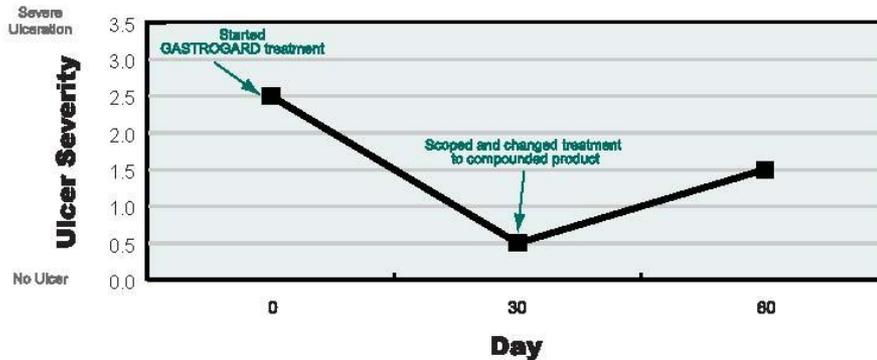
Take Home Message: Results from this study demonstrate differences in potency of the active ingredient, pergolide mesylate, in the various formulations/products obtained from different veterinary compounding pharmacies. This could have important consequences both from an efficacy and toxicity standpoint.

STUDY RESULTS

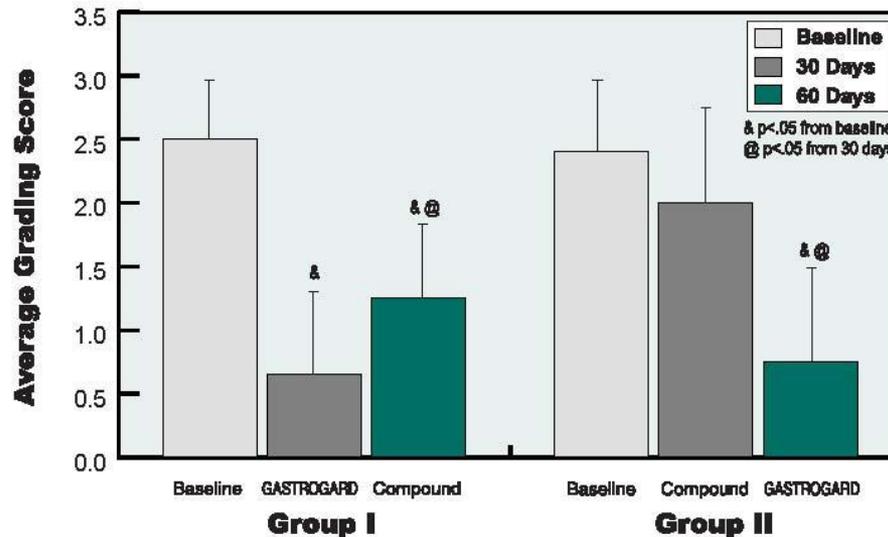
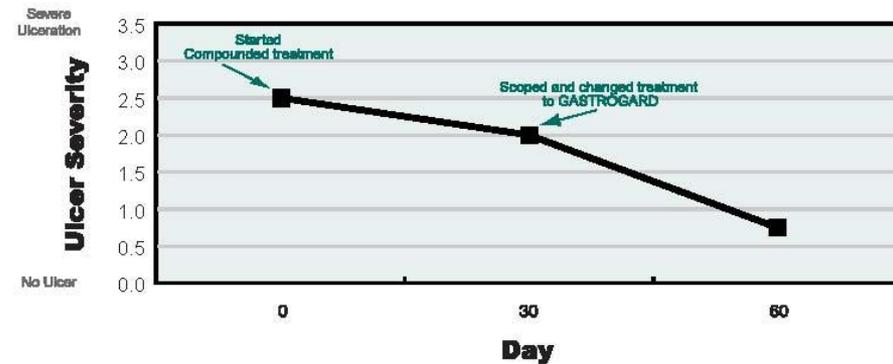
- Prascend™ vs Pergolide 28 tested products
- Compounded products many having concentrations **well below the label claim.**
- High degree of variation in concentrations between two containers of **same product ordered from same pharmacy on the same date.**
- **(57%)** of tested products **did not meet FDA requirement** for potency at onset of the study.
- Only 3 of 14 liquid products were above the required potency after 15 days. **All liquid products were sub-potent by 30 days.**
- The only solid product meeting the potency requirement after 60 days was determined to be **120% of the target potency concentration** at the outset of the study.

OMEPRAZOLE VS GASTROGARD™

Average Scores for Group I
Initial treatment with GASTROGARD, Day 30 switch to compounded omeprazole



Average Scores for Group II
Initial treatment with compounded omeprazole, Day 30 switch to GASTROGARD



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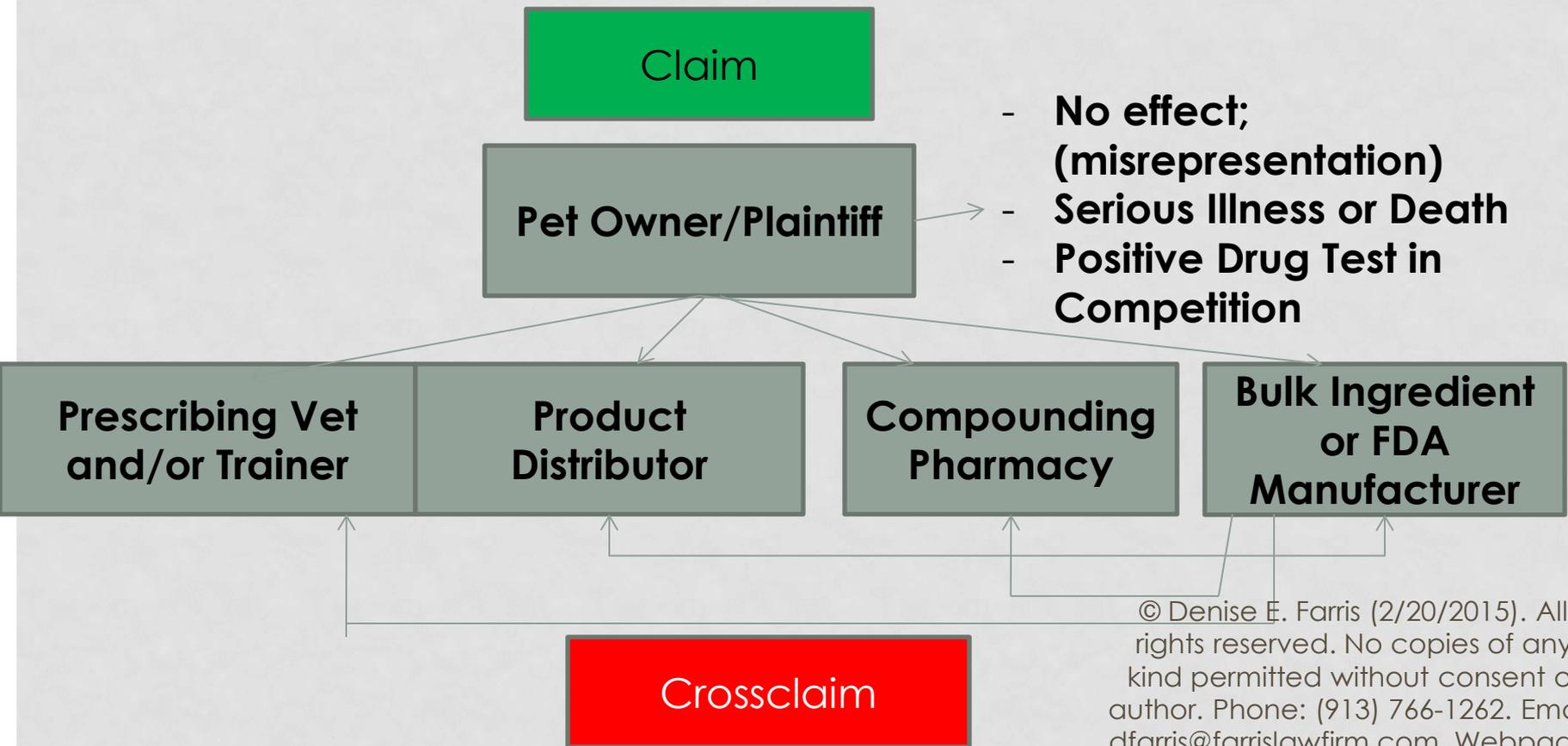
LANHAM & CONSUMER PROTECTION ACTS APPLY TO COMPOUNDING CLAIMS

- **Lanham Act**
 - Primary federal trademark law
 - Creates a private cause of action
 - For violations of:
 - Trademark infringement
 - Trademark dilution
 - False or Misleading Advertising (i.e. representations re: efficacy)
- **Consumer Protection Acts**
 - Misrepresentations made in the sale of products to consumers



WHY SHOULD YOU CARE?

- **Litigation Parties**



Not Covered by CGL /E&O Insurance !!!³⁹

KNOW THE RULES! DISCUSS WITH YOUR VET! AAEP/AVMA GUIDELINES



- **COMPOUNDING TYPICALLY PERMISSIBLE WHEN:**
 - a. A valid **vet/client/patient relationship** exists (VCPR Rule)
 - b. Use is limited to unique need in **a specific patient** or group of patients
 - c. No other method or type of drug delivery is practical, **AND**
 - d. **No equivalent FDA approved product is on the market.**

- **COMPOUNDING TYPICALLY NOT PERMISSIBLE WHEN:**
 - a. Exceeds VCPR rule (i.e., mass manufacture, advertising and distribution except in limited circumstances)
 - b. Mass advertised for large population of end users without justification (i.e. lack of other products to treat condition in that species)
 - d. Compounded product mimics **equivalent FDA approved product available on market**

V. MORE HOT TOPICS IN EQUINE LAW

- Equine Sales: Import/Export
- Reproductive Cases:
 - Cloning: AQHA Case 5th Circuit
 - Associations rights to create/enforce their own rules
 - Is the AQHA required to register cloned Horses?
 - ICSI: Intra-cytoplasmic sperm injection
 - Embryo/In Utero Sales, Property Rights
- Competition Drug Rules
 - Evolving sophistication of tests
 - Higher duty to disclose medical treatments at or near time of competition
- Equine Verbal Partnerships
- Hiring Minors
- Internet Slander/Defamation
- Intellectual Property Law
- Workers Compensation Laws:
 - Most horse barns no longer considered “agricultural”
 - Workers Compensation typically now required for employees
- Carcass Disposal Laws





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2015	Board Member, Kansas Horse Council
2015	Martindale-Hubbell National List "Preeminent Women Lawyers"
2012-2014	Super Lawyers Top 100 Attorneys MO/KS and Top 50 Female Attorneys MO/KS
2013	EQUUS Magazine 2013 Leaders in Equine Law
2010-2014	Kansas City Business Journal "Best of the Bar"
2011	WIPP (Women Impacting Public Policy) National Member of the Year

As a lifelong equestrian, in 1997 Denise and the Farris Law Firm LLC became one of only 47 firms nationally to list a focus niche in "equine law". She was featured in the March 2013 issue of EQUUS magazine in its "2013 Leaders in Equine Law" feature. The firm recently launched "Perspectives Mediation", providing affordable dispute resolution services to the equine and agricultural community. The Firm's equine law services include risk management and compliance consulting, state Equine Activity Liability Act compliance; contract preparation including boarding, breeding, sales, training, lesson and syndication agreements; corporate formations, labor, employment and immigration issues; environmental and zoning; stable, veterinarian and farrier insurance defense services; association rule infractions; and regulatory issues at the local, state and federal levels including a heavy focus on developments in animal pharmaceutical compounding. Denise has served on numerous advisory committees opening the Missouri Katy Trail for equine trail use; the Kansas Flint Hill eco-tourism project; and various legislative activities pertaining to the Missouri and Kansas Equine Liability Acts and/or creation or updates to the states' Equine Business Economic Impact Studies. She has donated *pro bono* services to the Missouri Equine Council, the Kansas Horse Council, and National Association of Trail Ride Conference (NATRC). As an acclaimed author and presenter, Denise's keynote presentations include: Boehringer Ingelheim Vetmedica and Merial Ltd. National Practice Series; AAEP Hambletonian Conference- East Rutherford NJ; the national Equine Law Practitioner's Conference Lexington, KY; The National Multiple User Trail Conflict Symposium at Clemson University; Purina Mills National VIP conferences, NATRC National Conventions, and the American Farriers National Conventions. Denise was a regular contributor to "Equine Veterinarian Management" magazine, and a variety of her risk management articles can be viewed at: www.farrislawfirm.com.

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