

Illegal Drug Compounding: Your Legal Nightmare Waiting to Happen©
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Drugs

FDA says a drug is

- any substance, food or nonfood that is used to treat, cure, mitigate, or prevent a disease,
- any nonfood substance that is intended to affect the structure or function of the animal,
- any substance administered by injection

FDA says: A new drug is unsafe unless there is in effect an approval of a new animal drug application and unless the intended use of a drug and its labeling conform to the approved application

“Regulatory Players”

Food and Drug Administration

- Animal foods, veterinary drugs, medicated animal feeds

Center for Veterinary Medicine

- office within the FDA which assists in providing for the health care needs of animals through the approval and post-approval monitoring of safe and effective animal drugs, medical devices, and feeds

www.fda.gov/cvm

State Veterinary and Pharmacy Bds

SHOULD THERE BE REGULATION?

Paternal views weighed against individualism

It's about protecting the consumer

Consumer “Be Ware”

Food, Drug, and Cosmetic Act (“FDCA”)

The FDA . . .

- enforces the FDCA, thereby assuring the safety and effectiveness of drugs, devices, and safety of food supply

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- is responsible for the approval and regulation of animal foods, veterinary drugs and medicated animal feeds

Drug Approval Process

- To be approved, NEW ANIMAL DRUGS must be established by scientific testing as effective and safe by the sponsor of the drug product
- Effective means that the product will do what it is claimed it will do consistently and uniformly
- Safe means the product is safe to animals and persons administering the product or otherwise associated with the animal, that food products derived from animals are safe, and safe to the environment
- Good Manufacturing Practices

Drug Approval Process

- Adulterated Drugs . . .
contain unsanitary components,
lack adequate control in manufacture,
differ in strength from that recognized in official compendium, or
that are mixed with another substance to reduce their quality or strength
- Includes mixing several drugs in a syringe
Bute-Banamine-Dex
Valium-Ketamine
DMSO + ??

Compounding leads to Adulteration

- Compounding is any manipulation of drug formulation to produce dosage form other than that manipulation that is provided for in the directions for use on the labeling of the approved drug product

Compounding leads to Adulteration

- Examples of Compounding
combine or dilute FDA approved drugs for “better” delivery
prepare finished dosage forms from bulk drug substances
prepare injectables from oral dosage forms
Ivermectin, Ventipulmin
. . . . to obtain products that differ from the starting materials

Enforcement Discretion

COMPOUNDING IS NOT permitted by the FDA.....

however,

FDA recognizes that veterinarians often compound drugs and therefore exercises its ENFORCEDMENT discretion to permit compounding

FDA's Compounding Policy

(www.fda.gov/ora/compliance_ref/cpg/) (rev 7/14/03)

permitted for licensed practitioners who manufacture, prepare, propagate, compound or process drugs during the regular course of business, as long as the compounded product is NOT a new animal drug prescribed VCPR
 “in certain instances, but only rarely, such as to treat poisoning”

Permitted Compounding . . .

- Compounding of products from approved animal or human drugs
- Compounding of bulk substances
- Unless the finished product is a new animal drug
- Drugs withdrawn from the market ????

Licensed veterinarians may legally use or dispense veterinary prescription drug products ONLY within the course of their professional practice where a valid veterinary-client-patient relationship exists

Compounded Drugs Are NOT

- generics
- FDA approved drugs used in an extra-label manner (unless reformulated)
- substitutes of “approved drugs”
- for resale

Are

- Reformulations of (current and “former”)FDA approved drugs
- In context of “specific” VCPR
- Bulk combos

“Resale” . . . Look at the evidence?

- Fees charged to clients
- Mark-up of drugs compounded by pharmacies
- Administration fee
- Prescription fee

Vet’s stock pile

- How big is it?
- What’s the turnover?
- VCPR

Where is the liability?

- FDA penalties
- Veterinary State Board Action
- Lawsuits by Clients
- Negligence
- Breach of contract
- Fraud

- Prosecuted for animal abuse

FDA Penalties

- Warning letter advising recipient of violation
- Seizure of violative goods
- Injunction preventing further violations
- Criminal prosecution
- Felony
- Misdemeanor

State Veterinary Board Action Findings:

- Unprofessional conduct [aka “Ethical Violations”]
- Negligence
- Penalties
- License revocation, suspension
- Required CE, probation

Animal Law Jrnl

Bar Association Animal Law Committees

www.animalaw.info

What Is Negligence? Failing to exercise the level of care, skill, diligence, and treatment that is recognized as the standard of acceptable and prevailing veterinary medical practice

Proving Negligence: 4 elements

- Duty, Breach of Std of Care, Proximate Cause, Damages (the driver)

Standard of Care Set By . . .

- Veterinary colleagues
- Publications: texts and trade journals
- Guidelines: AAEP, AVMA. . .
- CE meetings: AAEP, CVC, WVC . . .

Legislation and the Courts

Statutory Violation Rule

Negligence per se if you violate FDCA

- the violation is the cause of the injury,
- the plaintiff is within the class of persons intended to be protected by the law, and
- the injury is within the area of risk intended to be avoided by the law

T J Hooper Case (1932)

“There are precautions so imperative that even their UNIVERSAL DISREGARD will not excuse their omission” (L. Hand)

Restatement of Torts

No group of individuals and no industry or trade can be permitted, by adopting careless and slipshod methods, to save TIME, EFFORT, MONEY, at the expense of the rest of the community. If the only test is to BE what has always been done, no one will ever have any great incentive to make any progress to the direction of safety

What “standards”

Failure to . . .

- use “legal” product
- inform client of risks with legally compounded prdts
- do “due diligence” on pharmacy
- maintain medical records
- recommend autopsy or referral
- Misrepresentation of product and tx

Human Injury, Pet Loss and Injury

Economic

- Veterinary expenses
- Lost income

“FMV” of animal

- Noneconomic
- Loss of companionship
- Pain and suffering
- Emotional Distress
- MDs

Noneconomic Damages

2001 Kentucky equine case: \$125,000 award

Owner gave custody of two horses to husband and wife

Custodians sold horses for slaughter within days of transfer

Custodians lied to owner about whereabouts of horses

Compensatory and punitive damages

Noneconomic Damages

Illinois Anti-cruelty Statute

Defines companion animal as animal commonly considered or considered by owner as pet, including, dogs, cats and *HORSES*

Owner Duties

food, water, shelter, vet care, humane care

Non-economic damages

\$500-25,000

State of Colorado HB 03-1260

Bill imposes civil liability for animal cruelty

and negligent animal healthcare professional practices affecting companion dogs and

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cats, and establishing specific standards of
 veterinary practice involving inoculations for companion animals
 Cap of \$100,000 for
 “loss of companionship”
 Pulled 2/14/03

Michigan Bill SB 1379 (Introduced 6/02)

The owner of a domestic animal may bring CIVIL action to recover non-economic damages up to \$250,000 for loss of the domestic companion animal caused by another person’s GROSS NEGLIGENCE or willful and wanton misconduct
 A dog, cat or HORSE is presumed to be a domestic companion animal

Noneconomic Damages

New Jersey Anti-cruelty Statute
 Introduced 2/13/03
 Creates civil remedy for person guilty of violating cruelty statute
 Up to \$500 for loss of companionship
 No cap on emotional distress
 Applies to cats, dogs, HORSES

Noneconomic Damages

New York AB 6340 (3/03)
 “Unjustifiable negligence”
 Copy cat drugs
 Loss of companionship
 Burial expenses
 Court costs and attorney fees
 Damages recovered by Guardian Ad Litem appointed by court and payable into a TRUST for the care of the animal

Massachusetts SB 932 (2003)

“negligent act”

Fraud

“A false representation of matter of fact, whether by..
 words or by conduct (compounded = generic)
 false or misleading allegations, or
 concealment of that which should have been disclosed,
 which deceives and is intended to deceive another so that he shall act upon it to his legal injury.”

Prosecuted for Animal Cruelty

Veterinarians are treating horses with products they know (or should know) to be illegal and for which they have no data to support the product’s safety, effectiveness and purity
 “unnecessary pain and suffering”

Heightening Status of Animals
Intent to impose more responsibility on
pet owners

- Berkley/SFO/WH, CA
- Boulder, CO
- Sherwood, AR
- Amherst, MA
- Menomonee Falls, WI
- Rhode Island

What are DVM's ethical and legal obligations?

- Who is going to decide?

Limiting YOUR Liability
Compound...

- Only when there is NO FDA approved drug
- To "reformulate" an approved animal or human drug
- To make formally FDA approved drugs that are no longer available (only under limited circumstances and this may not even be legal)
- VCPR

Don't compound to make....

- cheaper substitutes of FDA approved drugs
- new animal drugs

Limiting YOUR Liability

- Due diligence of Compounding Pharmacy
- Interview an officer (pharmacist) of the company
- References from colleagues
- Product liability insurance
- Financial status, longevity
- Visit facility
- Source of bulk "ingredients"
- Compliance with Good Compounding Practices

Limiting YOUR Liability

- Owner disclosure and consent
- Efficacy and safety is anecdotal
- Contact your professional malpractice carrier
- Don't "look" like a distributor
- Stock pile
- Computer "mark up" codes
- Ask yourself, "Is this drug safe and effective?"

Compounded Pdt “Red Flags”

- Vials: Sterile, Expiration Date, Lot number
- Cheaper substitute for FDA Approved drugs
- Adequan, Ventipulmin, Gastrogard
- AVMA Pharmacy Complaint Form (www.avma.org)

The Future

- Increased lawsuits
- Emergence of legal remedy for “loss of companionship”
- Increased owner responsibilities
- Increased owner/vet accountability
- Increased quality of care and consistency
- Increased cost of care

Few Words of Wisdom

- A client cannot consent to sub-standard care
- You get what you pay for
- No good deed goes unpunished
- Do the right thing by the patient...always
- Don't be the one to make case law

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