

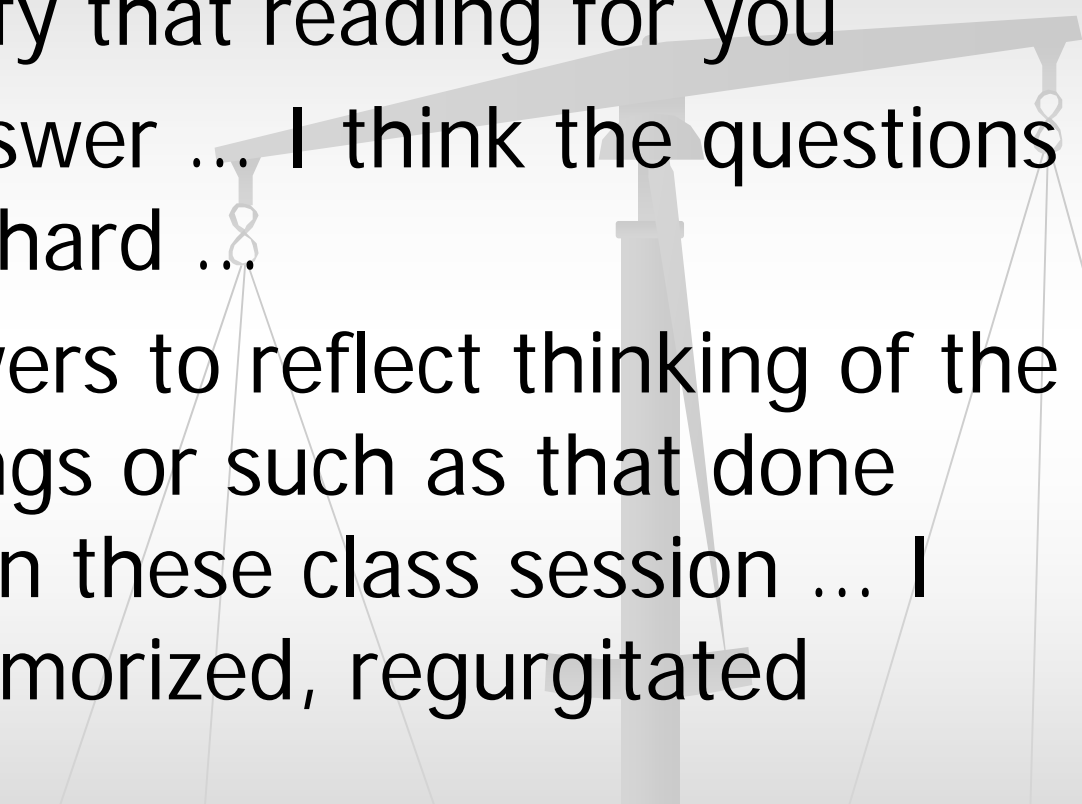
Law and Veterinary Medicine



Controlled Substances
December 8, 2006

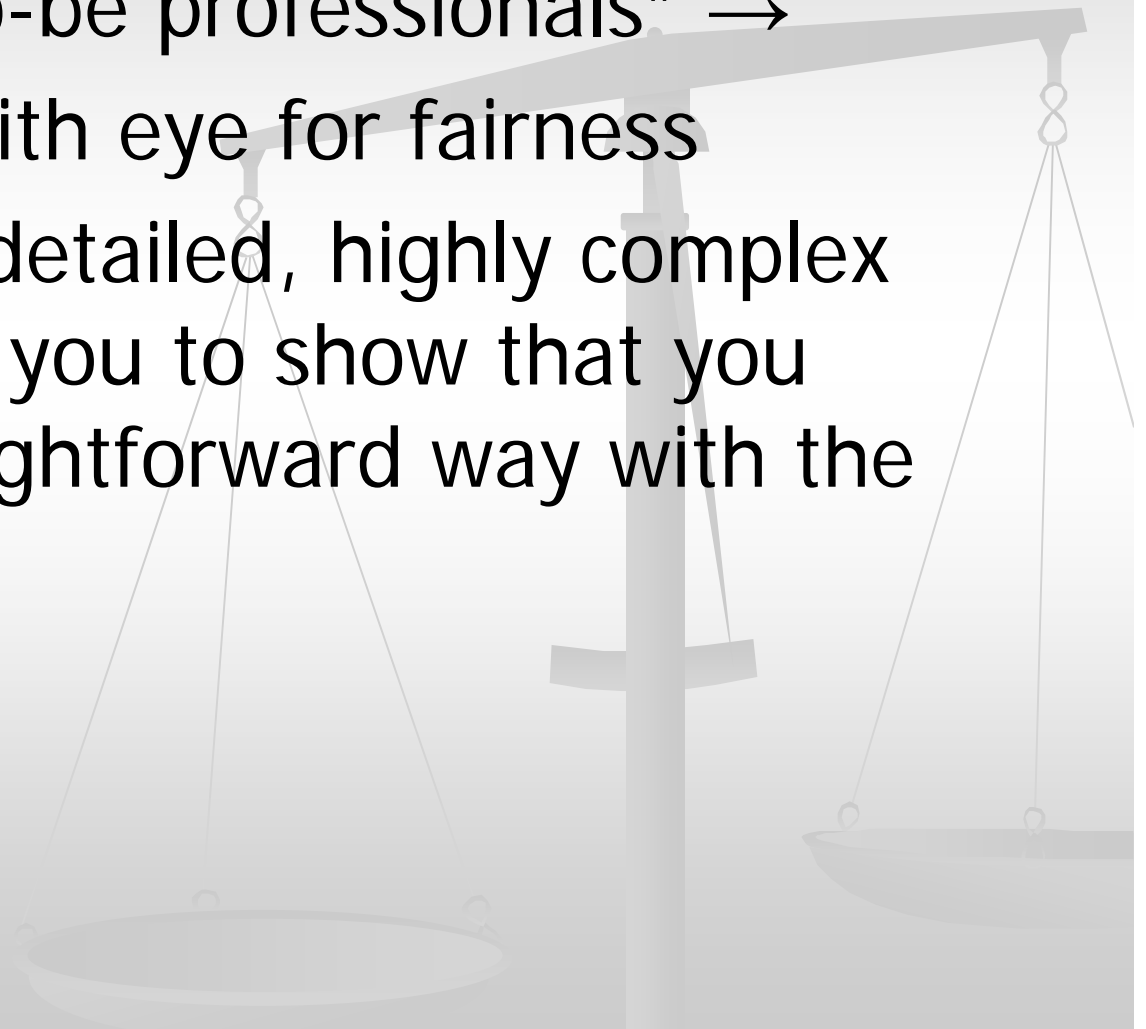
Paul Waldau, D.Phil., J.D.

Business

- Exam – if I want you to comment on a reading, I'll specify that reading for you
 - Exam is short-answer ... I think the questions will at first seem hard ...
 - I want your answers to reflect thinking of the kind in the readings or such as that done again and again in these class session ... I don't care for memorized, regurgitated answers
- 

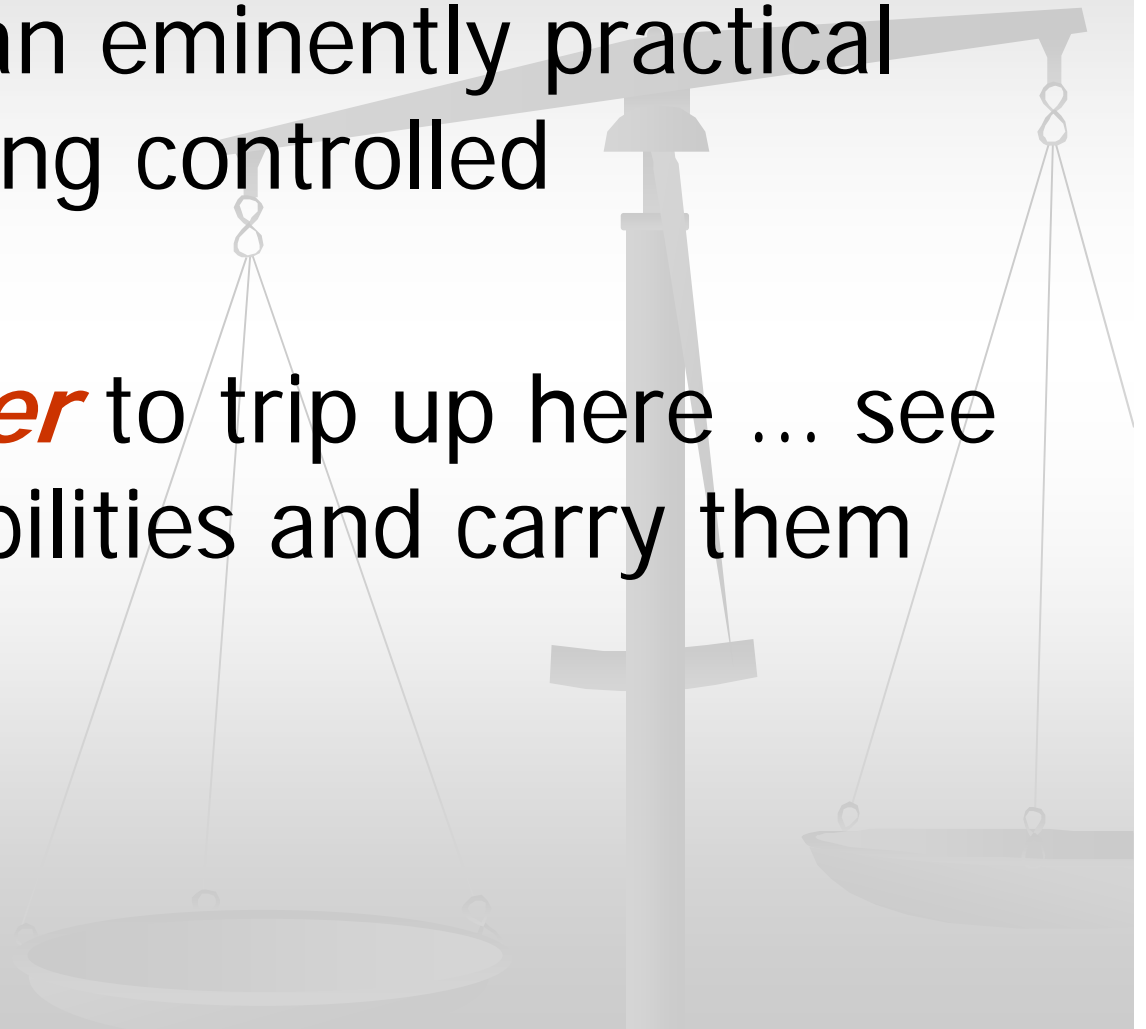
Business

- Because I know you aren't ethicists ... but instead "about-to-be professionals" →
- I grade lightly, with eye for fairness
- No need to give detailed, highly complex answers—I want you to show that you grapple in a straightforward way with the basic issues



Today's topic

- We end with an eminently practical topic ... handling controlled substances
- No reason *ever* to trip up here ... see your responsibilities and carry them out

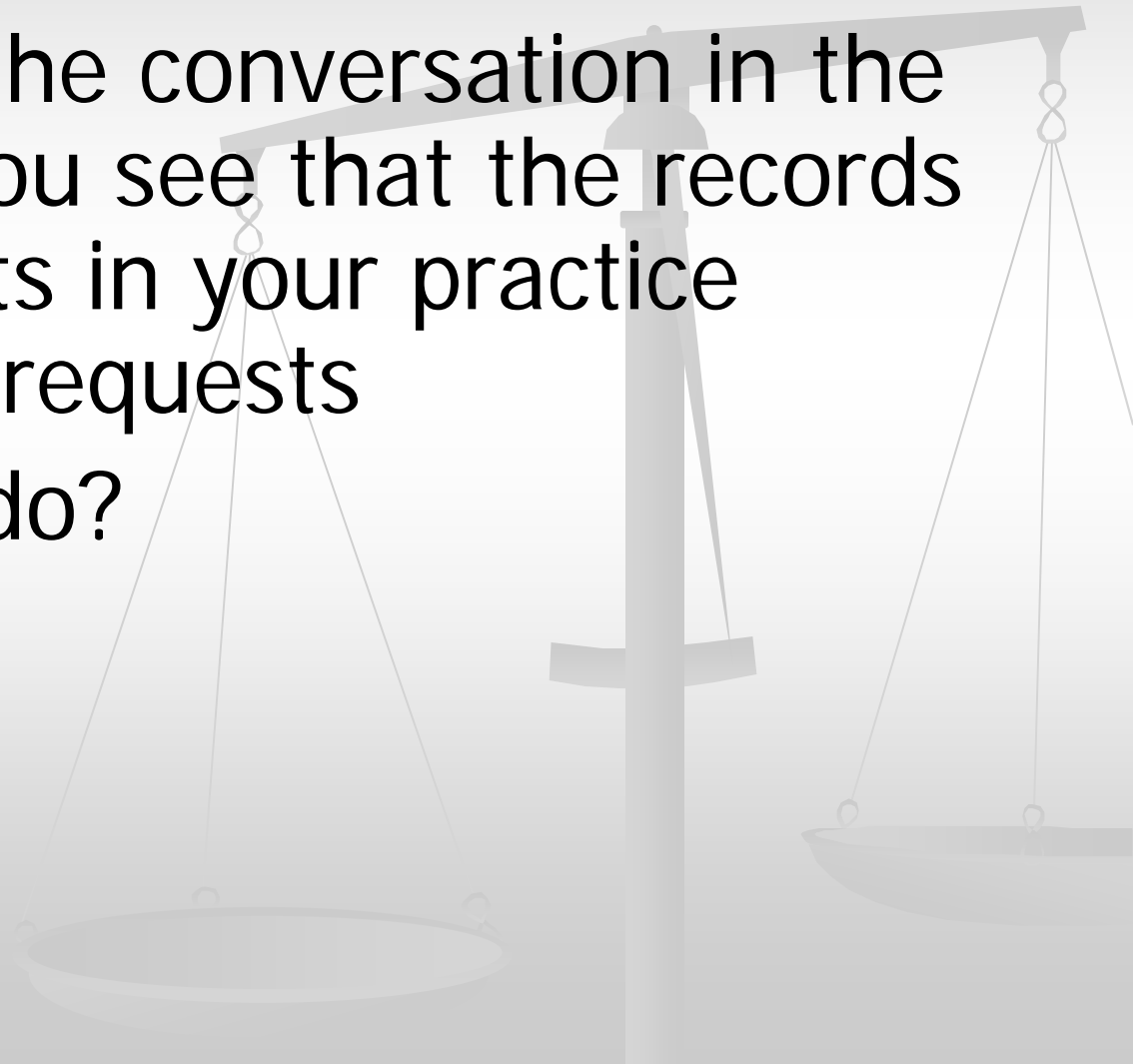


Hypo 1

- After surgery on the dog of a long-standing client, you prescribe a week's worth of a scheduled drug
- 3 days later, client tells you, "Can you refill the prescription. When struggling with the childproof cap, I spilled all but a few of the remaining pills down the sink." →

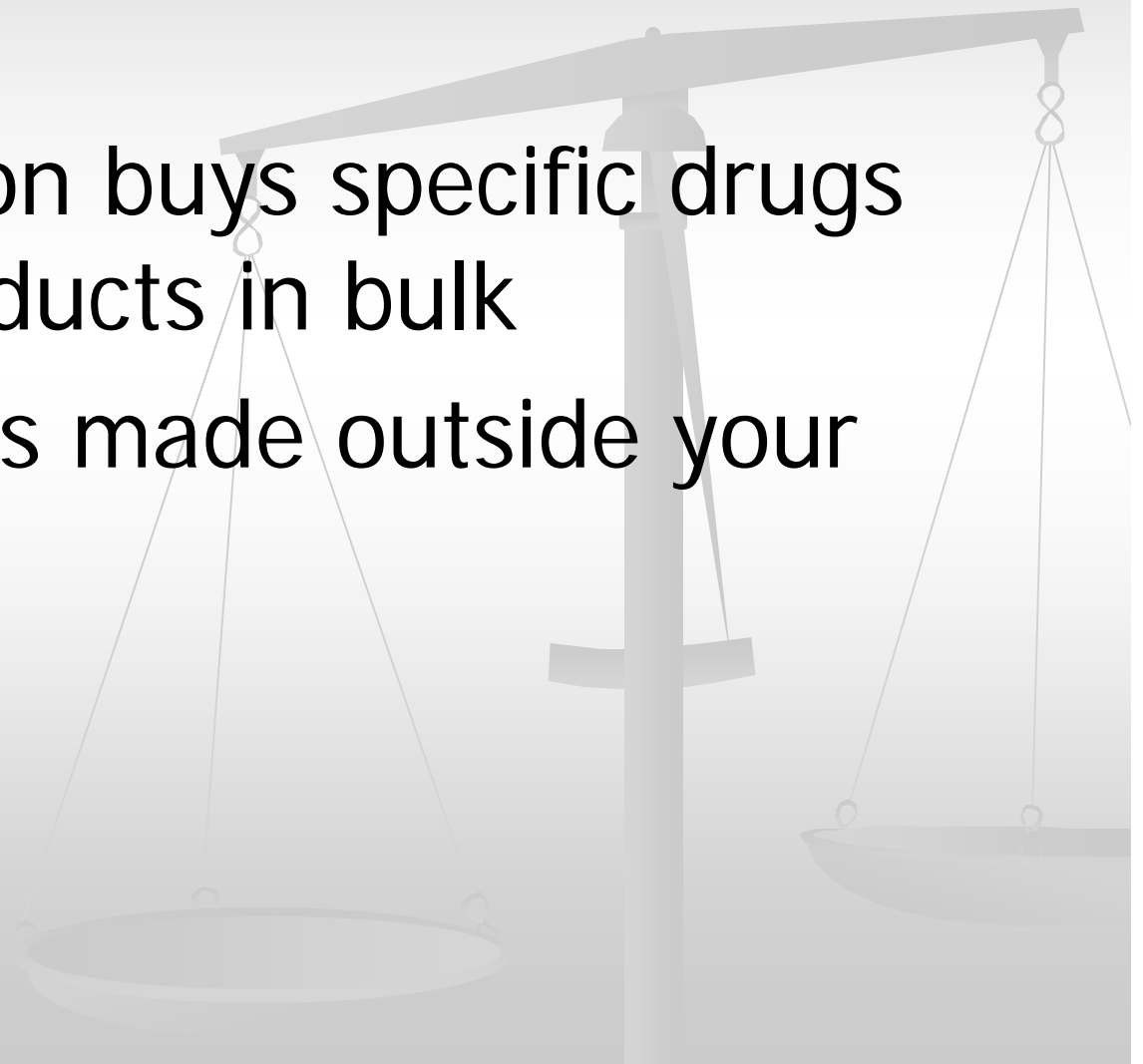
Hypo 1

- No reason to disbelieve
- When noting the conversation in the client chart, you see that the records from other vets in your practice reflect similar requests
- What do you do?



Hypo 2

- You work for a corporate veterinary practice
- The corporation buys specific drugs and other products in bulk
- This decision is made outside your office →



Hypo 2

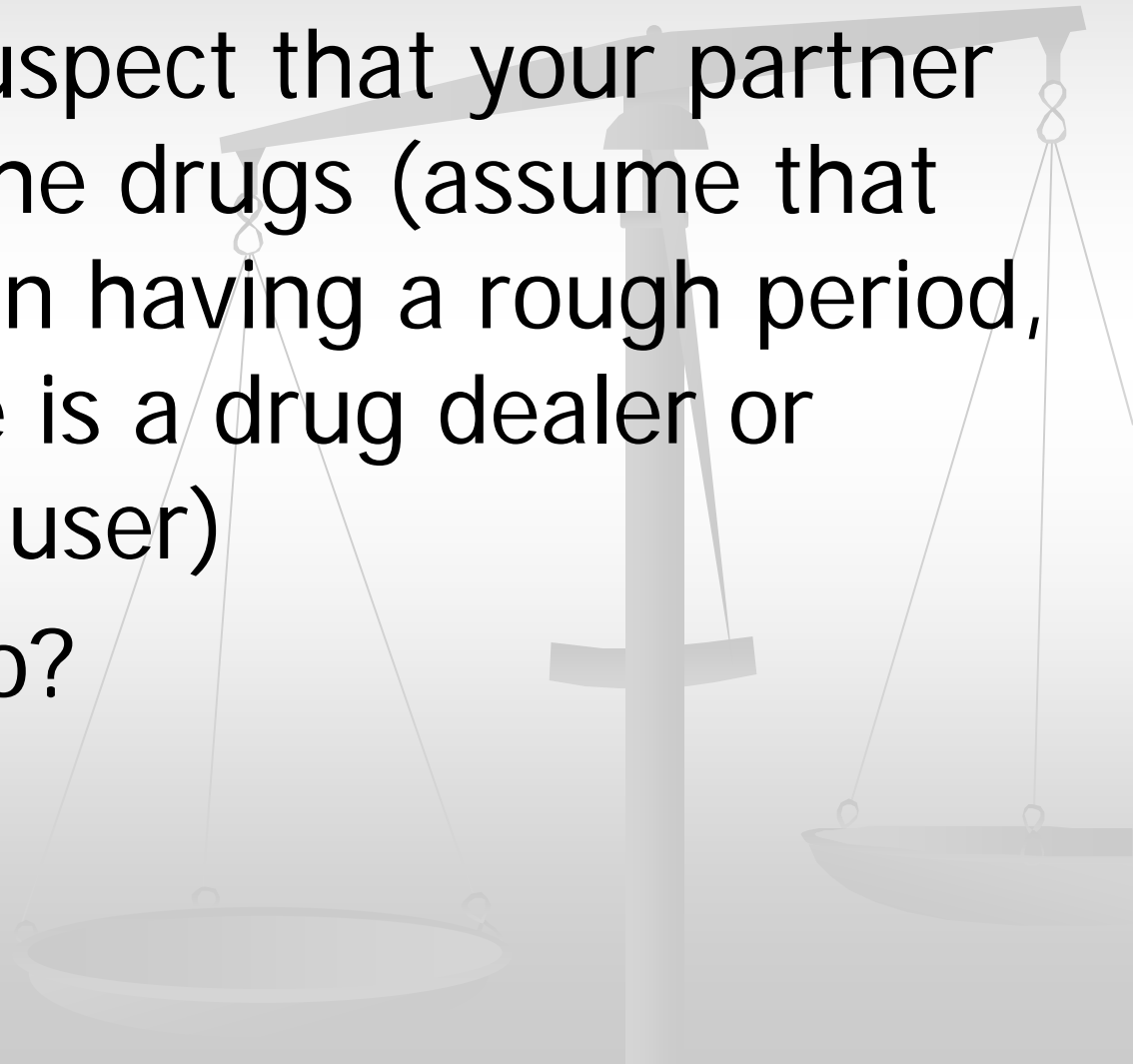
- What if, when treating a problem, you truly think there is a better drug for the problem, but that drug isn't one that the corporation buys in bulk?
- Should you recommend the competing product despite the corporation's policies of using the drugs purchased by the corporation in bulk?

Hypo 3

- You are an intern, and begin a personal relationship with a fellow intern
- You notice that your partner sometimes records specific drug doses on patient charts that are higher than those administered to the patient

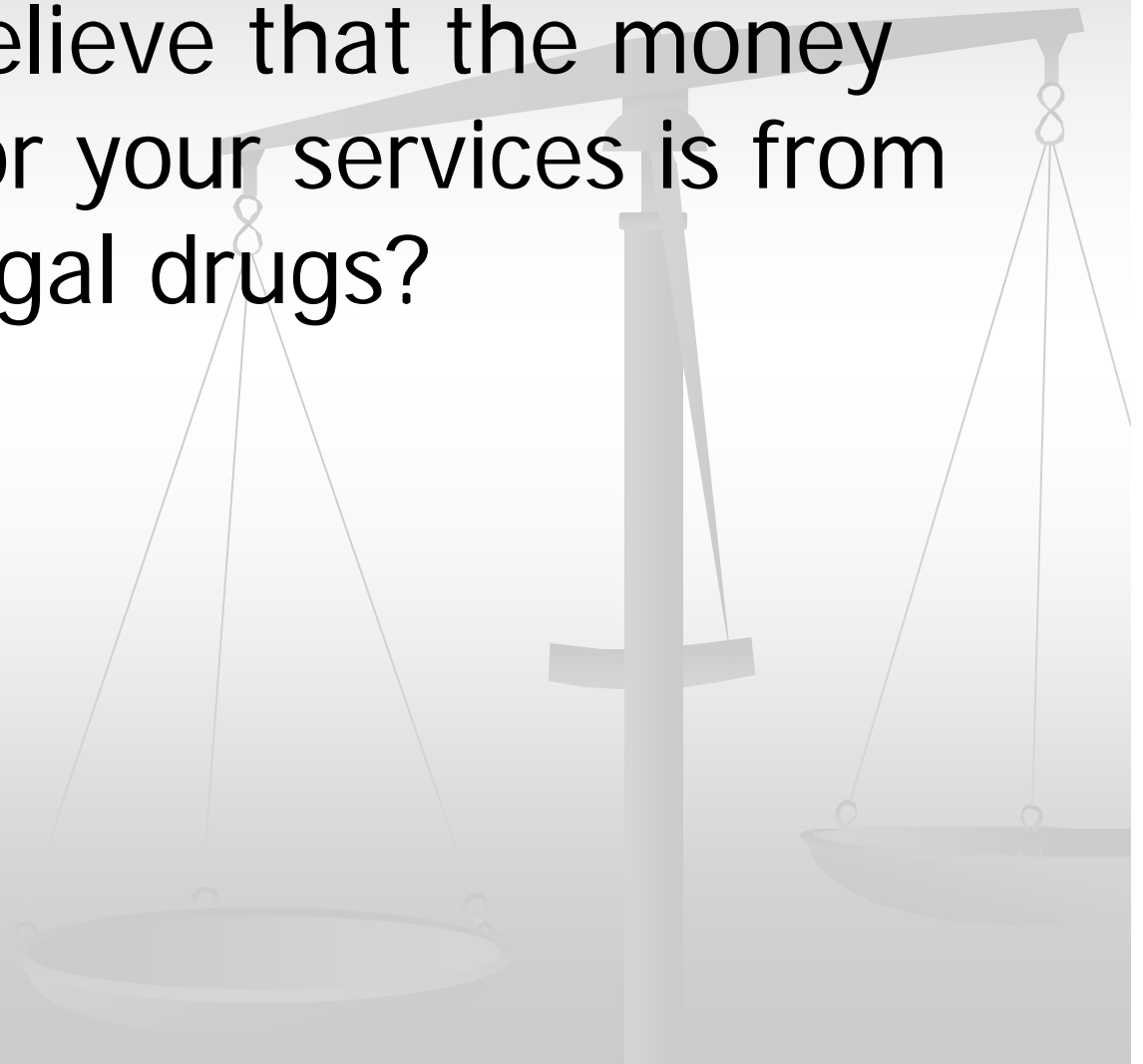
Hypo 3

- The drugs involved are all narcotics
- You begin to suspect that your partner may be using the drugs (assume that he/she has been having a rough period, not that he/she is a drug dealer or hardened drug user)
- What do you do?



Hypo 4

- What if you believe that the money used to pay for your services is from the sale of illegal drugs?

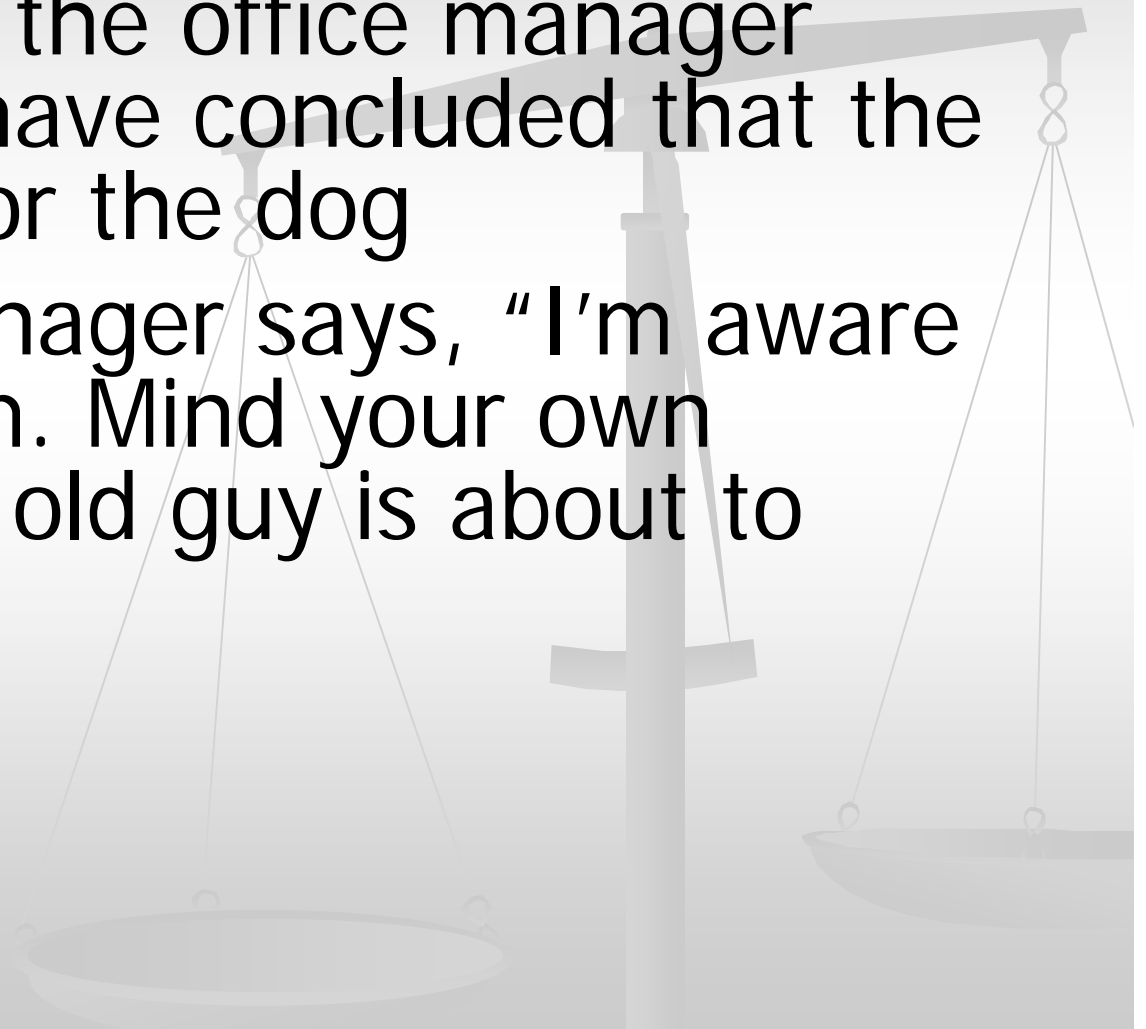


Hypo 5

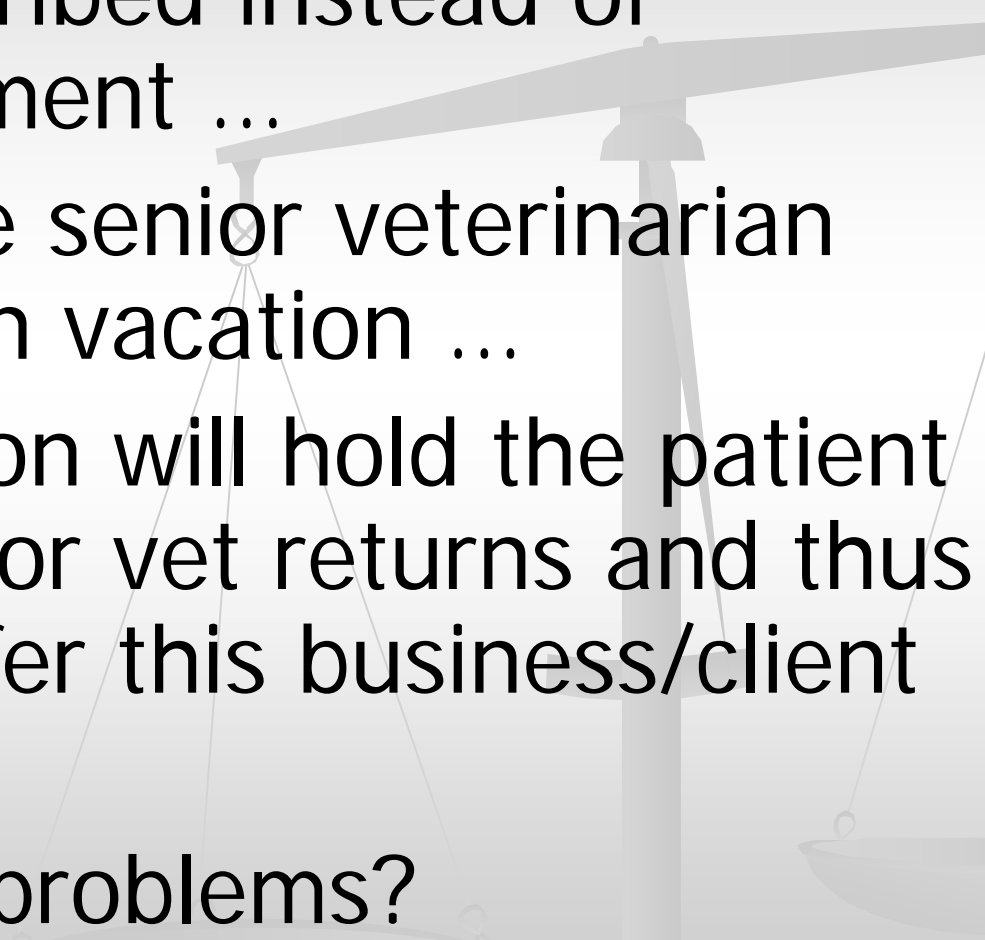
- After you are hired by an aging sole practitioner, you notice that the controlled substance logs for the practice are not accurate (say, the inventory doesn't match up)
- You also notice that the owner of the practice frequently prescribes 100 tabs of valium for his 15 year old Labrador Retriever

Hypo 5

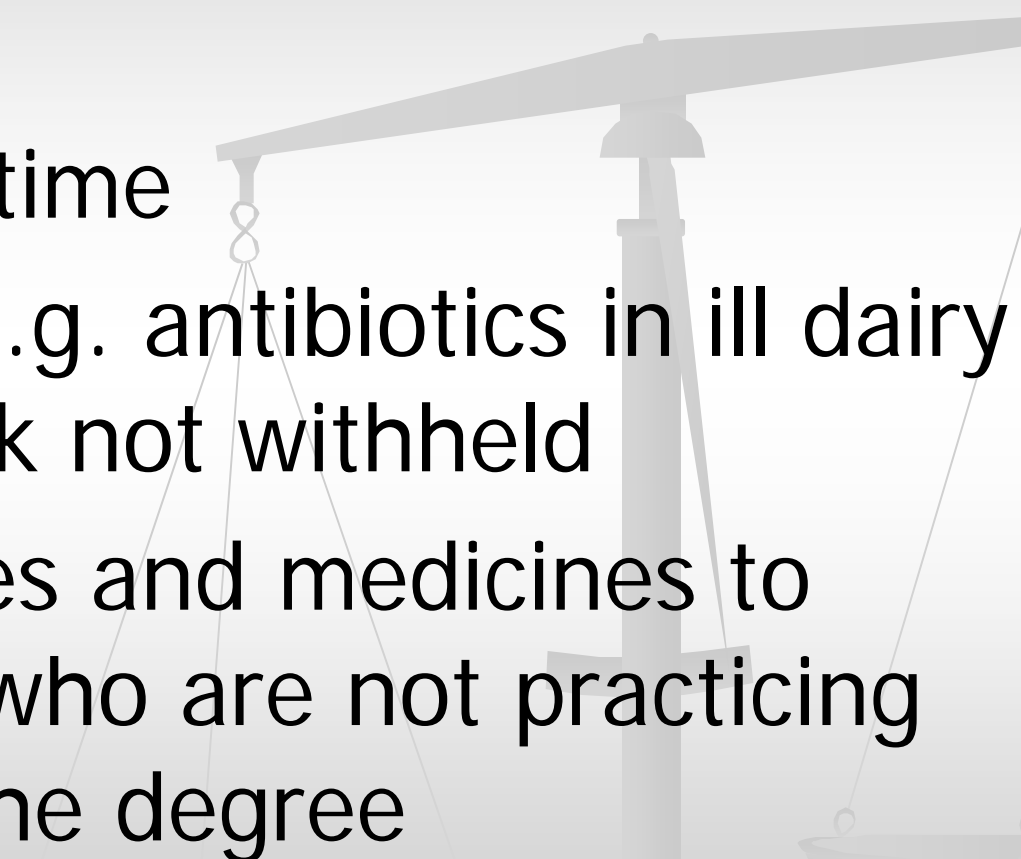
- You approach the office manager because you have concluded that the drugs aren't for the dog
- The office manager says, "I'm aware of the problem. Mind your own business. The old guy is about to retire"



Hypo 6

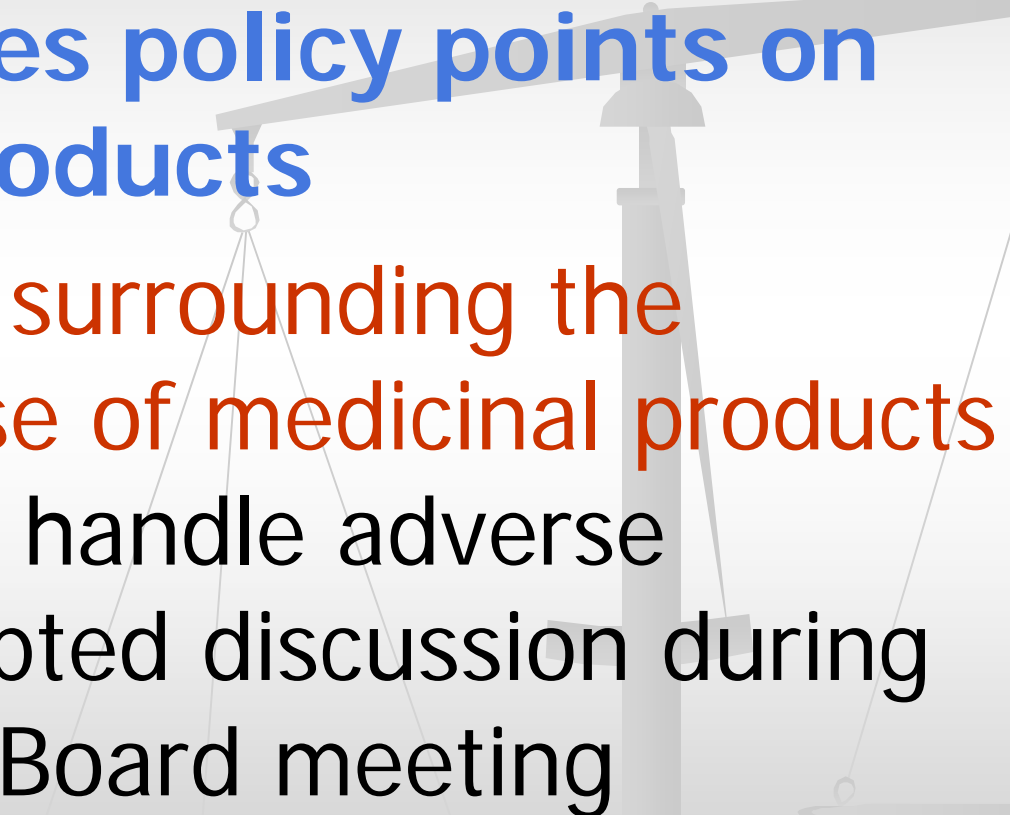
- Steroids prescribed instead of detailed treatment ...
 - ... because the senior veterinarian wants to go on vacation ...
 - The prescription will hold the patient over until senior vet returns and thus no need to refer this business/client elsewhere
 - What are the problems?
- 

Other areas of concern raised by students

- Antibiotics
 - Withdrawal time
 - Reporting, e.g. antibiotics in ill dairy cow and milk not withheld
 - Selling vaccines and medicines to veterinarians who are not practicing but still hold the degree
- 

JAVMA News

Medicinal products **May 15, 2006**

- **Board debates policy points on medicinal products**
 - **Thorny issues surrounding the appropriate use of medicinal products** — and how to handle adverse events—prompted discussion during the Executive Board meeting
- 

JAVMA News

Medicinal products May 15, 2006

- Board members postponed revising the policy on Human-Labeled Drug Products, Sale to Veterinarians. On recommendation of the Council on Biologic and Therapeutic Agents, the board adopted a new policy on Adverse Event Reporting, and revised the Guidelines for Veterinary Prescription Drugs and the Guidelines for Use of Autogenous Biologics.
- In postponing revisions to the policy on Human-Labeled Drug Products, the board requested input on liability issues on a **proposed new point** in the revision: **"Veterinarians bear full responsibility when using human-labeled prescription products in the treatment of animals."**

JAVMA News

Medicinal products May 15, 2006

- Dr. Bonnie V. Beaver, immediate past president of the AVMA, raised **legal concerns about the word “full” in front of the word “responsibility.”** She gave an **example of a bad batch of drugs being outside a veterinarian’s control.**
- In reference committee deliberations, **AVMA President Henry E. Childers** had said veterinarians bear full responsibility for all actions under their licensure.
- But Dr. Larry Kornegay, District VIII representative, said **product problems are always possible with prescriptions.** Dr. Guy Pidgeon, District I representative, added that **extralabel use always carries some risk.** The **Food and Drug Administration** has not substantiated the safety and efficacy of using human-labeled drugs in animals.
- Following discussion, Dr. Childers said the new point about full responsibility does make him a little nervous. The **board asked the staff to seek advice on the wording.**

Other points of discussion

- Other revisions to the policy on Human-Labeled Drug Products would describe why veterinarians need access to human-labeled prescription drugs, note that veterinarians usually seek human-labeled medications from distributors or suppliers rather than manufacturers, and acknowledge the passage of the Animal Medicinal Drug Use Clarification Act and the need to comply with AMDUCA regulations.

Other points of discussion

- The board went ahead with a new policy advocating stronger systems for reporting adverse events from use of medicinal products. The Council on Biologic and Therapeutic Agents wants to reduce the potential to falsely flag spurious events as cause for concern and reduce the potential to fail to detect unique subgroups at increased risk.
- **The council has been discussing pharmacovigilance** with the FDA Center for Veterinary Medicine and the Department of Agriculture's Center for Veterinary Biologics. The Animal Health Institute has working groups addressing the subject. At the council's recommendation, the board also adopted the following policy:

Other points of discussion

- ... The board approved revising the Guidelines for Veterinary Prescription Drugs, with one alteration to the council's suggestions.
- The revisions clarify that, according to federal regulations, a drug container must bear certain minimum information so people administering the drug have adequate directions in their hands when treating animals. But the board removed a sentence regarding additional instructions: "The animal owner must keep the additional instructions with the original drug container that has the attached label."
- Dr. Beaver said the requirement would be unrealistic, and it would mandate action by owners rather than veterinarians. Dr. James O. Cook, District V representative, said a requirement for veterinarians to tell owners to keep instructions may be appropriate—but would be another burden for veterinarians. The board voted to strike the sentence.

Summary/Warning from Wilson, 215

**“...the system and body of regulation
are now quite complex.”**

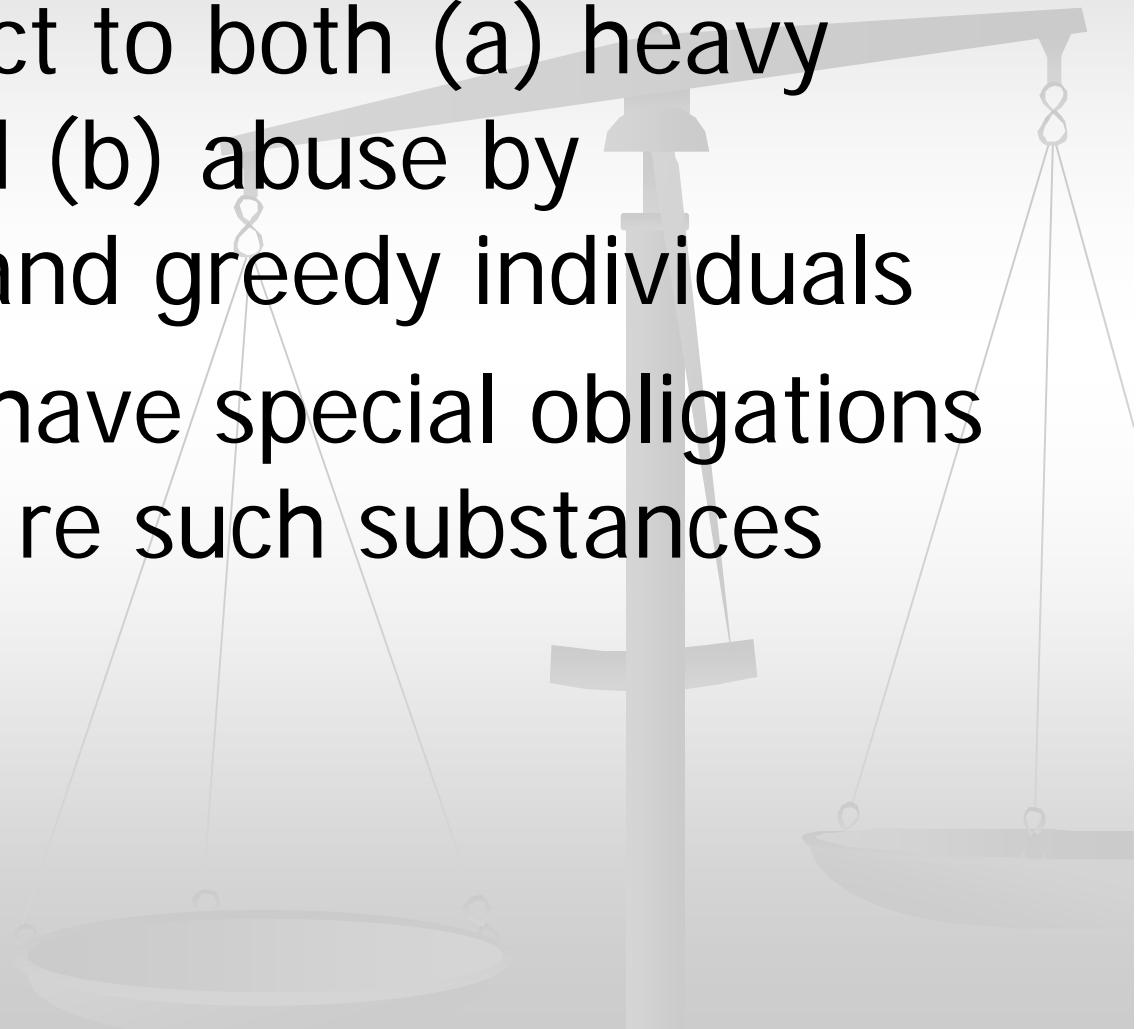


Your Obligation/Reading #5

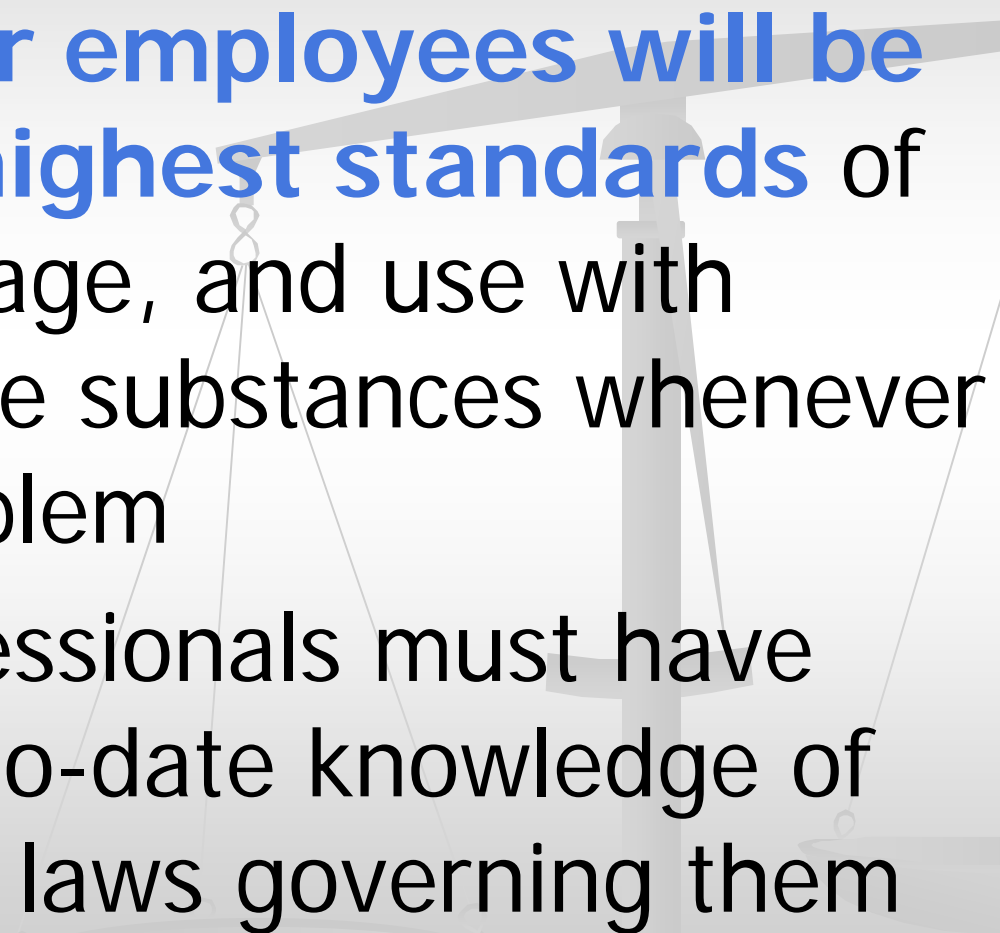
- JAVMA, November 1, 2001, "Negligence in use of medication and drugs"
- Listing of appeals court rulings that illustrate mistakes made by practitioners
- **Vaccine problems, dip/bath problems, administering internal medicine and vaccinations to herds, drug/medicine choices**
- **Class experience?**

Summary (1st reading) – Drugs as a Legal and Ethical Issue

- “Drugs” subject to both (a) heavy regulation and (b) abuse by irresponsible and greedy individuals
- Professionals have special obligations and privileges re such substances



Summary (1st reading) – Drugs as a Legal and Ethical Issue

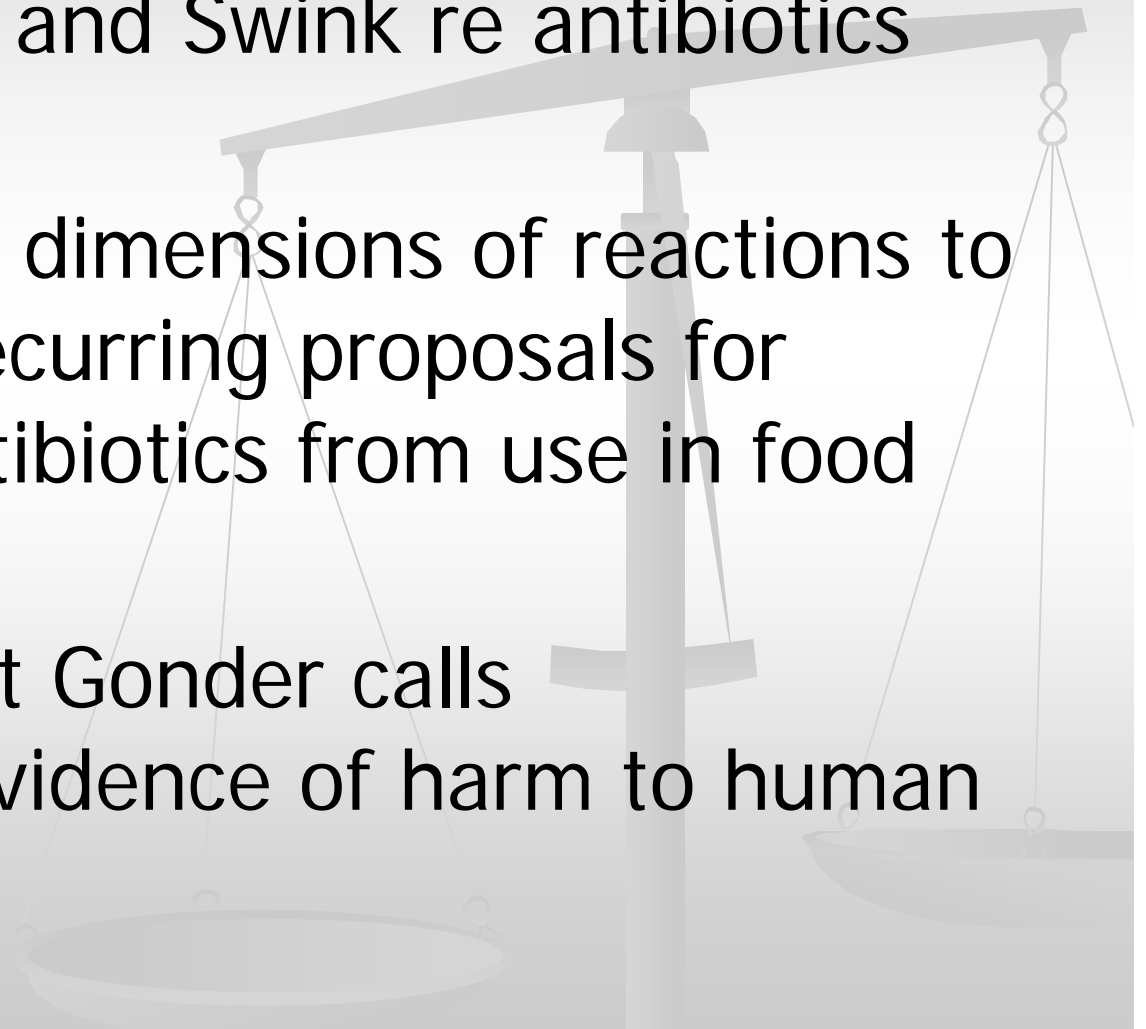
- **You and your employees will be held to the highest standards** of handling, storage, and use with regard to these substances whenever there is a problem
 - Licensed professionals must have technical, up-to-date knowledge of drugs and the laws governing them
- 

Summary (1st reading) – Drugs as a legal and ethical issue

- **Wilson 1993 has extensive materials** on the legal aspects of federal, state, and your profession's concern that drugs be used properly (in particular, see Chapters 9-11 for information on legal use of veterinary drugs, the law governing veterinary biologicals and pesticides, and provisions governing controlled substances generally).
- Profession's publications touch on veterinary use of drugs for any number of reasons (quality care, malpractice concerns).
- JAVMA has regular features
- Donald C. Plumb's *Veterinary Drug Handbook* – 4th edition has just been published by Iowa State Press

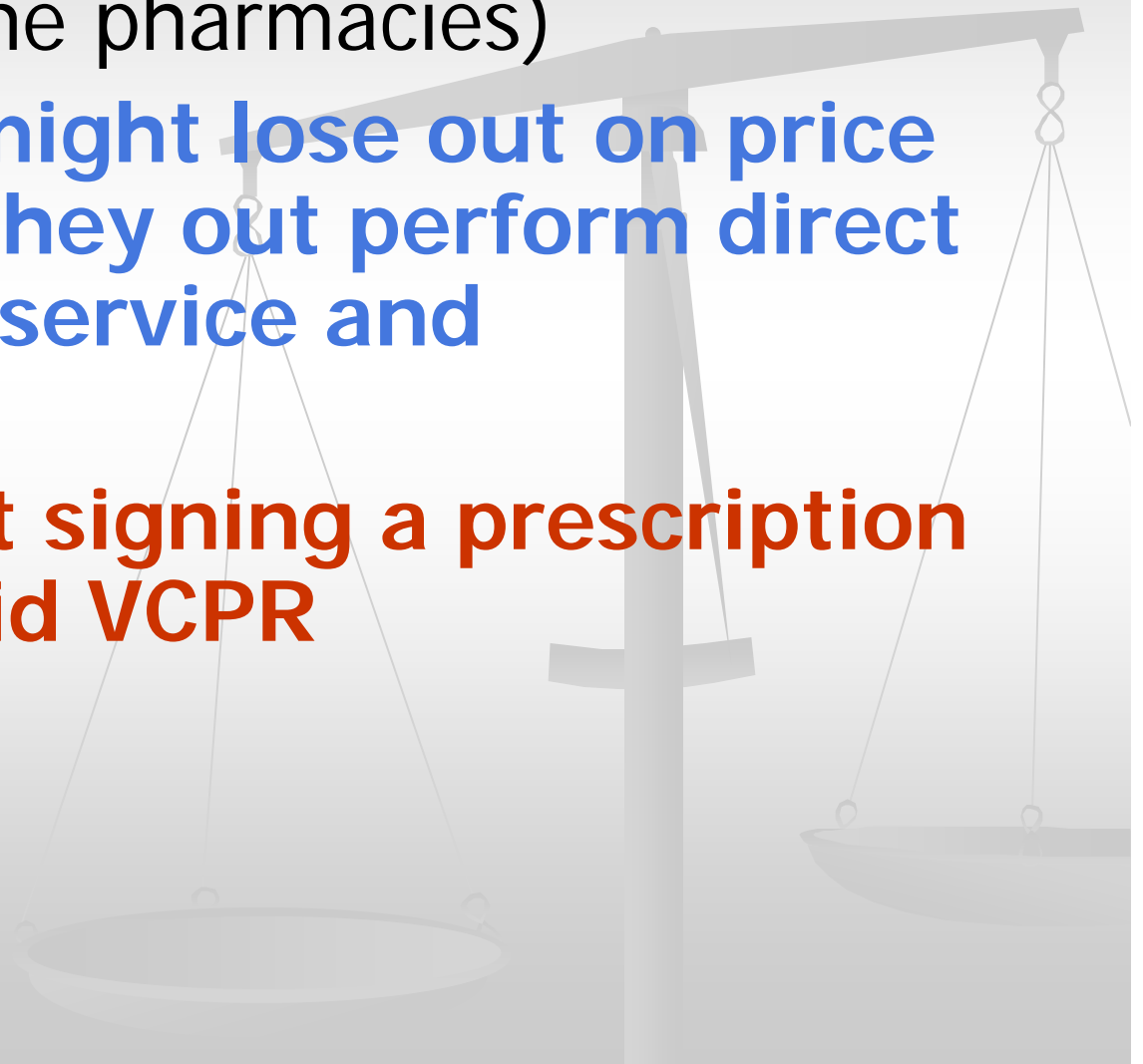
Reading #3

- JAVMA, July 15, 2006, at page 204, Letters to editor by Gonder and Swink re antibiotics withdrawal ...
- ... reflect political dimensions of reactions to and support of recurring proposals for withdrawal of antibiotics from use in food animals
- Debate over what Gonder calls “overwhelming evidence of harm to human health”



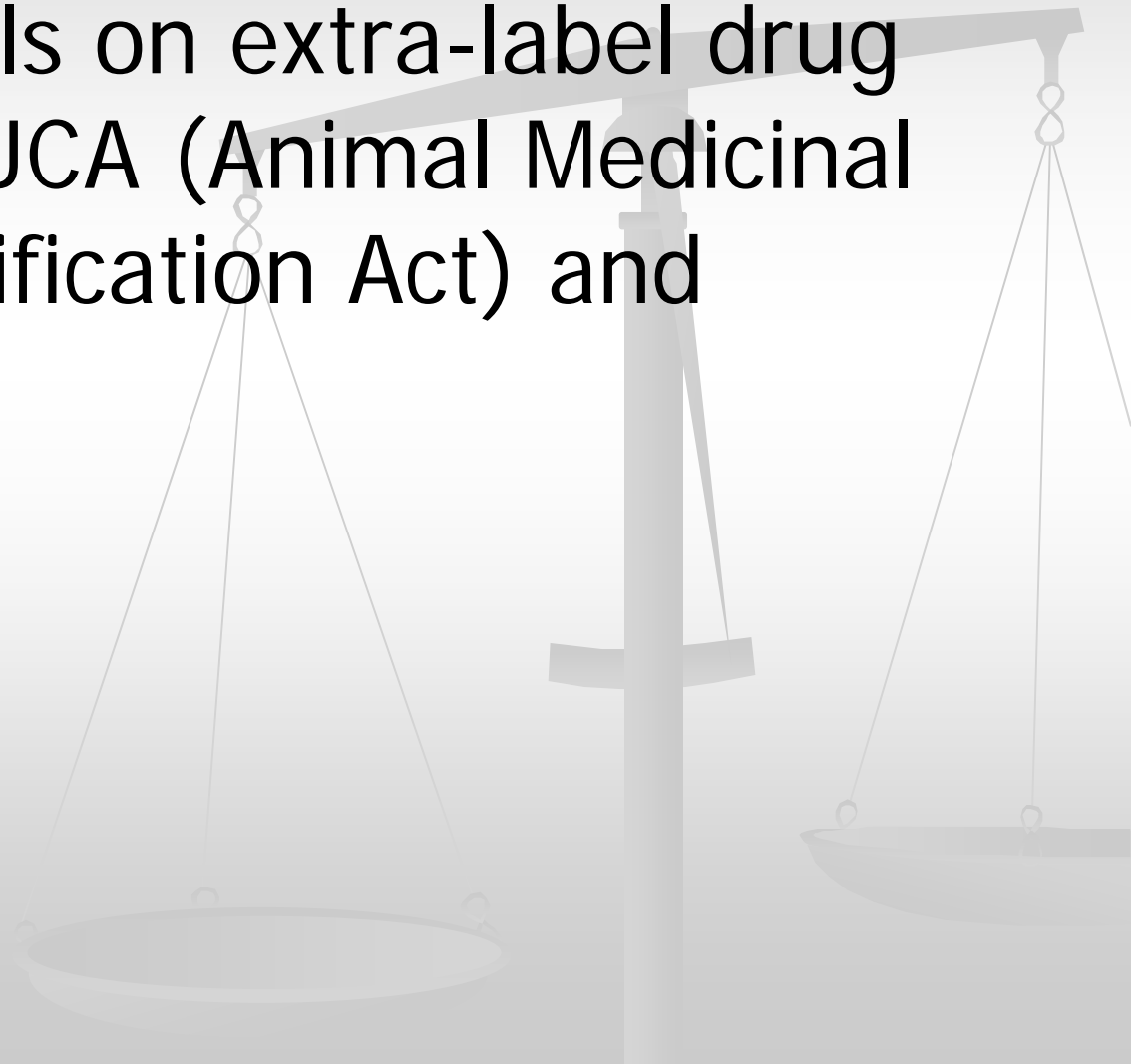
Reading #2

- “The Secrets to Fighting Big Pharmacies”
(deals with online pharmacies)
- **Though vets might lose out on price competition, they out perform direct marketers on service and convenience**
- **Reminder that signing a prescription requires a valid VCPR**



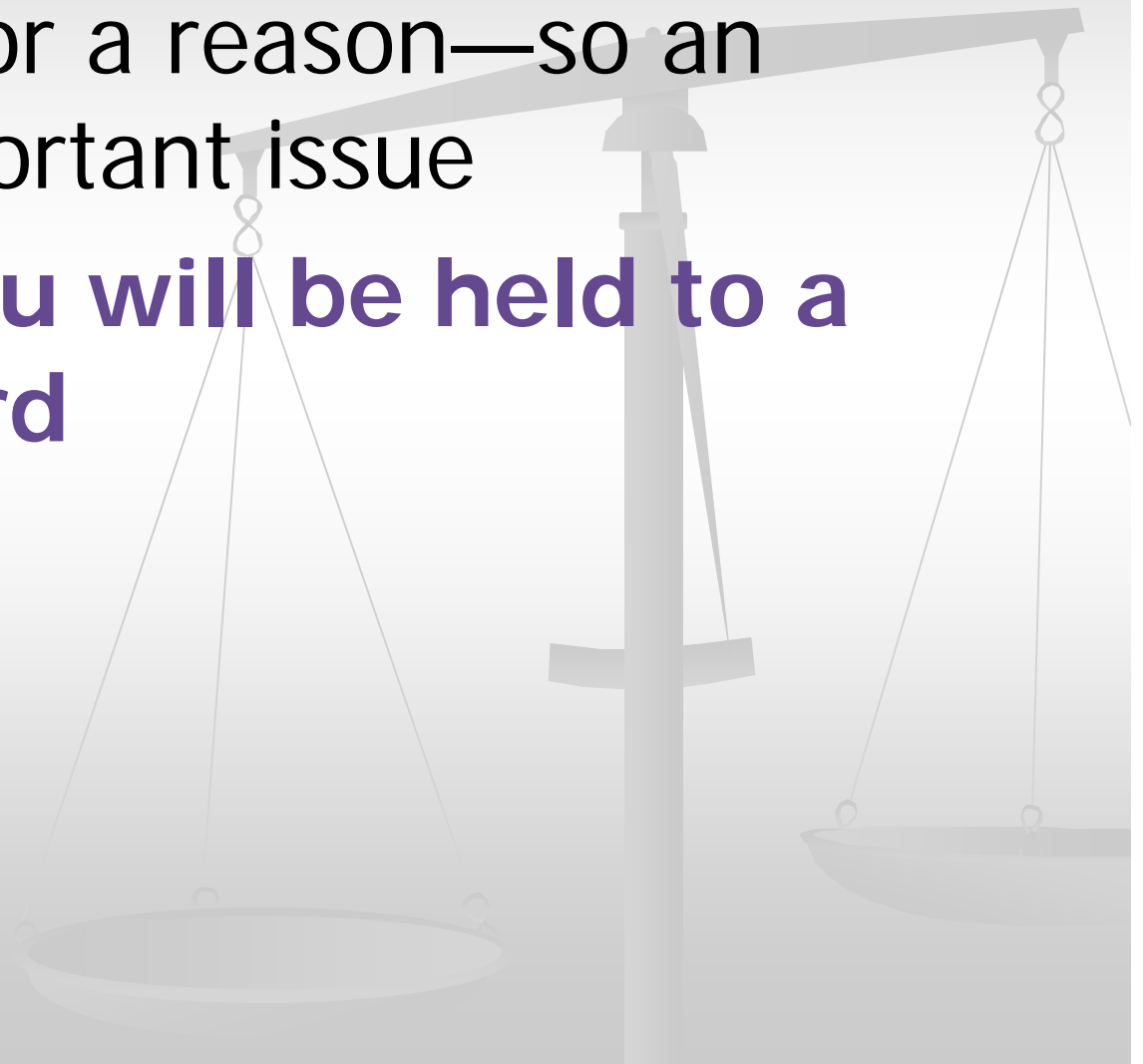
Reading #4

- AVMA materials on extra-label drug use and AMDUCA (Animal Medicinal Drug Use Clarification Act) and compounding



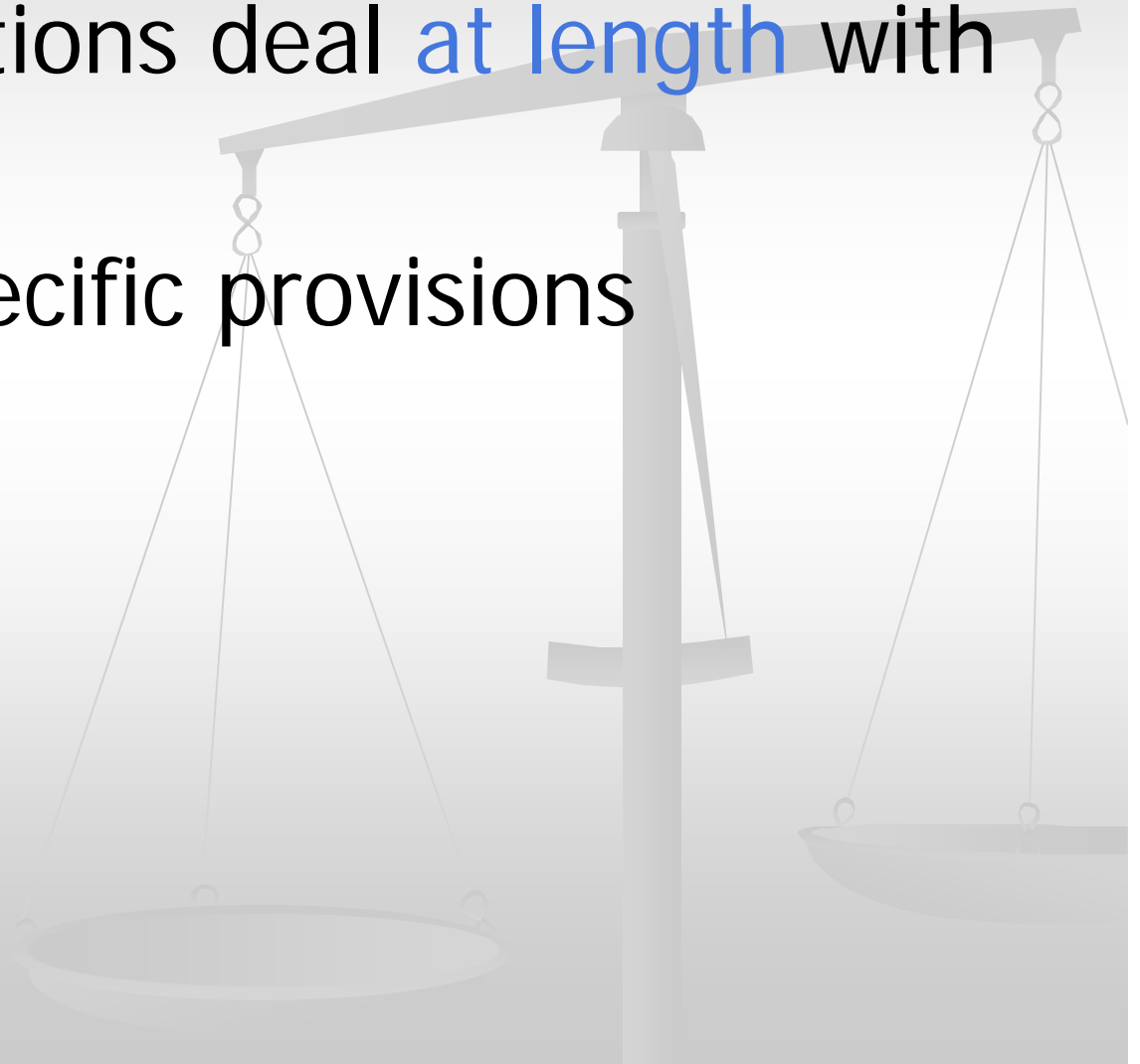
Basics on controlled substances

- “Controlled” for a reason—so an obviously important issue
- Practically, **you will be held to a high standard**

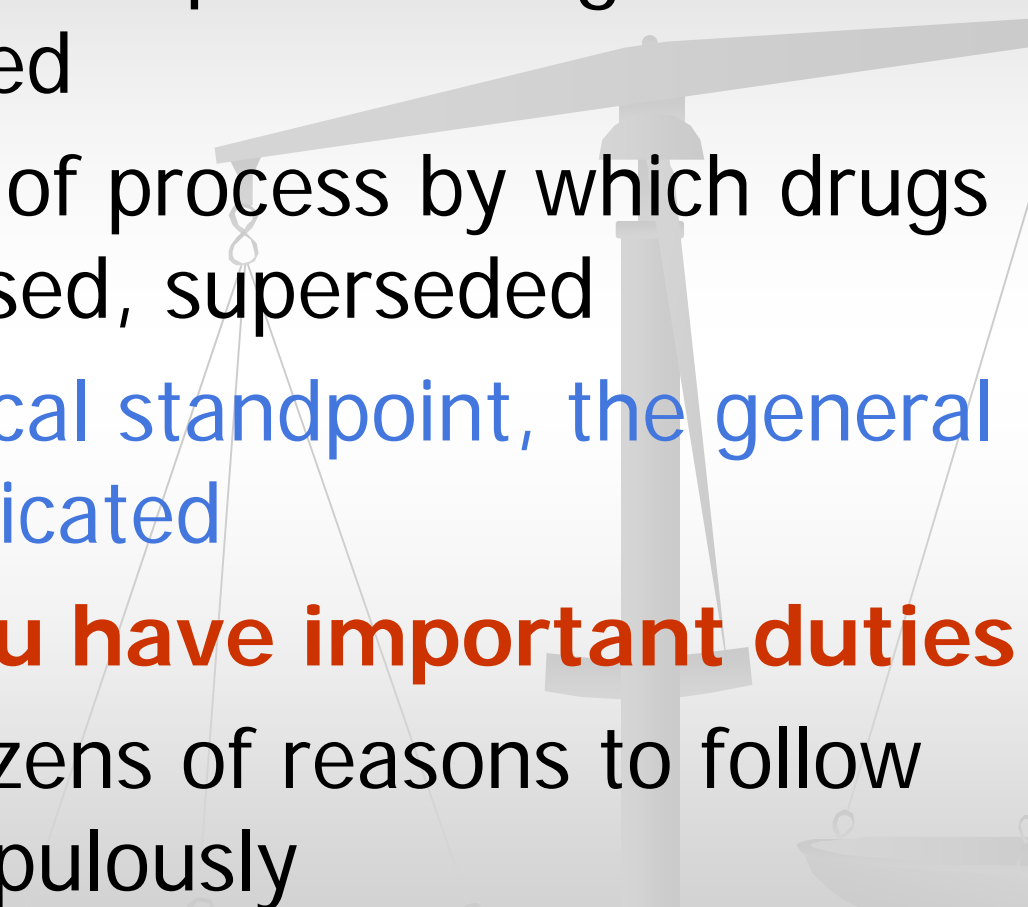


Signals

- States' regulations deal **at length** with this issue
- PVME has specific provisions

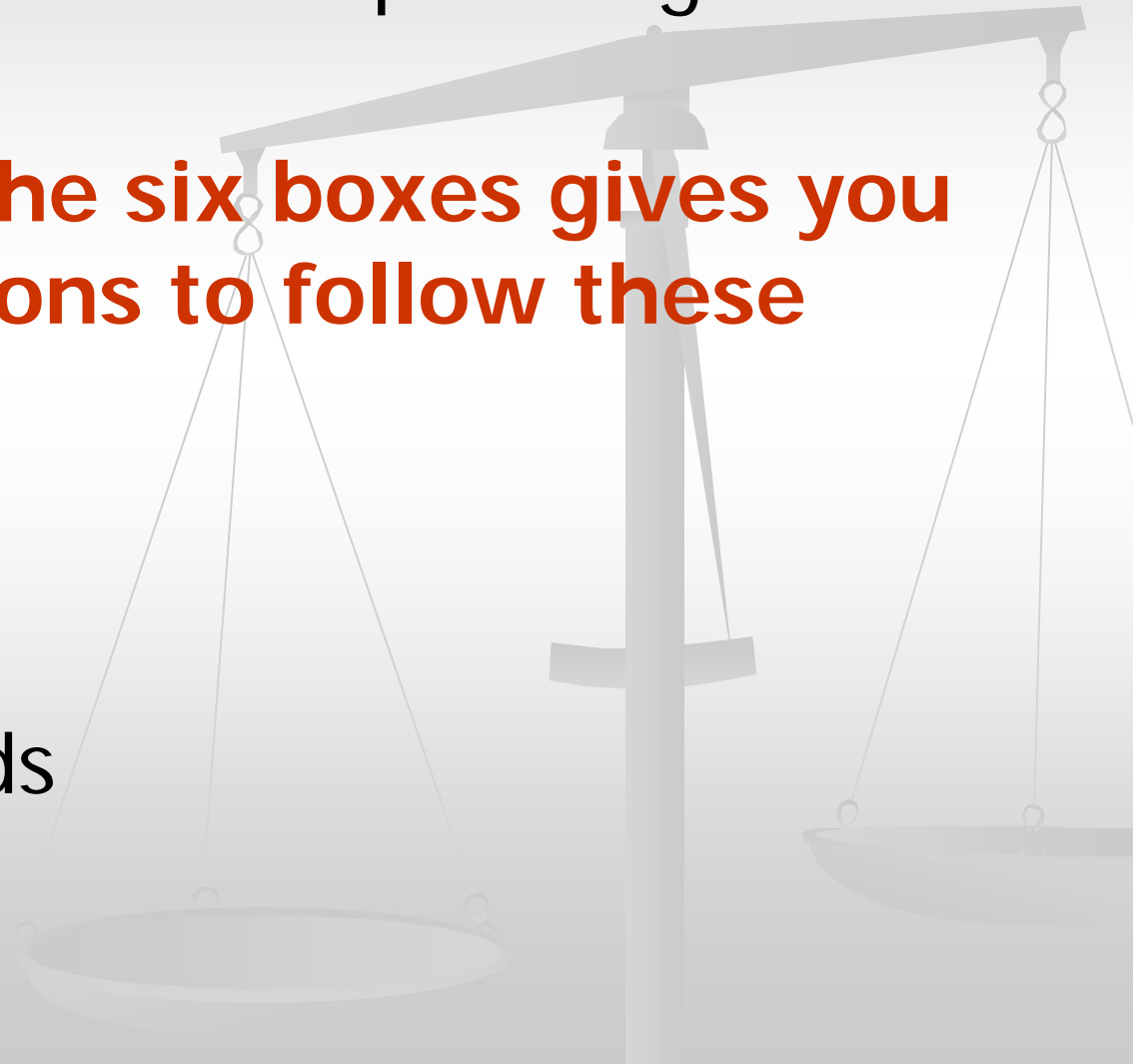


Technical features

- At one level—that of specific drugs—this area is complicated
 - Must stay on top of process by which drugs are developed, used, superseded
 - **But** from an ethical standpoint, the general area is not complicated
 - **Simply said, you have important duties**
 - And you have dozens of reasons to follow those duties scrupulously
- 

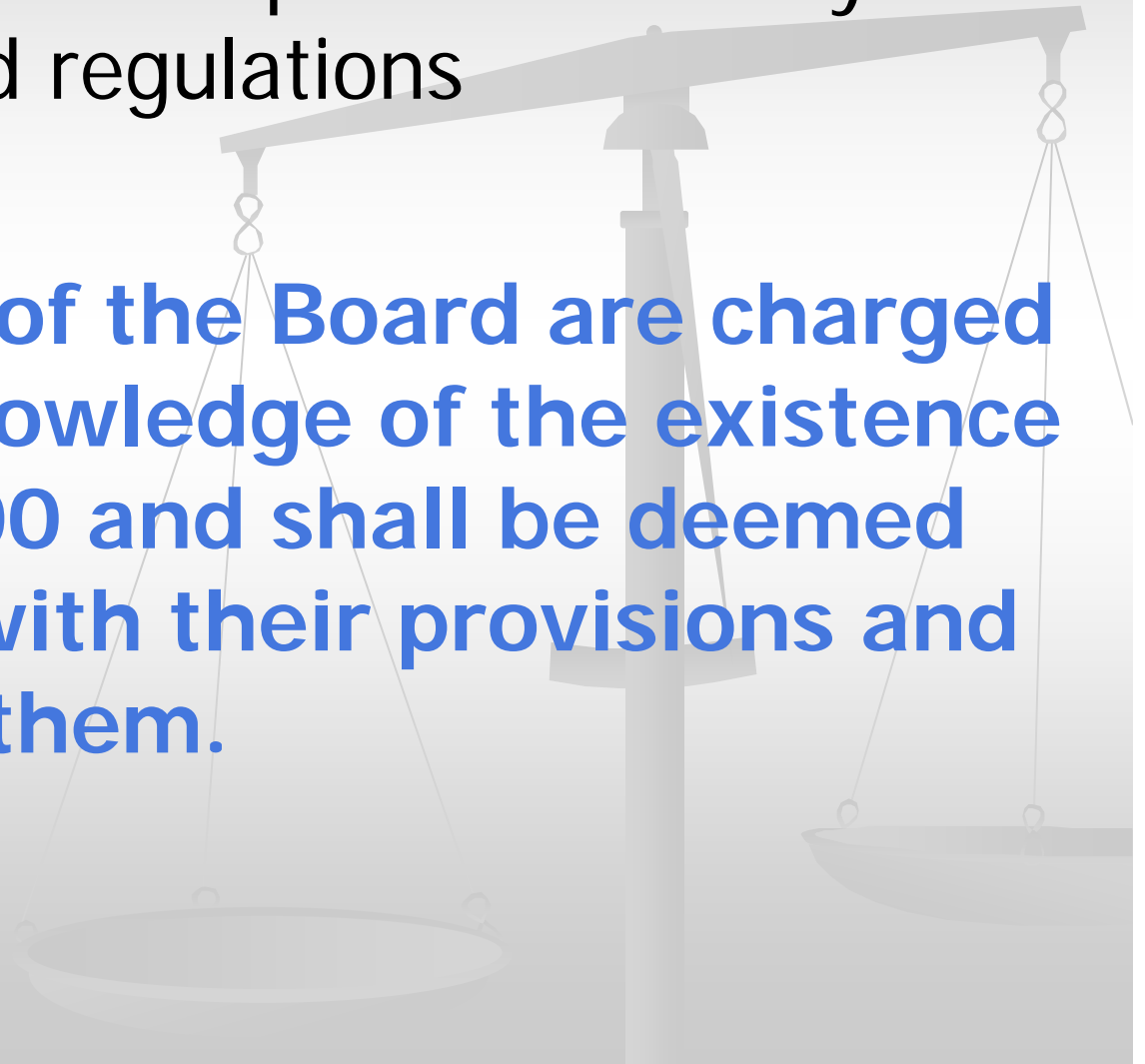
The six boxes

- A case of complete overlap among the boxes
- **Every one of the six boxes gives you powerful reasons to follow these rules**
- Law
- Prudence
- Ethics of all kinds




A presumption

- Your state practice acts presumes that you know the law and regulations
- MA Regs **2.01**
- ... **all licensees of the Board are charged with having knowledge of the existence of 256 CMR 2.00 and shall be deemed to be familiar with their provisions and to understand them.**

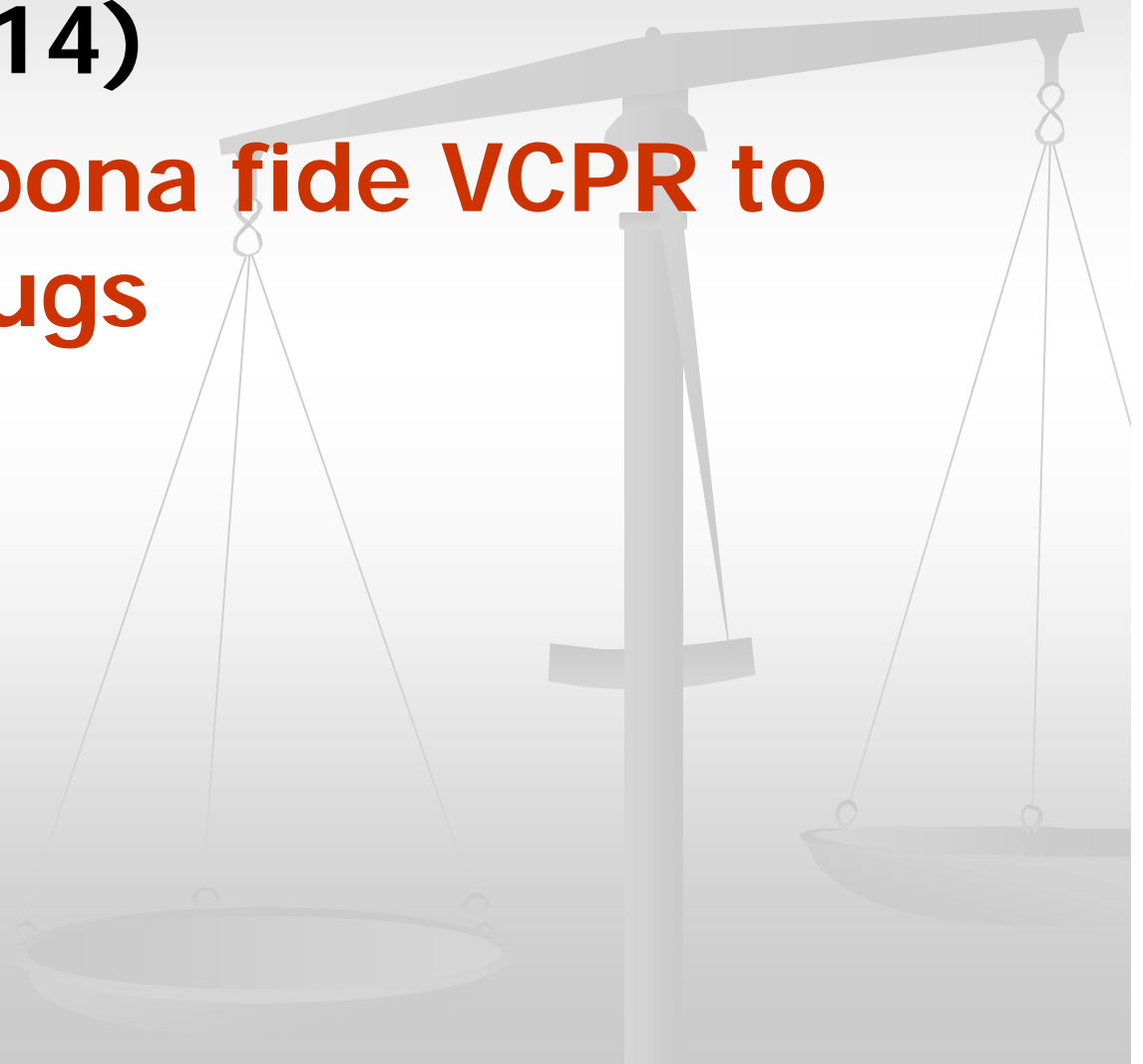


Mass Regs in the syllabus

- **5.02: Drugs and Medications**
 - A veterinarian shall **comply with all of the following requirements** for the handling, dispensing and administering of drugs and medications:
- 

Another crucial state regulation

- Mass Regs 7(14)
- **You need a bona fide VCPR to prescribe drugs**

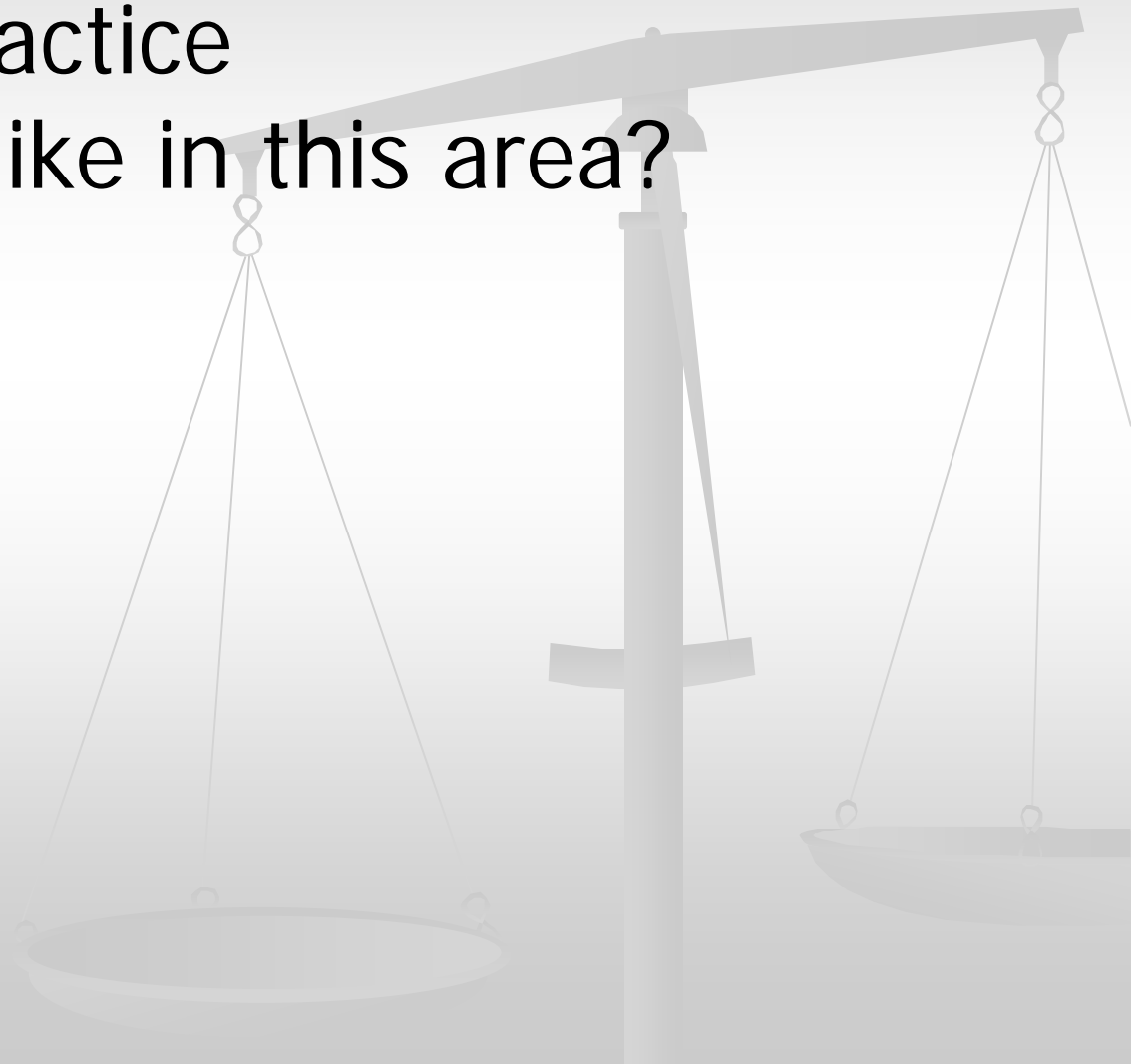


PVME—Unusual detail

- Section XI
- Legend drugs = veterinary prescription drugs (XI 1. E), which is “a drug restricted by federal law to use by or on the order of a licensed veterinarian, according to section 503(f) of the federal Food, Drug and Cosmetic Act. The law requires that such drugs be labeled with the statement: Caution, federal law restricts this drug to use by or on the order of a licensed veterinarian.
- OTC drugs – can be labeled with adequate direction to enable it to be used safely and properly by a consumer who is not a medical professional
- Prescription Drug: cannot be labeled with adequate direction to enable its safe and proper use by non-professionals
- “Prescribing” is defined as “the transmitting of an order authorizing a licensed pharmacist or equivalent to prepare and dispense specified pharmaceuticals to be used in or on animals in the dosage and in the manner directed by a veterinarian.”

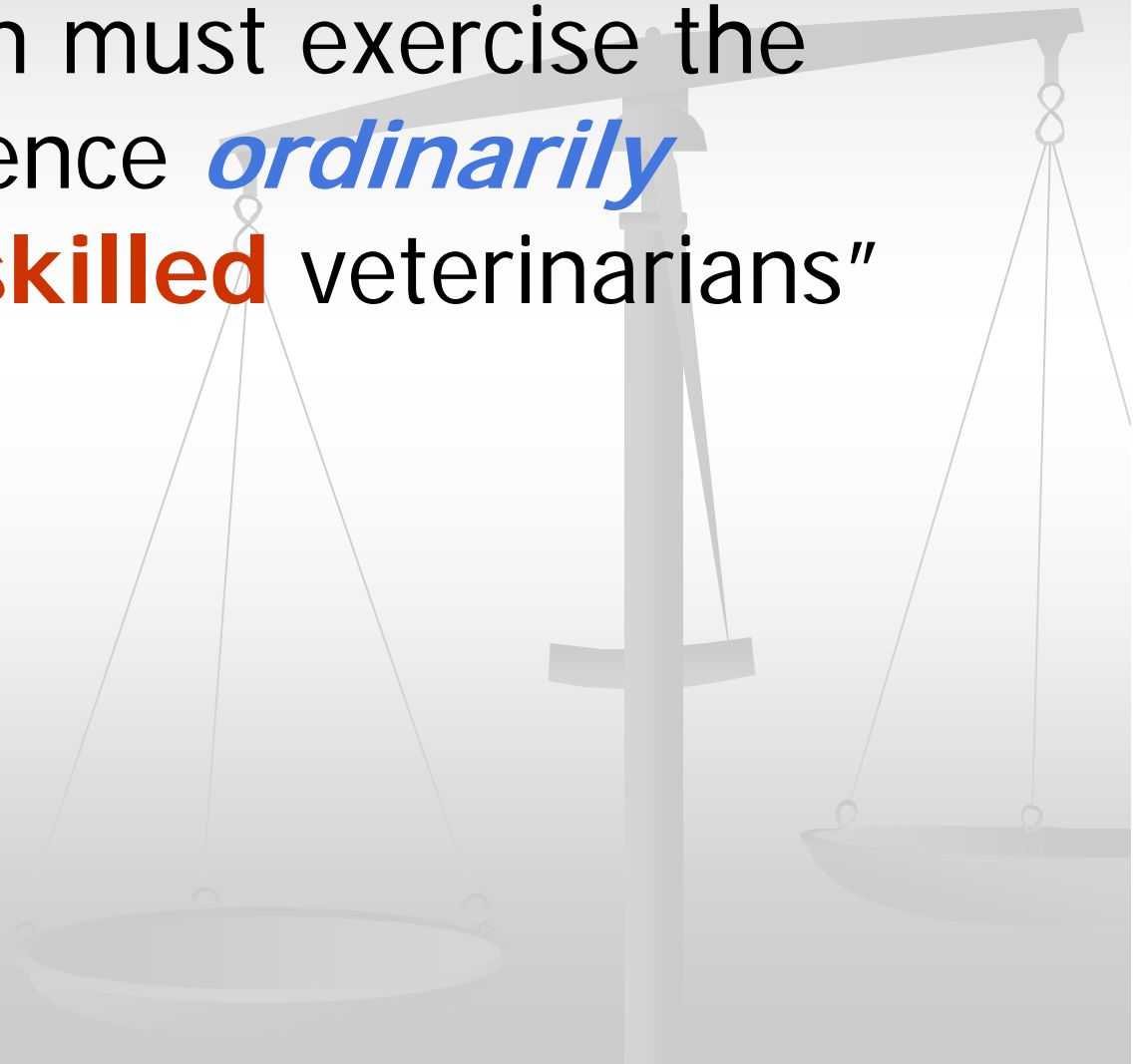
Basic questions ...

- What is malpractice going to look like in this area?



Malpractice standard

- “A veterinarian must exercise the care and diligence *ordinarily* exercised by **skilled** veterinarians”



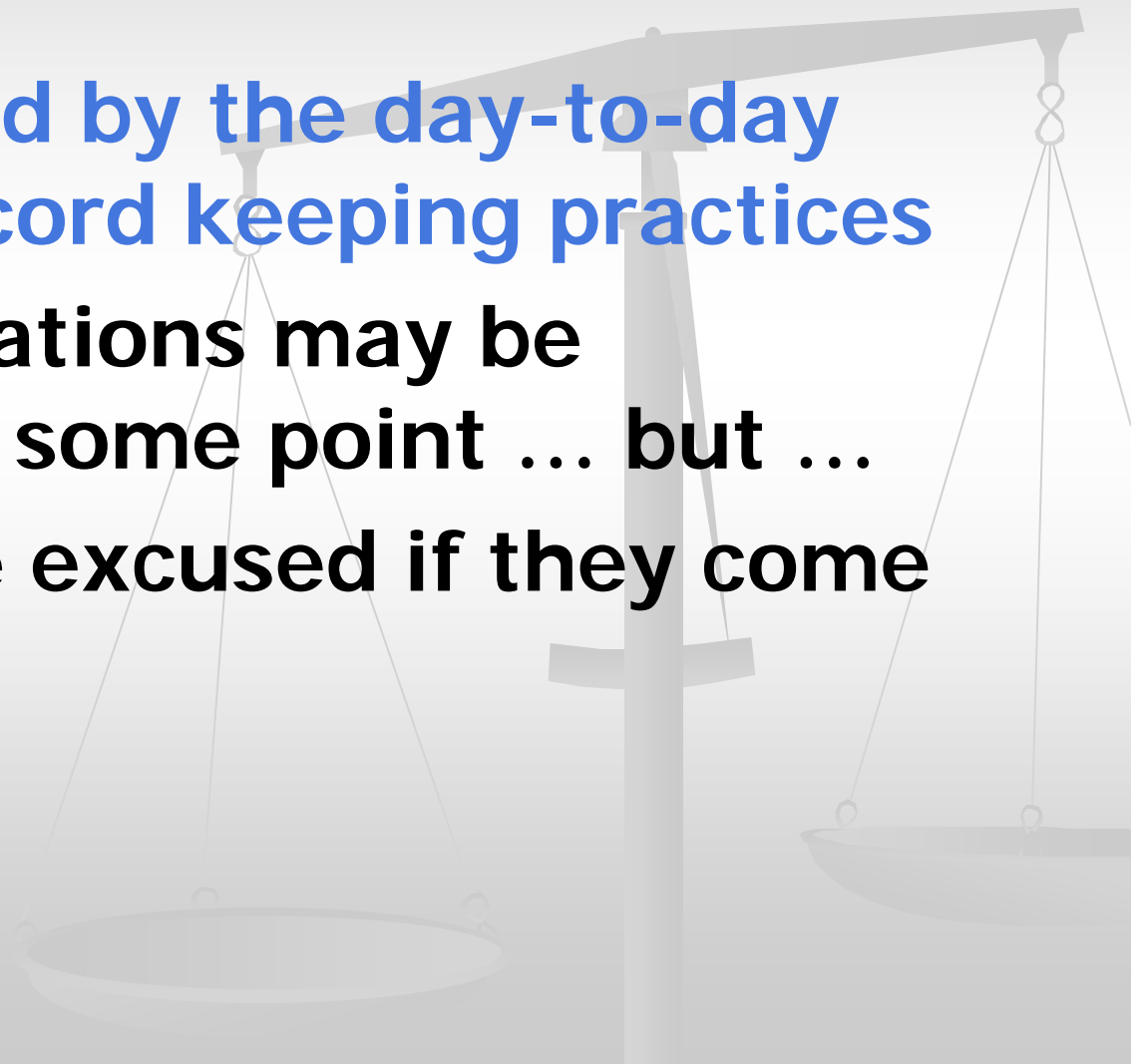
Basic questions ...

- What is a regulatory violation going to look like?



Be careful with “ordinary practices”

- Don't be fooled by the day-to-day realities of record keeping practices
- Technical violations may be overlooked at some point ... but ...
- They **won't** be excused if they come to light



Standard applicable to you ...

this is one area that you will be held to

... the highest standard

... the letter of the law



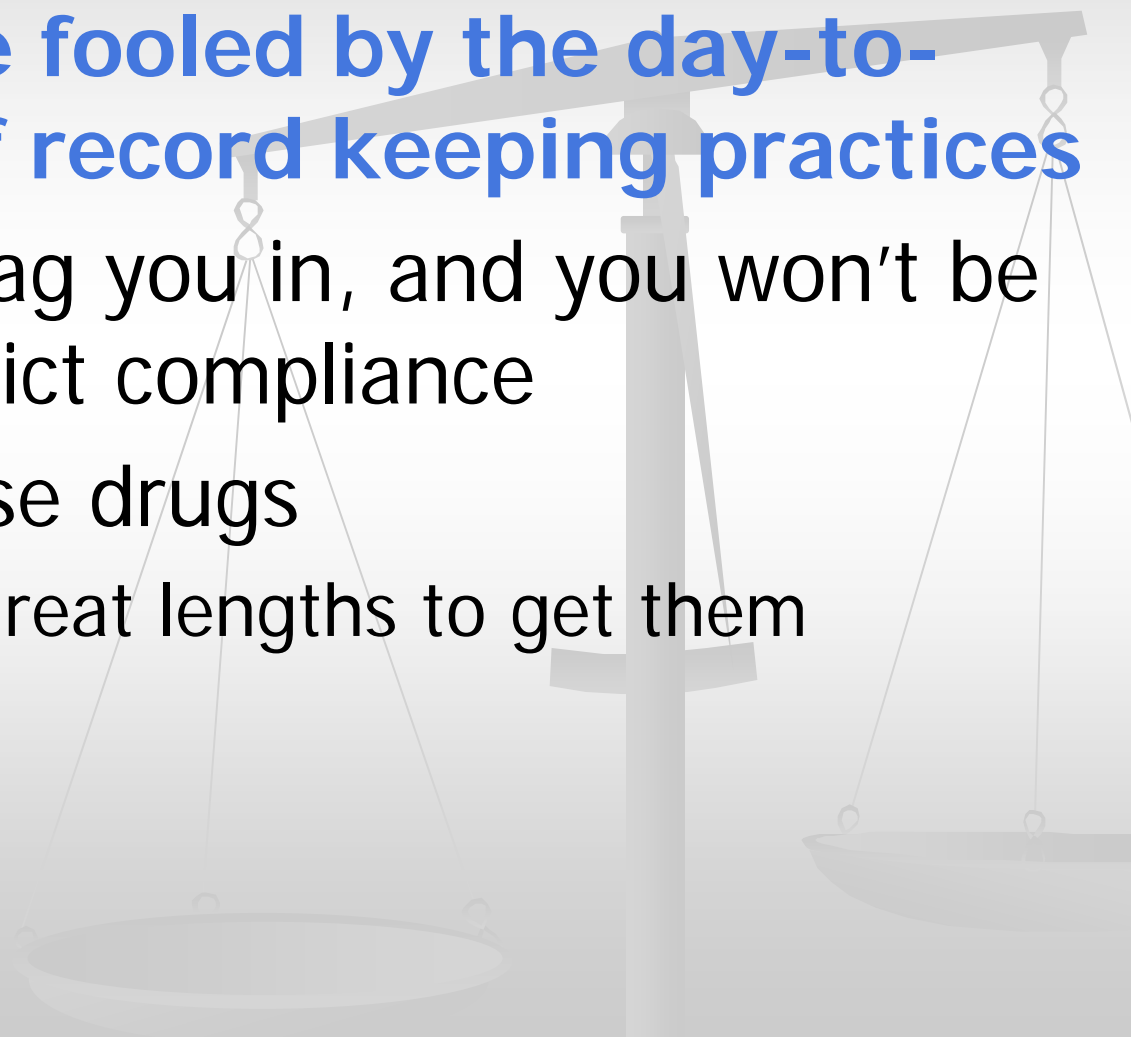
Good news

- There will be systems in place at your employer



Bad news

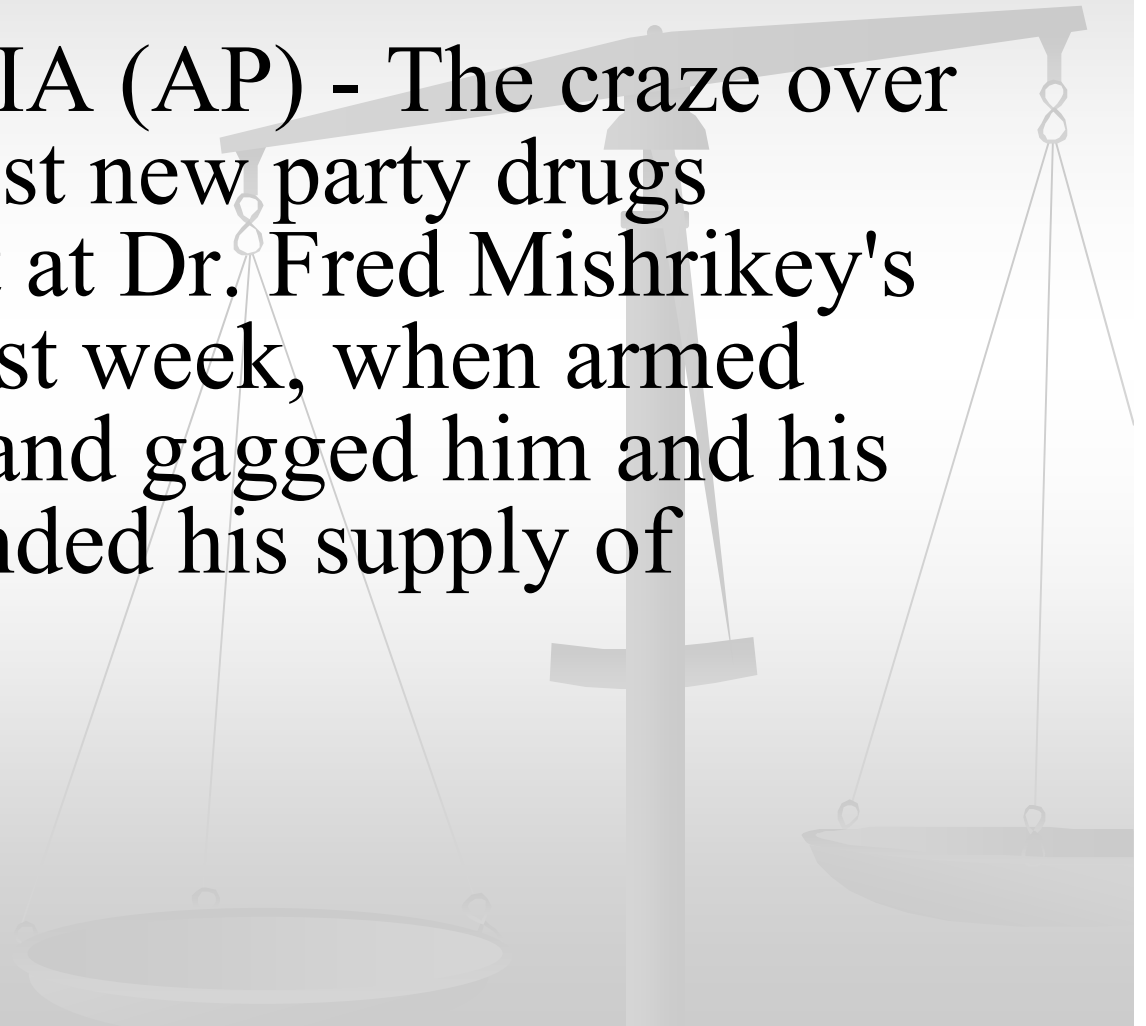
- There are abuses
- **Again, don't be fooled by the day-to-day realities of record keeping practices**
- Violations will drag you in, and you won't be excused from strict compliance
- People want these drugs
 - They will go to great lengths to get them



News story—vets as targets

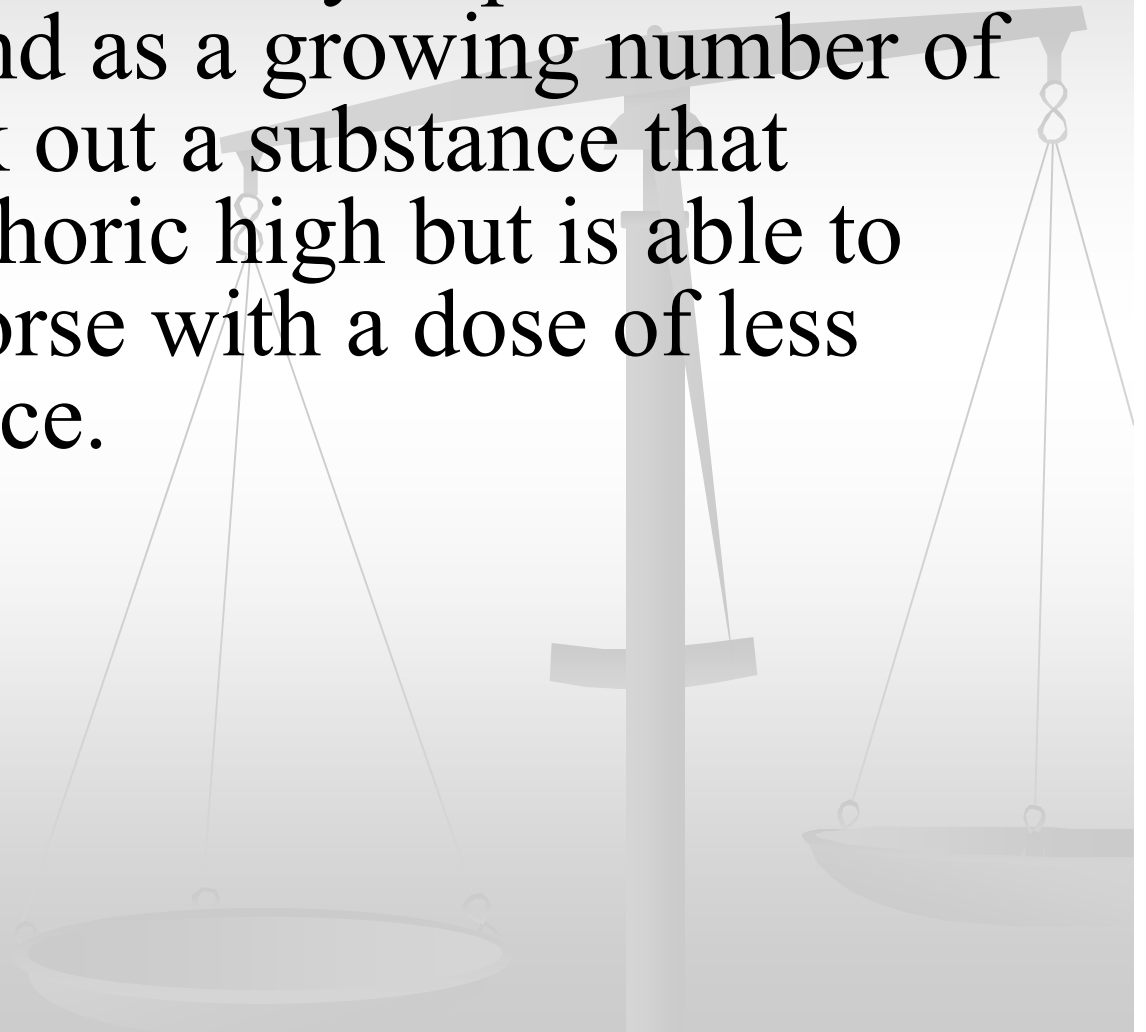
Veterinarians Being Targeted for Drug...

- PHILADELPHIA (AP) - The craze over one of the hottest new party drugs became evident at Dr. Fred Mishrikey's animal clinic last week, when armed robbers bound and gagged him and his wife and demanded his supply of “Special K”



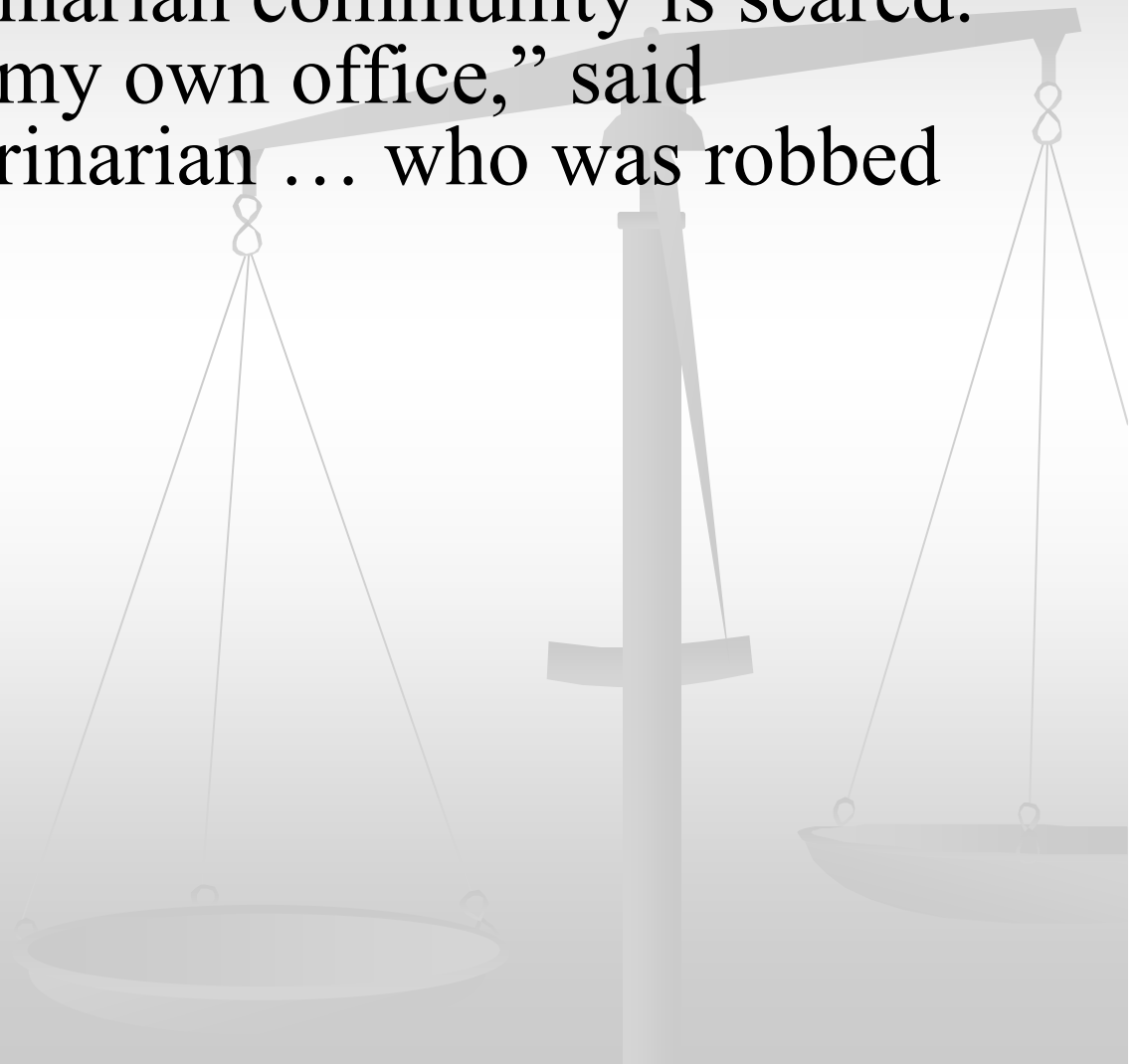
News story—vets as targets

- Officials say the robbery is part of a nationwide trend as a growing number of drug users seek out a substance that produces a euphoric high but is able to tranquilize a horse with a dose of less than a half-ounce.



Quote

- “The whole veterinarian community is scared. I’m a prisoner in my own office,” said Philadelphia veterinarian ... who was robbed in June



Quotes

- Chemically similar to PCP, ketamine hydrochloride can be smoked, inhaled like cocaine or added to drinks for a hallucinogenic high. A single dose of the drug - known on the street as Special K or Cat Valium - sells for \$20.
- “It’s been abused for a number of years, but with the club scene, it’s becoming more popular,” said a special agent with the DEA in Philadelphia.

Quotes



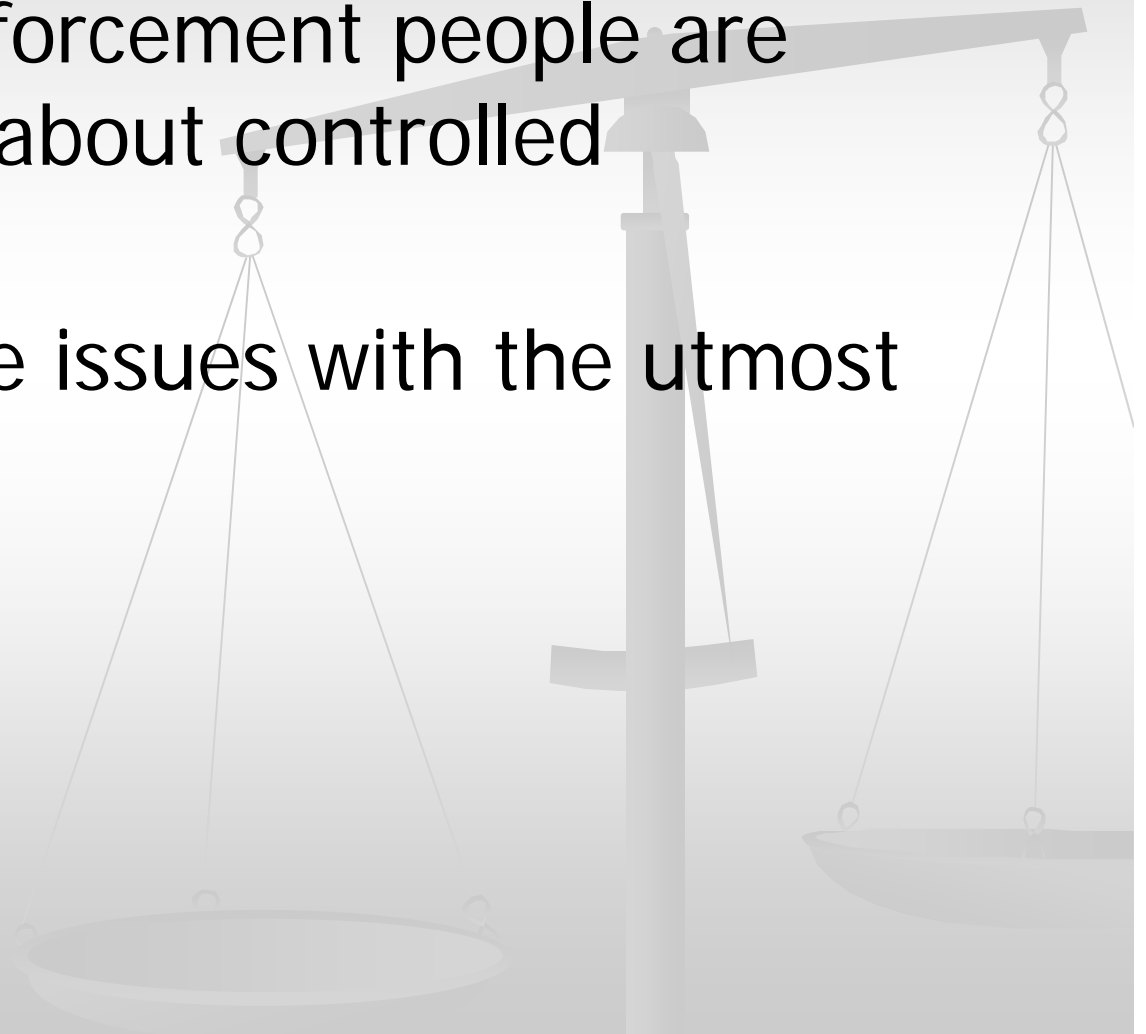
- In Allentown, Pa., four people were arrested for allegedly threatening to firebomb a veterinary practice unless they were given ketamine.
- In Arvada, Colo., thieves looking for ketamine allegedly broke into two animal clinics in one night.
- In Virginia, Maryland and North Carolina, thieves posing as vet clinic workers sought to “borrow” vials of ketamine from other clinics.

Quotes

- The assailants entered the clinic with their dog and told the vet the poodle had diarrhea. But after following the vet and the dog into the examination room, the two thieves threatened him with a gun and demanded to know where he kept his supply of ketamine.
- Then they bound the vet to a chair with duct tape and taped his mouth shut, doing the same to his wife.

Public health

- Government enforcement people are hyper sensitive about controlled substances.
- So ... treat these issues with the utmost respect



What about pet meds
websites?



What information is needed to purchase an “RX required” medication?

- “All we need is your veterinarian’s name and phone number and we will obtain your pet’s prescription for you free of charge. We will ask for the necessary information during your checkout. If you have a written prescription please mail it to us at 1441 SW 29th Avenue, Pompano Beach, FL 33069 or have your veterinarian fax it to us at 1-800-600-8285.”

From Pet Meds website FAQ

8/29/2004

- **“Does my veterinarian have to be contacted for me to buy prescription medications?”**

Yes, unless you have a written prescription that you can mail to us at 1441 SW 29th Avenue, Pompano Beach, FL 33069 or have your veterinarian fax it to us at 1-800-600-8285.”

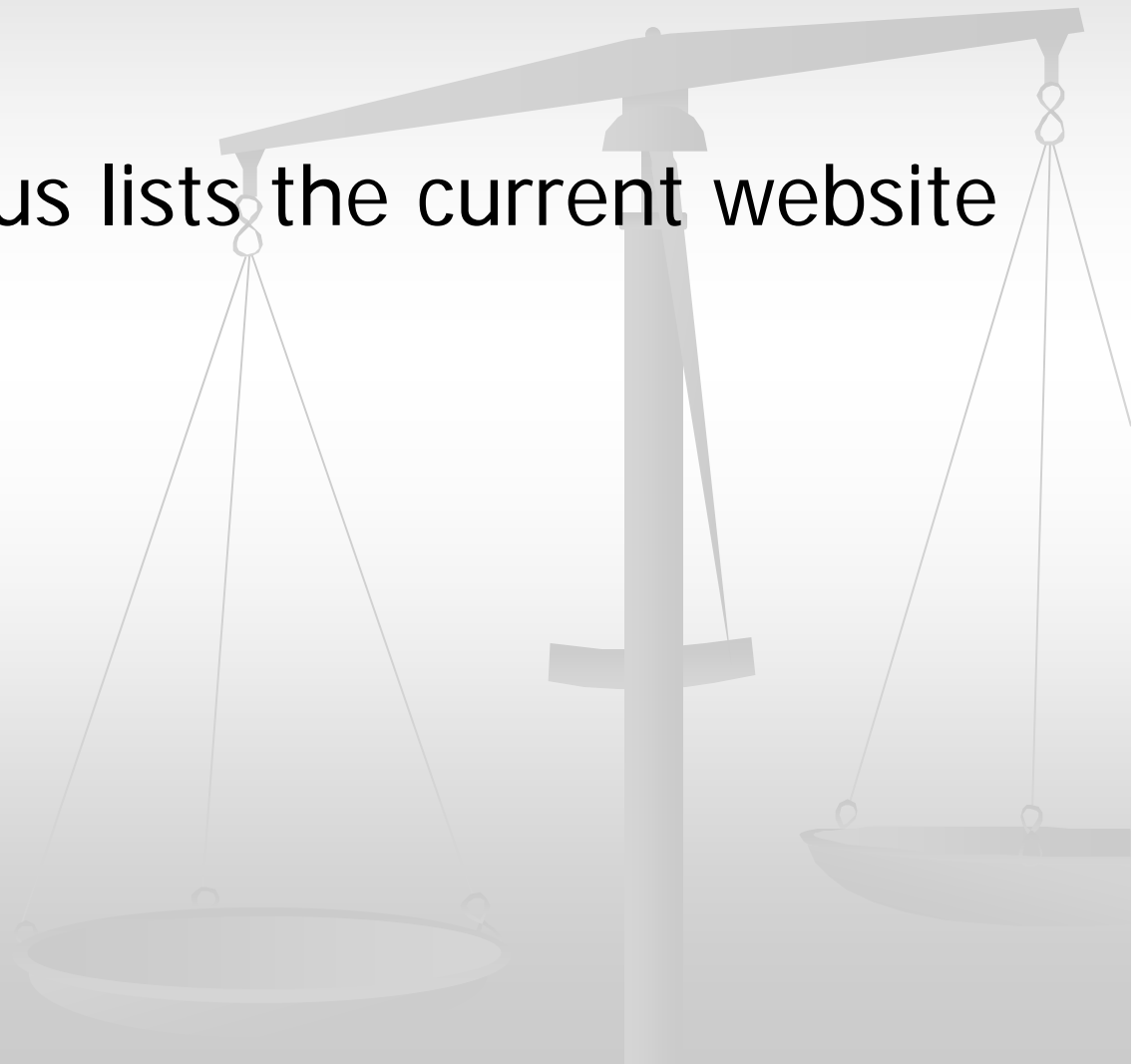
Help on the Internet



- What is the real (v. imagined) liability for vets in this area and how does it interfere with optimal patient care and the duty to treat pain?
- [Veterinary Drugs Information at Business.com](http://www.business.com/directory/pharmaceuticals_and_biotechnology/veterinary_drugs/) -
http://www.business.com/directory/pharmaceuticals_and_biotechnology/veterinary_drugs/

BASICS—where to find answers about your obligations

- State Regs
- Materials Syllabus lists the current website for the MA regs
- Easy to find



Federal

- Food and Drug Administration
Center for Veterinary Medicine –
www.fda.gov/cvm



Federal



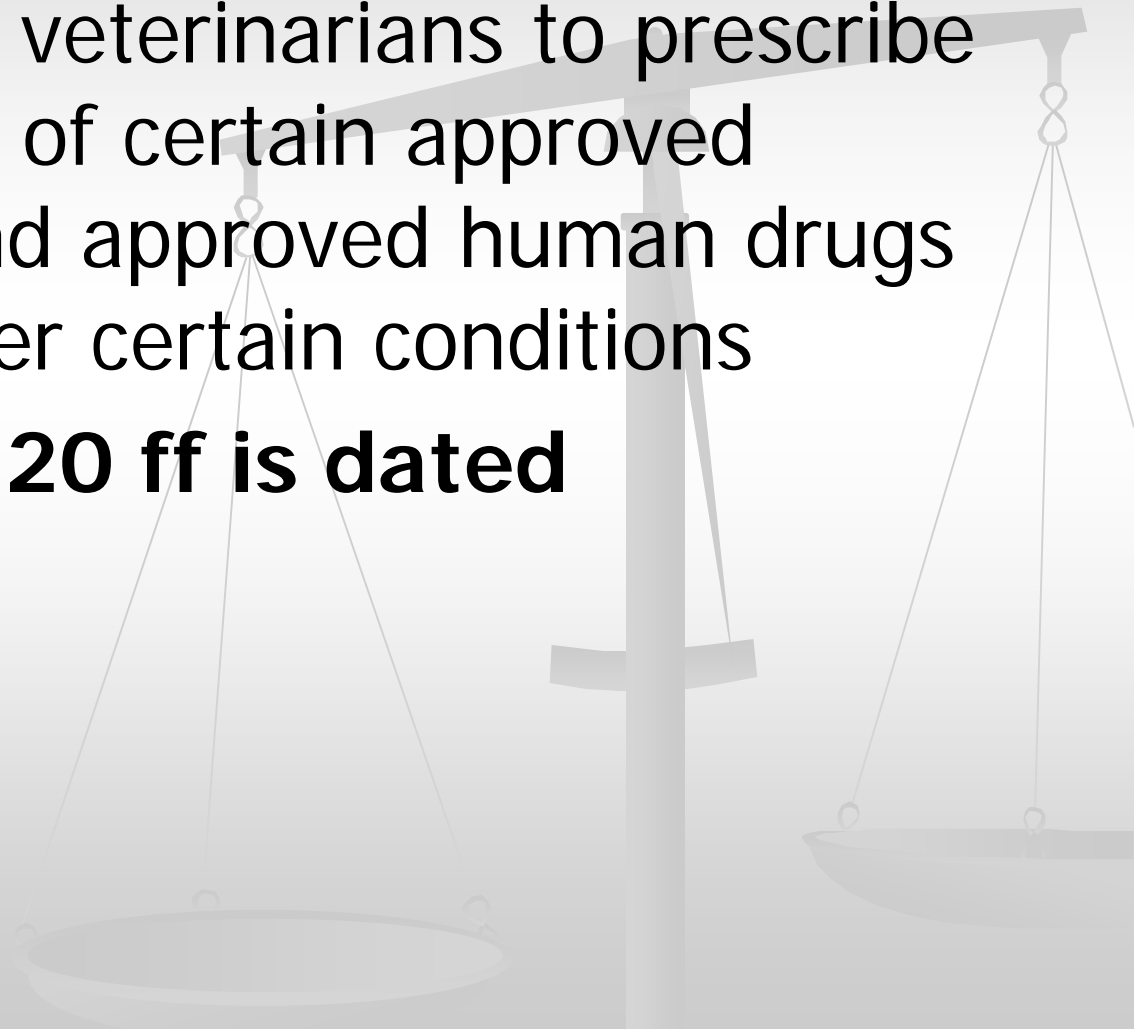
- DEA enforces the Controlled Substances Act (1970)
- ... major federal law regulating the manufacture, distribution, dispensing, and delivery of substances that have the potential for abuse, physical dependence, or psychological dependence.
- DEA site not easy to negotiate
- Use the www.fda.gov/cvm

Extra label drug use

- **Definition?**
- Use of approved drug in manner not in accordance with approved label directions
- **Look at AMDUCA (Animal Medicinal Drug Use Clarification Act of 1994)**
- Can find this at the **Center for Veterinary Medicine** website

AMDUCA—Extra label use

- AMDUCA allows veterinarians to prescribe extra-label uses of certain approved animal drugs and approved human drugs for animals under certain conditions
- **Wilson page 220 ff is dated**

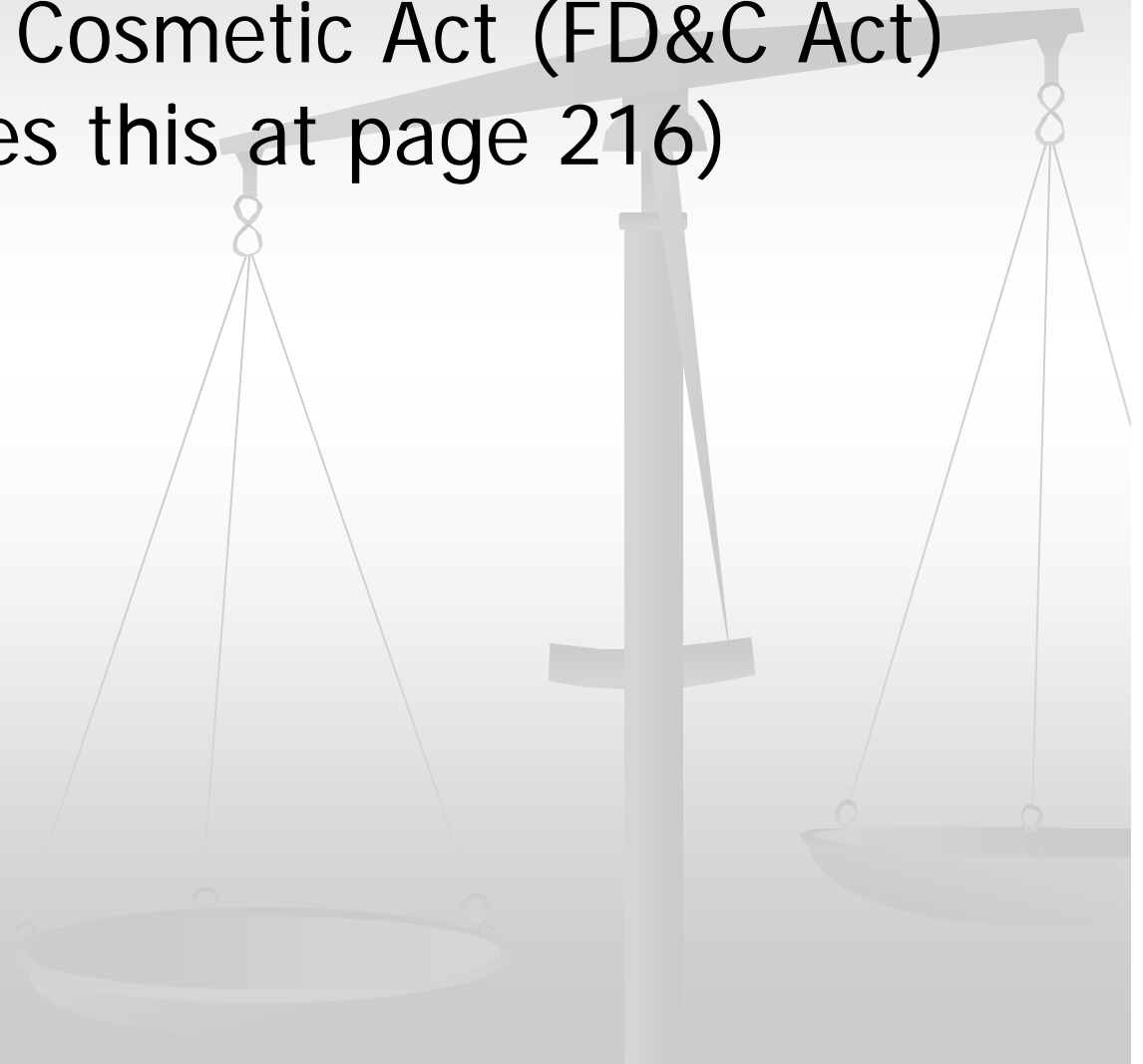


Key AMDUCA provisions

- Key constraints of AMDUCA
- **any** extralabel use must be by or on the order of a veterinarian within the context of a veterinarian-client-patient relationship
- must not result in violative residues in food-producing animals
- use must be in conformance with the implementing regs published at 21 CFR 530
- List of drugs specifically prohibited from extralabel use ([530_41.txt](#) and [530_41.pdf](#)) appears in the Code of Federal Regulations

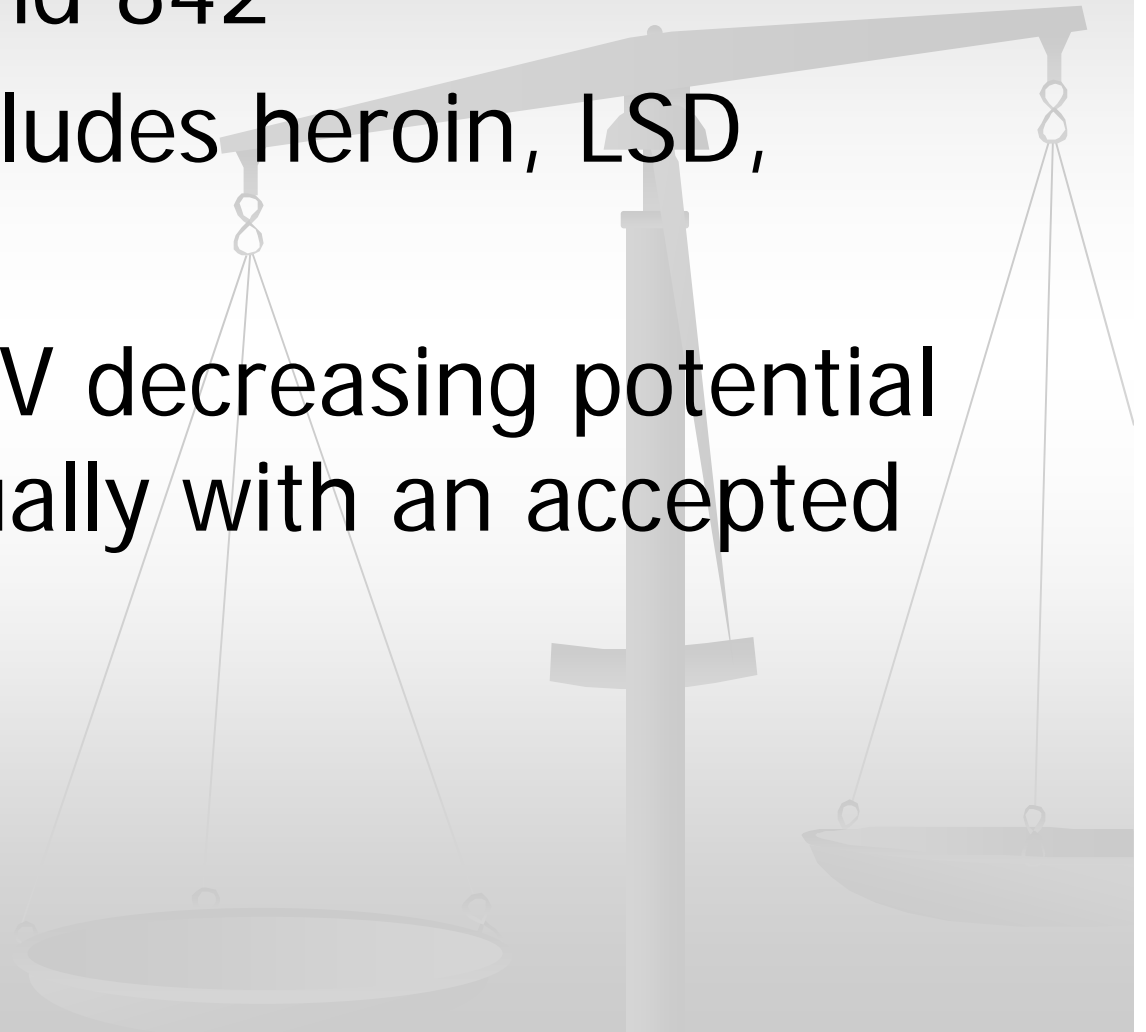
More federal stuff

- Food, Drug and Cosmetic Act (FD&C Act)
(Wilson describes this at page 216)



Different schedules of drugs

- 21 USC 841 and 842
- Schedule I includes heroin, LSD, mescaline
- Schedules III-V decreasing potential for abuse, usually with an accepted medical use



Reminder

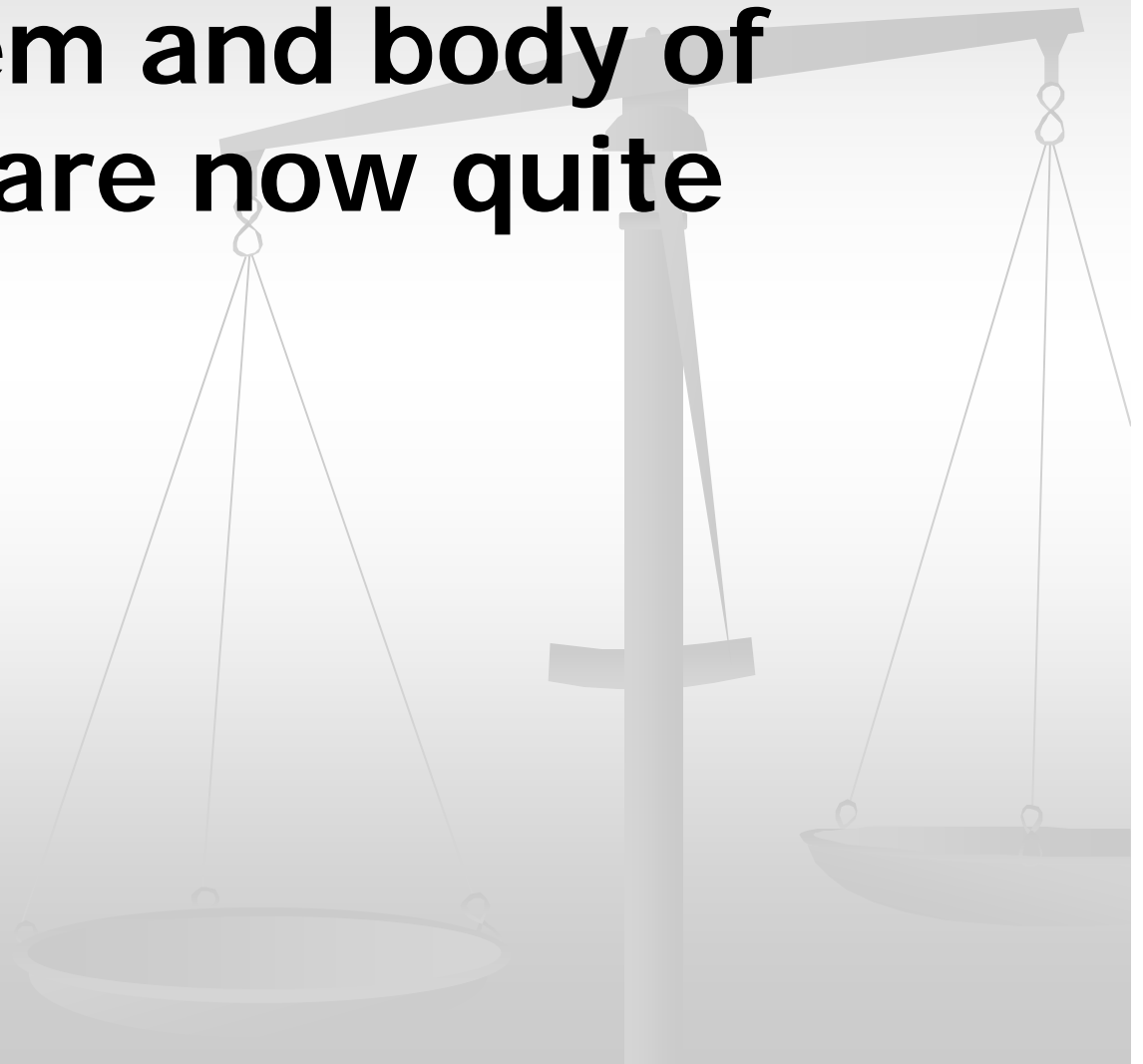
- “Concurrent state law”
- **There are several sets of laws affecting controlled substances**



Hence, Wilson's comment
again

**"... the system and body of
regulation are now quite
complex."**

(Wilson 215)



Wilson devotes THREE chapters to this topic

- Page 262, “Veterinarians who unwittingly violate these laws ...
- ... are subject to police investigations, action by state boards of examiners, and civil penalties up to \$25,000.
- Violations of controlled substance laws committed with knowledge or intent incur ... →→→

Penalties



- ... criminal penalties of up to 15 years in prison,
- A fine of up to \$25,000,
- Or both **for the first offense,**
- **And possibly veterinary license suspension or revocation."**

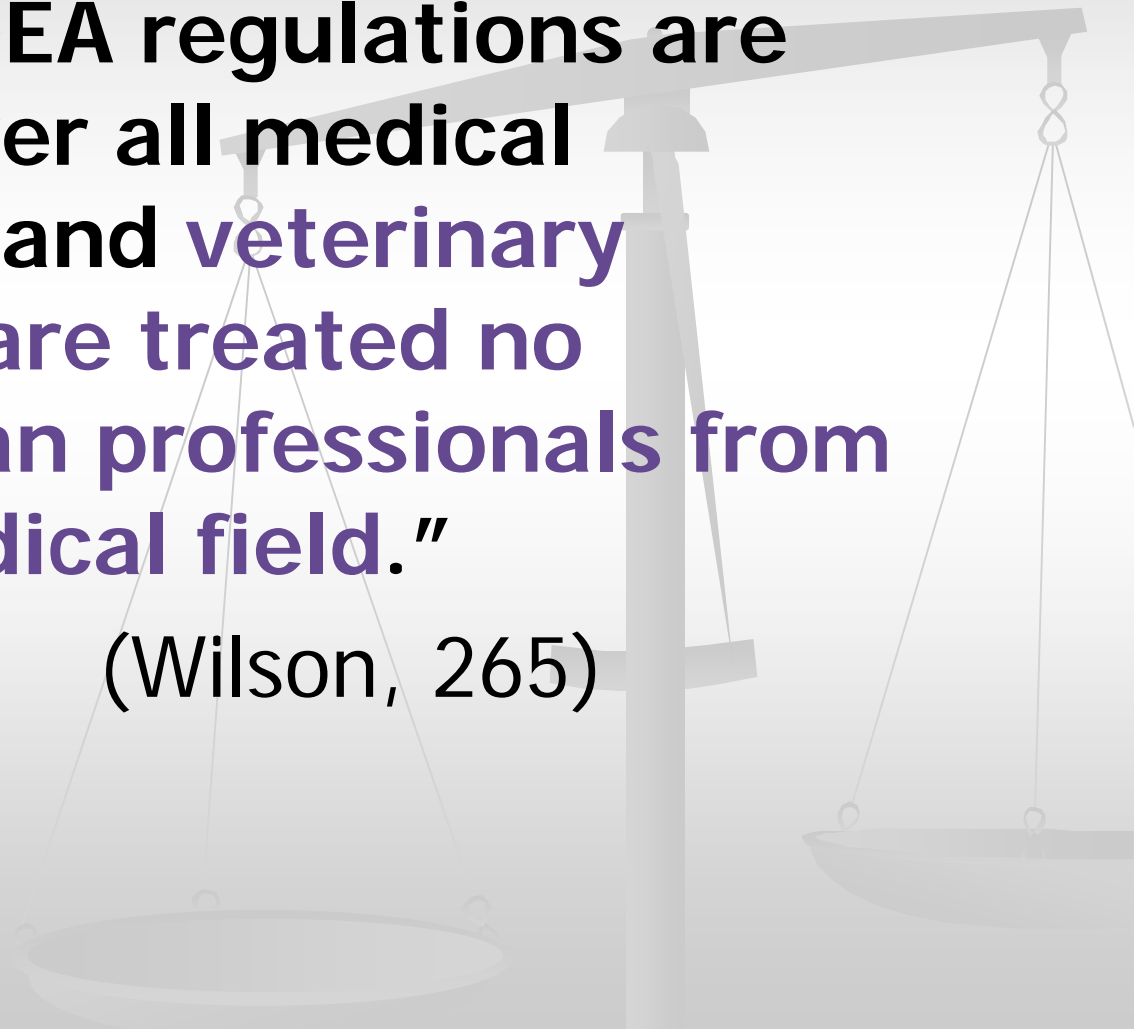
Who is governed?

- “Practitioners”
- Wilson (265) quotes 1 CFR 1304.02 re definition
 - **“A physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed ... to distribute, dispense, ... administer ... a controlled substance in the course of professional practice or research ...”**

Welcome to the big time

- **“In general, DEA regulations are written to cover all medical practitioners, and veterinary practitioners are treated no differently than professionals from any other medical field.”**

(Wilson, 265)

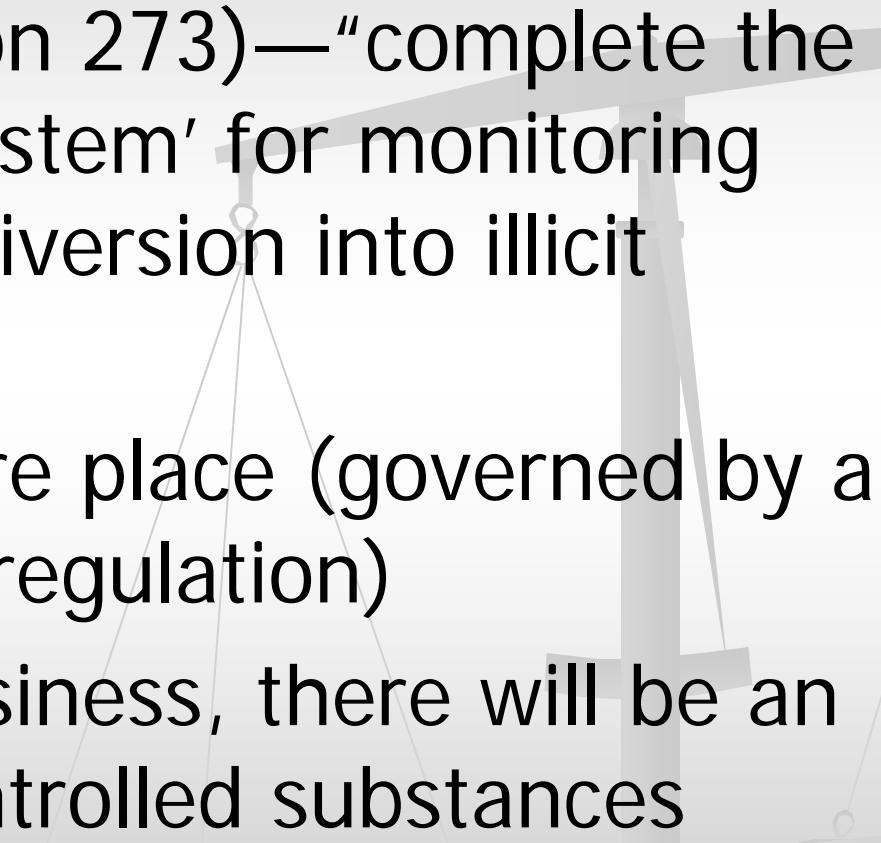


Lots of technical, special paperwork

- Special rules on registering with DEA
- Ordering rules exist
- **Record keeping is critical**

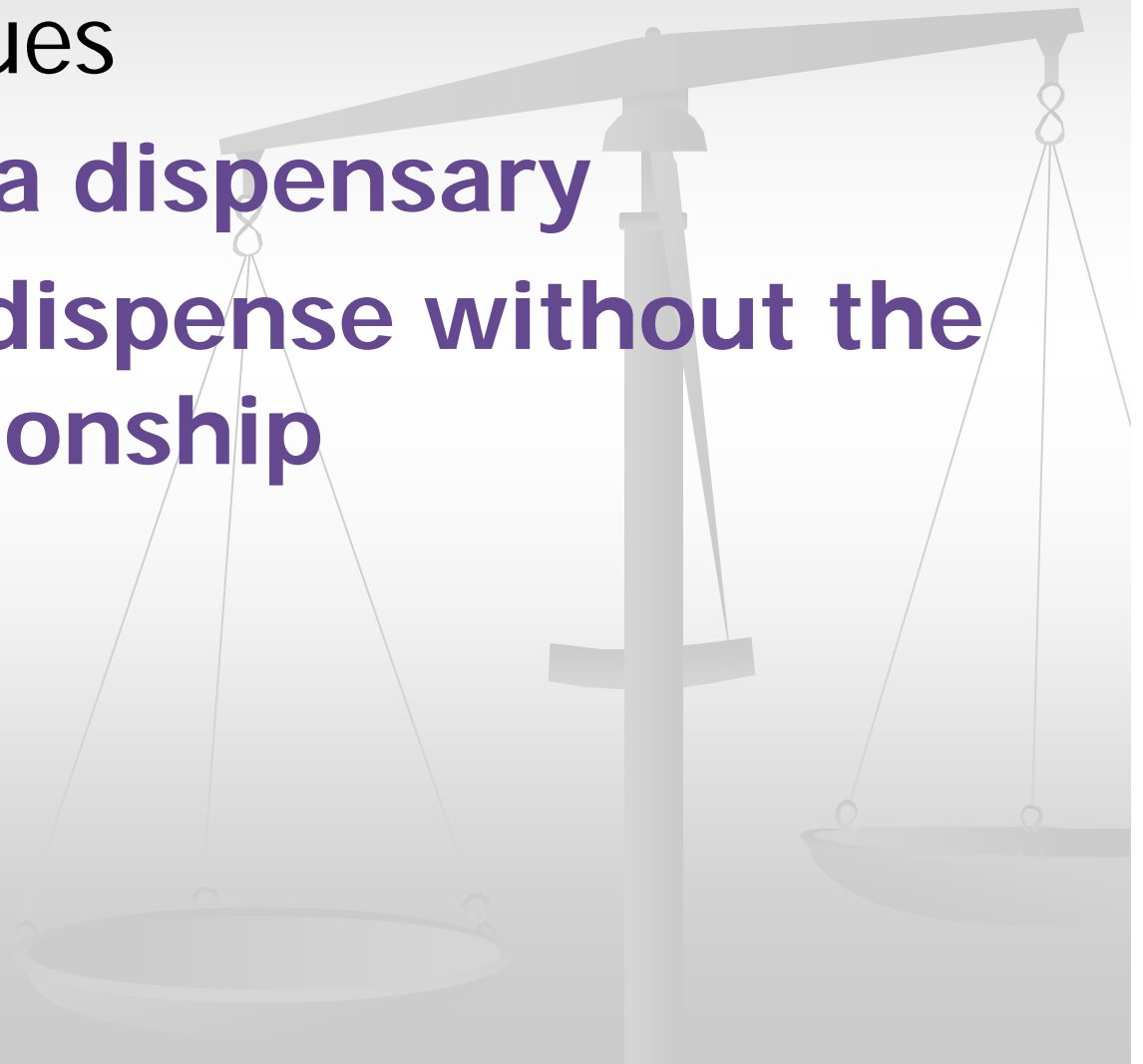


Lots of technical, special paperwork

- Rationale (Wilson 273)—“complete the DEA’s ‘closed system’ for monitoring possibilities of diversion into illicit channels.”
 - Storage in secure place (governed by a specific federal regulation)
 - If you buy a business, there will be an inventory of controlled substances
- 

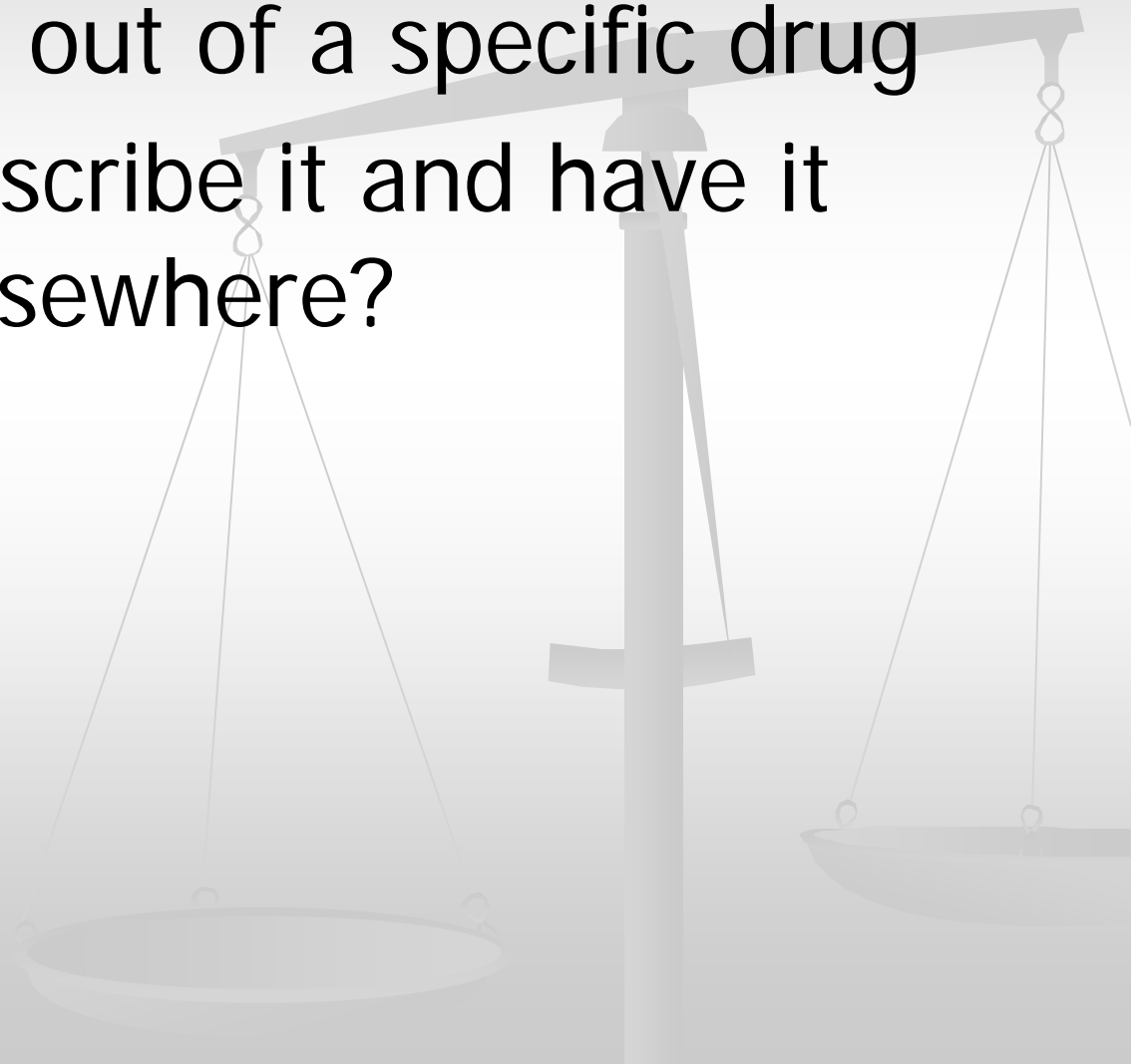
Practical realities

- Borrowing issues
- **You are not a dispensary**
- **You *cannot* dispense without the proper relationship**

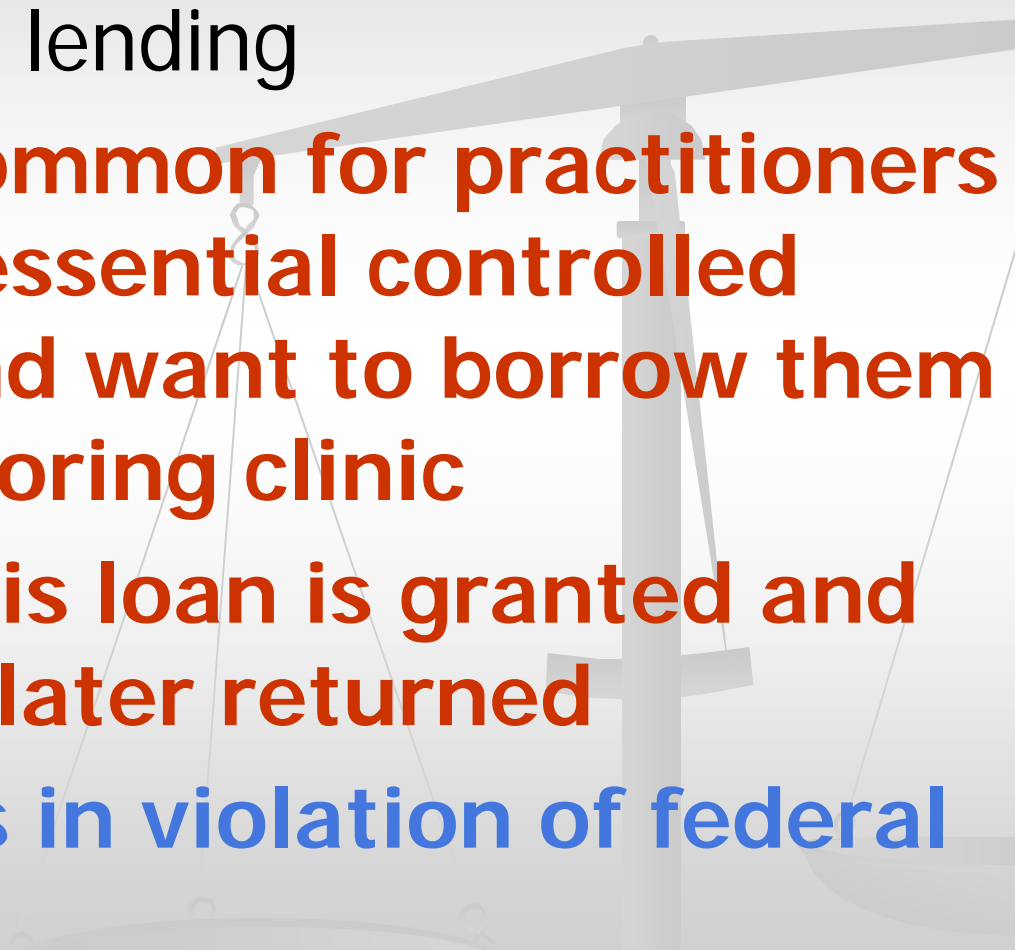


Practical realities

- Issue – you're out of a specific drug
 - Can you prescribe it and have it picked up elsewhere?

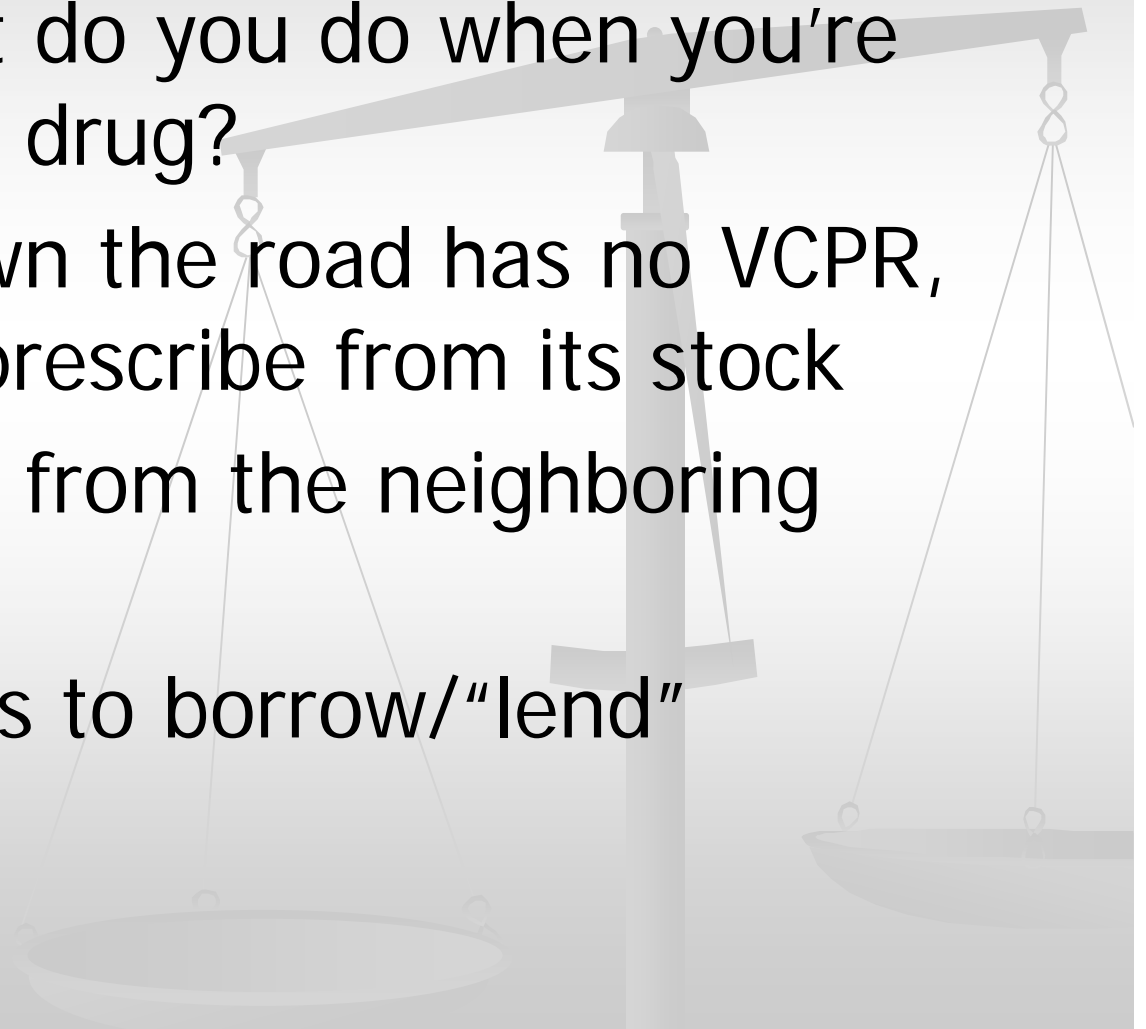


“Neither a borrower nor a lender be”

- Wilson (276) on lending
 - **“It is not uncommon for practitioners to run out of essential controlled substances and want to borrow them from a neighboring clinic**
 - **Frequently, this loan is granted and the drugs are later returned**
 - **This activity is in violation of federal law”**
- 

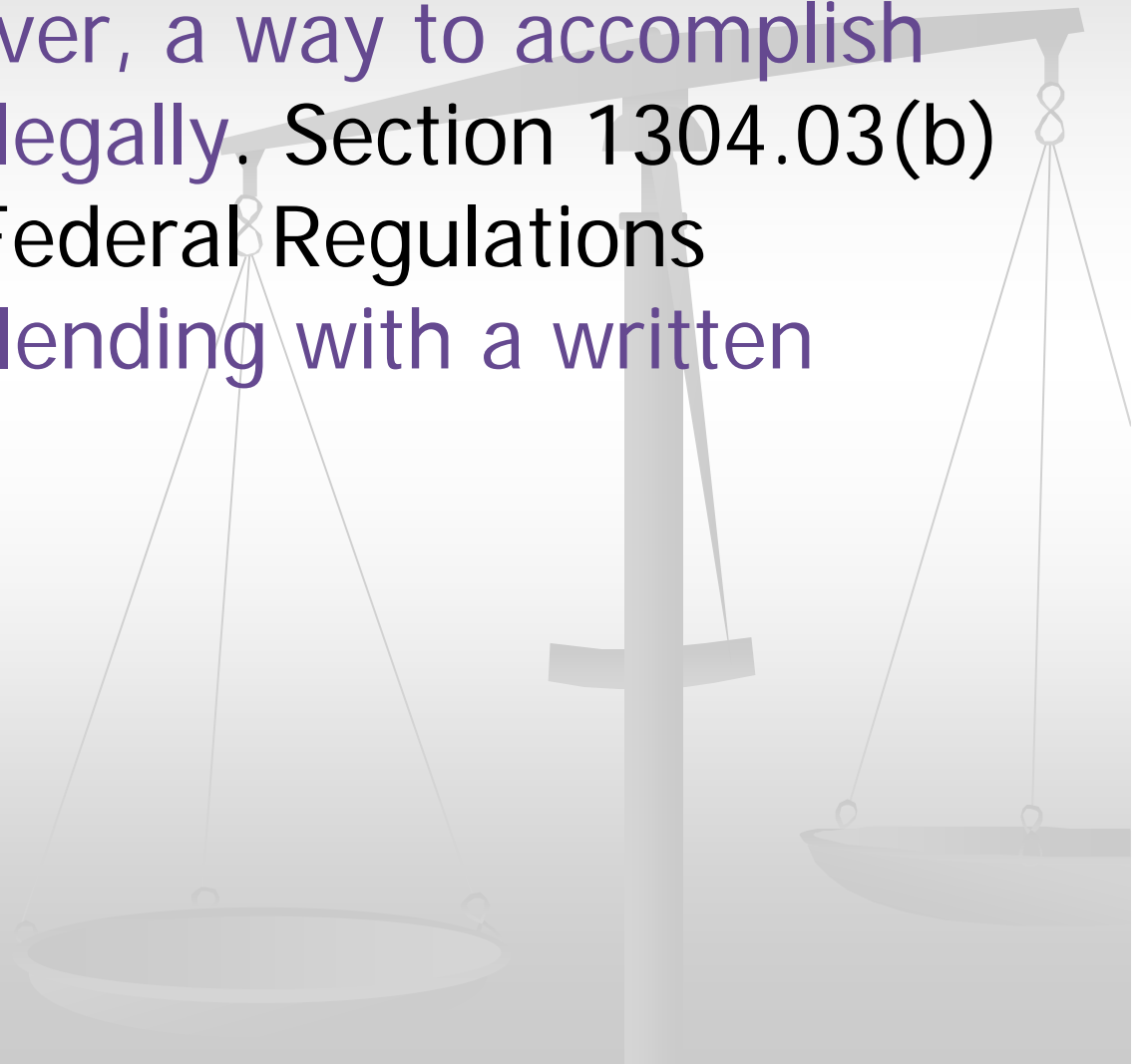
Practical realities

- Issue – So what do you do when you're out of a specific drug?
 - The clinic down the road has no VCPR, so you can't prescribe from its stock
 - You can't buy from the neighboring clinic.
 - The practice is to borrow/"lend"



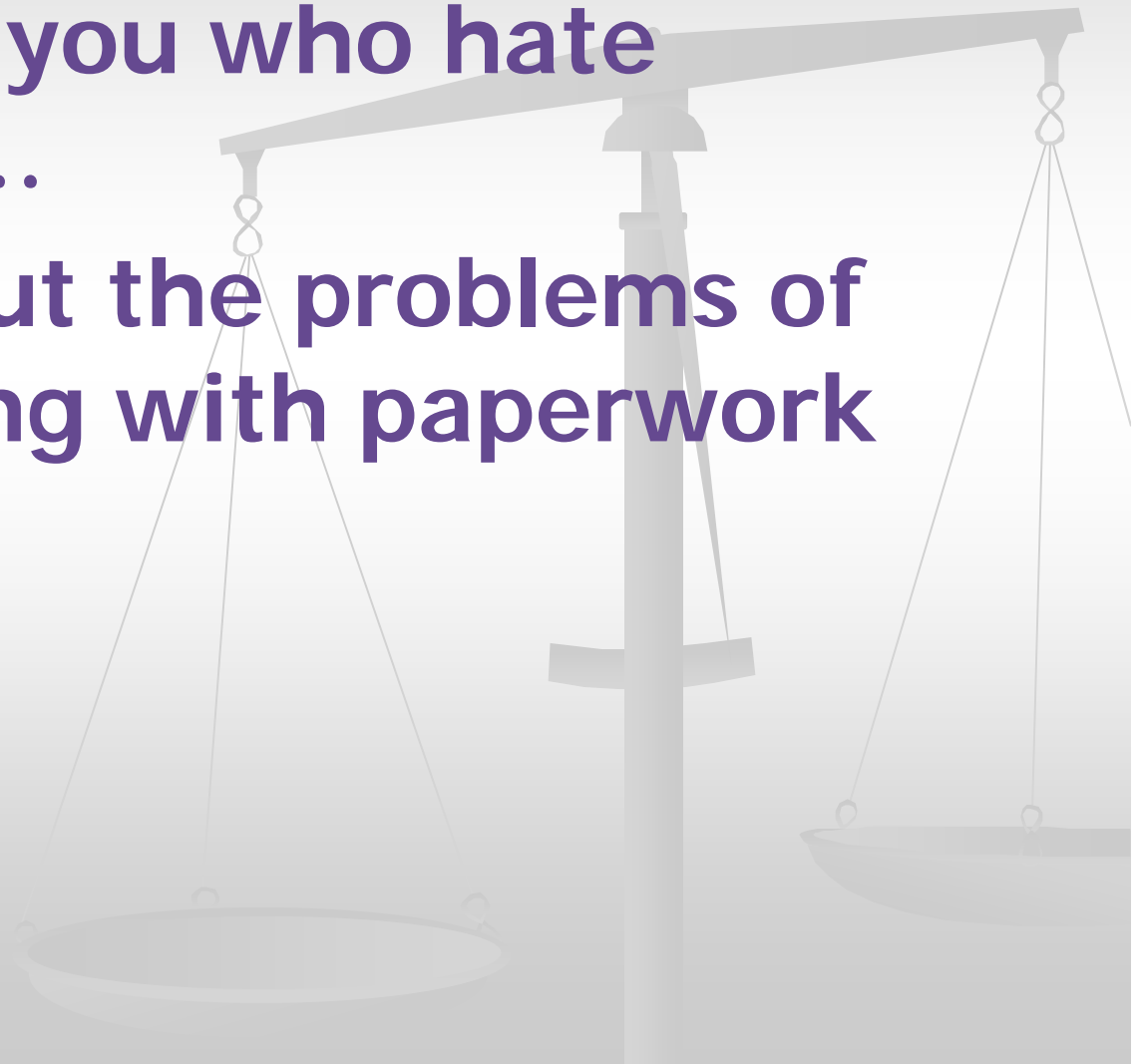
How to lend/borrow legally

- “There is, however, a way to accomplish the transaction legally. Section 1304.03(b) of the Code of Federal Regulations [explanation of lending with a written record]”



... paperwork ...

- For those of you who hate paperwork ...
- get real about the problems of not complying with paperwork



Tufts' internal policies

- Pain management and liability:
- Tufts won't send potentially addictive meds - opiates, usually - home under any circumstances.
- What should your practice's policy be?

