

The conundrum of compounded drugs

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A few weeks ago, while at the barn with my personal horse, a friend asked if I would administer a dose of Adequan® to her horse. Although I knew the horse, had examined him many times before, and knew that this class of medication would help based upon the horse's history, I did not prescribe the medication. When I asked if it is real Adequan or compounded, her response was not actual

Adequan but "generic." I apologized and said there is no generic Adequan and that I cannot administer a compounded drug when there is a legend drug approved by the FDA for the same purpose.

As it happened, a veterinary colleague was in the barn for her weekly chiropractic rounds. Out of the corner of my eye, I caught her giving me a thumbs up. This led to a discussion between the two of us about the difficulties we had encountered with compounded drugs. She revealed that she most often receives requests for compounded drugs when another veterinarian or the client's friend's veterinarian recommends a compounded version of a legend drug. The client then asks my colleague to prescribe or dispense the compounded drug. She believes that the FDA-approved product will work best for the horse and that the compounded drug may not be effective. Ethically, and based upon her best professional judgment, she refuses to prescribe these drugs, leading to an uncomfortable discussion with her client.

As a veterinarian working for a private company that owns racetracks, I often see veterinarians and vendors who want to sell and prescribe compounded drugs in lieu of FDA-approved medications at the racetrack. These drugs are marketed to horsemen who are usually unaware of the rules or the risks associated with compounded drugs. Often, state racing commission regulations specifically prohibit the sale of these compounded drugs but, like most things, the common argument in favor of compounded drugs is cost. I've seen many ethical veterinarians lose business to a vendor or another veterinarian willing to prescribe cheaper compounded versions of the same drug, which may be less effective or even dangerous. For me, this often leads to difficult conversations with veterinarians, trainers and vendors. In one memorable case, it led to another veterinarian shaking his finger at me while yelling, "Listen, little missy, you just don't know how things are done around here."

The use of compounded medications sometimes is indeed innocent, usually by veterinarians who lack the understanding of the differences between the classes of drugs and the applicable laws. The lack of clarity for compounding regulations is aggravated by unclear messaging from the FDA. Several years ago, the FDA began a revision of its guidance regarding the use of compounded drugs in veterinary practice; at that time, it pulled the existing guidance document. This left veterinarians without much direction on how the FDA would approach enforcement activities with respect to veterinary compounding, especially as it relates to compounding from bulk drug substances. The new FDA guidance is set to be released in the coming months and has been the subject of much debate among compounders, drug companies and veterinarians. The guidance document likely will lay out the criteria/circumstances whereby the FDA will exercise enforcement discretion with respect to compounding from bulk drugs.

Unclear guidance from the FDA and clients asking for cheaper treatment alternatives creates the perfect storm of incentive for the veterinarian to take the easy route by just providing the compounded drug. The client is happy to save money and the veterinarian is unlikely to face any legal consequences for prescribing a compounded version. But does that make it ethical?

American philosopher Aldo Leopold wrote, "Ethical behavior is doing the right thing when no one else is watching—even when doing the wrong thing is legal." This oft-quoted statement is particularly applicable to dealing with compounded drugs. For the most part, clients don't understand the difference between compounded, generic or legend drugs. Even if something goes wrong with a horse, the client may not connect it with the use of a compounded drug. Unless there is a specific complaint from a client or another regulatory body, the veterinarian runs little risk of enforcement by the FDA or the state pharmacy board. Quite simply, no one is watching our behavior when we make these decisions. Because of this, it is crucial that we, as veterinarians, act ethically when it comes to prescribing and administering medication.

The use of compounded medication should be limited to instances where it is absolutely necessary for the health and welfare of a horse when there are no other options available to the veterinarian. As veterinarians, it is our job to educate clients about the value of legend and generic medications so that they understand that with increased cost comes research, purity, consistency and other safeguards that protect their horse. Ultimately, if that doesn't work, it is our job to say we won't improperly prescribe a compounded drug.

