

Second look at compounding

Renegade compounders are in the minority, says one pharmacist, who believes profession is unfairly targeted

by Denise Steffanus

IN the second part of an examination into the controversy over compounded medications, compounders defend their profession overall as ethical and in the best interests of the horse, and they place responsibility for allowing illegal compounding to persist squarely on the shoulders of veterinarians whose collusion makes it possible.

Compounders respond

"There are many accusations made that I am not sure have any basis," said Paul Franck, R.Ph., president of Franck's Compounding Lab Inc. in Ocala. "There are a good number of [Food and Drug Administration]-registered suppliers of ingredients to compounding pharmacies across the [United States]. These suppliers are inspected and regulated by the FDA, and they routinely test ingredients to ensure quality. It is hard to imagine that pharmacies are not using appropriate ingredients. We hear the accusation, but is there any evidence to support that claim?"

Actually, the FDA does not register and inspect suppliers. It is the U.S. Pharmacopeial Convention (USP) that establishes government-enforceable standards for the manufacture of materials used in drug manufacturing, plus specifications and procedures for the supplier to test drug components to ensure product uniformity and quality. The USP itself does not test drug components.

"The supplier of drug products must supply a Certificate of Analysis of every lot or batch of product to the compounding pharmacy as official documentation of this testing," said Anne Gresham, R.Ph., director of Rood & Riddle Veterinary Pharmacy in Lexington.

Reputable pharmacies use only USP suppliers, but according to Joe Bertone, D.V.M., professor of equine medicine at Western University and a former veterinary medical officer for the FDA, for every reputable pharmacy operating within the law, 50 renegade pharmacies place profit above quality and use whatever supplies are the cheapest.

"These are the companies that are ruining the reputation of the profession for ethical compounders," he said.

Franck defended compounders who adhere to ethical practices in producing medications that ultimately benefit veterinary medicine, saying



NEW DELIVERY METHOD

One form of compounding is to crush tablets of a commercially available, FDA-approved medication and mix the powder with a paste to change its method of delivery, if the approved drug is not available in paste form

he believes his industry is being unfairly targeted.

"This does indeed do a disservice," Franck said. "There may well be abuses by pharmacies, and we do occasionally see a pharmacy advertising a copy of a commercially available medication. State boards of pharmacy and self-regulatory efforts should expose and curtail such cases. We should engage veterinarians and pharmacists together to educate that such practices are not acceptable."

Government regulation of pharmacies falls under the jurisdiction of the respective state's oversight board, which conducts inspections whenever it deems necessary, usually in response to one or more complaints about a specific pharmacy.

"In Kentucky, this inspection includes verification that a compounding pharmacy has standard operating

procedures in place for all phases of compound drug production," Gresham said. "This includes procedures for the acquisition, handling, and storage of materials, containers, labels, finished compounds, et cetera, as well as appropriate facilities, equipment, personnel, and documentation."

A new organization, the Pharmacy Compounding Accreditation Board, hopes to self-regulate the industry and make it easier for veterinarians to identify ethical compounders.

Veterinarian's responsibility

The Code of Federal Regulations specifies that compounding of veterinary drugs is permitted only to fill a prescription written by a licensed veterinarian. By its nature, a prescription is to be used to treat only the specific animal for which it is written. The bottom line is that compounders cannot operate without the cooperation of a prescribing veterinarian, and it is the veterinarian's responsibility to assure the medication used on the client's animal at his or her direction is produced by a compounding pharmacy that operates with diligence, integrity, and respect for the law.

Some veterinarians defend the use of knockoffs by saying that some clients do not want to pay the high price for FDA-approved drugs, which are more expensive to recoup the high cost of research and development necessary to obtain FDA approval.

"Veterinarians really don't want the client who wants the cheap stuff that may not work," Bertone said he

tells veterinarians. "You want the clients who want the best for their horses and who thank the veterinarian for helping them to understand the difference."

A liability issue also exists for veterinarians who prescribe or distribute illegally compounded drugs, which constitutes de facto negligence and nullifies a practitioner's malpractice insurance coverage.

Kenton Morgan, D.V.M., chairman of the American Association of Equine Practitioners drugs and medication committee, said its mission is to educate its membership on when the use of compounding is appropriate and lawful. He advised practitioners: "If you're using a compounder who is not willing to follow the rules, you need to look for a compounder who is. That's ultimately what our message has to be."

Bertone said that considering all the efforts that have been made to educate veterinarians about when it is proper to use a compounded medication, the issue of using a knockoff rather than the FDA-approved medication comes down to greed.

"Unfortunately, what happens is that many veterinarians sell the compounded product for the same or near the same price they would sell the approved product," he said. "So in several cases, they are making 1,000% to 5,000% markup, and that's not an exaggeration. It's not a point of education anymore. I say to veterinarians who are doing this, 'It's either lack of ethics or lots of ignorance.'"

Bertone advocates the AAEP's adoption of a standard-of-care policy that specifically states that the use of compounded products that are meant to replace FDA-approved drugs be labeled as unethical.

No compounding at trade show

This year, the AAEP will ban compounding from its annual convention's trade show for the first time (THOROUGHBRED TIMES, September 6). Pharmacies will be permitted to host a booth at the trade show, but they will not be able to exhibit, display, or market their compounded products and services—nor will any other company, such as a distributor, be permitted to promote compounding. Anyone who does not comply can be asked to leave the trade show.

The AAEP took this action after most pharmacies participating in its trade show in recent years consistently were found to be in violation of FDA regulations on compounding, said Morgan, who offered this written statement of the AAEP's position:

"1) We are about the health and welfare of the horse and educating our membership.

"2) AAEP is not 'anti' compounding, we are 'pro' legitimate compounding. We recognize there are situations where none of the approved products in their available dosage forms will meet the needs of a specific patient, and where the

health of the animal is in jeopardy and suffering or death may result if treatment is withheld. This is when the practitioner may need to use a compounded product.

"3) With respect to our decision of restricting promotion of compounded products and services at our upcoming 2008 convention, this decision was made after it became obvious that in recent years during the convention, the vast majority of compounding vendors were offering or promoting products or services that were not consistent with AMDUCA [Animal Medicinal Drug Use Clarification Act of 1994] and/or the current [FDA] Compliance Policy Guidelines. Last year, to more specifically address our concerns, we required that each compounding vendor sign an agreement that it would be in compliance with these requirements during their participation at our meeting. At last year's convention, it became obvious that again, this was not the case.

"4) The AAEP is not a regulatory organization. We expect our membership to practice in an ethical manner and consistent with applicable veterinary medical requirements, as do all veterinary membership organizations. We are asking the same from the compounding vendors who participate at our convention. We just want them to play by the rules, that's all."



USE OF REPUTABLE SUPPLIERS

Materials used in compounding, such as dimethyl sulfoxide (DMSO) gel, should be supplied by a manufacturing facility that observes government-enforceable standards established by the United States Pharmacopeial Convention (USP)

Franck and others want to put an end to all the controversy over compounding, and he insists that most compounding pharmacies operate ethically and for the welfare of the animal.

"The positive, life-saving stories are overwhelming," he said. "There is so much good being done here, and that's the story that really needs to be told." ✦



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Compounding explanation

AS OUTLINED in the October 18 issue ("Veterinary Spotlight," page 48), compounding is any manipulation of a drug approved for use by the Food and Drug Administration beyond that stipulated on the label. For example, if a veterinarian needs a paste form of a specific FDA-approved antibiotic for use in an individual animal but that antibiotic is not available in a paste, a pharmacist who fills that prescription by mixing crushed tablets containing that antibiotic with a paste is formulating a compounded drug. (The terms "compounded drug" and "generic drug" are not interchangeable. A generic drug must acquire FDA approval.)

Compounding commonly involves:

- Combining two or more FDA-approved injectable drugs so the horse needs just one needle stick;
- Adding flavoring to an FDA-approved drug; or
- Altering the method of administration of an FDA-approved drug (as for the paste antibiotic mentioned above).

Compounding pharmacies are expressly forbidden from producing a knockoff drug. This regulation is designed to protect the interests of pharmaceutical manufacturers that spend millions of dollars and years of work developing and testing new animal drugs in compliance with FDA regulations.—Denise Steffanus