

Guest Opinion: Pharmacy error in death of horses demonstrates need for accreditation

By Sarah A. Rigg

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Each year approximately 4 billion prescriptions are filled in the United States. Of those, 30-40 million are custom compounded prescriptions (prescriptions that are formulated or assembled in the pharmacy) created to meet a need not met by a commercial manufactured product.

Death or injury that occurs as a result of a prescription dispensing error is always unfortunate. When injury occurs in mass, as it did last week amongst 21 Brazilian professional polo horses, the shock is especially traumatic. As it turns out, the incorrectly dispensed prescription was a custom compounded vitamin injection dispensed by a Florida pharmacy.

Naturally, after answering "who" is to blame, we consider "how" to protect ourselves. When a pharmacy compounds a medication for my pet, or my child, how am I protected? Who regulates these prescriptions?

The first entity regulating the pharmacy is the State in which the pharmacy is licensed. The second entity is FDA who regulates the raw materials. The last entity, the United States Pharmacopeia (USP), though not a regulatory body, sets practice standards for manufacturers and pharmacies designed to improve safety and care.

Before 2004, pharmacy as a profession lacked a unified approach to standards governing prescription compounding. In 2004 this changed when eight major pharmacy organizations collaboratively organized the Pharmacy Compounding Accreditation Board (PCAB) whose mission is to:

1) promulgate policies and standards for the practice of pharmacy compounding in the public interest; and

2) to accredit pharmacies that adhere to these policies and standards to improve the quality and safety of pharmacy compounding. PCAB standards reflect matters of concern to FDA as well as embrace the standards set by USP.

The PCAB standards are rigorous. PCAB uses two methods to determine whether a pharmacy is in compliance with its standards:

1) extensive review of written policies and procedures; and

2) an on-site survey of the pharmacy. The later is where the rubber meets the road - is the pharmacy doing what they say they do.

Medical associations recognize the periodic need for quality compounded medications. As such, the American Medical Association (AMA) and American Veterinary Medical Association (AVMA) both recommend that when a physician feels a custom compounded medication is warranted, a PCAB accredited pharmacy should be utilized to formulate the medication.

To date, 51 compounding pharmacies have been nationally accredited by PCAB. These pharmacies are recognized on the PCAB website (www.pcab.org) and by PCAB signage within the pharmacy.

With approximately 25,000 community pharmacies nationally to choose from, people need a tangible method to verify their pharmacies qualifications. PCAB accreditation provides this assurance when you need a medication compounded.

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