

By Chris E. Wittstruck, Esq.



Chris

Wittstruck

Living creatures are fragile, and horses are no exception. Illnesses, injuries and accidents sometimes cause us to lose our cherished campaigners well before their time. In the case of fire, the Grim Reaper often takes multiple head of horses from us in one fell swoop. My first Thoroughbred fractional interest was in an undefeated two-year-old filly that succumbed to laminitis while being prepped for a Grade I race at Saratoga. Regrettably, my story is not unique; we all have one.

On a spring afternoon in Florida in 2009, elite horses of the Venezuela Polo Team scheduled to compete in a major international competition began to keel over. Despite immediate veterinary intervention, one by one, each of the horses that were felled eventually expired. The final death toll was 21. While foul play was the immediate suspicion, the post-mortem investigation revealed something much less sinister.

The horses' veterinarian had prescribed a nutritional supplement in the nature of a mix that required the longstanding practice of "veterinary compounding." Due to a mathematical error made by the pharmacy that filled the prescription, Franck's Compounding Lab of Florida, the horses received an overdose of the mineral selenium. The overdose caused veins to dilate, resulting in irreversible lung hemorrhaging.

The unfortunate deaths were ruled accidental, and the Florida Board of Pharmacy imposed penalties on Franck's for what was, in essence, a misfilled prescription. Suspension, however, was not one of the penalties imposed, and Franck's was permitted to continue the accepted practice of compounding.

While the result was shockingly sad for the horses' connections, it wasn't the end of the saga for Franck's. A year after the tragic incident, the Federal Food and Drug Administration ("FDA") sought to enjoin (legally stop) Franck's from "bulk" compounding. In a lengthy decision issued on September 12, 2011 U.S. District Court Judge Timothy Corrigan ruled that the FDA had no authority to regulate veterinary bulk compounding to fill prescriptions. To understand the decision, it's important to understand just what bulk compounding is all about.

According to the United States Pharmacopeia (USP), the text that sets forth standards for medicines, food ingredients, dietary supplement products and ingredients, compounding involves the preparation, mixing, assembling, packaging, and labeling of a drug or device in accordance with a licensed practitioner's prescription. The USP states, "compounding is an integral part of pharmacy practice and is essential to the provision of health care."

Despite advances in pharmacology over the decades, compounding is still a necessary practice, both for animals and humans. Compounding is typically used where, for instance, a patient is allergic to an ingredient in a mass-produced product. In the case of non-food producing animals like horses, compounding is necessary because limited

commercially available products exist and the available products are often inadequate due to the animal patient's size, species, and/or intolerance to active ingredients.

Franck's compounds raw chemical materials (bulk) and not manufactured drugs, mixing the active ingredients to appropriately fill veterinarians' prescriptions. Even the FDA agreed that the use of bulk materials was not a factor in the death of the polo horses. So what was the basis of the FDA's concern? It was the agency's claim that by compounding bulk materials Franck's was, in essence, manufacturing drugs and thus came under the strict regulatory purview of the FDA. It argued that the product of bulk compounding required "new drug" approval even when the process was conducted by a state-licensed pharmacist for an individual animal patient pursuant to a valid veterinary prescription.

The court's opinion started by pointing out that in the over seven decades since Congress created the FDA, the agency had never before sought to enjoin a state-licensed pharmacist from engaging in the traditional practice of bulk compounding of animal drugs. It additionally noted that Franck's has a reputation for refusing to compound drugs that are commercially available; in other words, where compounding is totally unnecessary.

The court alluded to scientific treatises that set forth the premise that customized, compounded medications prescribed by licensed veterinarians and prepared by trained, licensed compounding pharmacists are not only the best practice for treating the animal patient, but might in many instances provide the animals with their only access to life-saving drugs. Further, while the court noted that medication can be compounded from finished drug products, it recognized that bulk substances are preferred because their use ensures that the compounded medicine is of the expected purity, potency and quality.

The court then turned its attention to the Federal Food, Drug and Cosmetic Act ("FDCA"). Here, Judge Corrigan found that Congress defines a "new animal drug" as something not generally recognized as safe and effective for use under the conditions prescribed. The court went on to state that the FDA's own 1992 compliance guidelines in furtherance of this congressional mandate exempted "reasonable quantities" of substances compounded upon receipt of a valid prescription for an individually identified patient from a licensed practitioner from new animal drug enforcement.

The guidelines changed in 1996, and those regulations exempted a bulk compound only if there was no marketed approved animal drug available to address a legitimate medical need with an appropriate dosage regimen for a particular animal. The court stated that the FDA would ordinarily exempt such compounders from regulatory action as long as there was a pharmacist-veterinarian-patient relationship present. Then, in 2003, guidelines that were promulgated without published notice or public comment attempted to outlaw unregulated bulk compounding in its entirety.

In interpreting the FDCA and factually distinguishing previous cases that might lend support to the FDA's position, Judge Corrigan ruled that in enacting the FDCA in 1938,

Congress did not intend to give the FDA authority to enjoin the long-standing, widespread, state-regulated practice of pharmacists filling a veterinarian's prescription for a non food-producing animal by compounding from bulk substances. In sum, the Court did not view the filling of singular prescriptions as animal drug manufacturing subject to federal regulation.

If pharmacies were required to either find an exemption or file an application for a new animal drug for every bulk compound prepared, the practice would more than likely come to a halt. The losers in such circumstance would be our horses; animals living in the 21st century, but who would be denied the benefits of 21st century veterinary pharmacology because of arcane 21st century regulation. The Federal Court has rejected such a draconian result, and we can only await the appeals process to play out to determine if our prized possessions will ultimately be ensured the customized veterinary medicine necessary for treatment of their respective diseases and conditions.

Chris E. Wittstruck is an attorney, a director of the Standardbred Owners Association of New York and a charter member of the Albany Law School Racing and Gaming Law Network.