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ANIMAL DRUGS

Is racehorse doping a violation of the misbranding provisions of the FDCA?

On June 2, the FDA Office of Criminal Investigations announced that a grand jury had returned additional counts on the indictment of a Pennsylvania thoroughbred trainer arising from alleged doping of thoroughbreds under her control at the Penn National Race Course in 2013. Previously the jury had returned charges of wire fraud and criminal conspiracy involving administration of prohibited substances to horses entered by the trainer, Murray L. Rojas, in 13 races in 2013.

The new charges in a superseding indictment expand the scope of the indictment to cover additional races dating to 2009. The indictment alleges that Rojas conspired with "unnamed and unindicted coconspirator veterinarian(s) to administer substances to horses on race day in violation of Pennsylvania criminal laws and horse racing rules." The indictment further alleges that acts to conceal the conspiracy taken by Rojas included back dating invoices for the sale and administration of drugs that were administered on race day, and submission of fraudulent veterinarian treatment reports to the Pennsylvania Horse Racing Commission.

In addition to the wire fraud and conspiracy charges, the indictment charges Rojas with felony misbranding of an animal drug in that she misbranded the drugs with intent to defraud or mislead, in violation of 21 USC §§ 331(k), 333(a)(2), and, particularly § 353(f)(1)(C), which requires that prescription-only animal drugs are misbranded if the drug is not "dispensed by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice."

Rojas moved to dismiss the FDCA-related charges, arguing, according to the Court, that "misbranding of animal drugs in violation of [the FDCA] can only occur if an unlicensed veterinarian – or non-veterinarian – administers the drug to an animal, and because all of Defendant's co-conspirators in the alleged doping scheme were licensed veterinarians, these charges fail as a matter of law." The Court disagreed, finding that Rojas ignored "two of the three elements required to meet the prescription drug exemption to misbranding;" i.e., that the prescription or order be issued lawfully by the veterinarian, and that it be in the due course of the veterinarian's practice. "Whether Defendant herself," the Court opined, "administered any prescriptions is immaterial for the purposes of a misbranding charge pursuant to § 331(k) because § 331 prohibits '[t]he following acts *and the causing thereof.*' 21 USC § 331. As alleged in the Indictment, although the veterinarians were licensed, they were acting on the demand of Defendant, not pursuant

to a prescription or other lawful order, when they administered the prescription drugs to the horses ... Stated more simply, even a licensed veterinarian can act unlawfully and therefore violate the Act." The Court found that the indictment sufficiently alleges acts which would violate the FDCA and cause the drugs to be misbranded.

The Court, of course, did not rule on whether the alleged actions of Rojas and her veterinarians were in fact in violation of the FDCA. "It will be for the factfinder to determine at trial whether the licensed veterinarians dispensed any prohibited substances to horses in contravention of Pennsylvania law, and if so, whether they were acting lawfully in accordance with their professional practices or merely at the behest of Defendant during such administration." [U.S. v. Rojas, Crim. No. 1:15-CR-00169, M.D. Penn., June 14, 2017]