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## FDA's Authority to Regulate State-Licensed Pharmacist Medications for Horses ([/full-blog/2011/12/fdas-authority-to-regulate-state.html](#))



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By: Chris DeAgano, Senior Staff Member

The issue of whether the Food and Drug Administration (FDA) has the authority to regulate state-licensed pharmacies from compounding drugs for horses has been debated very recently in a Florida federal court in *United States v. Franck's Lab, Inc.*[1] This case originated because a Florida pharmacy produced a vitamin and mineral compound(through “compounding”) that was blamed for the deaths of 21 polo horses last year.[2] Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient.[3] Compounding is typically used to prepare medications that are not commercially available.[4]

In *U.S. v. Franck's Lab, Inc.*, the federal court ultimately sided with the Florida compounding laboratory and ruled that the FDA lacked the authority to prevent the laboratory from producing and distributing animal medications compounded from bulk ingredients without the agency's approval.[5] In its decision, the court noted that while the FDA has a difficult task in protecting the health of both humans and animals, the FDA's authority is not unlimited and courts have a role to play in determining whether the agency's actions exceed the statutory powers given to it by Congress.[6]

With the practice of drug compounding being widely-practiced by state-pharmacies, there is a significant interest in a federal agency, such as the FDA, being able to regulate this practice. Furthermore, it may be beneficial to have a uniform set of guidelines for all states, rather than each state having its own laws to regulate state-licensed pharmacies and their compounding practices. While *U.S. v. Franck's Lab, Inc.* was decided against the FDA's power to regulating drug compounding in Florida, there will likely be lawsuits in other states with similar dilemmas in the near future.

[1] *United States v. Franck's Lab, Inc.*, 2011 WL 4031102 (M.D. Fla. Sept. 12, 2011).

[2] Pat Raia, FDA Seeks Injunction Against Florida Pharmacy for Polo Pony Deaths, TheHorse.com, <http://www.thehorse.com/ViewArticle.aspx?ID=16220> (<http://www.thehorse.com/ViewArticle.aspx?ID=16220>) (last visited 10/10/2011).

[3] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61, 122 S. Ct. 1497, 1500, 152 L. Ed. 2d 563 (2002).

[4] *Id.*

[5] Pat Raia, Judge Backs Pharmacy in Veterinary Drug Compounding Case, TheHorse.com (Sept. 20, 2011), <http://www.thehorse.com/ViewArticle.aspx?ID=18853> (<http://www.thehorse.com/ViewArticle.aspx?ID=18853>) (last visited 10/10/2011). [6] *Franck's Lab, Inc.*, 2011 WL 4031102 at \*35.

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