ALERTS AND UPDATES

U.S. District Judge Rejects FDA's Attempted Regulatory Authority over Compounding Pharmacies in United States v. Franck's Lab, Inc.

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On September 12, 2011, the U.S. District Court for the Middle District of Florida in *United States v. Franck's Lab, Inc.* denied a request by the U.S. Food and Drug Administration ("FDA") for an injunction and summary judgment against a compounding pharmacy, Franck's, and firmly rejected the FDA's contention that it had *per se* authority to regulate pharmacies compounding drugs for animal use. This landmark case is likely to have broad implications for the future of compounding pharmacies, and serves as the latest round in a long-standing debate between the FDA and compounding pharmacies over the scope—if any—of the FDA's authority in this area. Despite this recent victory for the compounding industry, this area of the law remains obscure at best. Pharmacies that have questions or receive inquiries from the FDA or their respective state boards related to compounding activities should consider seeking legal counsel.

Franck's is a national pharmacy chain based in Florida, which distributes and compounds drugs for both animal and human use. The *Franck's* case began when, in 2004 and 2005, the FDA inspected Paul Franck's—Franck's CEO, owner and a duly licensed Florida pharmacist—compounding facilities, citing concerns that Franck's was impermissibly manufacturing drugs; compounding drugs outside a valid veterinarian-client-patient relationship; and compounding drugs when approved drugs were otherwise available. After Franck's initial response to this inquiry, the FDA did not approach Franck's until 2009, when Franck's was investigated and reprimanded by the Florida Board of Pharmacy for a misfilled prescription. This incident prompted the FDA to reinspect Franck's facilities and issue an FDA Form 483. Then, in April 2010, the FDA sought a preliminary injunction to enjoin Franck's from distributing animal drugs compounded from bulk substances, asserting that it was a *per se* violation of the federal Food, Drug and Cosmetic Act ("FDCA") to compound animal medications from bulk substances. In essence, the FDA's contention was that "th[e] traditional compounding practice implicate[d] the same concerns under the FDCA as the mass-production, mass-marketing, and mass-distribution of unapproved animal drugs by

an unlicensed manufacturer."[1] In contrast, Florida law permits pharmacists to compound animal medications from bulk substances, as does the law in many other states.[2]

In this significant decision, the district court denied the FDA's request for a preliminary injunction and summary judgment, concluding that the FDCA did not "give the FDA *per se* 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."[3] In so holding, the court relied on several key factors that belied the FDA's assertion of authority over Franck's compounding activities. First, the court noted that although the literal language of the FDCA's new drug provisions might be "sufficiently capacious" to grant authority over compounding and pharmacists, there was no language to indicate Congress' attempt to impose the new drug-approval requirements on pharmacies compounding animal drugs—in fact, the legislative history demonstrated that manufacturers were the target of those requirements. Additionally, the court found that the FDA had the authority, but had failed to exercise it, to draw a regulatory line between traditional compounding pharmacies and manufacturing. Thus, the court disagreed with the FDA's assertion that its "judicious exercise of its enforcement discretion" was sufficient to delineate authorized and unauthorized compounding activities, finding that the "first-of-its-kind enforcement action" in *Franck's* was plainly an improper basis to expand statutory authority. The court found the impropriety of this "enforcement discretion" to be exacerbated by the fact that violations of the FDCA could carry stiff criminal sanctions, and that the "arbitrary enforcement [would therefore be] antithetical to our system of criminal justice."[4]

The *Franck's* decision is significant for compounding pharmacies because it sets a barrier for the FDA's regulatory authority and serves as a reminder of the FDA's obligation to clearly and formally provide guidance to the industry on the scope of the FDCA and its regulatory counterparts. In the months that follow, compounding pharmacies should closely monitor the FDA's regulatory efforts. *Franck's* may serve as the impetus for clarified regulations for compounding pharmacies, and one more step toward ending the long-lasting scrimmage between the FDA and compounding pharmacies.

For Further Information

If you have any questions about this *Alert*, please contact Frederick R. Ball, any member of the Pharmaceutical, Pharmacy and Food industry group or the attorney in the firm with whom you are regularly in contact.

Notes

1. *United States v. Franck's Lab, Inc.*, No. 5:10-cv-00147, slip op. at 38 (M.D. Fla. Sept. 12, 2011).
2. If the FDA was correct that Franck's activities were a *per se* violation of the FDCA, that may trump Florida law on federal preemption grounds.
3. *Franck's Lab, Inc.*, No. 5:10-cv-00147, slip op. at 79–80.
4. *Id.* at 78.

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