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Client Alert

Appellate and FDA & Life Sciences Practice Groups

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U.S. District Court for the Middle District of Florida Holds that FDA Lacks Authority to Enjoin Traditional, State-Permitted Bulk Compounding of Animal Drugs

On September 12, 2011, the United States District Court for the Middle District of Florida entered an order denying the U.S. Food and Drug Administration's request for an injunction barring Franck's Lab, a Florida-based pharmacy, from engaging in traditional, state-licensed bulk compounding of animal drugs and granting Franck's motion for summary judgment. *See United States v. Franck's Lab, Inc.*, No. 5:10-cv-147-Oc-32TBS (M.D. Fla.). The United States brought this first-of-its-kind enforcement action on the novel theory that all animal medications compounded from bulk ingredients are "new animal drugs" requiring FDA approval under the Food, Drug, and Cosmetic Act (FDCA). The Court rejected FDA's position and, ruling in Franck's favor on all issues, held that FDA lacked 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."

Judge Timothy J. Corrigan's scholarly and comprehensive 80-page opinion has significant ramifications for all FDA-regulated industries because it rejects FDA's reliance on non-binding guidances and makes clear that FDA's enforcement discretion is limited by substantive and procedural legal rules. The rule that FDA sought to enforce against Franck's—that compounding animal medications from bulk ingredients in accordance with state law is a per se violation of the FDCA—is not clearly stated in the statute itself, and FDA has never created such a rule through notice-and-comment rulemaking. Judge Corrigan held that FDA therefore lacks authority to enforce such a rule in an injunctive action.

Background

Compounding is "a process by which a pharmacist combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual human or animal patient." Compounding is necessary when a drug is not commercially available or when a commercially available drug is unsuitable, for example, because a patient needs a different dosage, dosage form, or formulation. Florida and other states expressly permit pharmacists to compound medications when they are prescribed for a specific patient by a licensed veterinarian or in anticipation of prescriptions based on routine, observed prescribing patterns.

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Located in Ocala, Florida, Franck's is one of the nation's leading pharmacy compounders. The essential medications it compounds are relied on by animal owners and veterinarians to treat ailing animals across the country.

In 2010, FDA filed suit against Franck's in a first-ever attempt in an enforcement action to assert federal jurisdiction over traditional state-permitted pharmacy compounding practices. Franck's retained King & Spalding to defend its interests. After an effort to reach a mutually acceptable resolution failed, Franck's moved to dismiss the complaint and FDA sought a preliminary injunction. In August 2010, the Court denied both motions and, because the parties agreed that no material facts were in dispute, positioned the case for resolution on summary judgment.

The Court's Order

The question before the Court was whether the FDCA, as enacted in 1938, intended to subject traditional, state-permitted compounding of animal drugs from bulk ingredients to the statute's onerous requirements for FDA approval of "new drugs." Because that question involved FDA's construction of a statute it administers, the Court applied *Chevron USA, Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). Under *Chevron*'s familiar two-step analysis, if Congress has spoken directly to an issue in plain statutory language, a court is required to give effect to Congress's intent; if the statute is silent or ambiguous, a court should defer to the agency's interpretation only if it is reasonable and the agency has followed appropriate procedures in reaching and announcing its interpretation in a form carrying the force of law.

Applying *Chevron*, the Court here found that Congress "did not ... by any contextual ambiguity give FDA the authority to enjoin traditional pharmacy compounding of animal drugs." The Court reasoned that Congress would not have "hidden an elephant in a mousehole" by granting FDA such sweeping and novel authority in such a circumspect fashion. As the Court explained, the statute's new drug approval provisions target previously unregulated manufacturers, not compounding pharmacists then as now regulated by the States, and drugs compounded for individual patients are "ill-suited" for the costly studies required for new manufactured drugs. Accordingly, the Court held that, although FDA may "draw distinctions between manufacturing and compounding generally," Congress did not grant FDA authority to prohibit traditional, state-permitted compounding of animal drugs, "a practice never before regulated by a federal agency and never mentioned in the FDCA."

The Court also found that, even if the FDCA were ambiguous, FDA's interpretation was unreasonable. For half a century after the FDCA was enacted, it did not occur to anyone, including FDA, that the FDCA essentially banned traditional, state-licensed compounding of animal medications from bulk ingredients. Although FDA suggested such a position in non-binding guidance documents beginning in the 1980s, the Court explained that FDA has never attempted to test through appropriate notice-and-comment rulemaking proceedings its view that traditional bulk compounding of animal drugs poses a threat to the approval process for manufactured drugs. FDA also failed to dispute compelling evidence presented by Franck's that the practice of compounding "is an essential component of veterinary medicine" and that granting FDA's request to outlaw that practice "could destabilize the pharmacy profession and leave many animal patients without necessary medication." The Court reasoned that "FDA cannot simply upset the expectations it helped to create through decades of inaction without explanation, especially where its asserted expansion of authority impacts the federal-state balance and potentially subjects many individuals and companies to criminal liability."

The Court concluded by emphasizing that FDA "has long been on notice that its statutory authority to regulate traditional, state-licensed veterinary pharmacy compounding was questionable," and held that Congress did not intend to grant FDA per se authority to enjoin traditional, state-permitted bulk compounding of animal drugs.

Potential Ramifications

The Court's rejection of FDA's attempt to assert enforcement authority against Franck's sets an important precedent with ramifications for all FDA-regulated industries. FDA often seeks to rely on non-binding guidances and a broad conception of its enforcement discretion, rather than promulgating regulations through notice-and-comment rulemaking. *Franck's Lab* is an important reminder that non-binding guidances do not create legal prohibitions and that FDA cannot create a prohibition through an enforcement action; before FDA may enforce a rule in court, FDA must create the rule through proper rulemaking proceedings. This case may signal that FDA should reassess its practice of using informal guidance to announce its interpretations of the law and to set enforcement policy. Judge Corrigan's decision is also an important reminder that when a federal agency takes a novel and aggressive position that lacks a firm legal basis—perhaps expecting a company or individual to give in—the federal courts will carefully scrutinize the government's position if the company or individual instead fights back.