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## Surprise! Fifth Circuit Rejects DEA’s Longstanding Interpretation of a Pharmacist’s “Corresponding Responsibility” and “Usual Course of Professional Practice” Regulations

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One year ago, we [blogged](#) on a DEA [decision](#) revoking the registration of a Louisiana pharmacy, Neumann’s Pharmacy, LLC, based on the pharmacy’s purported violation of its “corresponding responsibility” (21 C.F.R. § 1306.04(a)) and filling of prescriptions without resolving so-called “red flags” of diversion. The pharmacy appealed the Administrator’s decision to the Fifth Circuit, arguing, in part, that DEA “misinterpreted” its own regulations. In a [decision](#) that obliterates DEA’s longstanding interpretation of a pharmacist’s “corresponding responsibility” and “usual course of professional practice” regulations—and now reflects a circuit split—the Fifth Circuit sided with the pharmacy and remanded the case back to DEA.

This *was* a fairly run-of-the-mill case for DEA. The agency alleged that the pharmacy violated its corresponding responsibility by dispensing controlled substances without resolving certain “red flags.” These red flags included dangerous **drug cocktails** (i.e., opioids/benzodiazepines, butalbital/benzodiazepines), **multiple formulations** of the same drug to the same patient (i.e., “therapeutic duplication”), **cash payments** for controlled substances by patients when insurance covered non-controlled substance prescriptions, and prescriptions written for **family members** in violation of state law standards. The Administrator applied testimony from DEA’s expert witness to its interpretation of [21 C.F.R. § 1306.04\(a\)](#) (defining a valid prescription and a pharmacist’s “corresponding responsibility”) and [21 C.F.R. § 1306.06](#) (stating that a pharmacist must only fill prescriptions when “acting in the usual course of his professional practice”) to conclude that the pharmacy had violated the CSA and its registration should be revoked.

The Fifth Circuit fully rejected DEA’s interpretation of its own regulations.

***“Corresponding Responsibility”***

The Fifth Circuit's three-judge panel decided that DEA misinterpreted 21 C.F.R. § 1306.04(a), which sets forth the pharmacist's corresponding responsibility requirement. The regulation states:

**A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.**

The court explained that this “corresponding responsibility” regulation only imposes liability on a pharmacist if the following three elements are met: “the pharmacist (1) fills (2) an invalid prescription (3) knowingly.” *Id.* at 11. The court stated that DEA misapplied the second and third elements.

As to the second element (invalidity), the Fifth Circuit held that pharmacists can only violate their corresponding responsibility under the regulation if the prescription was “invalid when issued.” *Id.* at 12. According to the court, the Administrator must find that the evidence supports that the “prescribing physician issued the prescriptions outside the usual course of professional practice.” *Id.* In other words, to find that a pharmacy registrant violated its corresponding responsibility under 21 C.F.R. § 1306.04(a), DEA must also show that the underlying prescriptions were *in fact invalid*.

Under the third element (knowledge), the Fifth Circuit rejected DEA's traditional interpretation that 21 C.F.R. § 1306.04(a) prohibits a pharmacist from filling a prescription when the pharmacist either “knows or has reason to know that the prescription was not written for a legitimate medical purpose.” *Id.* 12-13. The court explained that the word “knowingly” modifies **both** the act of filling the prescription and the prescription's invalidity, and it held that a pharmacist violates the regulation “only if she **knows** the prescription was invalid.” *Id.* at 15 (emphasis added). The court dismissed DEA's suggestion that its historical knowledge standard (i.e., knew or should have known) equated to the doctrine of “willful blindness,” noting that a true willful blindness standard requires (1) that the defendant subjectively believe that there is a high probability that a fact exists and (2) that the defendant must take deliberate actions to avoid learning of that fact. Willful blindness, the court explained, is a *subjective* test, not an *objective* test as DEA's interpretation imposed. The “willful blindness” standard harkens back to a 2010 DEA administrative decision, first blogged about [here](#), 16 years ago.

### ***“Usual Course of Professional Practice”***

The court next turned to the Administrator’s finding that the pharmacy violated 21 C.F.R. § 1306.06 when the pharmacist filled prescriptions outside “the usual course of [the pharmacist’s] professional practice.” While the DEA Administrator found that the pharmacy violated this regulation by equating “the usual course of professional practice” with the “state-law standard of care,” the Fifth Circuit found this interpretation was “legal error.” *Id.* at 17.

The court explained that the phrase “usual course of professional practice” is a term of art under the CSA and its predecessors that meant “*bona fide* medical practice.” *Id.* As applied to pharmacies, the court held that this phrase includes “filling prescriptions in good faith within the *bona fide* operations of a pharmacy.” *Id.* at 18. The court noted that applying this phrase to *physicians* means only restricting a physician to dispensing or prescribing drugs in the *bona fide* treatment of a patient’s disease,” meaning the physician “cannot sell drugs to a dealer nor distribute drugs intended to cater to cravings of an addict . . . under the guise of treatment.” *Id.* at 19. As applied to pharmacies/pharmacists, the court opined that DEA’s “standard of care” interpretation of the regulation’s “usual course of professional practice” language is in tension with the meaning of the statute and prior precedent. Incorporating the state law standard of care, according to the court, “would risk exceeding the DEA’s statutory authority under the CSA.” *Id.*

The court further explained that incorporating a “state-law standard of care” would “convert every act of negligence under state law into a federal felony,” and it would “elide the difference between acting as a *bad* pharmacist and ceasing to act as a pharmacist at all.” *Id.* at 20. Accordingly, the court held, proof of a violation of a state-law standard of care, standing alone, is not sufficient to establish a violation of 21 C.F.R. § 1306.06. Lastly, the court concluded with a stark reminder for DEA:

**[E]ven the most urgent regulatory goals do not permit an agency to depart from the regulations it has adopted while claiming to enforce them. The DEA may pursue stricter standards through lawful means; it may not do so by misreading the regulations that govern this case.**

### ***Takeaways***

The Fifth Circuit’s decision is a significant shakeup of DEA’s longstanding interpretations of two critical regulations involving pharmacies. Proof of actual invalidity of the prescriptions presents a heavy burden on the government to prove that the pharmacy violated the law. Further, the narrowing of the objective knowledge standard (i.e., knew or should have known) to actual, subjective knowledge of a prescription’s invalidity breaks with years of agency precedent and conflicts with decisions in other circuits that

have addressed this issue. *See, e.g., Medicine-Shoppe – Jonesborough v. DEA*, 300 Fed. App'x 409, 412 (6th Cir. Nov. 13, 2008) (upholding DEA's interpretation that 21 C.F.R. § 1306.04(a) requires a pharmacist to refuse to fill a prescription "if he knows or has reason to know that the prescription was not written for a legitimate medical purpose").

Going forward, DEA's reliance alone on expert testimony related to state law standards of care likely will not suffice in pharmacy show-cause matters. DEA, at least for registrants within the Fifth Circuit, will be required to show how the pharmacy's conduct ventured outside the regular practice of pharmacy and into the world of illegal drug distribution. This would indeed be a heavy evidentiary burden for DEA to carry, and likely a rare occurrence in *any* pharmacy.

It remains to be seen how DEA will apply this Fifth Circuit decision and whether it will constrain DEA enforcement actions against pharmacists and pharmacies. Regardless, pharmacy registrants facing DEA revocation hearings should carefully analyze with experienced counsel the impact of the *Neumann Pharmacy* decision on their cases.