United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
February 13, 2026
Lyle W. Cayce
Clerk

No. 25-60068

NEUMANN'S PHARMACY, L.L.C.,

Petitioner,

versus

DRUG ENFORCEMENT ADMINISTRATION,

Respondent.

Petition for Review of an Order of the
Drug Enforcement Agency
Agency No. FN4373293

Before ELROD, *Chief Judge*, and RICHMAN and WILLETT, *Circuit Judges*.

DON R. WILLETT, *Circuit Judge*:

Under the Controlled Substances Act, the Drug Enforcement Administration plays a vital role in protecting the public from drug misuse and diversion. Federal courts play a different role: ensuring that, when an agency exercises the authority Congress has granted, it adheres to the statutes and regulations that bind it. When an agency claims to apply

governing text but instead substitutes a different rule of decision, we do not defer—we set the action aside.[1]

That is this case. The DEA revoked Neumann's Pharmacy's registration to dispense controlled substances based on the agency's professed application of two regulations and Louisiana law. The DEA unquestionably has broad authority to deregister pharmacies and substantial discretion to shape policy within statutory bounds. But it may not say it is applying existing regulations while quietly rewriting them in practice. Because the DEA's decision rests on interpretations the governing texts will not bear, we VACATE the deregistration order and REMAND for further proceedings consistent with this opinion.

I. Background

A. The Controlled Substances Act

"Shortly after taking office in 1969, President Nixon declared a national 'war on drugs.'"[2] As its opening salvo, "Congress set out to enact legislation that would consolidate various drug laws on the books into a comprehensive statute, provide meaningful regulation over legitimate sources of drugs to prevent diversion into illegal channels, and strengthen law enforcement tools against the traffic in illicit drugs."[3] The result was the Comprehensive Drug Abuse Prevention and Control Act of 1970—Title II of which is the Controlled Substances Act (CSA).[4] "[T]he CSA creates a

---

[1] *See* 5 U.S.C. § 706(2)(A) ("The reviewing court shall . . . set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]").

[2] *Gonzales v. Raich*, 545 U.S. 1, 10 (2005) (citation omitted).

[3] *Id.*

[4] Pub. L. 91–513, 84 Stat. 1236, 1242 (1970).

comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the Act's five schedules."[5]

As relevant here, the CSA requires "[e]very person who dispenses . . . any controlled substance" to "obtain from the Attorney General a registration."[6] The statute directs the Attorney General to "register practitioners (including pharmacies, as distinguished from pharmacists) to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices."[7] However, "[t]he Attorney General may deny an application for such registration" if she "determines that the issuance of such registration or modification would be inconsistent with the public interest."[8]

To guide that determination, the statute lists five factors that "shall be considered" "[i]n determining the public interest":

> (A) The recommendation of the appropriate State licensing board or professional disciplinary authority.
> (B) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
> (C) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

---

[5] *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006) (citations omitted).

[6] 21 U.S.C. § 822(a)(1).

[7] *Id.* § 823(g)(1).

[8] *Id.*

(D) Compliance with applicable State, Federal, or local laws relating to controlled substances

(E) Such other conduct which may threaten the public health and safety.[9]

Once granted, a registration "may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration . . . inconsistent with the public interest."[10] In making that determination, the Attorney General must consider the same statutory factors that govern initial registration.[11] The Attorney General has delegated this revocation authority to the Administrator of the Drug Enforcement Administration.[12]

B. Neumann's Pharmacy

Neumann's is a retail pharmacy located in Tallulah, Louisiana. Its owner and pharmacist-in-charge is Laura Neumann, who has been licensed to practice pharmacy in Louisiana since 1995. After working for several independent pharmacies, Ms. Neumann purchased her own pharmacy in 2014 and renamed it Neumann's Pharmacy. Neumann's is licensed under Louisiana law to dispense controlled substances and, before the proceedings at issue here, was also registered under the CSA.

The DEA began investigating Neumann's after receiving a tip that Ms. Neumann was filling prescriptions for herself. Following that investigation, the DEA issued Neumann's an order to show cause why its

---

[9] *Id.*

[10] *Id.* § 824(a)(4).

[11] *See id.* (providing that the Attorney General should assess "the public interest as determined under [§ 823]").

[12] 28 C.F.R. § 0.100(b); *see Humphreys v. DEA*, 96 F.3d 658, 661 (3d Cir. 1996).

certificate of registration should not be revoked. The order alleged—and the DEA ultimately found—that Neumann's filled prescriptions while disregarding certain "red flags," indicators suggesting that the prescriptions may not have been valid.[13]

1. Patient C.E.

First, in July, October, and December of 2021, Neumann's filled prescriptions for patient C.E. for both hydrocodone acetaminophen (an opioid) and clonazepam (a benzodiazepine). Because of their interaction when used together, opioids and benzodiazepines form a "drug cocktail."[14] Like other drug cocktails, opioid–benzodiazepine combinations increase the risk of overdose or death and are also associated with diversion of controlled substances from lawful to illicit channels.

At the agency hearing, Ms. Neumann testified that she addressed this red flag by reviewing the diagnosis codes on the prescriptions and speaking with C.E. She stated that C.E. was receiving hydrocodone to manage "injuries or shoulder pain" while switching between two specialists, and clonazepam to treat anxiety. She further testified that she did not believe the risk of overdose was high because C.E. received only a limited number of prescriptions. Ms. Neumann did not, however, document her conversations with C.E. or her resolution of this red flag.

---

[13] *See Neumann's Pharmacy*, 90 Fed. Reg. 8039, 8040 (Dep't of Just., Drug Enf't Admin. Jan. 23, 2025) (defining "red flags").

[14] In this context, a "drug cocktail" refers to a combination of controlled substances that is widely known to be abused or diverted and that significantly increase the patient's risk of serious medical consequences.

2. Patient J.H.R.

Next, between September 2020 and January 2022 Neumann's filled monthly prescriptions for patient J.H.R. for both hydrocodone acetaminophen and alprazolam (another benzodiazepine). Like other opioid–benzodiazepine combinations, hydrocodone acetaminophen and alprazolam constitute a "drug cocktail." J.H.R.'s prescriptions also raised a separate red flag: although she used insurance to pay for non-controlled substance prescriptions, she paid out of pocket for her controlled-substance prescriptions. The DEA's expert, Dr. DiGi Graham, testified that out-of-pocket payments may signal diversion because patients sometimes pay cash to avoid the additional scrutiny insurers apply to prevent abuse.

With respect to the drug cocktail, Ms. Neumann testified that she contacted the prescribing physician, Dr. T.N.—who is also her father—when J.H.R. first became a patient in 2015. According to Ms. Neumann, Dr. T.N. explained why he prescribed the combination, and that explanation satisfied her. Ms. Neumann documented that resolution by making notations on the back of the prescriptions. She did not, however, document any resolution for the prescriptions issued between 2020 and 2022—the prescriptions at issue in the agency proceedings.

As for the out-of-pocket payments, Ms. Neumann testified that in approximately March 2021, J.H.R.'s insurance company rejected coverage for one of her prescriptions. When Ms. Neumann asked whether J.H.R. had a new insurance card, J.H.R. responded that she had lost her job and no longer had insurance. Ms. Neumann testified that, from that point forward, J.H.R. paid out of pocket for all her prescriptions. J.H.R.'s payment records, however, reflect different methods of payment for her controlled-substance prescriptions and her non-controlled substance prescriptions. The

DEA interpreted that discrepancy to suggest that J.H.R. maintained insurance but paid cash for her controlled substances.

3. Patient S.W.

Finally, on six occasions between October 2020 and December 2021, Neumann's filled prescriptions for patient S.W. for three different butalbital-based medications—butalbital-aspirin-caffeine, butalbital--acetaminophen-caffeine, and ASCOMP with codeine—along with diazepam. Combinations of butalbital or codeine with diazepam constitute drug cocktails, and the presence of three different butalbital formulations also raised a distinct red flag called "therapeutic duplication," which occurs when a patient is prescribed "multiple controlled substances that have essentially the same effect." In addition, S.W. paid for her prescriptions out of pocket—another red flag.

Ms. Neumann testified that she spoke with the prescribing physician, Dr. T.N.—her father—about the prescriptions and was satisfied with his explanation. She also testified that she knew S.W. lived in the United Kingdom and therefore did not have health insurance in the United States. Ms. Neumann did not, however, document either resolution.

4. Ms. Neumann's Own Prescriptions

In addition to these red-flag-laden prescriptions for patients, Neumann's also filled a prescription for Ms. Neumann herself. The prescription was written by Dr. T.N.—Ms. Neumann's father—in violation of Louisiana law, which deems it unprofessional conduct for a physician to prescribe controlled substances to a family member, including a child.[15] Ms. Neumann testified that she had previously filled the same prescription at

[15] *See* LA. ADMIN. CODE tit. 46, pt. XLV, § 7603(A)(11).

another pharmacy without issue, even after Louisiana adopted the prohibition on prescribing controlled substances to family members.

C. Agency Proceedings

At a two-day hearing before an administrative law judge (ALJ), each side presented one fact witness and one expert witness. The Government began its case with Group Supervisor Theresa Bass, who had conducted the investigation into Neumann's. The ALJ found Bass "a credible, reliable witness." The Government's expert witness was Dr. DiGi Graham, a licensed pharmacist based in Oklahoma. Neumann's did not object to qualifying Dr. Graham as an expert in "Louisiana pharmacy practice, including the applicable standards of care in Louisiana for the dispensing of controlled substances within the usual course of pharmacy practice." The ALJ found "Dr. Graham's testimony to be fully credible and reliable."

Neumann's first witness was Dr. Julie Akers, a Washington-based pharmacist and professor at the Washington State University School of Pharmacy and Pharmaceutical Sciences, who was qualified without objection as an expert "in the standard of care and professional responsibility required of a pharmacy in Louisiana pursuant to the governing federal and state of Louisiana rules and regulations." The ALJ found "that Dr. Akers had limited reliability as an expert," in part because her testimony was "at times, unclear and contradictory." Accordingly, the ALJ credited Dr. Graham's testimony over Dr. Akers's where the two disagreed.

Ms. Neumann also testified, and the most relevant portions of her testimony are recounted above. However, the ALJ found that "Ms. Neumann's testimony had diminished credibility" because she was "guarded and not forthcoming." The ALJ therefore gave "Ms. Neumann's testimony little weight."

After the hearing, the ALJ issued a 41-page recommendation, making extensive findings of fact and ultimately concluding that Neumann's violated several provisions of state and federal law and that deregistration was an appropriate sanction.

In a 33-page order of her own, the Administrator "adopt[ed] and incorporate[d] by reference the entirety of" the ALJ's analysis, "and summarize[d] and clarifie[d] portions thereof."[16] Accordingly, she deregistered Neumann's and "den[ied] any pending applications of Neumann's . . . to renew or modify [its] registration, as well as any other pending applications of Neumann's . . . for additional registration in Louisiana."[17]

II. Standard of Review

The CSA vests the Attorney General—and, by delegation, the Administrator—with broad discretion to deregister pharmacies.[18] "[W]hen an agency exercises discretion granted by a statute, judicial review is typically conducted under the Administrative Procedure Act's deferential arbitrary-and-capricious standard."[19] "Under that standard, a court asks not whether it agrees with the agency decision, but rather only whether the agency action was reasonable and reasonably explained."[20]

---

[16] *Neumann's Pharmacy*, 90 Fed. Reg. at 8039.

[17] *Id.* at 8048.

[18] *See Oregon*, 546 U.S. at 292 (Scalia, J., dissenting) ("Sections 823(f) and 824(a) explicitly grant the Attorney General the authority to register and deregister physicians, and his discretion in exercising that authority is spelled out in very broad terms.").

[19] *Seven Cnty. Infrastructure Coal. v. Eagle Cnty.*, 605 U.S. 168, 179–80 (2025).

[20] *Id.* at 180 (citations omitted).

That deference, however, has limits. "Even if the substance of an agency's decision is beyond review as discretionary, an agency's failure to follow its own regulations may be challenged under the APA."[21] We therefore "will not hesitate to overturn agency action as arbitrary and capricious if the agency fails to 'comply with its own regulations.'"[22]

By contrast, the DEA's factual determinations are "conclusive" so long as they are "supported by substantial evidence."[23]

III. Discussion

Neumann's principally contends that the DEA misinterpreted its own regulations and Louisiana law. We agree. And because those errors require vacatur, we do not reach the alternative arguments that the

---

[21] *Ellison v. Connor*, 153 F.3d 247, 252 (5th Cir. 1998); *see Fort Stewart Schs. v. FLRA*, 495 U.S. 641, 654 (1990) ("It is a familiar rule of administrative law that an agency must abide by its own regulations."(citations omitted)).

[22] *Nat'l Biodiesel Bd. v. EPA*, 843 F.3d 1010, 1018 (D.C. Cir. 2016) (quoting *Environmentel, LLC v. FCC*, 661 F.3d 80, 85 (D.C. Cir. 2011)); *accord N.M. Farm & Livestock Bureau v. U.S. Dep't of Interior*, 952 F.3d 1216, 1231 (10th Cir. 2020) ("When an agency does not comply with its own regulations, it acts arbitrarily and capriciously." (citation omitted)); *Conservancy of Se. Fla. v. U.S. Fish & Wildlife Serv.*, 677 F.3d 1073, 1078 n.10 (11th Cir. 2012) ("An agency's failure to follow its own regulations is arbitrary and capricious." (citation omitted)).

The DEA does not invoke deference under *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945), and *Auer v. Robbins*, 519 U.S. 452 (1997). We therefore decline to consider whether such deference might otherwise apply. *See Ortiz v. McDonough*, 6 F.4th 1267, 1275 (Fed. Cir. 2021) (declining to decide whether *Seminole Rock*/*Auer* deference applied "because the Secretary does not invoke the doctrine"); *Robinson Knife Mfg. Co. v. CIR*, 600 F.3d 121, 134 n.11 (2d Cir. 2010) ("[T]he Commissioner has not argued *Auer* deference, so any such argument is forfeited."); *cf. HollyFrontier Cheyeene Refin., LLC v. Renewable Fuels Ass'n*, 594 U.S. 382, 394 (2021) ("declin[ing] to consider whether any deference might be due" under *Chevron v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), because "the government [was] not invoking *Chevron*").

[23] 21 U.S.C. § 877.

deregistration order was arbitrary and capricious, unsupported by substantial evidence, or violative of due process.

A. The Corresponding-Responsibility Regulation

First, Neumann's challenges the DEA's interpretation of 21 C.F.R. § 1306.04(a). That regulation places primary "responsibility for the proper prescribing and dispensing of controlled substances" on the prescribing physician, while imposing a "corresponding responsibility" on "the pharmacist who fills the prescription."[24] Section 1306.04(a) provides:

> 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.[25]

Read as a whole, the regulation imposes liability on a pharmacist only if three conditions are met: the pharmacist (1) fills (2) an invalid prescription (3) knowingly. Neumann's does not dispute that it filled the prescriptions at issue, so the first requirement is satisfied. But we agree with Neumann's that the DEA misapplied the regulation's second and third requirements.

---

[24] 21 C.F.R. § 1306.04(a).

[25] *Id.*

1. Invalidity

The first issue is straightforward. By its terms, § 1306.04(a) applies only when a pharmacist fills "such a purported prescription"—a clear reference to the regulation's earlier description of "[a]n order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research."[26] Put simply, a pharmacist violates § 1306.04(a) only by filling a prescription that was invalid when issued—that is, one written outside the prescribing physician's usual course of professional practice.

Here, neither the Administrator nor the ALJ made that finding. They did not analyze whether the prescribing physician issued the prescriptions outside the usual course of professional practice. Instead, they focused exclusively on whether Neumann's dispensed the prescriptions "outside the course of professional practice" for a pharmacy. That inquiry may be relevant under § 1306.06, as discussed below. But it is irrelevant under the plain text of § 1306.04(a). By finding a violation of § 1306.04(a) without first determining that any prescription was invalid when issued, the DEA misapplied the regulation.

2. Knowledge

The second issue requires more extensive analysis. Section 1306.04(a) applies only when a "person *knowingly* fill[s]" an invalid prescription.[27] The DEA, however, has "long interpreted [§ 1306.04(a)] as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows *or has reason to know* that the prescription was not written for a

---

[26] *Id.*

[27] *Id.* (emphasis added).

legitimate medical purpose.'"[28] Neumann's challenges that interpretation as inconsistent with the regulation's text.

On this point as well, Neumann's has the better argument. The dispute turns on the scope of the regulation's *mens rea* requirement: whether "knowingly" modifies only the act of filling a prescription, or whether it also extends to the prescription's invalidity. The DEA's interpretation adopts the former view—treating knowledge of invalidity as unnecessary. That reading cannot be squared with the text, for several reasons.

As the Supreme Court explained in *Flores-Figueroa v. United States*, "where a transitive verb"—here, "fills"—"has an object, listeners in most contexts assume that an adverb (such as knowingly) that modifies the transitive verb tells the listener how the subject performed the entire action, *including the object as set forth in the sentence.*"[29] The Court illustrated the point with a simple example: "[i]f a child knowingly takes a toy that belongs to his sibling, we assume that the child not only knows that he is taking something, but that he also knows that what he is taking is a toy *and* that the toy belongs to his sibling."[30] As the Court noted, "[s]imilar examples abound," while "dissimilar examples are not easy to find."[31] Thus, "[a]s a matter of ordinary English grammar, it seems natural to read the

---

[28] *JM Pharmacy Grp.*, 80 Fed. Reg. 28667, 28670 (Dep't of Just., Drug Enf't Admin. May 19, 2015) (emphasis added) (quoting *Medic-Aid Pharmacy*, 55 Fed. Reg. 30043, 30044 (Dep't of Just., Drug Enf't Admin. July 24, 1990)).

[29] 556 U.S. 646, 650 (2009) (emphasis added).

[30] *Id.* at 651 (emphasis in original).

[31] *Id.*

[regulation's] word 'knowingly' as applying to all the subsequently listed elements of the [violation]."[32]

That principle is not "an overly rigid rule of statutory construction."[33] Context always matters.[34] But the context here underscores—rather than undermines—the natural grammatical reading. Although § 1306.04(a) is not itself a criminal statute, a "[v]iolation is a criminal offense, and often a felony, under 21 U.S.C. § 841."[35] And background principles of criminal law strongly support applying the knowledge requirement to each element of the violation. The "deeply rooted presumption" is that the Government must "prove the defendant's *mens rea* with respect to each element of a federal offense."[36] To be sure, Congress or an agency may sometimes assign different mental states to different elements.[37] But "courts ordinarily read a phrase in a criminal statute that introduces the elements of a crime with the word 'knowingly' as applying that word to each element."[38] The Supreme Court has even applied that presumption where doing so was not "[t]he most

---

[32] *Id.* at 650; *see also id.* at 657 (SCALIA, J., concurring in part and concurring in the judgment) ("Ordinary English usage supports this reading, as the Court's numerous sample sentences amply demonstrate.").

[33] *Id.* at 659 (ALITO, J., concurring in part and concurring in the judgment).

[34] *Id.*

[35] *Oregon*, 546 U.S. at 261 (majority opinion).

[36] *Wooden v. United States*, 595 U.S. 360, 378 (2022) (KAVANAUGH, J., concurring) (citations omitted); *see* BRYAN A. GARNER & ANTONIN SCALIA, READING LAW 303 (2012).

[37] *See United States v. Bailey*, 444 U.S. 394, 406 (1980).

[38] *Flores-Figueroa*, 556 U.S. at 652 (majority opinion) (citation omitted).

natural grammatical reading."[39] That is unnecessary here, because the presumption merely confirms what the text already says in ordinary English.

Finally, dicta from our decision in *United States v. Hayes* strongly supports applying the knowledge requirement to the fact of the prescription's invalidity.[40] Although *Hayes* dealt with § 1306.04(a)'s validity rather than its precise meaning, the court observed that § 1306.04(a) applies when the pharmacist "*knows* the practitioner issued [the purported prescription] in other than the usual course of medical treatment."[41] And it went on to explain that "[v]erification by the issuing practitioner on request of the pharmacist . . . is not an insurance policy against a fact finder's concluding that the pharmacist had *the requisite knowledge*," but "is evidence that the pharmacist lacks *knowledge that the prescription was issued outside the scope of professional practice*."[42] This discussion presupposes what a close analysis of the text confirms independently: a pharmacist violates § 1306.04(a) only if she knows the prescription was invalid.

The Government offers a meager, half-hearted defense of the DEA's interpretation, suggesting that the agency simply "equated the 'know[edge]' necessary for liability under section 1306.04(a) [with] 'willful blindness.'" But while "[t]he doctrine of willful blindness"—which prevents defendants from "escap[ing] the reach of" a statute requiring knowledge "by deliberately shielding themselves from clear evidence of critical facts"—"is well established in criminal law,"[43] it differs fundamentally from the standard

---

[39] *See United States v. X-Citement Video, Inc.*, 513 U.S. 64, 68 (1994).

[40] 595 F.2d 258 (5th Cir. 1979).

[41] *Id.* at 259–60 (emphasis added).

[42] *Id.* at 260 (emphasis added).

[43] *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011).

the DEA applied here. Willful blindness has "two basic requirements: (1) The defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact."[44] It "is a 'subjective state of mind.'"[45] By contrast, the standard the DEA employed is objective, asking whether the pharmacist "has reason to know that the prescription was not written for a legitimate medical purpose."[46] Thus, even if willful blindness satisfies § 1306.04(a),[47] it does not follow that the DEA's interpretation is consistent with the regulation.

The Government also notes that the statute governing deregistration, 21 U.S.C. § 824, does not have a scienter requirement of its own. But that is a red herring. "It is 'a simple but fundamental rule of administrative law' that reviewing courts 'must judge the propriety of [agency] action solely by the grounds invoked by the agency.'"[48] Here, one of those grounds was the DEA's conclusion that Neumann's violated § 1306.04(a)—a conclusion reached through a misinterpretation of the regulation. While it may be that the DEA *could* have deregistered Neumann's without relying on this interpretation of § 1306.04(a), it *did* not do so. And we cannot "affirm[] the

---

[44] *Id.* at 769.

[45] *United States v. Stadtmauer*, 620 F.3d 238, 255 (3d Cir. 2010) (quoting *United States v. One 1973 Rolls Royce*, 43 F.3d 794, 808 (3d Cir. 1994)).

[46] *Neumann's Pharmacy*, 90 Fed. Reg. at 8047 (quoting *JM Pharmacy Grp., Inc.*, 80 Fed. Reg. 28667, 28670 (Dep't of Just., Drug Enf't Admin. May 19, 2015)).

[47] *See Global-Tech Appliances*, 563 U.S. at 768 (noting "the long history of willful blindness and its wide acceptance in the Federal Judiciary").

[48] *Calcutt v. FDIC*, 598 U.S. 623, 624 (2023) (per curiam) (alteration in original) (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947)).

[DEA's] sanctions against petitioner based on a legal rationale different from the one adopted by the [DEA]."[49]

B. The Usual Course of Professional Practice

The DEA also found that Neumann's violated 21 C.F.R. § 1306.06, which requires a pharmacist to fill prescriptions only "in the usual course of his professional practice,"[50] on the theory that Neumann's failure to resolve certain red flags fell "beneath the Louisiana standard of care."[51] Equating the usual course of professional practice with the state-law standard of care was legal error.

The phrase "course of professional practice" in § 1306.06 is borrowed from the CSA itself.[52] And the term in the CSA is "directly traceable to the Harrison Act, which prohibited 'any person' from distributing coca leaves or opium 'except in pursuance of a written order' issued by a practitioner 'in the course of his professional practice only.'"[53] Under the Supreme Court's Harrison Act precedents, the phrase "refer[red] to '*bona fide* medical practice,' which meant that any prescription issued 'in good faith' qualified as an authorized act of dispensing one of the drugs proscribed by the statute."[54]

---

[49] *Id.*

[50] 21 C.F.R. § 1306.06.

[51] *See Neumann's Pharmacy*, 90 Fed. Reg. at 8044 ("The Agency . . . finds that there is substantial record evidence that Respondent's dispensing fell below the Louisiana standard of care, *and thus* was outside the usual course of professional practice." (emphasis added)).

[52] *See* 21 U.S.C. § 802(21).

[53] *Ruan v. United States*, 597 U.S. 450, 478 (2022) (ALITO, J., concurring in the judgment) (citation omitted).

[54] *Id.* (citations omitted)

Where "a term of art" is "obviously transplanted from another legal source, it brings the old soil with it."[55] Accordingly, when the CSA and its implementing regulations used the phrase "course of his professional practice," they presumably used the phrase in the same sense ascribed to it in the Supreme Court's Harrison Act precedents.[56] Absent some indication to the contrary, the phrase "course of his professional practice" includes filling prescriptions in good faith within the *bona fide* operations of a pharmacy.

The Supreme Court's decision in *United States v. Moore* further supports that conclusion.[57] The defendant in *Moore* "concede[d] . . . that he did not observe generally accepted medical practices."[58] But after finding that "the scheme of the statute . . . reveals an intent to limit a registered physician's dispensing authority to the course of his 'professional practice,'" the *Moore* Court explained that "the understanding that [a physician] is authorized only to act 'as a physician'" is "[i]mplicit in . . . registration."[59] It also expressly tied this conclusion to the CSA's use of the term "in the course of professional practice or research."[60] Under *Moore*, then, a physician acts in the course of his professional practice even if he deviates from the standard of care, so long as he acts "as a physician." There is no principled reason the same phrase would not also cover a pharmacist who

---

[55] *George v. McDonough*, 596 U.S. 740, 746 (2022) (cleaned up).

[56] *See Ruan*, 597 U.S. at 478 (ALITO, J., concurring in the judgment) ("Nothing in the CSA suggests that Congress intended to depart from the preexisting understanding of action 'in the course of professional practice.'").

[57] 423 U.S. 122 (1975).

[58] *Id.* at 126.

[59] *Id.* at 140–41.

[60] *Id.* at 141.

deviates from the standard of care but nevertheless continues to act "as a pharmacist."

Our decision in *United States v. Collier* illustrates the same point.[61] We explained that the same language "restrict[s]" a physician "to dispensing or prescribing drugs in the bona fide treatment of a patient's disease," meaning that he "cannot sell drugs to a dealer nor distribute drugs intended to cater to cravings of an addict" "under the guise of treatment."[62] And in rejecting a right-to-privacy challenge to the CSA and its implementing regulations, *Collier* explained that the statute and regulations "bar[] only activities outside the physician's professional practice, where a physician acts, in essence, as a 'pusher.'"[63]

The DEA's "standard of care" interpretation of "the usual course of his professional practice" is in tension not only with the history of the phrase as a term of art and the interpretations in *Moore* and *Collier*, but also with the Supreme Court's decision in *Gonzales v. Oregon*.[64] The Court explained that the CSA "regulates medical practice" only "insofar as it bars doctors from using their prescription-writing powers as means to engage in illicit drug dealing and trafficking."[65] "Beyond this," the Court continued, "the statute manifests no intent to regulate the practice of medicine generally."[66] Thus, if § 1306.06 were interpreted to incorporate the state-law standard of care, it would risk exceeding the DEA's statutory authority under the CSA.

---

[61] 478 F.2d 268 (5th Cir. 1973).

[62] *Id.* at 271–72.

[63] *Id.* at 274.

[64] 546 U.S. 243.

[65] *Id.* at 269–70.

[66] *Id.* at 270.

Finally, adopting the DEA's interpretation would, as JUSTICE ALITO has observed, convert every act of negligence under state law into a federal felony.[67] It would elide the difference between acting as a *bad* pharmacist and ceasing to act as a pharmacist at all.[68] In part for that reason, each of our sister circuits that has addressed the issue has concluded that falling below the standard of care is insufficient to establish action outside the course of professional practice.[69] To be sure, those decisions (like the decisions discussed above) dealt with physicians, not pharmacists. And they considered uses of the phrase "course of his professional practice" without the modifier "usual." But it is hard to see how either difference could transform the meaning of a settled term of art so dramatically as to make every violation of state-law standards of care a federal offense. We therefore conclude that a violation of the state-law standard of care, standing alone, is not sufficient to establish a violation of § 1306.06.

C. Louisiana's Ban on Prescribing to Family Members

In addition to regulatory violations, the DEA also found that Neumann's violated a provision of the Louisiana Administrative Code, which makes it unprofessional conduct for "physicians" to "prescribe controlled substances for themselves or their immediate family members"—including, as relevant here, "the physician's . . . children."[70] The record does not make clear whether this finding served only to bolster the DEA's conclusion that Neumann's deviated from the state-law standard of care or instead operated as an independent basis for the DEA's conclusion that

---

[67] *See Ruan*, 597 U.S. at 479 (ALITO, J., concurring in the judgment).

[68] *Id.* (emphasis in original).

[69] *See United States v. Feingold*, 454 F.3d 1001, 1011 (9th Cir. 2006) (collecting cases).

[70] LA. ADMIN. CODE, tit. 46, pt. XLV, § 7603(A)(11).

Neumann's failed to "[c]ompl[y] with applicable State, Federal, or local laws relating to controlled substances"—a separate factor the DEA may consider in deciding whether to revoke a registration.[71]

If the DEA relied on the Louisiana law to find a deviation from the state-law standard of care, that was error for two reasons. First, as explained above, a deviation from the state-law standard of care is not sufficient to establish that a physician or pharmacist acted outside the usual course of professional practice. Second, again as explained above, a violation of § 1306.04(a) requires knowledge of the prescription's invalidity, and the final agency order acknowledges that Ms. Neumann was not aware of the prohibition on prescribing controlled substances to family members.[72]

But even if the DEA relied on the Louisiana law as an independent basis for deregistration, it erred because the alleged misconduct falls outside the provision's clear scope. By its terms, the provision applies only to the act of "prescrib[ing] controlled substances"—not to filling the resulting prescriptions—and only when performed by a "physician[]"—not by a pharmacy.[73] Because Neumann's is a pharmacy, not a physician, and because it filled a prescription rather than prescribing a controlled substance, its conduct does not fall within the provision's reach.

D. Remedy

That leaves the question of remedy. "[V]acatur of an agency action is the default rule in this Circuit,"[74] though "[i]n rare cases . . . we do not

---

[71] *See* 21 U.S.C. § 823(g)(1)(D).

[72] *See Neumann's Pharmacy*, 90 Fed. Reg. at 8046 (finding "Ms. Neumann's . . . lack of knowledge" to be an aggravating factor warranting deregistration).

[73] LA. ADMIN. CODE, tit. 46, pt. XLV, § 7603(A)(11).

[74] *Cargill v. Garland*, 57 F.4th 447, 472 (5th Cir. 2023) (en banc).

vacate the action but instead remand for the agency to correct its errors."[75] Here, however, the Government did not argue that remand without vacatur is appropriate, and any such argument is therefore forfeited.[76] Accordingly, we will vacate the deregistration order.

Neumann's urges us to go one step further and vacate without remanding to the DEA. It contends that rejecting the DEA's errors "means destroying the entire theory of this revocation proceeding," leaving "nothing to remand." We disagree. "Generally speaking," when an agency adjudication produces a decision that lies within an agency's discretion but rests on impermissible reasoning, "a court of appeals should remand [the] case to an agency for decision of a matter that statutes place primarily in agency hands."[77] The DEA's deregistration authority "is spelled out in very broad terms."[78] Although the DEA may not rely on its erroneous interpretations of §§ 1306.04(a) and 1306.06 or its misapplication of Louisiana law, it is possible that the agency could reach the same result based on a correct interpretation of those provisions—or based on one of the other factors listed in § 823(g)(1). We express no view on whether such a result would be warranted. We hold only that the agency should have the opportunity to make that determination in the first instance.

---

[75] *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019).

[76] *See Data Mktg. P'ship, LP v. U.S. DOL*, 45 F.4th 846, 860 (5th Cir. 2022) ("The Department makes no developed argument that the district court abused its discretion in following the default [vacatur] rule, so the Department forfeited the argument.").

[77] *I.N.S. v. Orlando Ventura*, 537 U.S. 12, 16 (2002) (per curiam).

[78] *Oregon*, 546 U.S. at 292 (SCALIA, J., dissenting).

IV. Conclusion

There is no doubt, as one of the Government's experts testified, that pharmacists are often "the last line of defense" against the diversion and misuse of controlled substances. But even 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.

Because the DEA's decision rests on erroneous interpretations of its regulations and a misapplication of Louisiana law, we VACATE the deregistration order and REMAND for further proceedings consistent with this opinion.