Nos. 20-1410, 21-5261

In The Supreme Court of the United States

DR. XIULU RUAN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

SHAKEEL KAHN,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

On Writs Of Certiorari To The United States Courts Of Appeals For The Tenth And Eleventh Circuits

AMICUS CURIAE BRIEF OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*[1]

Pharmacists play a critical role in our nation's healthcare system, daily ensuring that, among other things, millions of patients receive the medicines they need as well as instructions for safely using them. Whether in independent pharmacies or chain drug stores, pharmacists and their employers share the same mission when it comes to prescribed treatment: to deliver to patients the medicines that licensed practitioners have determined they need.

The National Association of Chain Drug Stores (NACDS) is a leading organization supporting pharmacies in promoting and fulfilling that mission. A non-profit, tax-exempt organization incorporated in Virginia, NACDS represents traditional drug stores, community pharmacies, supermarkets, and mass merchants with pharmacies. NACDS chain members operate over 40,000 pharmacies and employ nearly 3 million individuals, including 155,000 pharmacists; its 80 chain member companies include regional chains, with a minimum of four stores, and national companies.

NACDS continually strives to help its members to maintain and enhance the safe care of patients who rely on pharmacists' training, judgment, and

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[1] No party's counsel authored any part of this brief or made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus*, its members, or its counsel contributed money intended to fund the brief's preparation or submission. All parties have provided written consent to the filing of this brief.

professionalism. That care depends on pharmacists' ability to understand their obligations when filling prescriptions for controlled substances. NACDS members seek to deliver that care and practice their profession under clear and consistent rules, without regulatory uncertainty, and free from the threat of severe penalties just for doing their jobs. To that end, NACDS regularly files *amicus* briefs in cases that have the potential to alter or clarify pharmacists' obligations.

Kahn v. United States (No. 21-5261) and *Ruan v. United States* (No. 20-1410) are such cases. Although they concern the scope of physicians' potential liability for *prescribing* medications in violation of the Controlled Substances Act (CSA), the manner in which the Court decides the questions presented could—directly or indirectly—affect the scope of pharmacists' potential liability for *dispensing* medications in violation of the CSA.

While NACDS takes no position on Petitioners' ultimate culpability under 21 U.S.C. § 841(a), it does have a strong interest in the Court's proper interpretation of that statute and the regulations implementing the CSA. Key among those regulations is 21 C.F.R. § 1306.04(a), which places primary "responsibility for the proper prescribing and dispensing of controlled substances" on the "prescribing practitioner," but also imposes a "corresponding responsibility" on the pharmacist who fills the prescription.

NACDS writes to explain how the Court's construction of the relevant statutes and regulations may affect pharmacists, and to assist the Court in reaching correct interpretations that effectuate Congress's intent to hold wrongdoers liable while avoiding the inadvertent or unwarranted imposition of liability.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

As with most of its docket, the Court's resolution of the questions presented here could have an impact far beyond the specific context in which these cases arise. In particular, the Court's interpretation of 21 C.F.R. § 1306.04—the regulation at the center of Petitioners' good-faith defense—could have a potentially sweeping effect on pharmacists and the practice of pharmacy.

Section 1306.04(a) clarifies that an "effective" prescription is one issued "for a legitimate medical purpose" by a prescriber "acting in the usual course of his professional practice." In addition to establishing when a prescriber may issue a prescription, § 1306.04(a) imposes liability on pharmacists for "knowingly filling" a prescription that fails the regulation's requirements. A separate provision applicable to pharmacists, 21 C.F.R. § 1306.06, utilizes the same usual-course-of-professional-practice language in identifying when a pharmacist may fill a prescription for a controlled substance. How the Court interprets and applies the language of

§ 1306.04(a) may well affect, in turn, how lower courts and administrative agencies assess pharmacists' alleged violations of § 1306.06.

In view of the potentially far-reaching consequences of the Court's interpretation, this brief submits three points to assist in the Court's resolution of these cases.

First, § 1306.04(a) includes an important safeguard that recognizes the division of responsibility between physicians and pharmacists—that a pharmacist may only be held liable if she "*knowingly* fill[s]" a "purported" prescription, *i.e.*, a prescription that was not written "in the usual course of professional treatment." 21 C.F.R. § 1306.04 (emphasis added). This limitation on liability reflects the very real constraints on a pharmacist presented with a facially valid prescription for a controlled substance. Recent civil litigation and enforcement actions against pharmacists and pharmacies, however, have sought to sidestep that scienter requirement and also to expand pharmacists' liability under § 1306.06. Mindful of those alarming efforts (albeit made in a context different from these cases), NACDS urges the Court to avoid any interpretation here that inadvertently would increase pharmacists' exposure to unwarranted liability.

Second, in interpreting the meaning of the "usual course of . . . professional practice," the Court should confirm what it stated more than forty years ago in *United States v. Moore*, 423 U.S. 122 (1975): acting outside "the usual course of . . . professional practice"

means completely abandoning one's professional obligations, not merely failing to comply with a professional standard. *Id.* at 142–143. The Court should decline to read "usual course of . . . professional practice" as requiring perfect compliance with *all* professional standards. Doing so would expose pharmacists to unwarranted civil and criminal enforcement under § 1306.06 for even the most minor, unintentional deviation from the ideal standard of care.

Third, recognizing appropriate limits on the liability of pharmacists is consistent with Congress's goal in the CSA of punishing true wrongdoers "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Raich*, 545 U.S. 1, 12 (2005).

ARGUMENT

I. In interpreting § 1306.04(a) to determine the scope of prescriber liability, the Court should in no way undermine the knowledge requirement that protects pharmacists from unwarranted liability.

Although these cases involve the liability of prescribing practitioners, NACDS is concerned that the Court's interpretation of "usual course" language in § 1306.04(a) could have an unintentional and inappropriate collateral impact on the scope of pharmacists' liability. In considering the questions in this case, it is important that the Court remain cognizant of the

different function performed by prescribers, on the one hand, and pharmacists, on the other, and do nothing either to undermine the protection from liability that § 1306.04(a)'s scienter requirement is meant to provide to pharmacists, or to adopt an interpretation of "usual course" that would improperly expand pharmacists' liability under § 1306.06, where the same language appears. NACDS is especially wary of such unintended results here because recent civil suits and enforcement actions have intentionally sought to impose liability on pharmacists based on similarly expansive and unwarranted readings of the regulations.

A. Reflecting the distinct roles of prescribers and pharmacists, § 1306.04 imposes liability only on pharmacists who "knowingly" fill an illegitimate prescription.

Although § 1306.04(a) regulates both prescribers and pharmacists, the two roles are far from interchangeable, including for purposes of determining potential liability. With different licenses, education, skill sets, responsibilities, and workplaces from physicians, pharmacists play a vital but distinct role in a patient's care. Specifically, when dispensing a controlled substance to a patient, as prescribed by a physician, a pharmacist relies on the *physician*'s assessment of the patient's needs. The pharmacist has neither examined nor diagnosed the patient, and lacks the information the physician has collected on the patient's medical

situation, records, and history, including such things as x-rays, ultrasounds, lab results, and treatment plans.

The CSA recognizes pharmacists' circumscribed role in dispensing controlled substances. It provides that pharmacists may not dispense Schedule II controlled substances "without the written prescription of a practitioner," 21 U.S.C. § 829(a), and that they risk criminal and civil liability if they do, *see id.* §§ 841(a), (c), 842. The CSA's implementing regulations further explain that a prescription for a controlled substance "must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). The regulations separately provide that such a prescription "may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed" by a registered entity. 21 C.F.R. § 1306.06.

Consistent with the division of responsibility between prescribers and pharmacists, § 1306.04 limits when pharmacists may be held liable for filling controlled-substance prescriptions to situations where a pharmacist *knows* a prescription is illegitimate:

> 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.

21 C.F.R. § 1306.04(a) (emphasis added). A pharmacist violates this provision only if the pharmacist "*knowingly* fill[s]" a "purported" prescription—*i.e.*, a prescription that was not written "in the usual course of professional treatment." *Ibid.* (emphasis added).

These critical limitations on a pharmacist's possible liability under § 1306.04 are no accident. They were added to the regulation intentionally to avoid the unwarranted and counterproductive imposition of liability. When first proposed in 1971, the regulation lacked the word "knowingly," which would have allowed penalties for any "person filling [an illegitimate] prescription." *Purpose of Issue of Prescription*, 36 Fed. Reg. 4847, 4948 (Mar. 13, 1971). Pharmacists protested such an expansive rule, however, and during the comment period specifically "objected to the responsibility placed upon a pharmacist under § [1306.04] to determine the legitimacy of a prescription." *Comments and Objections to Part 306*, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971). The DEA agreed with these comments and changed the legal standard in the final regulations, noting the "language [was] revised to require knowledge." *Ibid.*

These limitations sensibly reflect the very real constraints on pharmacists presented with prescriptions for controlled substances. To be sure, pharmacists can do things like inspect prescriptions for indicia of facial invalidity to determine if they can be filled—*e.g.*, tampering, missing or incorrect information, a forged signature, or a prescribing physician who is not DEA-registered. *See* 21 C.F.R. § 1306.05(a). When presented with a facially valid prescription, however, a pharmacist cannot be expected to second-guess the prescriber's medical judgment that the prescribed medicine is appropriate, to interrogate the patient regarding whether they actually need the prescribed medication, or to obstruct the patient's care by withholding it. Indeed, none of the myriad state and federal laws with which pharmacists must comply authorizes, much less requires, pharmacists to supersede the medical judgment of the prescriber. The law should not unduly chill a pharmacist's performance of her duties to make medications safely available to patients who need them. The knowledge requirement in § 1306.04 properly reflects this circumscribed role.

B. The Court should not resolve these cases in a way that undermines the knowledge requirement for pharmacist liability.

In resolving the issues presented in these cases—including whether a good-faith defense is available to a practitioner charged with violating 21 U.S.C. § 841(a)—the Court should take care not to weaken the

knowledge requirement in § 1306.04, insofar as it applies to pharmacists. That requirement is a critical safeguard against unwarranted liability, which could unduly chill pharmacists from performing duties vitally important to public health.

This is no abstract concern. In recent enforcement actions it has filed across the country, accusing pharmacists and pharmacies of unlawfully dispensing medicines, the U.S. Department of Justice (DOJ) has aggressively attempted to sidestep § 1306.04's knowledge requirement. Citing pharmacists' "corresponding responsibility," DOJ has argued that pharmacists are liable for filling prescriptions that allegedly present so-called "red flags"—factors that do not necessarily bear on a prescription's facial validity but that, in DOJ's opinion, suggest the prescriber may have written it for an illegitimate purpose. Under DOJ's theory, the presence of one or more "red flags" not only proves that a prescription is illegitimate but that a pharmacist who fills it must be doing so "knowingly."

The "red flags" advanced by DOJ include patients seeking to fill "[n]ew prescriptions for controlled substances a patient has never received before";[2] certain combinations of prescribed drugs;[3] providing physician-ordered refills when "one to three days of supply

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[2] Compl. ¶ 79, *United States v. Ridley's Family Markets, Inc.*, No. 1:20-cv-00173-TS-JCB (D. Utah Dec. 4, 2020), ECF No. 2.

[3] *See*, *e.g.*, *id.* ¶¶ 68–72.

remained";[4] late filling of prescriptions;[5] dispensing the same medications "for the same patients over long periods of time";[6] prescriptions for doses above "90 [morphine milligram equivalents]/day";[7] and prescriptions for more than one "[i]mmediate-release opioid[] . . . sufficiently close in time that the supplies would have overlapped."[8] Even though in many circumstances these supposed "red flags" have legitimate explanations (medical or otherwise), DOJ has gone so far as to argue that the presence of one or more of these elements is "*near conclusive*[] evidence of a prescription's invalidity."[9] According to DOJ, when faced with a prescription presenting one or more "red flags," a pharmacist must identify each issue, take steps to resolve it, and document in writing how it was resolved—no matter how many times the same patient has presented the prescription. Until and unless each "red flag" is resolved, DOJ says, a pharmacist *must* second-guess the prescription's appropriateness, override the

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[4] Compl. ¶ 67, *United States v. Shaffer Pharmacy*, No. 3:21-cv-00022-JZ (N.D. Ohio Jan. 6, 2021), ECF No. 1.

[5] S*ee*, *e.g.*, Compl. ¶ 72, *United States v. Howen*, No. 1:21-cv-00106-DAB-SAB (E.D. Cal. Jan. 26, 2021), ECF No. 1.

[6] Compl. ¶ 66, *United States v. WeCare Pharmacy, LLC*, No. 8:21-cv-00188-MSS-AEP (M.D. Fla. Jan. 26, 2021), ECF No. 1.

[7] Compl. ¶ 75, *United States v. Chip's Discount Drugs, Inc.*, No. 2:20-cv-00010-LGW-BWC (S.D. Ga. Feb. 12, 2020), ECF No. 1.

[8] Compl. ¶ 361, *United States v. Walmart Inc.*, No. 1:20-cv-01744-CFC (D. Del. Dec. 22, 2020), ECF No. 1.

[9] Mem. in Opp'n to Def.'s Mot. to Dismiss at 5 (emphasis added), 8, *United States v. Ridley's Family Markets, Inc.*, No. 1:20-cv-00173-TS-JCB (D. Utah Mar. 8, 2021), ECF No. 31.

prescriber's medical judgment, and refuse to fill it—or else face the threat of liability.

There are many problems with DOJ's "red flags" theory. It has no basis in the CSA or its implementing regulations, or even in the DEA's Pharmacist's Manual. It imprudently dismisses the individualized, case-by-case approach that pharmacists take when filling prescriptions in favor of a categorical approach to culpability.[10] And it traps pharmacists in an untenable position—either face liability under the CSA for filling a facially valid prescription that raises a "red flag," or face state-based professional liability,[11] and even civil suits,[12] for refusing to fill such a prescription.

But the critical point here is that § 1306.04 provides a protection for pharmacists that the Court should not inadvertently eliminate: a pharmacist may

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[10] *See Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006) (noting that "each case must be evaluated based on its own merits in view of the totality of circumstances").

[11] *See*, *e.g.*, Wis. Pharmacy Examining Bd., *Administrative Warning*, Division of Legal Services and Compliance Case No. 17 PHM 095 (Dec. 6, 2018).

[12] *See*, *e.g.*, First Amended Compl. ¶ 2, *Fuog v. CVS Pharmacy, Inc.*, No. 1:20-cv-00337-WES-LDA (D.R.I. Aug. 26, 2020), ECF No. 6 (challenging "corporate wide discriminatory practices in refusing to fill, without a legitimate basis, valid and legal prescriptions for opioid medication"); *Reasor v. Walmart Stores E., L.P.*, No. 3:19-CV-27-CRS, 2019 WL 5597302, at *3 (W.D. Ky. Oct. 30, 2019) (defamation suit by physician asserting that "the failure to fill his patient's prescriptions necessarily imputed illegal conduct because pharmacists are required to fill prescriptions unless the [p]harmacist has reason to know of some irregularity").

only be held liable if the pharmacist "knowingly fill[s]" a "purported" prescription. In other words, unless a pharmacist subjectively knows that a facially legitimate prescription has been prescribed for illegitimate reasons, the pharmacist should not face potential liability for dispensing medication based on that prescription. A strict adherence to this knowledge element is critical to ensuring that pharmacists acting in good faith are not punished for filling facially valid prescriptions written by licensed and registered prescribers—punishment that, if rendered, would chill other pharmacists from performing their duties. In addressing the related issues raised in these cases, the Court should be careful not to undermine this important safeguard.

II. Acting outside "the usual course of . . . professional practice" means completely abandoning professional obligations, not merely failing to adhere to a professional standard.

The Court's decision in these cases may also affect the scope of pharmacists' potential liability by how it resolves the question of what it means for conduct to fall outside "the usual course of . . . professional practice" for a physician. *See*, *e.g.*, *United States v. Bek*, 493 F.3d 790, 798 (7th Cir. 2007) ("[T]o convict . . . a practitioner registered to distribute controlled substances, of violating § 841(a)(1), the government must show that he prescribed controlled substances outside 'the course of professional practice.'"). While this case

involves physicians, the Court's interpretation of this language will likely affect pharmacists, too.

The Court should answer that question by confirming what it stated in *United States v. Moore*, 423 U.S. 122, 124 (1975): a practitioner acts outside the usual course of professional practice when he *completely abandons* his professional obligations—and fails to act as a physician at all—not when he merely fails to comply with any single professional standard.

A. The Court should confirm *Moore*'s determination of what constitutes acting outside the usual course of professional practice.

This Court's decision in *Moore* supports the plain, narrow meaning of the phrase "usual course of . . . professional practice." There, the Court held that a physician registered by the DEA could be prosecuted under 21 U.S.C. § 841 "when [his] activities fall outside the usual course of professional practice." *Ibid.* The Court held that the evidence was sufficient to show that Dr. Moore's conduct "exceeded the bounds of 'professional practice'" because "[i]n practical effect, he acted as a large-scale 'pusher' not as a physician." *Id.* at 143. Dr. Moore "gave inadequate physical examinations or none at all," "ignored the results of the tests he did make," "did not give methadone at the clinic and took no precautions against its misuse and diversion," "did not regulate the dosage at all," and "did not charge for medical services rendered, but graduated his fee

according to the number of tablets desired." *Id.* at 142–143.

Accordingly, the Court indicated, a practitioner acts outside the usual course of professional practice when he completely abandons his professional obligations, and fails to act as a physician at all. That the Court intended this conclusion is apparent not only from its appraisal of the evidence but also its observation about the congressional intent underlying the CSA. The Court noted that § 841 prohibited "the significantly greater offense of acting as a drug 'pusher,'" *id.* at 138, and that, in enacting the CSA, "Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels," *id.* at 135 (emphasis added); *see also Gonzales*, 545 U.S. at 12 (noting that one of the "main objectives of the CSA" was to "control the legitimate and illegitimate traffic in controlled substances").

Thus, a prescriber would completely abandon his professional obligations if he were to intentionally divert a controlled substance from a patient who needs a prescription for pain management (a legitimate channel) to someone who uses a prescription to satisfy an addiction (an illegitimate channel). By contrast, the mere failure to comply with a professional or state-imposed standard—such as paperwork requirements—would not rise to the same level. Nor would imposing liability for such a minor failure serve the CSA's purpose of effectively controlling drug manufacture, distribution, and dispensation.

Since *Moore*, some circuits have followed the Court's lead and construed conduct outside of "professional practice" to mean deliberate, egregious conduct beyond the scope of a practitioner's professional role. *See United States v. Feingold*, 454 F.3d 1001, 1011 (9th Cir. 2006) (interpreting § 1306.04 as "unquestionably impos[ing] a higher burden on the government than proving deliberate malpractice"); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994) (reasoning that § 841 requires proof that physician's "authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, i.e., the personal profit of the physician").[13] But others have signaled that *any* departure from a professional standard—no matter how slight, and without regard to whether the practitioner has ceased to act as a physician at all—might be sufficient to establish guilt. *See*, *e.g.*, *United States v. Sabean*, 885 F.3d 27, 45 (1st Cir. 2018) (reasoning that

[13] *See also*, *e.g.*, *United States v. Volkman*, 797 F.3d 377, 386 (6th Cir. 2015) ("In the past, we have endorsed a broad approach to determining what conduct falls outside the accepted bounds of professional practice so as to constitute a CSA violation, eschewing a preestablished list of prohibited acts in favor of a case-by-case approach."); *United States v. Naum*, 832 F. App'x 137, 144 (4th Cir. 2020) (holding that an instruction "that the jury must consider the totality of the circumstances in making its determination that Naum acted outside the scope of professional medical practice was consistent with . . . our precedents" and noting favorably the court's instruction that "violation of an applicable professional regulation alone, however, is not determinative"), *petition for cert. filed* (U.S. Apr. 22, 2021) (No. 20-1480).

failing to adhere to a professional standard "is undeniably relevant"); *Bek*, 493 F.3d at 799 (approving jury instruction to consider the norms of professional practice).

Neither the Tenth Circuit in *Kahn* nor the Eleventh Circuit in *Ruan* indicated what conduct constitutes action outside the scope of professional practice. As the petitions stress, however, those Circuits do not recognize a good-faith defense to a charge under the "professional practice" prong of § 841(a). Instead, they permit a conviction when a physician merely fails to act in "accordance with the standards of medical practice generally recognized and accepted in the United States." *United States v. Ruan*, 966 F.3d 1101, 1167 (11th Cir. 2020); *see United States v. Kahn*, 989 F.3d 806, 825 (10th Cir. 2021) ("[T]he only relevant inquiry under that second prong is whether a defendant-practitioner objectively *acted* within that scope, regardless of whether he *believed* he was doing so." (emphasis added)).

The Court should reject such an expansive interpretation. If one can exceed the bounds of professional practice merely by failing to adhere to any unspecified professional standard, then any practitioner who accidentally or unknowingly makes even a small, ministerial mistake has broken the law and could find himself the target of a government enforcement action, which would proceed on a knowledge standard akin to strict liability. Even the government has recognized that this cannot be—in its opposition to the *Ruan* petition, it conceded that the Section 841 standard is "higher than

the standard for civil liability on a medical-negligence or medical-malpractice claim." Br. for the United States in Opp'n at 22, *Ruan v. United States*, No. 20-1410 (U.S. July 7, 2021). But the standard advanced by the Tenth and Eleventh Circuits would collapse that distinction. To avert that outcome, the Court should confirm *Moore*'s conclusion that a practitioner acts outside the usual course of professional practice by completely abandoning professional obligations.

B. The Court should reject any interpretation of "usual course of . . . professional practice" that would expose pharmacists to liability under 21 C.F.R. § 1306.06 for minor infractions or mere non-compliance with professional standards.

Although the scope of liability imposed by 21 C.F.R. § 1306.06 is not expressly at issue in these cases, any interpretation of the scope of "usual course of . . . professional practice" in § 1306.04(a) directly implicates it. Employing the same critical language, that regulation provides that a prescription "may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed" by a registered entity.

The proper interpretation of § 1306.04(a) will ensure that § 1306.06 cannot be used as an end-run around the requirements in § 1306.04, and that pharmacists can continue to effectively serve patients and the public health. Again, this is not an abstract

concern. Recently, DOJ has developed a web of theories to impose liability on pharmacists under § 1306.06. DOJ has contended that noncompliance with § 1306.06 establishes a violation of 21 U.S.C. § 842(a)(1)—subjecting a pharmacist to the civil penalty provision contained in § 842(c)(1)[14] and, for knowing violations, the criminal penalty provision contained in § 842(c)(2),[15] regardless of whether the underlying prescription actually was invalid.[16] DOJ also has argued that a pharmacist's mere failure to comply with *any* relevant state regulation or professional norm is sufficient to show action outside the usual course of professional practice, and therefore a violation of § 1306.06—a position indistinct from the Tenth and Eleventh Circuits' "strict liability" approach to prosecutions under the "professional practice" prong of § 841(a).[17] And, as

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[14] *See* 21 U.S.C. § 842(c)(1)(A) ("any person who violates this section shall . . . be subject to a civil penalty").

[15] *See* 21 U.S.C. § 842(c)(2) (knowing violation of § 842 may be prosecuted criminally).

[16] *See* Compl. ¶ 89, *United States v. Walmart Inc.*, No. 1:20-cv-01744-CFC (D. Del. Dec. 22, 2020) ("A person dispensing controlled substances not in compliance with any of the three requirements identified above [§ 1306.04(a)'s legitimate purpose and professional practice requirements and § 1306.06's professional practice requirement] violates 21 U.S.C. § 829 and thus 21 U.S.C. § 842(a)(1).").

[17] *See* Compl. ¶ 21, *United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207 (E.D.N.C. Oct. 30, 2020) (asserting that "acting in the usual course of pharmacy practice includes compliance with all relevant state laws and regulations"); Compl. ¶ 21, *United States v. Ridley's Family Markets, Inc.*, No. 1:20-cv-00173 (D. Utah Dec. 4, 2020) (alleging the "usual course of pharmacy practice includes compliance with all relevant state laws and regulations").

discussed above, DOJ also has invoked professional norms in pursuing the nebulous "red flags" theory of liability.[18]

The Court should construe "professional practice," as used in both § 1306.04 and § 1306.06, to limit these unwarranted threats of liability against pharmacists. In particular, the Court should reject any definition of "usual course of . . . professional practice" that would allow pharmacists to be held liable or even prosecuted for minor, technical, or unintentional violations under § 1306.06. DOJ's contention that a pharmacist exceeds the usual course of professional practice by failing to comply with *any* professional standard sweeps far too broadly. Perhaps most importantly, that interpretation of § 1306.06—combined with DOJ's view that all violations of § 1306.06 qualify as violations of 21 U.S.C. § 829 for purposes of civil penalties under 21 U.S.C. § 842(a)(1)—guts § 1306.04(a)'s scienter requirement. If DOJ need only prove that a pharmacist made missteps in filling a prescription, then it will rarely if ever have to meet the much higher burden of proving that the pharmacist *knowingly* filled an *invalid* prescription.

That interpretation has other problems as well. Among other things, it ignores the wide sweep of standards to which pharmacists are subject: not only federal and state controlled-substances laws, but a

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[18] *See* Compl. ¶ 88, *United States v. Walmart Inc.*, No. 1:20-cv-01744-CFC (D. Del. Dec. 22, 2020) (maintaining that identifying and resolving "red flags" is "a well-recognized responsibility of a pharmacist in the professional practice of pharmacy").

myriad of state-imposed professional obligations. For example, Delaware regulates matters ranging from the font size on signs posted in pharmacies, to how long records of prescriptions must be retained, to requirements for automated pharmacy systems;[19] Texas has regulations that dictate how long a pharmacist has to give notice of an address change;[20] and other States regulate a host of other incidents of pharmacy practice, including continuing education requirements. Yet, under DOJ's understanding of the "professional practice" requirement, a pharmacist could face criminal prosecution for using the wrong font size on pharmacy signs or for forwarding a new address a few days late. It would be both alarming and incongruous for a pharmacist to face liability and penalties under the CSA for alleged violations of state pharmacy law—all without the involvement or professional judgment of the relevant state board of pharmacy.[21]

The CSA contains no language indicating that Congress intended to impose criminal liability for failure to perfectly comply with professional norms in every case, which is an impractical standard. Such

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[19] *See* 24 DEL. ADMIN. CODE § 2500-3.9, 5.1.12.3, 15.0.

[20] *See* 22 TEX. ADMIN. CODE §§ 295.1, 295.9.

[21] Whether or not DOJ would *likely* pursue an enforcement action based on such trivial conduct is irrelevant—that there is even an actionable possibility demonstrates why creating federal liability for departing from state regulations and professional norms is an inherently flawed approach. The Court need not wait until a pharmacist-defendant appeals from a conviction based on this standard to understand now the problems such an interpretation poses.

failures do not implicate Congress's stated concerns regarding drug diversion, and the Court's discussion in *Moore* throws cold water on such a conclusion. *See Moore*, 423 U.S. at 143. Moreover, as Professors Oliva and Dineen correctly observe in their *amicus* brief in support of Dr. Ruan's petition, *see* Br. of *Amici Curiae* Profs. of Health Law & Policy in Supp. of Pet'r at 15–25, *Ruan v. United States*, No. 20-1410 (U.S. May 7, 2021), construing the CSA to criminalize negligent medical conduct plainly invades an area of the law long reserved to the States (regulating medical malpractice), triggering significant federalism concerns, *see Linder v. United States*, 268 U.S. 5, 18 (1925).

Accordingly, the Court should define what constitutes conduct outside the "usual course of . . . professional practice" consistent with its interpretation in *Moore*. This would appropriately limit efforts to impose federal civil and criminal liability against pharmacists (whether based on state-imposed professional requirements, "red flags," or other nebulous standards of practice), and would allow pharmacists to serve their patients without fear that any minor misstep could lead to crushing sanctions.

III. The Court can adopt standards that allow for punishment of wrongdoers while allowing pharmacists to practice their profession free from the unwarranted threat of liability.

Proper interpretations of the relevant statutes and regulations will allow true wrongdoers to be held liable without preventing pharmacists from practicing their profession, serving their patients, or filling facially valid prescriptions free from anxiety that they will later be found to have violated federal law.

First, the goal of holding wrongdoers accountable is hardly compromised by the requirement that a pharmacist may be held liable only if the pharmacist "*knowingly* fill[s]" a prescription that was not written "in the usual course of professional treatment." § 1306.04 (emphasis added). Pharmacists who lack knowledge of a prescription's illegitimacy should not face potential criminal or civil liability, and the Court should refrain in these cases from adopting any interpretation that suggests otherwise. Indeed, the contrary interpretation would have dire consequences. Lowering or eliminating a prosecutor's burden to demonstrate knowledge could well have the effect of chilling pharmacists from filling controlled-substance prescriptions—including facially valid ones—thereby depriving patients of medicines they need. *See*, *e.g.*, 21 U.S.C. § 801(1) (recognizing that many drugs subject to the CSA "have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people"); 71 Fed. Reg.

at 52719–20 (recognizing DEA's own "obligation to ensure that there is no interference with the dispensing of controlled substances to the American public in accordance with the sound judgment of their physicians").

Second, reiterating the Court's conclusion in *Moore* that practitioners act outside the "usual course of . . . professional practice" when they completely abandon their professional role will ensure that egregious conduct will continue to be punished without creating crippling consequences for slight missteps. It also would give pharmacists the clarity they need to perform their important functions. By contrast, interpreting "professional practice" to require compliance with all professional standards would improperly subject pharmacists to substantial civil liability or even criminal sanctions for simple mistakes, creating confusion and uncertain legal risks for pharmacists; chill pharmacists in the practice of their profession, threatening patients with loss of access to necessary medications; and have the baneful effect of driving pharmacists from the profession altogether.

In sum, the expansive interpretation proposed by DOJ would undermine the CSA by threatening the vital role that pharmacists play in our nation's healthcare system. Pharmacists, who are widely trusted as acting in good faith,[22] should only face CSA liability

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[22] Pharmacists are consistently ranked among the most honest and ethical professionals. *See* NACDS.org Staff, *Americans' Trust in Pharmacists Should Speak Volumes to Government, NACDS*

when they knowingly abandon those responsibilities, not when they strive to comply with them.

CONCLUSION

In resolving the questions raised in this case, the Court should not ignore the potential impact its rulings may have on pharmacists, nor should it construe the CSA and its implementing regulations in any way to undercut the protections they provide pharmacists from unwarranted liability.

Respectfully submitted,

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Says, https://www.nacds.org/news/americans-trust-in-pharmacists-should-speak-volumes-to-government-nacds-says/ (last visited Dec. 22, 2021).