IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

WALMART INC., Plaintiff, v. U.S. DRUG ENFORCEMENT ADMINISTRATION; ACTING ADMINISTRATOR TIMOTHY J. SHEA; U.S. DEPARTMENT OF JUSTICE; ATTORNEY GENERAL WILLIAM P. BARR, Defendants.	No. 4:20-cv-00817-SDJ ORAL ARGUMENT REQUESTED

WALMART'S MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

In its Complaint, Walmart Inc. ("Walmart") explained why it, and the pharmacy industry more broadly, needs declaratory relief clarifying the scope of its obligations under the Controlled Substances Act ("CSA") and its regulations. The Drug Enforcement Administration ("DEA") and its parent agency, the Department of Justice ("DOJ"), are seeking to distract from their own failures in combating the opioid crisis by shifting responsibility to pharmacists who fill prescriptions issued by state-licensed and DEA-registered doctors. Unsupported by statute or regulation, Defendants have invented a slew of purported obligations, all driving toward their broader position that pharmacists and pharmacies must rigorously second-guess doctors' judgments before filling their prescriptions. At the same time, pharmacists and pharmacies face conflicting guidance and legal risk from state regulators, doctors, and patients who strenuously object to what they view as invasion of the doctor-patient relationship and unauthorized practice of medicine.

Walmart now seeks summary judgment on five discrete questions of law, each a point of ripe controversy with Defendants, that the Court can resolve expeditiously without the cost of factual development. Defendants' insistence on their sweeping legal contentions—and threats of enforcement—create an urgent need for clarification. *See* Fed. R. Civ. P. 57 ("The court may order a speedy hearing of a declaratory-judgment action."). Partial summary judgment is thus appropriate, despite the litigation's early stage, in this unique case.

First, the Court should reject Defendants' view that a pharmacist can incur liability under the CSA just by filling a prescription without documenting in writing how she resolved certain so-called "red flags"—that is, potential reasons to question whether a doctor wrote a prescription outside the ordinary course of professional treatment. DEA's rules prohibit pharmacists only from *knowingly* filling a prescription issued outside the usual course—but neither mandate a process for

investigating a prescription nor require documenting the reason the pharmacist chose to fill it as a matter of professional judgment. Liability requires proof both that the prescription was illegitimate and that the pharmacist knew that it was—not just an alleged procedural failing.

Second, the Court should reject Defendants' view that the CSA and its regulations forbid pharmacists to fill entire categories of prescriptions, without regard to individual facts and circumstances. Federal health agencies, courts, and (historically) even DEA itself have agreed that, given unique patient needs and genuine disagreement among medical professionals, there can be no such bright-line rules when it comes to proper dispensing.

Third, the Court should reject Defendants' novel view that the CSA and its regulations impose duties on businesses that operate pharmacies other than those imposed on their individual pharmacists. The regulatory framework sensibly entrusts primary responsibility for proper dispensing to doctors, with a corresponding responsibility to trained and licensed pharmacists; corporate officials have no independent duties on that front under the CSA or its regulations.

Fourth, the Court should reject Defendants' view that the CSA and its regulations not only require controlled-substance distributors to report to DEA orders flagged as "suspicious," but also forbid them from shipping those orders without first conducting their own investigation. Under existing law, it is *DEA* that is expected to act on the reports if it believes they raise sufficient concerns of abuse. Defendants have all but conceded the point by recently proposing to *amend* the regulations to add the restriction they claim has always existed.

Fifth, the Court should reject Defendants' view that failure to submit suspicious order reports gave rise to civil penalties under the CSA even before Congress amended the statute to so provide in October 2018. The plain text of the statute refutes that view, which would also render the congressional amendment pointless.

There is a common theme here. Unhappy with the statutory scheme Congress created and the regulatory scheme they themselves promulgated, Defendants are seeking to impose, through litigation and threats of litigation, new duties and obligations, after-the-fact and without following the administrative procedures necessary to confer the force and effect of law. Instead, they either construct these new duties and obligations out of whole cloth or purport to rely on informal presentations or letters, or dicta in one-off adjudicative decisions, to manufacture new substantive obligations. They then seek to collect enormous sums in retroactive liability from those who "violated" these extra-legal "rules," with no regard to the pharmacists' good faith in exercising their professional judgment in a challenging regulatory context. This Court should not hesitate to declare that none of this is supportable.

STATEMENT OF THE ISSUES TO BE DECIDED[1]

1. Whether the CSA or its regulations impose liability on a pharmacist who, when filling a controlled-substance prescription written by a state-licensed and DEA-registered doctor, does not document resolution of "red flags" that may be associated with the prescription.

2. Whether the CSA or its regulations require pharmacists to refuse to fill entire categories of prescriptions, without regard to the individual facts and circumstances of each case.

3. Whether the CSA or its regulations impose additional duties on pharmacy businesses when filling prescriptions, beyond those imposed on the pharmacists themselves.

4. Whether the CSA or its regulations require controlled-substance distributors not only to report "suspicious" orders to DEA but also to investigate and clear those orders before shipping them.

[1] Local Rule Civil 56(a) requires summary judgment motions to contain a "Statement of Undisputed Material Facts." Because Walmart's motion for partial summary judgment raises only pure questions of law, there are no such facts to identify.

5. Whether the CSA, before Congress amended it in 2018, subjected controlled-substance distributors to civil penalties for failing to submit suspicious-order reports required only by DEA's regulations but not by the statute itself.

ARGUMENT

This is a case about agency power. Congress often authorizes agencies to enforce statutory duties and obligations. Sometimes, Congress also authorizes agencies to promulgate regulations, carrying the force and effect of law, which those agencies can then enforce. But fundamental rule-of-law principles limit agency enforcement proceedings to those sources of binding obligations. *See, e.g.*, *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015) ("Rules issued through the notice-and-comment process ... have the force and effect of law," while rules issued in other ways "do not have the force and effect of law and are not accorded that weight."); *Schofield v. Saul*, 950 F.3d 315 (5th Cir. 2020) (limiting consideration to sources with "force and effect of law").

Of course, only Congress can enact statutory obligations, and agencies must abide by the substantive and procedural requirements of the Administrative Procedure Act to promulgate valid regulations. Driven by regulatory zeal, agencies have been known to circumvent those limitations in a variety of ways. Sometimes, they issue informal "guidance" that purports to define new duties, and then try to enforce those manufactured obligations. That is impermissible, as DOJ itself has confirmed in a recent regulation. *See* 28 C.F.R. § 50.27(b)(1) ("guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation," and so DOJ "should not treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations"). Other times, agencies seek to rely on reasoning from their own *adjudicatory* decisions, transforming those into binding rules. That too flouts the law, because adjudication is a means to interpret *existing* duties, not to impose *new* ones. *See NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 765–66 (1969) (plurality opinion) (rejecting notion that "commands,

decisions, or policies announced in adjudication are 'rules' in the sense that they must, without more, be obeyed by the affected public"). And, sometimes, agencies try to invent novel obligations out of whole cloth, without even the pretense of guidance or adjudication.

As discussed further below, Defendants here are authorized to enforce the CSA and its duly promulgated implementing regulations. Yet they have adopted positions that cannot be justified by those sources of law, instead relying on non-binding guidance, inapplicable adjudications, or in some instances nothing at all. This Court should reject those positions.

I. PHARMACISTS CANNOT BE HELD LIABLE FOR FAILING TO DOCUMENT RESOLUTION OF "RED FLAGS."

Defendants have adopted the position that pharmacists may be liable under the CSA for filling prescriptions without documenting the resolution of all "red flags" associated with them. (Compl. ¶ 132.) That is legally misguided. The phrase "red flags" "does not appear in the [CSA], DEA regulations, or the DEA's Pharmacist Manual." *Jones Total Health Care Pharmacy, LLC*, 81 Fed. Reg. 79188, 79218 (Nov. 10, 2016). Rather, it is shorthand for various indicia—often subject to professional debate over their existence and weight, and sometimes found only in PowerPoints (Comp. ¶ 125)—that might give a pharmacist some reason to suspect that the doctor did not issue the specific prescription for a legitimate medical purpose. Examples might include the distance a patient traveled to see her doctor, prescriptions involving certain quantities or doses, and customers who pay for a prescription with cash. But a pharmacist is not subject to penalties under the CSA merely for filling a prescription that might raise a "red flag," much less for failing to document how she investigated or resolved that "red flag." Instead, penalties are available only if (1) the prescriber wrote a specific prescription for something other than a legitimate medical purpose and (2) the pharmacist filled the prescription with *knowledge* that it was illegitimate.

A. Starting with the statute, the CSA prohibits "any person … who is subject to the requirements of part C to … dispense a controlled substance in violation of section 829 of this title." 21 U.S.C. § 842(a)(1). Section 829, entitled "Prescriptions," provides that no controlled substance "may be dispensed without the written prescription of a practitioner." *Id.* § 829. As the Supreme Court has explained, § 829 is "a provision that ensures patients use controlled substances under the supervision of a doctor." *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006). The statute is thus concerned only with ensuring that a properly licensed and registered doctor has authorized the use of the controlled substance by the patient. Nothing in the statute restricts a duly registered and licensed pharmacist from dispensing controlled substances under a prescription written by a duly registered and licensed doctor.

B. DEA's regulations do impose certain such restrictions on pharmacists, by fleshing out the requirements for a valid "prescription." Most of these are technical—*e.g.*, a licensed and registered practitioner must write the prescription, *see* 21 C.F.R. § 1306.03(a), it must "be dated as of, and signed on, the day when issued," and it must include certain information, such as "the drug name, strength, dosage form, quantity prescribed, [and] directions for use," *id.* § 1306.05(a). Under some circumstances, however—such as where the prescriber acts like a "drug 'pusher[]'" rather than a doctor—a prescription that meets these technical specifications may still be invalid, in which case it "is not a prescription at all for purposes of the statute." *United States v. Hayes*, 595 F.2d 258, 260–61 (5th Cir. 1979). Knowingly filling such a prescription would thus contravene the statute. But these regulations nowhere require pharmacists to address "red flags" in any particular way, much less document any steps taken before filling prescriptions.

The principal regulation defining a valid "prescription" and speaking to the circumstances under which a pharmacist may dispense controlled substances, 21 C.F.R. § 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 … is not a prescription within the meaning and intent of [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.

This regulation has three sentences. The first defines a valid prescription: The doctor must issue it for "a legitimate medical purpose" "in the usual course" of his practice. *Id.* The second sentence allocates responsibility for ensuring adherence to that rule: The principal duty falls, of course, "upon the prescribing practitioner," but the pharmacist also holds a "corresponding responsibility." *Id.* The third sentence spells out how those responsibilities operate in practice, and their implications: A "purported prescription" issued outside "the usual course of professional treatment" is not a prescription within the meaning of 21 U.S.C. § 829, and "the person issuing it" (the doctor) and "the person *knowingly* filling" it (the pharmacist) are both "subject to the penalties provided for violations" of the CSA. *Id.* (emphasis added). Thus, a pharmacist violates the CSA based on this regulation only if (1) the pharmacist filled prescriptions "that were not issued for a legitimate medical purpose," and (2) "he did so knowing that the prescriptions were invalid." *United States v. Veal*, 23 F.3d 985, 988 (6th Cir. 1994).

The scope of the pharmacist's duty and potential liability under the CSA's penalty provisions is clear: Pharmacists must not *knowingly* fill prescriptions issued by a doctor outside the usual course of treatment. The knowledge requirement was added specifically to protect pharmacists, who are not doctors or authorized to practice medicine. *See* Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971) (noting that the regulation was "revised to require knowledge" after

pharmacists "objected to the responsibility placed upon a pharmacist … to determine the legitimacy of a prescription"). But the regulation does not require pharmacists to document their resolution of any "red flags" that might arise in reviewing a prescription, or to follow any other process with respect to such "red flags," to avoid CSA liability. Nor is such a requirement implicit in the prohibition against knowingly filling invalid prescriptions.

A pharmacist who does not document resolution of a "red flag" is not necessarily (or even likely) filling an invalid prescription, let alone doing so with scienter. Depending on all the facts and circumstances of a particular prescription, the existence of one or more "red flags" at most might represent some evidence (although inconclusive evidence) making it more likely that it is invalid. But merely showing that a prescription presents "red flags" hardly establishes that the prescription is invalid, and the fact that a pharmacist did not *document resolution* of a "red flag" before dispensing under that prescription establishes neither the invalidity of the prescription as a medical matter nor the pharmacist's scienter in filling it.

For one thing, the pharmacist may resolve the "red flag" *without documenting it*. Imagine that a customer presents a prescription written by a doctor far from the pharmacy. While this might raise questions, it also might not: The pharmacist might, for instance, know from past encounters that the customer *works* near the pharmacy but *lives* near the doctor, so the prescription is legitimate. That pharmacist satisfies her responsibility—by not "knowingly fill[ing]" an invalid prescription—even if she conducts no investigation and never records *why she believes* the doctor wrote the prescription in the usual course of treatment. Or consider a husband and wife filling prescriptions for the same medication. In the abstract, that may raise concerns of diversion. But if the pharmacist knows that each member of the unfortunate couple suffers from serious back pain, she has satisfied her duty—even if she does not commit that knowledge to writing. In neither

event could there be any liability under the CSA, even though these prescriptions bear so-called "red flags" that the pharmacist neither investigated nor documented.

In addition, even if the pharmacist does *not* resolve the "red flag," that does not necessarily imply any violation by the pharmacist. After all, the "red flag" itself does not establish on its own that the prescription was improper, and there is no liability absent an invalid prescription.

Moreover, even if the prescription *is* invalid, a pharmacist is still not liable absent scienter, which a "red flag" does not establish. Recall that there is no official list in the statute or regulations of what they are, how much weight they deserve, or how a pharmacist can or should resolve them. Much of this is subject to legitimate professional debate. "Red flags" is thus just shorthand for indicia that may make impropriety somewhat more likely relative to prescriptions lacking that characteristic. But § 1306.04(a) is not a strict liability provision or even a negligence provision; it only forbids pharmacists to "knowingly fill[]" illegitimate prescriptions. The mere existence of an alleged "red flag" does not equate to a *knowing* violation.

The pharmacist thus might not recognize or agree with what Defendants later claim to be a "red flag." In that case, she would not investigate, much less document, the resolution of a "red flag"—she did not believe there was one. Yet she can violate § 1306.04(a) only if she "knowingly fill[s]" a prescription "issued not in the usual course of professional treatment."

C. There is another regulation that governs pharmacists in their dispensing of controlled substances. But it too imposes no liability for failure to document "red flags."

This second regulation states that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice." 21 C.F.R. § 1306.06. The Supreme Court has explained that acting outside "the usual course" of one's profession means abandoning all professional norms to the point of no longer acting in a professional capacity. In

United States v. Moore, for instance, the doctor "did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded." 423 U.S. 122, 143 (1975). He also "did not charge for medical services rendered, but graduated his fee according to the number of tablets desired." *Id.* Because "[i]n practical effect, he acted as a large-scale 'pusher' not as a physician," his activities "f[ell] outside the usual course of professional practice" and subjected him to CSA liability. *Id.* at 124, 143; *see also United States v. Evans*, 892 F.3d 692, 703–04 (5th Cir. 2018) (upholding convictions where doctor prescribed "more than a year and a half" of opioids to patients who traveled from long distances, provided only "barebones" medical records, and expressed sentiments inconsistent with the need for legitimate treatment); *United States v. Armstrong*, 550 F.3d 382, 401 (5th Cir. 2008) (requiring proof that defendant lacked "good faith intent to act within the scope of medical practice," not just "mere civil malpractice"). The meager case law applying § 1306.06 agrees. *See United States v. Williams*, 416 F. Supp. 611, 613 (D.D.C. 1976) (pharmacist "must have known that some of the prescriptions had been forged ... and that the bulk of them had not been issued in the course of legitimate medical practice"); *United States v. Barbacoff*, 416 F. Supp. 606, 609 (D.D.C. 1976) (pharmacist filled prescriptions "knowing that the signatures thereon were mechanically reproduced").

Under that standard, a pharmacist does not exceed the "usual course of his professional practice" merely by failing to document his resolution of "red flags" before filling a prescription. Even if Defendants or experts believe that this documentation is a good idea, a pharmacist who does not follow that practice *is still operating as a pharmacist* and does not violate § 1306.06. The regulation does not, in other words, mandate whatever courts, Defendants, or experts might believe are best practices for pharmacists. Nor could it. For one thing, that sweeping interpretation would present fatal vagueness problems. *See FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 253

(2012) ("A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required."). For another, it would swallow and render superfluous the more specific regulation governing dispensing, § 1306.04(a), which carefully forbids only knowingly filling invalid prescriptions. If § 1306.06 were construed to codify professional standards for pharmacists and require them to follow certain procedural steps before filling prescriptions, § 1306.04(a) would do nothing. *Cf. Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 153 (1976) (explaining that "a statute dealing with a narrow, precise, and specific subject is not submerged by a later enacted statute covering a more generalized spectrum"). For a third, it would offend federalism principles by turning the paradigmatic state power over professional standards into a matter of federal law. *See Jones v. United States*, 529 U.S. 848, 858 (2000) (courts disfavor interpretations that upset federal-state balance by extending "federal enforcement" over "traditionally local" matters). And, as if that were not enough, the CSA also provides for *criminal* sanctions. *See* 21 U.S.C. § 842(c)(2). That implicates the rule of lenity, which requires that courts avoid the "harsher" interpretation of a regulation unless it is *unambiguously* correct. *McNally v. United States*, 483 U.S. 350, 359–60 (1987); *see also Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004).

Defendants have also taken the extraordinary and unprecedented position that "acting in the usual course of pharmacy practice includes compliance with *all relevant state laws and regulations*." Complaint ¶ 21, *United States v. Seashore Drugs, Inc.*, No. 7:20-cv-207 (E.D.N.C.) (filed Oct. 30, 2020) (emphasis added); *see also* Complaint ¶ 19, *United States v. Farmville Disc. Drug, Inc.*, No. 4:20-cv-0018 (E.D.N.C.) (filed Jan. 29, 2020). That would have the bizarre effect of turning every state regulatory or administrative violation—which may be subject only to minor penalties, or even no penalties at all, under state law—into a violation of the CSA and potentially

a *federal crime*. And, contrary to the careful balance struck by § 1306.04(a), it would do so even if the underlying prescription was *not* illegitimate, and even if the pharmacist *did not* act with the requisite scienter. Section 1306.06 would thus incorporate widely disparate state rules, all suddenly subject to the CSA's serious civil and criminal enforcement tools, even where the pharmacist abides by the federal regulation that directly speaks to the issue. The same problems would also plague doctors, who may only prescribe controlled substances "in the usual course of [their] professional practice." 21 C.F.R. § 1306.04(a).

That must be wrong, and it *is* wrong. Just as a professional who does not adhere to all best practices is still operating in a professional capacity, a professional who violates a state-law rule has not thereby stepped "outside the bounds of professional practice" under federal law. *Moore*, 423 U.S. at 132. Beyond the canons above, Defendants' contrary reading would ignore the maxim that, "in the absence of a plain indication of an intent to incorporate diverse state laws into a federal criminal statute, the meaning of the federal statute should not be dependent on state law." *United States v. Turley*, 352 U.S. 407, 411 (1957); *see also Jerome v. United States*, 318 U.S. 101, 106 (1943) ("[W]hen Congress has desired to incorporate state laws in other federal penal statutes, it has done so by specific reference or adoption."). As explained above, acting outside the "usual course" means abandoning all professional norms and effectively ceasing the practice of pharmacy. That concept should not be conflated with, and reduced to, any breach of professional standards set by state regulators.

D. Defendants have also asserted that pharmacists' supposed duties with respect to the resolution of "red flags" have been established through agency adjudications. As explained above, however, adjudications cannot establish new binding duties—they can only construe and enforce existing obligations under the statute or regulations. *See supra* pp. 4–5; *Wyman-Gordon*, 394 U.S.

at 765–66 (plurality opinion); *see also SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947) (agencies must choose between "proceeding by general rule or by individual, ad hoc litigation"); *Neustar, Inc. v. FCC*, 857 F.3d 886, 895–96 (D.C. Cir. 2017) ("adjudicatory holdings a[re] inherently retroactive" and thus "likely to be specific to individuals or entities," while rulemaking is "inherently prospective" and therefore "rules tend to be matters of more general application"). Again, nothing in the CSA or DEA's regulations exposes pharmacists to civil liability for how they address or document their resolution of "red flags"—only for knowingly filling an improper prescription.

Moreover, the adjudications in question center on an entirely different provision of the CSA—the Attorney General's authority to revoke a dispenser's registration if that registration is "inconsistent with the public interest." *See* 21 U.S.C. § 823(f). That the Attorney General may conclude that a pharmacist's continued registration is inconsistent with the public interest does not mean that the pharmacist is liable under § 842(a)(1).

And, in any event, those administrative decisions do not actually support the notion that failing to address or document a "red flag" is itself a violation of federal law. In *Superior Pharmacy I & Superior Pharmacy II*, DEA acknowledged that violations of § 1306.04(a) require proof that the pharmacist "actual[ly] kn[ew]" or was "willfully blind" to a prescription's invalidity. 81 Fed. Reg. 31310, 31335 (May 18, 2016). DEA also made clear that, to "establish that a pharmacist acted with the requisite scienter," it is "not enough" to prove "that a pharmacist dispensed a controlled substance prescription without resolving a red flag"—much less that she did so without *documenting* that resolution. *Id.* at 31335 n.54. Instead, there must *also* be "subjective belief" of a "high probability that a prescription lacks a legitimate medical purpose"; only then can one infer the pharmacist's knowledge or willful blindness. *Id.*

To be sure, DEA did warn that it might "draw an adverse inference that a pharmacist failed to resolve a red flag (or flags) from the failure to document the resolution in any manner." *Id.* at 31335. And courts, applying highly deferential standards that govern review of DEA's registration decisions, have upheld revocations that rested on such inferences. *See, e.g.*, *Pharmacy Doctors Enters., Inc. v. DEA*, 789 F. App'x 724, 731 (11th Cir. 2019) (per curiam) (upholding revocation as supported by substantial evidence based on DEA's theory that "absence of *any* documentation of resolution of a red flag is probative of a failure to resolve it"). But an *evidentiary inference* from the absence of documentation of red-flag resolution does not create a *free-standing obligation* to keep such records. And while DEA may have flexibility in adopting evidentiary inferences when it decides whether to revoke registrations under the open-ended "public interest" standard, 21 U.S.C. § 823(f), Defendants must satisfy ordinary evidentiary rules if they seek to impose civil penalties in federal court for alleged violations of the CSA. There is no basis in the law for drawing any sort of adverse inference from the absence of records that a party *is under no legal obligation to create*. *Cf. Vick v. Tex. Emp. Comm'n*, 514 F.2d 734, 737 (5th Cir. 1975) (rejecting adverse inference where documents were destroyed in ordinary course, because "adverse inference to be drawn from destruction of records is predicated on bad conduct of the defendant"). And, as DEA has previously admitted, even the failure to address a "red flag" is not itself a basis for liability.

In short: The regulations simply forbid a pharmacist from knowingly filling a prescription issued by a prescriber outside the ordinary course of medical practice, or from herself dispensing outside the usual course of pharmacy practice. Defendants cannot circumvent these requirements through a wholly invented independent obligation to document the resolution of "red flags," and no liability for civil penalties attaches to mere failure to create, retain, or produce such documentation.

II. THE CSA AND ITS IMPLEMENTING REGULATIONS DO NOT REQUIRE PHARMACISTS TO REFUSE TO FILL ENTIRE CATEGORIES OF PRESCRIPTIONS WITHOUT REGARD TO INDIVIDUAL FACTS AND CIRCUMSTANCES.

Defendants have also asserted that categories of otherwise-valid prescriptions that raise certain "red flags" are per se invalid and that a pharmacist who fills one of these prescriptions is liable under the CSA. (Compl. ¶ 129.) Neither the CSA nor its regulations, however, identifies categories of impermissible prescriptions, and asking pharmacists to make those judgments would disrupt the doctor-patient relationship. To establish CSA liability, a court instead must evaluate a pharmacist's dispensing decisions case-by-case, considering the pharmacist's limited ability to second-guess medical judgments by licensed doctors. Walmart therefore seeks a declaration that the CSA does not require pharmacists to refuse to fill entire categories of prescriptions.

Defendants have identified a series of factors that purportedly place the prescription into a category no pharmacist can ever fill. The CSA and its regulations identify some such factors, and Walmart makes no objections to those categories that actually appear in the law—as explained, for example, a prescription must be written by a licensed and registered practitioner, and include certain information such as the date and patient's name. *Supra* p. 6. Any prescription that does not meet these requirements is invalid, and the CSA forbids writing or knowingly filling them.

Defendants have also sought, however, to enforce unwritten requirements related to drug combinations, quantities, and strengths, effectively treating entire categories of prescriptions as illegal on their face, regardless of a patient's facts and circumstances. (Compl. ¶ 129.) For example, DOJ has taken the position in some contexts that there is "no medical basis" for a so-called "trinity" prescription consisting of an opiate, a benzodiazepine, and a muscle relaxant, *see* Compl. ¶ 31, *United States v. Rodriguez*, No. 19-cv-1055 (N.D. Tex.) (filed May 2, 2019), and that any doctor who writes and any pharmacist who fills such a prescription therefore violates the CSA. Whether a particular type of prescription has a permissible medical purpose, however, is

not the type of judgment that the Attorney General can make. In *Gonzales v. Oregon*, the Supreme Court rejected the Attorney General's attempt to define the requirement that prescriptions must have "a legitimate medical purpose" as prohibiting dispensing controlled substances for physician-assisted suicide. 546 U.S. at 274–75. Acknowledging that the Attorney General has rulemaking authority, the Court still held that "he is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients" when that standard satisfied state law. *Id.* at 258. Instead, "[t]he CSA allocates decisionmaking powers among statutory actors so that medical judgments, if they are to be decided at the federal level and for the limited objects of the statute, are placed in the hands of the Secretary [of Health and Human Services]." *Id.* at 265.

Under *Gonzales*, the Attorney General lacks the authority under the CSA to declare that prescriptions featuring particular combinations, strengths, or quantities of drugs lack medical purpose and therefore dispensing such prescriptions is per se a violation of the CSA. The authority to determine medical legitimacy at the federal level instead belongs to the Secretary of Health and Human Services ("HHS"). But, for example, the Centers for Medicare & Medicaid Services within HHS declined to prohibit repayment for certain combination prescriptions, fatally undermining Defendants' articulated position that dispensing such a combination is per se unlawful. *See* CMS, Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (Apr. 4, 2016). At the state level, boards of medicine and pharmacy and legislatures also may determine whether certain categories of prescription lack medical legitimacy. So long as none of these entities has established a bar on certain categories or combinations of prescriptions, however, Defendants cannot hold a pharmacist liable under the CSA simply for knowingly filling prescriptions in those categories.

Along with seeking to impose categorical requirements with respect to what types of prescriptions a pharmacist may fill, Defendants have asserted that factors extrinsic to the prescription itself may create circumstances in which no pharmacist may fill the prescription. Many of these factors—such as repeatedly seeking to fill the same kind of prescription—implicate medical judgments and thus are beyond the Attorney General's authority to categorically prohibit. Other factors—such as whether multiple residents in a household receive pain medication or whether the pharmacy is far from the prescribing physician's office—do not implicate medical judgments, but there also is no regulatory basis for the Attorney General to declare that these factors establish per se violations of the CSA. That a patient seeks to fill a prescription far from his home, or that multiple residents in the same household may require pain medication, does not itself establish that the prescription was "issued not in the usual course of professional treatment" or that it has no "legitimate medical purpose," 21 C.F.R. § 1306.04(a), nor is there anything else in the regulations that prohibits filling a prescription with these factors present. The existence of certain factors may have *evidentiary value*, *see supra* p. 14, but unless those factors in themselves impart knowledge that the prescription *is* illegitimate, the mere fact that a pharmacist fills categories of prescriptions with those features cannot create per se violations of the CSA. To read the regulatory framework otherwise not only takes medical judgments away from doctors in favor of government officials with no medical training, but also demands that pharmacists insert themselves in the middle of the doctor-patient relationship by second-guessing the judgment of the prescriber who has examined and diagnosed the patient.

Courts have consistently accepted that the CSA and its implementing regulations do not establish categories of per se invalid prescriptions. For example, in *United States v. Lovern*, the government alleged that a pharmacist filled prescriptions issued "outside the usual course of

contemporary medical practice" because the prescriptions were "based solely on an online questionnaire, without anything more—without any existing doctor-patient relationship, without a physical exam, without any confirmation of the questionnaire's contents, without any further contact of any sort," and that the pharmacists had known that this is how the prescribers operated but filled the prescriptions anyway. 590 F.3d 1095, 1100 (10th Cir. 2009). Distinguishing *Gonzales*, the Tenth Circuit noted that the pharmacist was free to present evidence that these prescribing practices "*were* consistent with the usual course of professional practice," and that "the question what constitutes usual medical practice remained, at all times, within [the jury's] province, not the Attorney General's." *Id.* Other circuits have similarly determined that establishing CSA liability requires case-by-case analysis. *See, e.g.*, *United States v. Sabean*, 885 F.3d 27, 46 (1st Cir. 2018) ("There is no pat formula describing what proof is required to ground a finding that a defendant acted outside the usual course of professional practice. Rather, inquiring courts must approach the issue on a case-by-case basis and sift the evidence in a given case…."); *United States v. Volkman*, 797 F.3d 377, 386 (6th Cir. 2015) (describing the court's approach to CSA liability as "eschewing a preestablished list of prohibited acts in favor of a case-by-case approach").

Even the DEA historically acknowledged that there are no bright-line rules. For example, a 2006 policy statement, after identifying factors that courts had identified as indicating diversion or abuse, rejected that the existence of any of the factors "will automatically lead to the conclusion that the physician acted improperly," instead confirming that "each case must be evaluated based on its own merits in view of the totality of circumstances particular to the physician and patient." Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006) (Dispensing Controlled Substances).

But Defendants have threatened to pursue an enforcement action based on the notion of categorically invalid prescriptions. This Court should confirm that they may not do so, and that violations of the CSA must be established case-by-case based on all of the individual facts and circumstances associated with the particular prescription.

III. NEITHER THE CSA NOR ITS REGULATIONS IMPOSE SPECIAL DISPENSING OBLIGATIONS ON BUSINESSES THAT OPERATE PHARMACIES.

Defendants have also contended that businesses that operate pharmacies may be liable under the CSA for the filling of prescriptions even if no employee pharmacist knowingly filled a prescription issued outside the usual course or otherwise violated any regulations. (Compl. ¶ 142.) They assert that such businesses are required to affirmatively collect, analyze, and share information—such as data about the prescribing and prescription-filling habits of doctors and patients, and information about when pharmacists have refused to fill prescriptions—across their stores, so individual pharmacists have access to more information when they consider whether to fill prescriptions. So, for example, if one pharmacist refuses to fill a prescription and another pharmacist employed by the same business reaches a different conclusion in the exercise of her professional judgment, Defendants would infer wrongdoing *by the business*. Defendants also assert that pharmacy businesses must in some cases impose categorical blocks on prescriptions written by particular (state-licensed, DEA-registered) doctors, rather than leave those decisions to the case-by-case judgments of their pharmacist employees. Yet although some pharmacies have voluntarily implemented some of these practices, no law or regulation establishes any such obligations, and Defendants cannot seek to impose liability based on them.

First, Defendants claim that pharmacy businesses must collect, analyze, and share among their stores the data on when its pharmacists refuse to fill prescriptions, and more generally about the prescription histories of doctors and patients. But no provision of the CSA or its implementing

regulations comes close to setting out such an affirmative obligation. Indeed, the regulations do not require such pharmacies even to *maintain* any information about refusals to fill, much less to analyze or share it in a particular way. And, as discussed, the only specific duty that the CSA regulations impose regarding the dispensing of prescribed controlled substances—the so-called "corresponding responsibility"—exclusively "rests with *the pharmacist who fills the prescription*," not the business that owns or operates the pharmacy. 21 C.F.R. § 1306.04(a) (emphasis added). Simply put, there is no statutory or regulatory basis from which one could even remotely infer an affirmative duty on the pharmacy business itself to maintain, analyze, or share data about prescription histories or refusals to fill.

Indeed, the CSA's regulations specifically *exclude* controlled-substance dispensers from the requirement that other CSA registrants must "design and operate a system" to detect suspicious orders. Section 1301.74(b), explained below, *see infra* p. 23, requires manufacturers and distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." But the specific security provisions addressing pharmacies include no similar system-level requirement that would call for reporting of "suspicious" prescriptions. *See id.* § 1301.76(d) (requiring, for example, that "retail pharmacies" comply with certain requirements "when selecting private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy" and instructing them to "report[] in-transit losses upon discovery"). Defendants cannot establish a CSA violation by pointing to a corporate pharmacy's failure to adopt policies that are not required by the CSA or its regulations.

Second, and similarly, Defendants contend that pharmacy businesses must, at least in some cases, issue directives prohibiting their pharmacists from filling prescriptions written by particular doctors (even though the doctors remain duly licensed by the state, and registered by DEA, to

prescribe controlled substances). But no authority has ever suggested such an obligation. Again, the regulations place "responsibility for the proper prescribing and dispensing of controlled substances … upon *the prescribing practitioner*," with a "corresponding responsibility" on "*the pharmacist who fills the prescription*." *Id.* § 1306.04(a) (emphases added). That allocation of responsibility makes sense: Pharmacists—not businesses—are expected to exercise their own corresponding responsibility when filling a prescription by applying their professional judgment to the facts before them in light of their training, education, and experience. Federal law does not contemplate, much less require, that corporate officials would override their trained pharmacist employees to preclude, on a categorical basis, the filling of a registered practitioner's prescriptions. And state regulators have maintained that corporate-wide "blocks" actually violate state laws governing the practice of medicine and pharmacy, by interfering with the prescribing doctor's medical judgment and the pharmacist's ability to evaluate each prescription case-by-case, potentially subjecting pharmacists and pharmacies to state disciplinary action. *See* Compl. ¶¶ 86–90; *see also* Ex. 1, Letter from Steven L. Olsen, Idaho Deputy Attorney General, to Idaho Wal-Mart Pharmacies (Feb. 8, 2019) (alleging that Walmart's corporate-wide block policy "is preventing pharmacists from fulfilling their legal obligations ... and from exercising their obligation of corresponding responsibility"); Ex. 2, Wisconsin Pharmacy Examining Board, Administrative Warning, Division of Legal Services and Compliance Case No. 17 PHM 095 (Dec. 6, 2018) (threatening disciplinary action where Walmart pharmacy told local clinic it "would no longer fill controlled substance prescriptions from that clinic" and noting that "[t]he broad prohibition … deterred pharmacists ... from exercising their independent clinical judgment").

Indeed, DEA *itself* has emphasized that the decision to fill a prescription depends on prescription-by-prescription judgment. "A pharmacist is required to exercise sound professional

judgment ... when making a determination about the legitimacy of a controlled substance prescription." DEA, The Pharmacist's Manual 42 (2020); *see also* Dispensing Controlled Substances, 71 Fed. Reg. at 52723 ("[E]ach patient's situation is unique and the nature and degree of physician oversight should be tailored accordingly, based on the physician's sound medical judgment....").

To be sure, some businesses that operate pharmacies—including Walmart—have chosen *voluntarily* to adopt some of these practices, in part because of Defendants' pressure, and despite serious disagreement from medical professionals. But Defendants may not hold businesses liable for not requiring these practices sooner or for failing to implement other practices that have never been required by law. The Court should declare that the CSA and its regulations do not establish corporate liability for failing to aggregate and analyze data, to share information across multiple registrant locations, or to deploy a corporate block of state-licensed, DEA-registered doctors.

IV. DISTRIBUTORS HAVE NO DUTY UNDER CURRENT LAW TO INVESTIGATE AND CLEAR "SUSPICIOUS" ORDERS BEFORE DISTRIBUTING THEM.

Defendants have also adopted the position that controlled-substance distributors must investigate and clear "suspicious" orders before distributing them. (Compl. ¶ 146.) But as DEA's newly proposed regulations show, distributors have no such duty under existing law. Instead, they need only *report* "suspicious" orders to DEA, which can then investigate as necessary.

A. The CSA does not require distributors to investigate or clear "suspicious" orders before shipping them. When Walmart distributed controlled substances to its own pharmacies, the statute said nothing about "suspicious" orders at all. All it did was instruct the Attorney General to consider a distributor's "maintenance of effective controls against diversion" in determining whether to grant registration. 21 U.S.C. § 823(b). In October 2018, Congress amended the CSA to specify that registrants must design a system to detect "suspicious" orders and report them to

DEA for investigation, but even the amended statute does not require distributors to *withhold* those shipments or do anything besides notify DEA about them. *See id.* § 832(a) (requiring registrants to "design and operate a system to identify suspicious orders," "ensure that the system designed" complies with privacy laws, and "notify" DEA "upon discovering a suspicious order or series of orders"). Nothing in either version of the statute restricts the shipping of orders.

The CSA's implementing regulations contain no such restriction either. The regulation that is specifically directed toward "suspicious" orders requires distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). But it also makes clear what distributors must do with such orders: "The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* This section does not compel distributors to withhold reported orders for investigation before shipping them. And that is a meaningful omission, since other subsections of this regulation *do* require distributors to take certain steps before they ship certain orders. For example, § 1301.74(a) requires distributors to "make a good faith inquiry" into a purchaser's registration "[b]efore distributing a controlled substance" to that purchaser. And § 1301.74(d) requires distributors to receive a "prior written request" before distributing controlled substances "as a complimentary sample to any potential or current customer."

No other regulation imposes a "no-ship" duty either. While 21 C.F.R. § 1301.71(a) generally requires all registrants to "provide effective controls and procedures to guard against theft and diversion of controlled substances," that is not a distinct, free-standing obligation. That regulation then specifies that "[i]n order to determine whether a registrant has" met that requirement, "the [DEA] Administrator *shall use* the security requirements set forth in §§ 1301.72–1301.76 as standards for the ... controls and operating procedures necessary to prevent

diversion." (emphasis added). Thus, as to "suspicious" orders, the distributor's duty is defined by the specific obligation addressing that issue, § 1301.74(b). *Kirby Corp. v. Pena*, 109 F.3d 258 (5th Cir. 1997) (invoking "well known canon of ... construction that a specific ... provision governs the general").

B. Walmart is not alone in this reading of DEA's regulations; courts read them in the same way. In *United States v. $463,497.72 in United States Currency*, for instance, the Government tried to stop a distributor from recovering its portion of a pharmacy's seized funds, claiming that the distributor was not an "innocent owner" under the forfeiture laws because it had shipped flagged orders to the pharmacy without conducting its own due diligence. 853 F. Supp. 2d 675 (E.D. Mich. 2012). The court disagreed. "[A]ll the regulation requires" of a distributor "with respect to suspicious orders [i]s [to] report them to the DEA." *Id.* at 685. In fact, the record in that case revealed that even *DEA itself* has long understood and enforced its regulations that way: "the DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products, and that practice had been approved by the DEA." *Id.* at 682. *But see In re Nat'l Prescription Opiate Litig.*, No. 1-17-md-2804, 2019 WL 3917575, at *9 (N.D. Ohio Aug. 19, 2019) (erroneously finding a no-ship duty).

In recently seeking to promulgate *new* regulations to restrict the shipment of "suspicious" orders, DEA has confirmed that its existing regulations do not. *See* Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, 85 Fed. Reg. 69298 (proposed Nov. 2, 2020) (to be codified at 21 C.F.R. pt. 1301). Under the proposed rule, a registrant who receives a "suspicious" order would have two options: It may "decline to distribute pursuant to the suspicious order, immediately file a suspicious order report ... , and maintain a record of the suspicious order and any due diligence related to the suspicious order." *Id.* Or it can "conduct due diligence to

investigate each suspicious circumstance" and, if able to dispel each such circumstance within seven days, "distribute pursuant to the order" and "maintain a record of its due diligence." *Id.* at 69298–99. DEA is thus proposing to "*amend*[] *its regulations*," *id.* at 69288 (emphasis added), to establish the no-ship obligation that Defendants imagine exists under *current* law.

C. In the face of the above, Defendants seek to ground their no-ship duty in a DEA guidance letter and some administrative decisions revoking registrations. Neither succeeds.

First, as explained above, *supra* pp. 4–5, an informal letter cannot create new duties absent from the statute and regulations. In December 2007, Deputy Assistant DEA Administrator Joseph Rannazzisi told registrants, in a letter, that they "must conduct an independent analysis of suspicious orders prior to completing a sale." *See* Ex. 3. But agency letters like these, which are not subject to notice-and-comment procedures, lack the "force and effect of law." *Kornman & Assocs., Inc. v. United States*, 527 F.3d 443, 452 (5th Cir. 2008). DOJ itself has prohibited the use of such guidance documents as a basis to impose civil liability. Interim Final Rule, Processes and Procedures for Issuance and Use of Guidance Documents, 85 Fed. Reg. 63200 (effective Oct. 7, 2020). Per that regulation, DOJ cannot "treat a party's noncompliance with a guidance document as itself a violation of applicable statutes or regulations." 28 C.F.R. § 50.27(b)(1). Rather, "[t]he Department must establish a violation by reference to statutes and regulations." *Id.*

Second, DEA's attempt to locate the purported no-ship duty in past adjudicative decisions also fails, because these decisions *do not* and *cannot* purport to impose such an obligation. Like the decisions about a pharmacist's corresponding responsibility discussed above, *see supra* pp. 12–13, these decisions arise in the distinct context of revocation of registration, not civil liability. So they turn upon a different standard—whether the applicant's continued registration is

"inconsistent with the public interest," 21 U.S.C. § 824(a)(4)—and do not establish that there is any specific duty under existing law to withhold suspicious orders after reporting them.

In any case, the decisions the DEA highlights do not purport to establish a no-ship duty. In *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36487, 36499–500 (July 3, 2007), DEA concluded that the registrant had failed to maintain effective controls against diversion because it continued to distribute "massive quantities of controlled substances" despite "*being advised by agency officials* that its internet pharmacy customers were *likely engaged in illegal activity*." (emphasis added). DEA thus adopted only the limited principle that a registrant who "had reason to know that it was contributing to the diversion of [opioids] through most, if not all, of the pharmacies it supplie[s]," yet took no meaningful steps to investigate or report those pharmacies, should lose its registration. *Id.* at 36502. The agency did not thereby purport to create a new, independent duty for distributors to investigate all "suspicious" orders.

The DEA has also cited its decision about Masters Pharmaceuticals, later affirmed by the D.C. Circuit, as support for its no-ship duty. *Masters Pharm., Inc.*, 80 Fed. Reg. 55418 (Sept. 15, 2015); *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212 (D.C. Cir. 2017). But that case is even further afield. As the D.C. Circuit recognized, the Administrator "concluded that Masters' frequent violations of the Reporting Requirement warranted revocation of Masters' certificate of registration … [and] therefore had no need to consider whether Masters additionally violated the Shipping Requirement." *Masters*, 861 F.3d at 215. Because "the Administrator's holding rests on Masters' violation of the Reporting Requirement, not the Shipping Requirement," the court did not consider Masters' argument that DEA had "unlawfully ... amended the regulatory scheme by tacking the Shipping Requirement onto the settled list of 'security requirements' stated in sections

1301.72–1301.76." *Id.* at 221–22. As a result, the *Masters* revocation proceeding cannot sustain Defendants' purported no-ship obligation either.

In any event, even if DEA had sought to create a no-ship duty through adjudication, it could not do so. As explained, agency adjudication can be used to interpret existing duties, but not to create new ones. *See supra* pp. 4–5, 12–13. Here, Defendants are trying to create *new* substantive obligations—to "add[] content to the governing legal norms," *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 96 (D.C. Cir. 1997)—by inserting a novel no-ship duty into the CSA and its regulatory framework. This is impermissible as a matter of administrative law.

V. DISTRIBUTORS CANNOT FACE CIVIL PENALTIES FOR FAILING TO MAKE REPORTS REQUIRED BY REGULATION RATHER THAN BY THE CSA ITSELF.

Finally, Defendants claim that, even before Congress amended the CSA in 2018 to turn the *regulatory* duty to report "suspicious" orders into a *statutory* duty, the law authorized penalties against distributors who failed to report those orders. (Compl. ¶ 155.) That theory also fails, as the sole authorized remedy for such alleged failures at that time was revocation of registration.

The CSA makes it "unlawful for any person … to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information *required under this subchapter or subchapter II*." 21 U.S.C. § 842(a)(5) (emphasis added). Violations of that section are subject to civil penalties, not to exceed $10,000 per violation. *Id.* § 842(c)(1)(B) (2012). The italicized language—"under this subchapter or subchapter II"—refers to records required by the *statute*, not by *regulation*. And that omission was no slip of the pen: Other provisions of the CSA refer specifically to "this subchapter [and] regulations prescribed by the Attorney General," *id.* § 829(f)(1), or "subsection (d) [of this section] and regulations prescribed by [the Attorney General] pursuant to this section," *id.* § 828(a). Section 842(a)(5) thus provides liability for failure to file only those reports required by the CSA itself—not by its

regulations. *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("We refrain from concluding ... that the differing language in the two subsections has the same meaning in each.").

This plain language blocks Defendants' attempt to obtain civil penalties for a distributor's failure to file suspicious order reports before October 2018. The CSA requires registrants to make, keep, or furnish numerous records, reports, and the like. *See, e.g.*, 21 U.S.C. § 827(a)(1) (requiring registrants to make a "biennial inventory" of their stocks of controlled substances); *id.* § 827(a)(3) (requiring registrants to "maintain, on a current basis, a complete and accurate record of each [controlled] substance manufactured, received, sold, delivered, or otherwise disposed of"); *id.* § 828(c) (requiring distributors to "preserve" the orders they receive "for a period of two years"). But until 2018, the statute did *not* require distributors to "make, keep, or furnish" suspicious order reports; only 21 C.F.R. § 1301.74(b) did that. DEA could consider a distributor's violation of that requirement in determining whether to revoke its registration, 21 U.S.C. § 823(b), but that violation could not be the basis for the imposition of civil penalties under § 842.

The text alone proves this point, but the Supreme Court's decision in *Kucana v. Holder*, 558 U.S. 233 (2010), puts the matter beyond all doubt. There, Congress stripped jurisdiction to review certain immigration decisions "specified *under this subchapter* to be in the discretion of the Attorney General." 8 U.S.C. § 1252(a)(2)(B)(ii) (emphasis added). The lower court held that it lacked jurisdiction to review an immigrant's request to reopen his immigration proceedings even though it was a regulation—not the statute—that conferred discretion on the Attorney General in such matters. The Supreme Court disagreed. It held that the "key words 'specified under this subchapter'" referred "to statutory, but not to regulatory, specifications." 558 U.S. at 237. "In other provisions," the Court observed, "Congress expressed precisely" its desire to sweep in regulatory commands too. *Id.* at 248. As noted, the same is true of the CSA—both its operative

text and its surrounding provisions. Under *Kucana*, Defendants therefore cannot seek penalties for a distributor's failure to file suspicious order reports before October 2018.

Finally, subsequent government action confirms the point. In October 2018, the SUPPORT Act amended the CSA to require registrants to report suspicious orders. Pub. L. No. 115-271, 132 Stat. 3894 (2018). Congress also amended the CSA's penalty provision to specify penalties for violating the recordkeeping requirements "related to the reporting of suspicious orders for opioids." 21 U.S.C. § 842(c)(1)(B)(ii). "When Congress acts to amend a statute, [courts] presume it intends its amendment to have real and substantial effect." *Stone v. INS*, 514 U.S. 386, 397 (1995). The decision to amend the CSA to require such reports (and to specify the fine for violating that new mandate) thus corroborates that civil penalties were *unavailable* under § 842 beforehand.

CONCLUSION

The Court should grant summary judgment and declare the following:

(1) A pharmacist does not violate the CSA or its regulations by dispensing controlled substances without documenting the resolution of any "red flags" associated with the prescription, only by knowingly filling a prescription issued outside the usual course of professional treatment;

(2) The CSA and its implementing regulations do not prohibit pharmacists from filling entire categories of prescriptions, without regard to the individual circumstances of each case;

(3) The CSA and its implementing regulations do not impose duties on businesses that operate pharmacies, beyond the duties imposed on pharmacists themselves, to guard against filling invalid controlled-substance prescriptions;

(4) A controlled-substance distributor does not violate the CSA or its regulations by shipping a "suspicious" order without first investigating and clearing it; and

(5) Until Congress amended the CSA in October 2018, a controlled-substance distributor was not subject to civil penalties for failing to report "suspicious" orders to DEA.

Dated: November 16, 2020

Respectfully submitted,

/s/ Clyde M. Siebman

Clyde M. Siebman
Texas Bar No. 18341600
Elizabeth S. Forrest
Texas Bar No. 24086207
SIEBMAN FORREST BURG
& SMITH, LLP
Federal Courthouse Square
300 N. Travis
Sherman, TX 75090
Telephone: (903) 870-0070
clydesiebman@siebman.com
elizabethforrest@siebman.com

David W. Ogden*
Charles C. Speth*
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, DC 20006
Phone: (202) 663-6000
David.Ogden@wilmerhale.com
Charles.Speth@wilmerhale.com

*Admitted *pro hac vice*

/s/ Michael A. Carvin

Michael A. Carvin*
D.C. Bar No. 366784
Benjamin C. Mizer*
D.C. Bar No. 499651
Yaakov M. Roth*
D.C. Bar No. 995090
William G. Laxton, Jr.*
D.C. Bar No. 982688
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001.2113
Telephone: (202) 879-3939
macarvin@jonesday.com
bmizer@jonesday.com
yroth@jonesday.com
wglaxton@jonesday.com

Karen P. Hewitt*
California Bar No. 145309
JONES DAY
4655 Executive Drive, Suite 1500
San Diego, CA 92121-3134
Telephone: (858) 314-1200
kphewitt@jonesday.com

Jason S. Varnado
Texas Bar No. 24034722
JONES DAY
717 Texas, Suite 3300
Houston, TX 77002-2172
Telephone: (832) 239-3939
jvarnado@jonesday.com

Attorneys for Plaintiff
WALMART INC.

CERTIFICATE OF SERVICE

I hereby certify that on November 16, 2020, I electronically filed the foregoing motion with the Clerk of the Court using the CM/ECF system and served it on the following parties by certified mail:

U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530
Defendant

U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
Defendant

Attorney General William P. Barr
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530
Defendant

Acting Administrator Timothy Shea
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152
Defendant

By: */s/ Clyde Siebman*
Counsel for Walmart Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

WALMART INC., Plaintiff, v. U.S. DRUG ENFORCEMENT ADMINISTRATION; ACTING ADMINISTRATOR TIMOTHY J. SHEA; U.S. DEPARTMENT OF JUSTICE; ATTORNEY GENERAL WILLIAM P. BARR, Defendants.	)	No. 4:20-cv-00817-SDJ

DECLARATION OF JASON S. VARNADO

I, Jason S. Varnado, hereby declare:

1. I am a partner at the law firm Jones Day and counsel to Plaintiff Walmart Inc. ("Walmart") in this case. I file this declaration to submit to the Court true and correct copies of the following publicly available materials, which are cited in Walmart's Motion for Partial Summary Judgment:

2. Exhibit 1 to Walmart's Motion for Partial Summary Judgment is a true and correct copy of a letter from Steven L. Olsen, Idaho Deputy Attorney General, to Idaho Wal-Mart Pharmacies, dated February 8, 2019.

3. Exhibit 2 to Walmart's Motion for Partial Summary Judgment is a true and correct copy of an administrative warning issued by the State of Wisconsin Pharmacy Examining Board to Walmart Pharmacy # 10-1650, dated December 6, 2018.

4. Exhibit 3 to Walmart's Motion for Partial Summary Judgment is a true and correct copy of a letter from U.S. Drug Enforcement Administration Deputy Assistant Administrator Joseph Rannazzisi to registrants, dated December 27, 2007.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on November 13, 2020.

/s/ Jason S. Varnado

Jason S. Varnado
Texas Bar No. 24034722

Exhibit 1

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL
LAWRENCE G. WASDEN

February 8, 2019

VIA U.S. MAIL (Standard and Certified)

Wal-Mart Pharmacy 10-3472
Attn: Lyndell Baser, Pharmacist in Charge
3050 E. Mullen Ave.
Post Falls, ID 83854

Wal-Mart Pharmacy 10-4395
Attn: M. George Crawford, Pharmacist in Charge
6405 W. Pointe Pkwy
Post Falls, ID 83854

Re: Idaho Board of Pharmacy Investigation; Case No. BOP 19-056

Dear Gentlemen:

I am the Deputy Attorney General prosecuting disciplinary matters for the Idaho Board of Pharmacy ("Board"). Board staff has conducted an investigation and determined that Wal-Mart Pharmacy 10-3472 and Wal-Mart Pharmacy 10-4395 ("collectively referred to as "the Pharmacies") engaged in conduct that violated the laws and rules governing the practice of pharmacy in the state of Idaho and constitutes grounds for disciplinary action against each pharmacy's license. The violations are more specifically described in the enclosed Stipulation and Consent Order.

The Pharmacies have two options to resolve this matter. First, it may proceed with a formal hearing upon the allegations set forth in the Stipulation. In that case, an Administrative Complaint and Notice of Hearing will be served upon it. At the hearing, evidence will be heard, and findings of fact and conclusions of law will be made determining what discipline, if any, is appropriate. If the Pharmacies prefer to proceed with a formal hearing, please notify me as soon as possible.

The second option is to enter into the enclosed Stipulation and Consent Order, the Pharmacies agree to the stated violations and proposed disciplinary sanctions. If the Pharmacies choose to settle this dispute by stipulation, please sign the enclosed Stipulation and Consent Order and return the original to me in its entirety by **close of business on March 1, 2019**. The Stipulation

Civil Litigation Division
P.O. Box 83720, Boise, Idaho 83720-0010
Telephone: (208) 334-2400, FAX: (208) 854-8073
Located at 954 W. Jefferson 2nd Floor

will then be presented to the Board at its next meeting on April 11, 2019 and is subject to Board approval. There will be no hearing and you do not need to appear at the Board's meeting, although you are free to do so if you wish. The Board has the final authority to accept or reject the Stipulation. If the Board rejects the Stipulation, we will notify you of that decision.

If the Pharmacies do not return the signed Stipulation to me by **close of business on March 1, 2019**, I will assume that the Pharmacies do not agree to enter into the proposed stipulation and will serve an Administrative Complaint and a notice of hearing. Although I cannot give the Pharmacies any legal advice, I can answer questions that do not require legal guidance. If you desire any legal advice, you should contact a private attorney. Should the Pharmacies retain an attorney to represent them in this matter, please advise me and I will communicate directly with their attorney.

Sincerely,

STEVEN L. OLSEN
Deputy Attorney General

SLO:rdj
Enclosure
c: Berkeley S. Fraser, Deputy Executive Director, Idaho Board of Pharmacy (w/enc) (via email)

BEFORE THE BOARD OF PHARMACY

STATE OF IDAHO

In the Matter of the Licenses of: WAL-MART PHARMACY 10-3472, Community Pharmacy License No. 1642RP, WAL-MART PHARMACY 10-4395, Community Pharmacy License No. 14475RP, Respondents.	)	Case No. BOP-19-056 **STIPULATION AND CONSENT ORDER**

WHEREAS, information has been received by the Idaho Board of Pharmacy ("Board") that constitutes sufficient grounds for the initiation of an administrative action against WAL-MART PHARMACY 10-3472 and WAL-MART PHARMACY 10-4395 (collectively referred to as "Respondents"); and

WHEREAS, the parties wish to expeditiously settle this matter in lieu of proceeding to an administrative hearing before the Board; now, therefore,

IT IS HEREBY STIPULATED AND AGREED between the undersigned parties that this matter shall be settled and resolved upon the following terms:

A. JURISDICTION OF THE BOARD

A.1. The Board may regulate the practice of pharmacy in the state of Idaho in accordance with title 54, chapter 17, Idaho Code. The Board is further empowered by title 37, chapter 27, Idaho Code, to administer the regulating provisions of the Uniform Controlled Substances Act in the state of Idaho.

A.2. Respondents are licensees of the Board. Wal-Mart Pharmacy 10-3472 holds Community Pharmacy License No. 1642RP to operate a community pharmacy located at 3050 E. Mullen Avenue in Post Falls, Idaho. Wal-Mart Pharmacy 10-4395 holds Community Pharmacy

License No. 14475RP to operate a community pharmacy located at 6405 W. Pointe Parkway in Post Falls, Idaho. Respondents' licenses are subject to the provisions of title 54, chapter 17, Idaho Code, title 37, chapter 27, Idaho Code, and the Board's rules promulgated at IDAPA 27.01.01 *et seq*.

B. STIPULATED FACTS

B.1. In or around August 2018, Patient I.R. brought a buprenorphine prescription to a Wal-Mart Pharmacy 10-5869 in Moscow, Idaho ("the Moscow pharmacy"). Patient I.R.'s insurance informed the Moscow pharmacy that it was too early to fill the prescription and refused to cover the cost of it.

B.2. After the pharmacist on duty learned that Patient I.R.'s insurance was not going to cover the cost of the prescription, the pharmacist contacted Patient I.R.'s doctor, Dr. M.W., to ask that Dr. M.W. contact the insurance company to request prior authorization to get Patient I.R.'s prescription filled early. Dr. M.W. refused to contact the insurance company and asked the pharmacist to allow Patient I.R. to pay cash for the medication. The pharmacist then informed Dr. M.W. that the pharmacist considered the insurance company's refusal to pay for an early fill to be a red flag and thus would not allow Patient I.R. to pay cash.

B.3. Moscow pharmacy staff noted the incident in the Wal-Mart Archer system, which is reviewed by the corporate office. After the Archer system review, and with no further investigation into the matter, the corporate office blocked all controlled substance prescriptions written by Dr. M.W. The corporate office then sent Dr. M.W. a letter dated August 17, 2018 informing Dr. M.W. that, pursuant to Wal-Mart Health and Wellness Practice Compliance, controlled substance prescriptions written by Dr. M.W. could no longer be filled at Wal-Mart pharmacies.

B.4. At some point after Dr. M.W.'s controlled substance prescriptions were blacklisted from Wal-Mart pharmacies, another of Dr. M.W.'s patients, Patient X.X. (used for patient confidentiality), went to Wal-Mart Pharmacy 10-4395 in Post Falls, Idaho to have a controlled substance prescription filled.

B.5. Patient X.X. is employed by Wal-Mart. As a Wal-Mart employee, Patient X.X.'s health insurance will only cover prescriptions filled at Wal-Mart pharmacies.

B.6. Because the controlled substance prescription was written by Dr. M.W., Wal-Mart Pharmacy 10-4395 refused to fill the prescription and would not inform Patient X.X. why it would not fill the prescription.

B.7. Patient X.X. then went to Wal-Mart Pharmacy 10-3472, also in Post Falls, to have her prescription filled. Again, because the prescription was written by Dr. M.W., Wal-Mart Pharmacy 10-3472 refused to fill the prescription. Walmart Pharmacy 10-3472 also refused to inform Patient X.X. why it would not fill her prescription.

B.8. Because Wal-Mart restricted Dr. M.W.'s ability to have his controlled substance prescriptions filled at any of its pharmacies, Patient X.X. was not able to have her prescription filled at either of the Post Falls Wal-Mart pharmacies, which are licensed by the Board as Wal-Mart Pharmacy 10-3472 and Wal-Mart Pharmacy 10-4395. As a result, Patient X.X.'s insurance did not cover the prescription expense and she was forced to pay the full cost of the prescription.

B.9. Respondents' directive that certain doctors, like Dr. M.W., cannot have controlled substance prescriptions filled at Walmart pharmacies and thereby not allowing pharmacists to determine what constitutes a valid prescription, is preventing pharmacists from fulfilling their legal obligations as a pharmacist and from exercising their obligation of corresponding responsibility, which violates 21 C.F.R. § 1306.04(a). Further, by failing to fill the prescriptions as described

above, Respondents' actions fall below the accepted standard of care, as required by IDAPA 27.01.01.020.03 and 023.16.

B.10. Respondents' actions further constitute participation in a plan or agreement that compromises the quality or extent of professional services or limits access to provider facilities at the expense of public health or welfare, and thus violate IDAPA 27.01.01.023.12.

B.11. Respondents acknowledge their actions constituted violations of the statutes and rules governing the practice of pharmacy in Idaho. More specifically, Respondents admit the violations are subject to the following statutes and rules:

a. Idaho Code § 54-1726(1)(f) (the Board may suspend, revoke or restrict the registration of any person, upon one or more of the following grounds…being found by the Board to be in violation of any of the provisions of this chapter, chapter 27, title 37, or rules adopted pursuant to either chapter).

b. IDAPA 27.01.01.020.03 (to evaluate whether a specific act is within the scope of pharmacy practice in or into Idaho, a licensee of the Board must independently determine whether: performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee with similar education, training and experience).

c. Idaho Code § 54-1726(1)(a) (the Board may suspend, revoke or restrict the registration of any person, upon one or more of the following grounds…unprofessional conduct as that term is defined by the rules of the Board).

d. IDAPA 27.01.01.023.16 (the following acts or practices by any licensee are declared to be specifically, but not by way of limitation, unprofessional conduct and

conduct contrary to the public interest: providing health care services which fail to meet the standard provided by other qualified licensees in the same or similar setting).

e. IDAPA 27.01.01.023.12 (the following acts or practices by any licensee are declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest: participation in a plan or agreement that…limits access to provider facilities at the expense of public health or welfare).

f. 21 C.F.R. § 1306.04(a) (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).

g. Idaho Code § 54-1728(1)(f) (upon finding the existence of grounds for discipline, the Board may impose one or more of the following penalties…imposition of an administrative fine not to exceed $2,000 for each occurrence providing a basis for discipline).

B.12. Respondents, in lieu of proceeding with a formal disciplinary hearing, hereby agree the Board may enter a final order against their licenses as set forth in Section C below.

C. STIPULATED PENALTIES

C.1. Respondents shall adopt a procedure acceptable to the Board that will provide a prescriber, prior to Walmart's implementation of a decision prohibiting Walmart pharmacies from filling a prescription from a particular prescriber, with an adequate opportunity to contest such a decision.

C.2. Walmart agrees to provide the Board with a draft of that policy for review and approval by the Board within 30 days after entering this Stipulation.

C.3. Failure to comply with any of the terms of this Stipulation and Consent Order may result in additional action being taken against Respondents' community pharmacy licenses.

C.4. All costs associated with Respondents' compliance with the terms of this Stipulation and Consent Order shall be borne solely by Respondents.

D. COMPLIANCE WITH STIPULATION AND CONSENT ORDER

D.1. The Board has authority to enforce compliance with the terms and conditions of this Stipulation. By signing this Stipulation, Respondents waives their ability to challenge the Board's lack of authority to enforce compliance on appeal to a district court. If there is reason to believe Respondents have violated any of the terms or conditions of this Stipulation, the Executive Director of the Board shall file an administrative complaint, setting forth the allegations of non-compliance and notifying Respondents, and their attorney, if applicable, that Respondents may request a hearing regarding the allegations of non-compliance. If Respondents do not request a hearing on the administrative complaint, any allegations of non-compliance will be deemed admitted.

D.2. If Respondents fail to comply with this Stipulation, Respondents' licenses may be subject to further discipline, up to and including suspension or revocation. Therefore, the Board retains jurisdiction over this proceeding until all matters are finally resolved as set forth in this Stipulation. Any action taken by the Board to enforce compliance with this Stipulation shall be in accordance with this section.

D.3. Any additional costs and/or attorney fees incurred by the Board in any enforcement action shall be borne solely by Respondents.

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E. ACKNOWLEDGMENTS AND WAIVER OF RIGHTS

Respondents, by signature of their authorized representative hereto, hereby acknowledges the following:

E.1. Respondents admit to the allegations stated above in Section B. Respondents understand these allegations constitute cause for disciplinary terms upon their licenses. Respondents agree the Board has jurisdiction to proceed in this matter with their consent as indicated by signatures on their behalf hereto.

E.2. Respondents have read the above Stipulation fully and has had the opportunity to discuss it with legal counsel. Respondents understand and acknowledge that by its terms Respondents are waiving certain rights provided under Idaho law.

E.3. Respondents understand that they have, among other rights, the right to a full and complete hearing; the right to confront and cross-examine witnesses; the right to present evidence or to call witnesses, or to so testify on their own behalf; the right to reconsideration; the right to appeal this matter to district court; and all rights provided by the Idaho Administrative Procedure Act and the laws and rules governing the practice of pharmacy in Idaho. Respondents hereby freely and voluntarily waive these rights, without further process, in order to enter into this Stipulation as a resolution of the allegations contained herein.

E.4. Respondents understand that in signing this Stipulation, they are enabling the Board to impose disciplinary terms upon their licenses as set forth in Section C without further process.

E.5. Respondents understand the Board may approve this Stipulation as proposed, approve it subject to specified changes, or reject it. Respondents understand that, if approved as proposed, the Board will execute and issue this Stipulation and Consent Order according to the aforementioned terms, and Respondents hereby agree to the above Stipulation for settlement. If

the Board approves this Stipulation subject to changes, and those changes are acceptable, Respondents acknowledge the Stipulation will take effect, and an order modifying the terms of the Stipulation will be issued. If the changes are unacceptable or the Board rejects this Stipulation, this Stipulation will be of no effect. Admissions in this Stipulation and negotiations preceding the signing of this Stipulation will not be admissible at any subsequent disciplinary hearing.

E.6. In the event this Stipulation is rejected by the Board or any changes proposed by the Board are not accepted, Respondents waive any right they may have to challenge the Board's impartiality to hear the allegations in any subsequent administrative complaint based on the fact that the Board has considered and rejected this Stipulation.

E.7. Respondents understand the Board shall have the right to make full disclosure of this Stipulation and Consent Order to any state, agency or individual requesting information subject to any applicable provisions of the Idaho Public Records Act, title 9, chapter 3, Idaho Code.

E.8. Respondents understand this Stipulation and Consent Order is the resolution of a contested case and is a **public record**.

E.9. This Stipulation contains the entire agreement between the parties, and Respondents are not relying on any other agreement or representation of any kind, verbal or otherwise.

E.10. This Stipulation shall be presented to the Board with a recommendation for approval from the Executive Director of the Board and the Deputy Attorney General responsible for prosecution before the Board at the next regularly-scheduled meeting of the Board.

E.11. Except for paragraph E.6., which becomes effective when Respondents sign this Stipulation, this Stipulation shall not become effective until it has been approved by a majority of the Board, and a Board member signs the attached Order.

DATED this _____ day of _____, 2019.

WAL-MART PHARMACY 10-3472

By: _____

Printed: _____

Its: _____
Authorized Representative for Respondent
Wal-Mart Pharmacy 10-3472

DATED this _____ day of _____, 2019.

WAL-MART PHARMACY 10-4395

By: _____

Printed: _____

Its: _____
Authorized Representative for Respondent
Wal-Mart Pharmacy 10-4395

I concur in this Stipulation and Consent Order and recommend that the Board adopt the same.

DATED this _____ day of _____, 2019.

STATE OF IDAHO
OFFICE OF THE ATTORNEY GENERAL

_____
Steven L. Olsen
Deputy Attorney General

I also concur in this Stipulation and Consent Order and recommend the Board adopt the same.

DATED this _____ day of _____, 2019.

IDAHO BOARD OF PHARMACY

By: _____
Berkeley S. Fraser, RPh
Deputy Executive Director

ORDER

Pursuant to Idaho Code §§ 54-1728 and 37-2718, the Idaho Board of Pharmacy hereby accepts the terms and conditions of the foregoing Stipulation and Consent Order and incorporates them into this Order; and it is hereby ORDERED that Respondent comply with such terms and conditions.

DATED this _____ day of _____, 2019.

_____

Nicole Chopski, PharmD
Board Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this _____ day of _____, 2019, I caused to be served a true and correct copy of the foregoing by the following method to:

Wal-Mart Pharmacy 10-3472 Attn: Lyndell Baser, Pharmacist in Charge 3050 E. Mullen Ave. Post Falls, ID 83854	☒ U.S. Mail ☐ Hand Delivery ☒ Certified Mail, Return Receipt Requested ☐ Overnight Mail ☐ Facsimile:
Wal-Mart Pharmacy 10-4395 Attn: M. George Crawford, Pharmacist in Charge 6405 W. Pointe Pkwy Post Falls, ID 83854	☒ U.S. Mail ☐ Hand Delivery ☒ Certified Mail, Return Receipt Requested ☐ Overnight Mail ☐ Facsimile:
Steven L. Olsen Deputy Attorney General Civil Litigation Division P. O. Box 83720 Boise, ID 83720-0010	☐ U.S. Mail ☐ Hand Delivery ☐ Overnight Mail ☐ Facsimile: ☒ Email: steven.olsen@ag.idaho.gov colleen.funk@ag.idaho.gov

_____

Ellen Mitchell
Investigations Support Coordinator

Exhibit 2

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD # WAR1000000805

ADMINISTRATIVE WARNING
Division of Legal Services and Compliance Case Number 17 PHM 095

This administrative warning is issued by the Pharmacy Examining Board (Board) to Walmart Pharmacy # 10-1650 (license number 8132-42), 825 East Green Bay, Saukville, WI 53080, pursuant to Wis. Stat. § 440.205. The Board makes the following findings:

1) There is evidence of professional misconduct by Walmart Pharmacy # 10-1650, to wit:

   a. On May 17, 2017, Walmart Pharmacy # 10-1650 (Pharmacy) informed a local clinic that the Pharmacy would no longer fill controlled substance prescriptions from that clinic due to concerns of overprescribing.

   b. The broad prohibition above deterred pharmacists at the Pharmacy from exercising their independent clinical judgment regarding dispensing controlled substances pursuant to a prescription order.

2) This misconduct is a first occurrence for Walmart Pharmacy # 10-1650.

3) This misconduct is a minor violation of Wis. Admin. Code § Phar 10.03(2).

4) Issuance of this administrative warning will adequately protect the public and no further action is warranted.

The Board issues this administrative warning and hereby puts Walmart Pharmacy # 10-1650 on notice that any subsequent similar violation may result in disciplinary action. The investigation of this matter, case number 17 PHM 095, is closed.

Date: 12/6/18

Signature of authorized representative for the Pharmacy Examining Board

Right to Review

You may obtain a review of this administrative warning by filing a written request with the Pharmacy Examining Board within twenty (20) days of mailing of this warning. The review will offer the credential holder an opportunity to make a personal appearance before the Board.

The record that this administrative warning was issued is a public record.
The content of this warning is private and confidential.
This administrative warning does not constitute an adjudication of guilt or the imposition of discipline.

Exhibit 3

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov Washington, D.C. 20637

December 27, 2007

Dear Registrant:

This letter is being sent to every entity in the United States registered with the Drug Enforcement Administration (DEA) to manufacture or distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).

In addition to, and not in lieu of, the general requirement under 21 USC 823, that manufacturers and distributors maintain effective controls against diversion, DEA regulations require all manufacturers and distributors to report suspicious orders of controlled substances. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system. Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders. Past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system.

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unit purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the order were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

For additional information regarding your obligation to report suspicious orders pursuant to 21 CFR 1301.74(b), I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals Inc., 72 FR 36487 (2007). In addition to discussing the obligation to report suspicious orders when discovered by the registrant, and some criteria to use when determining whether an order is suspicious, the final order also specifically discusses your obligation to maintain effective controls against the diversion of controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

WALMART INC., Plaintiff, v. U.S. DRUG ENFORCEMENT ADMINISTRATION; ACTING ADMINISTRATOR TIMOTHY J. SHEA; U.S. DEPARTMENT OF JUSTICE; ATTORNEY GENERAL WILLIAM P. BARR, Defendants.	)	No. 4:20-cv-00817-SDJ

[PROPOSED] ORDER

Plaintiff Walmart Inc. filed its Motion for Partial Summary Judgment ("Motion") under Fed. R. Civ. P. 56 in the above-numbered cause. Upon consideration of Plaintiff's Motion, and the submissions and arguments of the parties, the Court finds that, with respect to the discrete questions of law raised in the Motion, there are no genuine issues of material fact, that Plaintiff is entitled to judgment as a matter of law, and that Plaintiff's Motion should be granted.

It is hereby ordered that Plaintiff's Motion is GRANTED. The Court hereby

1. DECLARES that a pharmacist does not violate the Controlled Substances Act ("CSA") or its regulations by dispensing controlled substances without documenting the resolution of any "red flags" associated with the prescription, only by knowingly filling a prescription issued outside the usual course of professional treatment;

2. DECLARES that the CSA and its implementing regulations do not prohibit pharmacists from filling entire categories of prescriptions, without regard to the individual circumstances of each case;

3. DECLARES that the CSA and its implementing regulations do not impose duties on business that operate pharmacies, beyond the duties imposed on pharmacists themselves, to guard against filling invalid controlled-substance prescriptions;

4. DECLARES that a controlled-substance distributor does not violate the CSA or its regulations by shipping a "suspicious" order without first investigating and clearing it; and

5. DECLARES that until Congress amended the CSA in October 2018, a controlled-substance distributor was not subject to civil penalties for failing to report "suspicious" orders to DEA.

It is SO ORDERED.