IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA, Plaintiff, v. WALMART INC. AND WAL-MART STORES EAST, LP, Defendant.	))))))))))	C.A. No. 20-1744-CFC

OPENING BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE COMPLAINT

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NATURE AND STAGE OF PROCEEDINGS

In this action, the Government seeks civil penalties and injunctive relief for alleged violations of the Controlled Substances Act ("CSA"). D.I. 1 ("Compl."). Walmart moves to dismiss for failure to state a claim.

SUMMARY OF ARGUMENT

The Government has sued Walmart on a set of legal theories that stretch the CSA and Drug Enforcement Administration ("DEA") regulations past the breaking point. The Complaint fundamentally misconceives the obligations of pharmacies and pharmacists under federal law. The Court should dismiss it entirely.

Under the CSA, the Government is responsible for registering and regulating manufacturers that produce prescription opioids; distributors that supply them; doctors who prescribe them; and pharmacists who dispense them. This suit is mostly about pharmacists. Pharmacists are not licensed to practice medicine and rarely have authority to examine patients. Presented with prescriptions from state-licensed and DEA-registered doctors, pharmacists are poorly positioned to second-guess those doctors' medical judgments, which are highly individualized based on each patient's unique circumstances. *See Dispensing Controlled Substances for the Treatment of Pain*, 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006). Identifying an invalid prescription in this context thus requires exercising professional judgment based on all the facts the pharmacist knows.

These realities dictate the limited nature of pharmacists' obligations under the CSA. *First*, pharmacists are forbidden by statute to dispense controlled substances absent a written prescription from a licensed, registered doctor. 21 U.S.C. § 829(a). *Second*, they are forbidden by regulation to fill a prescription if they "know[]" it was issued outside "the usual course of professional treatment." 21 C.F.R. § 1306.04(a). DEA specifically "revised" that regulation in 1971 "to require knowledge" in response to pharmacists' concerns about bearing "responsibility … to determine the legitimacy of a prescription." *Regulations Implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970*, 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971).

The Complaint focuses on this second rule, but fails to plead facts sufficient to show that Walmart pharmacists violated the law on even a single occasion. Despite a multi-year investigation, the Government has failed to identify even a single prescription the Government claims was *actually* invalid, much less that any individual pharmacist *knew* was invalid but filled anyway. Rather, the Complaint alleges only that Walmart had access to aggregate information suggesting that certain types of prescriptions, or prescriptions written by certain doctors, were subject to doubt and thus *might* have been invalid. The Government's Complaint is sensationalist but ultimately hollow, resting on legally impermissible shortcuts that are designed to cast aspersions on large numbers of prescriptions without actually alleging that individual Walmart pharmacists ever knowingly filled invalid ones.

I. Count I. Instead of analyzing the actual knowledge of individual pharmacists, the Government tries to establish scienter by *aggregating* knowledge across the entire company, challenging prescriptions filled by one pharmacist based on facts that *other* employees supposedly knew that cast doubt on their validity. That collective approach to scienter is unprecedented under the CSA, flouts agency-law principles, and has been correctly rejected in a wide variety of similar contexts.

The Government also claims that certain *types* of prescriptions are *likely to be* invalid. But it makes no effort to identify specific invalid prescriptions that Walmart pharmacists—who regularly rejected prescriptions of these types—ever filled, let alone knowingly filled. These generalized allegations are irreconcilable with the regulation's subjective-knowledge element and with the individualized nature of the practice of both medicine and pharmacy.

II. Count II. The Government says every challenged fill *also* violated a second regulation, 21 C.F.R. § 1306.06, which restricts pharmacists to dispensing "in the usual course" of practice. The Government's novel reading of that rule would swallow § 1306.04(a)'s scienter requirement, impose duplicative penalties, and hold pharmacies strictly liable for every minor deviation from professional standards.

This Court should reject the Government's sweeping attempts to bypass its burden of proof and impose billions of dollars in liability based on "collective" knowledge, overbroad generalizations, and attempted double recovery.

III. Count III. Finally, the Government asserts that when Walmart self-distributed opioids to its own stores (which it did until 2018), its systems to detect and report "suspicious orders" were inadequate. That is baseless Monday-morning quarterbacking by an agency that has long refused to provide any clear rules. Regardless, the CSA at that time provided only for administrative sanctions, not civil monetary penalties, for these alleged failures—so this claim fails as a matter of law.

STATEMENT OF FACTS

Walmart operates more than 5,000 pharmacies in communities nationwide. Compl. ¶ 3. Each pharmacy is registered with DEA. *Id.* ¶¶ 47, 67-68. Walmart pharmacists are authorized to dispense controlled substances, including opioids, pursuant to prescriptions from state-licensed, DEA-registered doctors. *Id.* ¶¶ 69-71.

In its Pharmacy Operations Manual, Walmart directed its pharmacists to fill only those prescriptions they "reasonably believe[d]" were valid and identified a list of "red flags" that pharmacists should consider in reaching professional judgments about prescriptions' validity. *Id.* ¶¶ 125-34. Following that guidance, Walmart's pharmacists "regularly" and "repeatedly" refused to fill prescriptions they perceived as invalid based on all of the facts they knew. *See, e.g.*, *id.* ¶¶ 18, 142-44.

Pharmacists completed "refusal-to-fill" forms to memorialize their refusals. *Id.* ¶¶ 17-18. The forms were sent to a "compliance team" at Walmart's corporate office, which in turn shared the refusal-to-fill data with DEA. *Id.* ¶¶ 123, 145-46.

(The Complaint does not allege what, if anything, DEA did with the material.) In 2015, Walmart introduced a platform that allowed pharmacists to search and review refusal-to-fill forms that other pharmacists had submitted. *Id.* ¶ 160.

Until May 2018, Walmart self-distributed controlled substances to its own pharmacies. *Id.* ¶¶ 478-82. Over the relevant period, Walmart used several different systems to monitor for suspicious orders from its own stores. *Id.* ¶ 504.

ARGUMENT

I. THE COMPLAINT DOES NOT PLAUSIBLY ALLEGE THAT ANY WALMART PHARMACIST KNOWINGLY FILLED AN INVALID PRESCRIPTION (COUNT I).

Count I asserts that Walmart "knowingly fill[ed]" prescriptions "issued not in the usual course of professional treatment," contrary to 21 C.F.R. § 1306.04(a). It identifies three sets of prescriptions: (1) those written by doctors who had written *other* prescriptions that *other* Walmart pharmacists had rejected ("problematic-prescriber theory"); (2) those that allegedly presented "red flags" about their validity ("red-flag theory"); and (3) those that one Walmart pharmacist filled after another Walmart pharmacist refused ("rejected-prescription theory"). Compl. ¶¶ 22-26.

The problematic-prescriber theory fails because the Complaint alleges knowledge only by "Walmart," *i.e.*, the corporation, rather than by any particular employee involved in the dispensing. Yet when the law forbids taking an action "knowingly," "willfully," or with some other mental state, a corporation violates that rule only if a *particular employee* involved in that action has that scienter.

As for the other theories, the Complaint fails to plead facts supporting a plausible inference that the dispensing pharmacists knew the prescriptions were invalid. It identifies types of prescriptions that *may* be—but are *not necessarily*—problematic. Walmart pharmacists allegedly filled some prescriptions of those types but the Government concedes that they refused to fill others. The Complaint alleges no basis to infer that the pharmacists filled invalid ones, let alone that they did so *knowingly* at the risk of personal criminal and civil liability.

A. The Government Cannot Establish a Violation by Aggregating Knowledge from Employees Not Involved in the Dispensing.

The Complaint admits that § 1306.04(a) imposes liability "only" on persons who "knowingly" fill invalid prescriptions. Compl. ¶ 91. A corporation, all agree, can be liable if its agent does so. *Id.* ¶ 94. But the Complaint's lead theory is that "Walmart"—not any given pharmacist—knowingly filled prescriptions that were likely invalid, because its pharmacists filled prescriptions written by certain doctors after *other* pharmacists had refused to fill *other* prescriptions by those doctors and reported as much to a corporate compliance unit. *Id.* ¶¶ 22, 108, 177-79.

This is a "collective knowledge" theory, seeking to establish liability not by showing that any individual Walmart employee who filled a prescription knew it was invalid, but by attributing to "Walmart" facts allegedly known by different employees, including those who had no hand in filling the disputed prescriptions. That approach is contrary to established law and finds no basis in the CSA.

1. A corporation acts with scienter only if a particular agent acts with the relevant state of mind.

Agency law informs "[c]orporate criminal and civil cases" because "[a] corporation and its agents relate to one another like a principal to its agents." *United States v. One Parcel of Land*, 965 F.2d 311, 316 (7th Cir. 1992). Under agency law, "[i]f knowledge ... is the important element in a transaction[] and the agent who has the knowledge is not one acting for the principal in the transaction," the principal is not charged with that knowledge. Restatement (Second) of Agency § 275 cmt. b (1958); *see also id.* § 272. In those situations, "the principal is not affected by the fact that the agent has the knowledge" and is not "responsible" for it. *Id.* § 275 cmt. b; *see also id.* § 268 cmt. d; Restatement (Third) of Agency § 5.03 cmt. d (2006).

Describing these longstanding principles, the Supreme Court has explained that "the malicious mental state of one agent cannot generally be combined with the harmful action of another agent to hold the principal liable." *Staub v. Proctor Hosp.*, 562 U.S. 411, 418 (2011). That is, in seeking to establish corporate liability, the Government cannot rely on the mental states of disparate employees who played no role in the transaction or conduct in question.

Although the Government has never pursued this theory under the CSA, courts in many other contexts have rejected using collective knowledge to establish corporate liability. Imposing liability by piecing together the knowledge of various agents and the acts of others misses the fundamental point of a scienter element.

For example, the Fifth Circuit holds "as a general rule" that if "an essentially subjective state of mind is an element of a cause of action," it cannot "be met by a corporation's collective knowledge." *Chaney v. Dreyfus Serv. Corp.*, 595 F.3d 219, 241 (5th Cir. 2010). Instead, that "state of mind" must "'actually exist' in at least one individual and not be imputed on the basis of general principles of agency." *Id.*

Likewise, the D.C. Circuit has explained that the "collective knowledge" or "collective pool of information" possessed by a corporation's agents "provides an inappropriate basis for proof of scienter," and "expressed a good deal of skepticism about corporate intent theories that rely on aggregating the states of mind of multiple individuals." *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1273-74, 1276 (D.C. Cir. 2010). Such theories lack "balance and precision," in that they "allow[] 'a plaintiff to prove scienter by piecing together scraps of "innocent" knowledge held by various corporate officials,'" not to mention "thousands of ordinary employees," *even if no single agent took the forbidden act with the forbidden intent*. *Id.* at 1275.

Other circuits agree that corporate liability cannot be established through a collective approach to scienter. *See Mizzaro v. Home Depot, Inc.*, 544 F.3d 1230, 1254 (11th Cir. 2008) (looking to mental states of individual corporate officials); *Woodmont, Inc. v. Daniels*, 274 F.2d 132, 137 (10th Cir. 1959) (rejecting "composite knowledge" where state of mind was "essential").

None of this is to say that the specific corporate agent with scienter must be identified *by name* in the pleading, but the allegations must show that "*someone* whose intent could be imputed to the corporation acted with the requisite scienter." *Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195-96 (2d Cir. 2008) (emphasis added).

Put simply, "[a] corporation can be held to have a particular state of mind only when that state of mind is possessed by a single individual." *First Equity Corp. v. Standard & Poor's Corp.*, 690 F. Supp. 256, 260 (S.D.N.Y. 1988) (Mukasey, J.). To hold otherwise effectively "treats knowledge as a species of negligence, holding corporations liable not for their knowledge, but for failing to maintain open channels of communication." Mihailis E. Diamantis, *Functional Corporate Knowledge*, 61 WM. & MARY L. REV. 319, 346-49 (2019). And doing that "punishes corporations more than any intuitive reading of what Congress deemed just." *Id.* at 349.

The Third Circuit has not directly addressed the collective-knowledge theory, but district courts have "expressed doubts" it could cohere with circuit law, and have rejected bids to establish liability without showing that "any individual employee" involved in the misconduct had the requisite mental state. *City of Roseville Emps.' Ret. Sys. v. Horizon Lines, Inc.*, 713 F. Supp. 2d 378, 402-03 (D. Del. 2010).[1]

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[1] *Accord ING Bank v. PNC Fin. Servs. Grp.*, 629 F. Supp. 2d 351, 355 (D. Del. 2009); *In re Tyson Foods, Inc.*, No. 01-cv-0425, 2004 WL 1396269, at *12 (D. Del. June 17, 2004); *Lind v. Jones, Lang LaSalle Ams., Inc.*, 135 F. Supp. 2d 616,

2. The Government never alleges that any particular Walmart employee knew these prescriptions were invalid.

Section 1306.04(a) imposes liability for "knowingly" filling a prescription issued outside "the usual course of professional treatment." Knowledge is thus an "important element" in the "transaction" of filling the prescription. Restatement (Second) of Agency § 275 cmt. b. The Government therefore cannot establish corporate liability by relying on facts known to Walmart employees who did not represent Walmart in—indeed, did not even know about—the specific transaction, *i.e.*, the specific act of dispensing. Rather, Walmart can be liable only if an employee involved in that dispensing knew the specific prescription was invalid.

Despite these clear principles, the Complaint's problematic-prescriber theory does not even *try* to allege that *any* single Walmart agent knew *any* prescription was invalid. Rather, the Complaint alleges that: (1) Walmart pharmacists filled certain prescriptions from certain doctors; (2) *other* Walmart pharmacists had previously refused to fill *other* prescriptions from those doctors; and (3) forms memorializing

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622 n.6 (E.D. Pa. 2001); *United States v. LBS Bank-New York, Inc.*, 757 F. Supp. 496, 501 n.7 (E.D. Pa. 1990); *see also In re Cognizant Tech. Sols. Corp. Sec. Litig.*, No. 16-cv-6509, 2018 WL 3772675, at *31-34 (D.N.J. Aug. 8, 2018). District courts outside this Circuit have done the same. *See, e.g.*, *United States ex rel. Adams v. Dell Comput. Corp.*, No. 15-cv-0608, 2020 WL 5970677, at *6 (D.D.C. Oct. 8, 2020); *United States ex rel. Martin v. Life Care Ctrs. of Am., Inc.*, 114 F. Supp. 3d 549, 567 (E.D. Tenn. 2014); *United States ex rel. Heathcote Holdings Corp. v. William K. Walthers, Inc.*, 779 F. Supp. 2d 735, 738-39 (N.D. Ill. 2011); *In re Cable & Wireless, PLC*, 321 F. Supp. 2d 749, 771-72 (E.D. Va. 2004); *Gutter v. E.I. Dupont de Nemours*, 124 F. Supp. 2d 1291, 1311 (S.D. Fla. 2000).

those refusals revealed concerns about the doctors' "prescribing practices." Compl. ¶ 178. The Complaint concludes that "*Walmart* knew" of a "very high probability" these doctors' prescriptions were questionable. *Id.* ¶¶ 21, 179 (emphasis added).

That is an improper collective-knowledge theory. Indeed, the Complaint says Walmart "did not notify its pharmacists" of refusals reported by other pharmacists. *Id.* ¶ 179. So there is no claim that the dispensing pharmacists knew of others' concerns with these doctors' practices (let alone that any particular prescriptions were invalid). Nor is there any allegation that the compliance team that collected refusal-to-fill forms and shared them with DEA had any role in making the specific dispensing decisions now being challenged—those decisions were made by Walmart pharmacists at the pharmacy level. The compliance employees did not work at any pharmacy, did not interact with the patients or prescribers, and were not even in a position to form a belief about the validity of any particular prescription.

Instead, the Government tries to aggregate information known by different Walmart employees and effectively impute it to the dispensing pharmacist. Some pharmacists had concerns about certain doctors; some compliance employees knew of those concerns; other pharmacists were presented with prescriptions from those doctors. The Complaint combines that "knowledge" and attributes it to a dispensing pharmacist who herself lacked scienter. Because the Government must prove a knowing violation, the law forbids exactly this mixing-and-matching.

At bottom, the Government's theory seems to be premised on a policy notion: that Walmart's compliance unit should have done more to analyze, share, or act on information it received. To be clear, there is no allegation that anyone at Walmart *intended* to keep pharmacists in the dark by withholding anything. The Complaint simply alleges that Walmart lacked systems to analyze or share information with all of its pharmacists. *See, e.g.*, *id.* ¶¶ 148-51, 153, 156-58, 161, 164-65, 176, 179. Even after Walmart adopted a new platform in 2015 to allow pharmacists to search and review other pharmacists' refusal-to-fill forms, the Government complains that Walmart did not adequately "train" its pharmacists to do so. *Id.* ¶¶ 160-62.

Those policy objections have no basis in law and cannot substitute for proof of scienter. The governing regulation imposes liability only for "knowingly" filling an invalid prescription. The inquiry is thus into what the pharmacist *actually knew*, not what she *could have discovered* or what other employees *could have told her*.

Congress or the agency could, if they wanted, impose information-sharing duties on pharmacies or their owners, as DEA has done for others in the controlled-substance supply chain. *Cf.* 21 C.F.R. § 1301.74(b) (distributors must maintain "system" to identify "suspicious orders" and "inform" DEA). But as the Complaint implicitly admits, no law or rule has *ever* imposed such duties on pharmacies. And the Government cannot impose that duty, after the fact and through the backdoor, by effectively imputing to every pharmacist knowledge it never required be shared with

them. Even if such information-sharing would be good policy, "an agency must have clearly communicated its policies before a private party may be sanctioned … for violating them." *United States v. Harra*, 985 F.3d 196, 213 (3d Cir. 2021).

For all of these reasons, the Court should dismiss Count I's problematic-prescriber theory (*i.e.*, the violations alleged in Part II.B of the Complaint).

B. The Complaint's Categorical Approach Provides No Basis To Infer That Walmart Knowingly Filled Invalid Prescriptions.

For the red-flag and rejected-prescription categories set forth in Parts II.C and II.D of the Complaint, the Government alleges in conclusory terms that Walmart pharmacists filled them despite knowing they were invalid. But those allegations of knowledge are categorical and flawed. Rather than identify particular prescriptions as invalid and facts showing the dispensing pharmacist knew as much, the Complaint says only that Walmart filled prescriptions that (i) "on their face" had characteristics indicating "a very high probability of being invalid"; or (ii) had previously been rejected by another Walmart pharmacist. Compl. ¶¶ 23-24, 360-440.

Neither theory supports a plausible inference that Walmart pharmacists ever "knowingly" filled prescriptions that were in fact illegitimate. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). At most, these allegations suggest a "mere possibility of misconduct," *id.* at 679, which is insufficient. The pleading failure is particularly acute because lawful conduct provides an "obvious alternative explanation" for the Complaint's allegations. *George v. Rehiel*, 738 F.3d 562, 586 (3d Cir. 2013).

To start, both theories rest on a numbers trick: The Government asserts that Walmart filled a large (albeit unspecified) number of prescriptions, each of which had characteristics allegedly associated with (but not establishing) invalidity, and so the Walmart pharmacists must have knowingly filled invalid prescriptions.

As a matter of logic, that conclusion does not follow. The Complaint admits that not all prescriptions in its categories are *actually* invalid; the allegation is only that they are "highly likely" to be so. *Id.* ¶ 21. That means some in each category were valid. The Complaint must therefore allege some facts to suggest that Walmart filled the invalid ones rather than only the valid ones. It tries to make that showing by emphasizing the *number* of these prescriptions that Walmart filled. But the focus on raw numbers is misdirection. Because of Walmart's size (Compl. ¶¶ 3, 12, 47), its pharmacists fill many prescriptions with a wide range of characteristics. And the Complaint admits that Walmart pharmacists *refused* to fill "many" prescriptions from these categories. *See, e.g.*, *id.* ¶¶ 18, 364, 365, 377, 384, 399, 405, 409, 422, 423, 424. Indeed, *every* pharmacist identified as having concerns with a prescription is alleged to have refused to fill it. Given these concessions, the Complaint offers no reason to believe that the challenged prescriptions were not the *valid* ones—and even less reason to believe that Walmart's pharmacists, despite regularly refusing to fill prescriptions from these categories, ever knowingly filled invalid ones.

To illustrate, assume each of Walmart's 5,000 pharmacies saw a prescription with these "red flags" only once weekly. Further assume, consistent with the notion that most are invalid, that Walmart pharmacists *rejected* 99% of those prescriptions. The pharmacists would still have filled more than 19,000 such prescriptions during the seven-and-a-half year period at issue. *See id.* ¶ 25. The allegation that Walmart filled "thousands" of red-flag prescriptions—without identifying the denominator (*i.e.*, the number of red-flag prescriptions that were *presented* to Walmart)—is thus perfectly consistent with *all* of the filled prescriptions being valid, even assuming that most red-flag prescriptions are not. That "obvious alternative explanation" for those fills renders these claims implausible. *George*, 738 F.3d at 586.

Breaking down the Government's theories further highlights the lack of any plausible allegations of scienter. *First*, the Complaint identifies four "red flags" that pharmacists allegedly would recognize as "indicating a high probability that the prescriptions were invalid." Compl. ¶ 357. But the Government does not allege that DEA has prohibited doctors from prescribing these treatments, or pharmacists from filling them. Nor does it claim such treatments may *never* be prescribed for valid medical reasons. Quite the opposite: The Complaint admits that such prescriptions may be warranted depending on the patient's needs. *See, e.g.*, *id.* ¶¶ 367, 369, 373, 411. DEA has likewise long acknowledged that red flags cannot "automatically" suggest invalidity, as treatment is highly individualized. 71 Fed. Reg. at 52720.

Meanwhile, the Complaint makes clear that Walmart trained its pharmacists to identify potentially invalid prescriptions (including by "red flags") and to refuse to fill those they believed invalid. Compl. ¶¶ 128-34, 217. And the Complaint admits Walmart's pharmacists routinely did just that. *See id*. ¶¶ 384, 399, 405, 409, 422, 423, 424 (dozens of examples of refusing to fill opioid prescriptions).

Given all of this, the Complaint's red-flag theory does not provide a plausible basis to infer that Walmart's pharmacists—who face massive personal liability, including criminal sanctions, for knowing violations—violated their legal duties and professional training by filling prescriptions they knew to be invalid.

Second, the Complaint points to prescriptions that Walmart pharmacists filled after other pharmacists refused. *Id.* ¶ 427. But evaluating a prescription's validity is a matter of professional judgment, and pharmacists may therefore reach different conclusions, even based on review of the same facts. *Cf. United States v. AseraCare, Inc.*, 938 F.3d 1278, 1296 (11th Cir. 2019) (rejecting notion that "clinical judgment ... is invalid or illegitimate merely because an unaffiliated physician reviewing the relevant records after the fact disagrees"). Just as two doctors may reach different diagnoses, or two lawyers may reach different views on a legal issue, two pharmacists may reach different beliefs about a prescription's validity.

Even apart from different professional judgment, there are many reasons why a second pharmacist may legitimately fill a prescription. The customer may provide

additional documentation, or the second pharmacist may be familiar with the patient or successfully contact the doctor to confirm a valid basis for the treatment. A prior rejection therefore cannot alone support a scienter inference. Good-faith conduct—different good-faith judgment, and good-faith decisions based on different facts—is again the "obvious alternative explanation." *George*, 738 F.3d at 586.

Finally, the problematic-prescriber theory addressed in Part I.A fails for this independent reason too. For those prescriptions, the Government says "Walmart" knew facts casting doubt on the doctors' prescribing practices. But that does not mean *all* of those doctors' prescriptions were invalid, as the Complaint implicitly admits. Compl. ¶ 149. And, again, the Complaint is full of allegations that Walmart pharmacists repeatedly refused to fill these doctors' prescriptions.[2] That leaves no basis to infer that the ones they filled were both invalid and known to be so.

In sum, DEA was right that "each case must be evaluated based on its own merits in view of the totality of circumstances." 71 Fed. Reg. at 52720. For that reason, the Complaint cannot support an inference that any prescription was invalid, or that the dispensing pharmacist knew as much, through categorical pleading based on no more than "red flags," a prior rejection, or another pharmacist's concerns about the doctor. The Court should therefore dismiss Count I in its entirety.

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[2] Compl. ¶¶ 178, 181, 187-89, 195-98, 204-09, 213-15, 244, 246-47, 252-53, 258-61, 267, 269, 271, 276, 279-82, 286-89, 293, 300-01, 309-13, 318, 327-28, 334-37, 342-46, 351-54.

II. THE COMPLAINT DOES NOT STATE VIABLE CLAIMS FOR RELIEF UNDER 21 C.F.R. § 1306.06 (COUNT II).

For every allegedly invalid prescription embraced by Count I, the Complaint claims Walmart also owes a *second* civil penalty because precisely the same conduct violates an adjacent regulation as well. Compl. ¶¶ 112, 440. That second regulation provides 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. According to the Complaint, a pharmacist runs afoul of that rule if she departs from "professional pharmacy practice standards," *even if the violation is not knowing*. Compl. ¶¶ 92, 112. Because those professional standards allegedly require the pharmacist to identify, resolve, and document her resolution of any "red flags" before filling a prescription bearing them, the Complaint concludes that every § 1306.04(a) violation is necessarily also a § 1306.06 violation, and on that basis seeks a duplicative set of statutory penalties. *Id.* ¶¶ 88, 440.

The Government is doubly mistaken. At the outset, whatever the meaning of § 1306.06, there is no statutory basis for a court to award civil penalties or injunctive relief for violations of that regulation. The Complaint invokes a statute that allows such relief for dispensing *without a prescription*. But § 1306.06 has nothing to do with that. On the Government's reading, a pharmacist can violate this rule through procedural missteps *while filling a perfectly valid prescription*. Not every regulation triggers statutory penalties, and § 1306.06 is one that does not.

Regardless, the Government is legally mistaken in treating any departure from professional norms as transgressing § 1306.06. In the doctor context, the Supreme Court has held that similar language makes unlawful only extreme misconduct, acting essentially as a drug "pusher." Especially if civil penalties *were* available, the Government's broader construction would also make nonsense of the regulatory scheme: It would render superfluous § 1306.04(a)'s targeted approach to scienter, and subject every professional foot-fault to severe federal penalties.

A. Violations of § 1306.06 Cannot Give Rise to Civil Penalties or an Action for Injunctive Relief.

Even if the Government correctly construes § 1306.06, Count II fails. Like many regulations, this one can be enforced only administratively, *e.g.*, by revocation of a pharmacy's registration. The CSA itself does not authorize other relief.

The CSA authorizes the Attorney General to promulgate rules "relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances." 21 U.S.C. § 821. But the Act does not impose civil penalties for every violation of these regulations. Rather, it enumerates a list of unlawful acts that trigger penalties. *Id.* § 842(a), (c)(1). Regulatory violations outside that list are hardly meaningless; DEA is empowered to revoke registrations using an open-ended "public interest" test that accounts for compliance with all applicable laws. *See id.* §§ 823(f), 824(a). Revocation is a serious sanction that can destroy a pharmacy business, and most CSA caselaw arises out of revocation proceedings.

This, however, is not a revocation proceeding. Instead, the Complaint invokes § 842(a)(1), violation of which triggers a civil penalty. *Id.* § 842(c)(1)(A). Section 842(a)(1) makes it unlawful "to distribute or dispense a controlled substance in violation of section 829." In turn, § 829 prohibits dispensing controlled substances "without the written prescription of a practitioner." *Id.* § 829(a). The bottom line is that dispensing *without a prescription* triggers a civil penalty.

Some regulatory violations necessarily imply a violation of that statutory rule, and therefore give rise to penalties. Section 1306.04(a) is an example. It defines what *is* a valid prescription: "A prescription ... to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). And it defines what is *not* one: "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]." *Id.* (emphasis added). The rule then spells out the consequence of those definitions: "[T]he 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." *Id.* That makes sense: Those who knowingly fill such a prescription have dispensed "without" a "written prescription" in violation of 21 U.S.C. § 829, because the prescription did not satisfy the agency's interpretation of what qualifies as a valid "prescription."

Section 1306.06 is different. It explains *who* may fill prescriptions: "only … a pharmacist." 21 C.F.R. § 1306.06. And it then explains *how* pharmacists may fill those prescriptions: "in the usual course of … professional practice." *Id.* But a pharmacist who violates that regulation does not necessarily violate § 829, because she has not necessarily dispensed *without a prescription*. The regulatory violation therefore cannot trigger an independent civil penalty under the statute.

For example, consider a pharmacist who resolves a "red flag" before filling a valid prescription—but does not document that resolution. Perhaps the patient lives many miles away, but the patient then explains he works next-door to the pharmacy, alleviating the pharmacist's initial concerns. On the Government's view, if the pharmacist neglects to record that explanation in her file, she has violated § 1306.06 because professional norms allegedly require written documentation. Yet she has obviously not dispensed a controlled substance "without the written prescription of a practitioner." 21 U.S.C. § 829. The point, again, is that a violation of § 1306.06 does not necessarily imply a violation of 21 U.S.C. § 829, and therefore cannot be a pathway to civil penalties. That is why § 1306.06—unlike § 1306.04(a)—includes no reference to § 829 or to "the penalties provided for violations" of the CSA.

This interpretation makes sense of the regulatory framework. Civil penalties kick in when doctors write (and pharmacists knowingly fill) invalid prescriptions, which strike at the CSA's core. Those penalties are not, however, a tool to enforce

industry "best practices." Rather, if DEA is concerned about a pharmacy's deviation from professional standards, the proper course is to revoke its registration as "inconsistent with the public interest." *Id.* §§ 823(f), 824(a)(4).

By contrast, the Government badly muddles the scheme. On its account, § 1306.06 subsumes § 1306.04(a), and is not even limited to "knowing" violations (Compl. ¶ 92). If that is true, *and if the same penalties are available for violating either rule*, § 1306.04(a) becomes superfluous and its adoption of a "knowingly" standard for filling invalid prescriptions serves no purpose: The Government can just proceed under § 1306.06 and recover the same penalty *without* proving scienter. *See Silverman v. Eastrich Multiple Inv. Fund, L.P.*, 51 F.3d 28, 31 (3d Cir. 1995) (regulatory scheme should be construed "so that effect is given to all its provisions").

In sum: If a pharmacist knowingly fills an invalid prescription, that violates § 1306.04(a) and 21 U.S.C. § 829, triggering a penalty for dispensing without a valid prescription. But there is no *second* penalty if, in doing so, the pharmacist failed to identify, resolve, or document a red flag. There has been only one statutory violation associated with the single act of dispensing. Meanwhile, if the pharmacist did *not* knowingly fill an invalid prescription, there is *no* violation of § 829 and no penalty—*even if* the pharmacist failed to identify, resolve, or document a red flag. Either way, § 1306.06 adds nothing: It is not an *additional* source of penalties if Walmart has violated § 829, nor is it an *alternative* source of penalties if Walmart has *not*.

The same is true for the Government's derivative request for injunctive relief. 21 U.S.C. § 843(f) authorizes "injunctive relief relating to violations of … section 842," but as explained, a regulatory violation of § 1306.06 does *not* itself amount to a statutory violation of § 842—and so, again, offers no additional relief.

For these reasons, the Court should dismiss Count II.

B. Section 1306.06 Does Not Prohibit Every Deviation from Standards of Professional Conduct.

Count II must also be dismissed for an independent reason: The Government is wrong about the substantive meaning of § 1306.06 and has not adequately alleged any violation under a proper construction. That regulation provides that pharmacists may dispense controlled substances only when they are acting *in their capacity as pharmacists*. It does not codify into federal law every professional norm and state-law requirement. Reading the regulation otherwise—especially if the Court holds, contrary to the above, that violations *do* lead to civil penalties—would confound the regulatory scheme and generate absurd results.

The Government maintains that every time a pharmacist fails to meet her "professional responsibilities"—allegedly such as by failing to "identify," "resolve," or "document" red flags—the pharmacist has acted outside the usual course of her professional practice in violation of § 1306.06. Compl. ¶¶ 84, 88. That is wrong.

It is "a basic tenet of statutory construction, equally applicable to regulatory construction," that a scheme "should be construed so that effect is given to all its

provisions, so that no part will be inoperative or superfluous, … and so that one section will not destroy another." *Silverman*, 51 F.3d at 31. The Government's construction of § 1306.06 does the latter. Section 1306.04(a) imposes liability on pharmacists who "knowingly fill[]" a "prescription issued not in the usual course of professional treatment." But there is no scenario in which a pharmacist *knowingly* fills an invalid prescription *without* departing from professional norms. Indeed, that is why the Complaint treats every § 1306.04(a) violation as an automatic § 1306.06 violation. *See* Compl. ¶ 440. This construction renders § 1306.04(a) superfluous.

Worse, § 1306.04(a) limits liability to pharmacists who *knowingly* fill invalid prescriptions; the agency added that mental state to the regulation nearly fifty years ago to protect pharmacists, who are not authorized to practice medicine and do not have access to the information doctors use for diagnosis and treatment. *See supra* at 2; 36 Fed. Reg. at 7777. Yet on the Government's interpretation of § 1306.06, a pharmacist is liable for every misstep, even if she sincerely believes the prescription is valid—and even if the prescription *actually is* valid. It is hard to think of a clearer example of one provision being read to "destroy" another. *Silverman*, 51 F.3d at 31. Under the Government's approach, § 1306.04(a)'s scienter element affords no real protection: If a pharmacist in good faith fills a red-flag prescription that turns out to be invalid, the Government can just invoke the more expansive § 1306.06 and argue that the pharmacist should have done more to identify the invalidity.

These problems are mitigated if § 1306.04(a) alone leads to civil or criminal liability, whereas enforcement of § 1306.06 is administrative. Each provision would serve a distinct role; neither would be superfluous or swallow the other. *Supra* Part II.A. But if the Court were to hold that both regulations trigger statutory penalties, then the Government's construction of the regulation certainly cannot stand.

Indeed, reading § 1306.06 to forbid every deviation from professional norms subject to civil penalties would not only leave § 1306.04(a) with no purpose but also lead to absurd results. Like other professionals, pharmacists must follow a long list of state-law regulations. *E.g.*, 24 Del. Admin. Code § 2500-5.2.1 (pharmacists must provide counseling that "may include," *e.g.*, "action to be taken in the event of a missed dose"); Fla. Stat. Ann. § 465.0244 (pharmacists must "inform" customers of "less expensive" generics). State law often imposes only administrative sanctions, not criminal or civil penalties, for violating these rules. *E.g.*, Del. Code Ann. tit. 24, § 2516 (authorizing letters of reprimand, suspension or revocation of license, and "administrative penalt[ies]" of up to $500); Fla. Admin. Code r. 64B16-30.001(2)(r) (imposing $500 fine and 12 hours of continuing education as minimum discipline, and one year of probation as maximum discipline, for first offense of failing to inform customer about cheaper alternatives). But on the Government's view, federal law saddles pharmacists with draconian penalties—including *tens of thousands of dollars in fines*—every time they depart, even innocently, from those same rules.

Again, the problem is actually worse. The implication of the Government's reading is that if a pharmacist deviates from professional norms "knowingly," she can be *criminally* liable. 21 U.S.C. § 842(c)(2)(A). That means every pharmacist who knowingly neglects to fill out some paperwork required by a state pharmacy board, for example, can be sent to federal prison. And because doctors also must prescribe only "in the usual course," 21 C.F.R. § 1306.04(a), the Government would transform every minor breach of medical practice protocols into a federal felony too.

Canons of construction prohibit this interpretation. Courts refuse to read provisions in a way that leaves their "outer boundaries ambiguous and involves the Federal Government in setting standards" reserved to state law. *McNally v. United States*, 483 U.S. 350, 360 (1987). That course is particularly appropriate for the CSA, which was never meant to "effect a radical shift of authority from the States to the Federal Government to define general standards of medic[ine]." *Gonzales v. Oregon*, 546 U.S. 243, 270, 275 (2006). It is further compelled by the rule of lenity, which demands that any ambiguity in laws with both civil and criminal applications be resolved in the defendant's favor. *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004).

All of this confirms that the Government's interpretation of § 1306.06's usual-course requirement is wrong. Courts have long construed the equivalent "usual course" language in the context of doctors. That authority confirms that merely departing from professional standards—and even "medical malpractice," *United*

States v. Rottschaefer, 178 F. App'x 145, 146 (3d Cir. 2006)—does not take the doctor outside the realm of usual practice. Rather, as the Supreme Court put it, a doctor leaves the usual course of practice when he acts "as a large-scale 'pusher'—not as a physician." *United States v. Moore*, 423 U.S. 122, 143 (1975). The question is whether the doctor "ceases to be a physician *at all*." *United States v. Feingold*, 454 F.3d 1001, 1010-11 (9th Cir. 2006); *see also United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994) (outside usual course means assisting "in the maintenance of a drug habit" or dispensing for "personal profit").

By the same token, a pharmacist does not exceed the "usual course" simply by failing to abide by professional best practices. Her conduct violates this provision only if she effectively has stopped acting as a pharmacist "at all" and instead is acting as a drug "pusher" operating for "personal profit" or other impermissible reasons—*e.g.*, by selling opioids for cash out of the pharmacy's parking lot.

Judged against that proper standard, the Complaint fails to state a claim. The Government alleges nothing that comes close to suggesting that Walmart or any of its pharmacists were "pushing" drugs rather than trying lawfully to dispense them, or acting for "personal profit" rather than in a legitimate professional capacity. Even assuming as true, at this stage of the litigation, the (disputed) allegation that Walmart pharmacists occasionally deviated from professional norms in the course of filling prescriptions, those departures do not rise to violations of § 1306.06.

III. THE GOVERNMENT CANNOT RECOVER CIVIL PENALTIES FOR ALLEGED HISTORICAL FAILURES TO "DETECT AND REPORT" SUSPICIOUS ORDERS.

Count III turns to Walmart's *distribution* of opioids to its own stores. Walmart outsourced distribution in May 2018, so the Complaint seeks only civil penalties (not injunctive relief) for these alleged CSA violations. Compl. ¶¶ 48, 710. Specifically, the Complaint alleges that Walmart violated a rule requiring distributors to "design and operate a system to disclose … suspicious orders" and to "inform" DEA of those orders "when discovered." 21 C.F.R. § 1301.74(b). The Government's hindsight complaints about Walmart's monitoring systems are misleading and meritless. But regardless, the Court should dismiss this count for two independent legal reasons.

First, the CSA did not, at the relevant time, impose civil monetary penalties for violations of this duty. The Complaint cites a statute penalizing failures to make reports "required under this subchapter," 21 U.S.C. § 842(a)(5), but Walmart's reporting obligation was only *regulatory* and so did not trigger that penalty. Congress confirmed as much by amending the CSA in October 2018 to add a punishable statutory duty to report suspicious orders.

Second, the regulatory reporting duty covers only suspicious orders that the distributor *discovers*. Here, the Government primarily alleges that, due to allegedly inadequate monitoring, Walmart failed to detect—in other words, *did not discover*—many suspicious orders. Yet on no reading of the statute is a distributor liable for civil penalties for failing to identify suspicious orders in the first place.

A. Before October 2018, the CSA Did Not Authorize Civil Monetary Penalties for Failing To Report Suspicious Orders.

The Government invokes 21 U.S.C. § 842(a)(5) as its basis for civil penalties under Count III. Compl. ¶¶ 708-09. That provision prohibits refusal "to make, keep, or furnish" any "record, report," and so forth "*required under this subchapter*." 21 U.S.C. § 842(a)(5) (emphasis added). Violations are subject to civil penalties. *Id.* § 842(c)(1)(B) (2012). But the italicized text—"under this subchapter"—refers to reports required *by the statute itself*, not by regulation. The CSA itself does require registrants to make, keep, or furnish numerous records. *E.g.*, *id.* § 827(a)(1), (a)(3); *id.* § 828(c). Yet, until late 2018, it did *not* require distributors to "make, keep, or furnish" reports of suspicious orders. *See* 21 U.S.C. § 842 (2018). The Complaint accordingly alleges only the violation of a *regulatory* reporting duty, under 21 C.F.R. § 1301.74(b). *See* Compl. ¶¶ 101, 479-80, 708. While DEA could have revoked a distributor's registration for violating that rule, civil penalties were not available.

The omission of regulatory requirements from § 842(a)(5) was no accident. Other CSA provisions refer to "this subchapter[and] regulations prescribed by the Attorney General," 21 U.S.C. § 829(f)(1), or to a particular section "and regulations prescribed by [the Attorney General]," *id.* § 828(a). This contrast underscores that § 842(a)(5) imposes liability only for reports required by the CSA itself. *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.").

The Supreme Court's decision in *Kucana v. Holder*, 558 U.S. 233 (2010), reinforces the plain statutory text. 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* that conferred discretion on the Attorney General in such matters.

The Supreme Court disagreed. Indeed, even the United States disagreed, causing the Court to appoint an *amicus* to defend the contrary position. *Kucana*, 558 U.S. at 240. The Court held that the "key words 'specified under this subchapter'" referred "to statutory, but not to regulatory, specifications." *Id*. at 237. "In other provisions," the Court noted, "Congress expressed precisely" its desire to sweep in regulatory commands. *Id.* at 248. Just the same is true of the CSA—both its operative text and surrounding provisions. Under *Kucana*, the Government cannot obtain penalties (the only relief it seeks here) based on a distributor's alleged failure to file suspicious order reports required only by regulation. *Accord Ardestani v. INS*, 502 U.S. 129, 136 (1991) (rejecting more sweeping interpretation of "under").

Finally, if text and precedent left any doubt, Congress has since removed it. In October 2018—after Walmart stopped acting as a distributor—the SUPPORT Act amended the CSA to require registrants to report suspicious orders. Pub. L. No. 115-

271, 132 Stat. 3894 (2018). Congress also then specified penalties for violating 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." *Intel Corp. Inv. Pol'y Comm. v. Sulyma*, 140 S. Ct. 768, 779 (2020). Congress' decision to amend the CSA to require suspicious-order reports (and to specify penalties for failing to file them) is further proof that civil penalties were *unavailable* beforehand.

B. In Any Case, the CSA Did Not Authorize Monetary Penalties for Suspicious Orders That Escaped Detection.

Even if civil penalties were otherwise available for reporting failures under 21 C.F.R. § 1301.74, that rule requires reporting only when suspicious orders are first "*discovered* by the registrant" through a monitoring system. 21 C.F.R. § 1301.74(b) (emphasis added). Even the Complaint acknowledges as much, by describing the distributor's duties as to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and "inform" DEA of those suspicious orders "*when discovered*." Compl. ¶ 28 (emphasis added).

In other words, the regulation does not expect registrants to do the impossible by reporting suspicious orders they did not detect. The DEA has never fully defined "suspicious order," and it would be severely inequitable to impose penalties based on DEA's after-the-fact determination that a particular undetected order should have been reported. Of course, a distributor with an inadequate monitoring system is

subject to registration revocation. 21 U.S.C. § 824(a)(4). But the statutory provision here authorizes civil penalties only for recordkeeping and reporting violations—not inadequacy of a monitoring system. *See id*. § 842(a)(5) (forbidding failure "to make, keep, or furnish any record, report, notification, declaration, order," etc.).

For those reasons, the Government grounds its demand for civil penalties in Walmart's alleged failures "to report suspicious orders." Compl. ¶ 708. But the Complaint's factual allegations do not match its legal theory. It primarily alleges that Walmart maintained an inadequate monitoring system and thus *failed to detect* suspicious orders—and only failed to report those *because they were never detected*. That is, the core complaint is that Walmart failed to "identif[y] suspicious orders in the first place." *Id.* ¶ 689. That is why the Complaint repeatedly accuses Walmart of failing to "*detect* and report" suspicious orders. *Id.* ¶ 478 (emphasis added); *see also id.* ¶¶ 8-9, 31, 34-35, 502, 537, 576, 644, 663, 681, 687.

In short, the Complaint focuses on Walmart's monitoring system and its purported failure to *detect* suspicious orders in the first place—not a failure to *report* suspicious orders it *had* detected. Indeed, the Complaint admits Walmart did report suspicious orders it detected. *Id.* ¶ 683. But even the Government does not claim civil penalties apply for *detection* failures. The remedy for an inadequate monitoring system was revocation of the distributor's registration, which DEA did not pursue against Walmart. For this reason too, the Court should dismiss Count III.

CONCLUSION

For these reasons, the Court should dismiss the Complaint.

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WORD COUNT CERTIFICATION

The undersigned hereby certifies that Defendants' Opening Brief in Support of its Motion to Dismiss contains 7,967 words (exclusive of the cover page, table of contents, table of authorities, and signature block) in Times New Roman 14-point font, counted using Microsoft Word's word count feature.

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