

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,

Defendants.

Civil Action No. 20-1744-CFC

Dylan J. Steinberg, UNITED STATES DEPARTMENT OF JUSTICE,
Wilmington, Delaware; Adam E. Lyons, Amanda N. Liskamm, Joshua Fowkes,
Kathleen B. Gilchrist, Katherine M. Ho, UNITED STATES DEPARTMENT OF
JUSTICE, Washington, D.C.

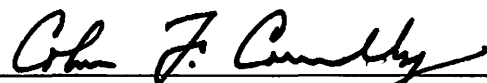
Counsel for Plaintiff

Kelly E. Farnan, Robert W. Whetzel, RICHARDS, LAYTON & FINGER, P.A.,
Wilmington, Delaware; Laura Jane Durfee, JONES DAY, Columbus, Ohio;
Yaakob M. Roth, Kristen A. Lejniaks, William G. Laxton, Jr., JONES DAY,
Washington, D.C.; Andrew J. Junker, Jason S. Varnado, JONES DAY, Houston,
Texas; Karen P. Hewitt, JONES DAY, San Diego, California; David W. Ogden,
Charles C. Speth, WILMER CUTLER PICKERING HALE AND DORR LLP,
Washington, D.C.

Counsel for Defendants

MEMORANDUM OPINION

March 11, 2024
Wilmington, Delaware



COLM F. CONNOLLY
CHIEF JUDGE

Defendants Walmart Inc. and Wal-Mart Stores East, LP (collectively, Walmart) have moved pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss three of the four counts alleged in the operative Second Amended Complaint (the Complaint) filed by the Government in this case. D.I. 110. The Government alleges in the three challenged claims that Walmart violated various provisions of the Controlled Substances Act (the CSA). D.I. 109 ¶ 1.

“Enacted in 1970 with the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances, the CSA creates a comprehensive, closed regulatory regime criminalizing the unauthorized manufacture, distribution, dispensing, and possession of substances classified in any of the Act’s five schedules.” *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). The regulatory scheme is characterized as “closed” because it requires each link in the supply chain of lawful controlled substances—including manufacturers, distributors, prescribing doctors, and pharmacies—to register with the Drug Enforcement Agency (DEA) and comply with regulations promulgated by the Attorney General. *See* 21 U.S.C. §§ 822(a)(2) and 823(f); 28 C.F.R. § 0.100; 21 C.F.R. § 1300.01.

Walmart is one of the country's largest pharmacy chains. It operates more than 5,000 pharmacies at Walmart and Sam's Club retail stores nationwide.

D.I. 109 ¶ 35. Through its pharmacies, Walmart dispenses controlled substances to customers. Until 2018, Walmart also acted as a wholesale distributor of controlled substances for its own pharmacies. D.I. 109 ¶ 36. At all times relevant to the claims alleged in the Complaint, Walmart had a compliance team of employees dedicated to ensuring that Walmart complied with various laws, including the CSA.

Walmart has moved to dismiss Counts II, III, and IV of the Complaint for failure to state a claim upon which relief can be granted. For ease of discussion, I will address the claims in reverse order.

I.

In Count IV, the Government alleges that “[d]uring the Distributions Violations Period, from June 26, 2013 through November 29, 2017, Walmart refused or negligently failed to report suspicious orders to [the DEA], in violation of 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.74(b).” D.I. 109 ¶ 778. The Government seeks “[f]or each violation” encompassed by this claim “a civil penalty under 21 U.S.C. § 842(c)(1)(B).” D.I. 109 ¶ 779.

At all times during the alleged Distributions Violations Period, § 842(a)(5) made 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 . . . subchapter [I] or subchapter II* of the CSA. 21 U.S.C. § 842(a)(5) (emphasis added). Section 842(c)(1)(B) imposed throughout this time frame a civil penalty of up to \$10,000 for a violation of § 842(a)(5). § 842(c)(1)(B). At all times during the Distribution Violations Period, § 1301.74(b) required each DEA registrant to “design and operate a system to disclose to the registrant suspicious orders of controlled substances” and to “inform the [DEA] of suspicious orders when discovered by the registrant.” 21 C.F.R. § 1301.74(b). Section 1301.74(b) defined “suspicious orders” during the Distribution Violations Period to “include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” *Id.*

Walmart argues that I should dismiss Count IV because nothing in either of the CSA’s two subchapters required a DEA registrant during the Distribution Violations Period to make, keep, or furnish to the DEA reports of suspicious orders. D.I. 84 at 31. The Government does not dispute that the CSA did not directly impose during this time frame a suspicious order reporting requirement. Tr. of Jan. 18, 2024 Hr’g at 13:1–12; 42:16–20. But it says that because the Attorney General promulgated § 1307.04(b) pursuant to §§ 821 and 871(b), both of which are in subchapter I of the CSA, “[§] 1307.04(b) was thus promulgated ‘under’ the CSA,” D.I. 93 at 35, and Walmart’s failure to submit to the DEA

suspicious order reports therefore “violated a CSA-imposed reporting obligation” that is unlawful under § 842(a)(5) and subjects Walmart to civil penalties under § 842(c)(1)(B), D.I. 93 at 33; *see also* Tr. 27:13–15; 31:20–22.

The fatal flaw of the Government’s argument is that although §§ 821 and 871(b) *empowered* the Attorney General to promulgate regulations during the Distribution Violations Period, neither § 821 nor § 871(b) *required* the Attorney General to promulgate *any* regulation, let alone a regulation that required DEA registrants to make, keep, and furnish to the DEA reports of suspicious orders. Section 821 provided that “[t]he Attorney General *is authorized* to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.” 21 U.S.C. § 821 (emphasis added). Section 871(b) similarly provided that “[t]he Attorney General *may* promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under [subchapter I of the CSA].” § 871(b) (emphasis added). Thus, even though § 1307.04 may have been—to use the Government’s words—“promulgated under” §§ 821 and 871(b), the CSA did not require the Attorney General to promulgate § 1307.04(b) or any of the reporting requirements set forth in § 1307.04(b). It necessarily follows that the reporting requirements in § 1307.04(b) were not “required under” the CSA. Thus,

a failure to comply with the reporting requirements of § 1301.74(b) during the Distribution Violations Period was not unlawful under § 842(a)(5) and did not trigger civil penalties under § 842(c)(1)(B).

This interpretation of § 842(a)(5) is confirmed by the fact that other sections of the CSA expressly distinguish regulations issued by the Attorney General from the CSA's subchapters. Section 829(f)(1)(B), for example, provides that “[a] prescription for a controlled substance in schedule II may be partially filled if the prescription is written and filled in accordance with this subchapter, *regulations prescribed by the Attorney General*, and State law[.]” § 829(f)(1)(B) (emphasis added). And § 880(d)(1) authorizes judges to “issue warrants for the purpose of conducting administrative inspections authorized by this subchapter *or regulations thereunder[.]*” 21 U.S.C. § 880(d)(1) (emphasis added). “[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” *Nken v. Holder*, 556 U.S. 418, 430 (2009) (internal quotation marks and citation omitted). Thus, it may be inferred from §§ 829(f)(1)(B) and 880(d)(1) that Congress intentionally omitted “regulations” from the scope of § 842(a)(5) and intentionally did not make mere regulatory violations subject to § 842(c)(1)(B)'s civil penalty provision.

That § 842(a)(5) and § 841(c)(1)(B) did not impose civil penalties for violations of § 1307.04(b) during the Distribution Violations Period is further confirmed by the fact that after the Distribution Violations Period ended, Congress amended the CSA to include in § 832(a) the suspicious order reporting requirement set forth in § 1307.04(b). *See* Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, § 832(a), 132 Stat. 3894, 3956 (2018); 21 U.S.C. §§ 832(a)(1), (3) (requiring each DEA registrant to “design and operate a system to identify suspicious orders” and “upon discovering a suspicious order or series of orders, [to] notify the Administrator of the [DEA].”). “When Congress acts to amend a statute, [courts are to] 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) (internal quotation marks and citations omitted). The revision of § 832(a) to include § 1307.04(b)’s reporting requirement would have had no purpose or effect if § 1307.04(b) already fell within the scope of § 842(a)(5).

In sum, I agree with Walmart that a failure to comply with the reporting requirement of § 1307.04(b) during the alleged Distribution Violations Period was not unlawful under § 842(a)(5) and not subject to civil penalties under § 842(c)(1)(B). Accordingly, I will dismiss Count IV.

II.

Count III of the Complaint alleges that “Walmart repeatedly violated 21 U.S.C. §§ 842(a)(1) and 829[(a) and (b)],¹ and 21 C.F.R. 1306.06, because it, through its agents and employees, did not adhere to the usual course of the professional practice of pharmacy in filling prescriptions for controlled substances.” D.I. 109 ¶ 772. The Government seeks “[f]or each violation” encompassed by Count III “a civil penalty as provided under 21 U.S.C. § 842(c)(1)(A),” D.I. 109 ¶ 774, and “appropriate injunctive relief tailored to restrain Walmart’s [future] violations” under § 843(f), D.I. 109 ¶ 775.

Section 842(a)(1) makes it unlawful “to distribute or dispense a controlled substance in violation of section 829 of [the CSA].” 21 U.S.C. § 842(a)(1). Section 842(c)(1)(A) imposes “a civil penalty of not more than \$25,000” for each violation of § 842(a)(1). § 842(c)(1)(A). Section 843(f) authorizes the Attorney General of the United States “to commence a civil action for appropriate declaratory or injunctive relief relating to violations” of § 842(a)(1). § 843(f)(1).

¹ Section 829 has six subsections. The Government admitted at oral argument that Count III alleges violations of only two of those subsections—namely, § 829(a) and § 829(b). Tr. 78:21–25; *see also* D.I. 109 ¶¶ 62, 67 (alleging that a pharmacist who fails to follow the “usual course of professional practice” violates § 829(a) and § 829(b)).

Section 829 is titled “Prescriptions,” and its first two subsections provide:

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq.*], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C. 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq.*], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

§§ 829(a), (b) (alterations in original).

Section 1306.06 provides that “[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy, a

registered central fill pharmacy, or registered institutional practitioner.” 21 C.F.R. § 1306.06. The phrase “usual course of his [or her] professional practice” is not used in either § 842, § 829(a), or § 829(b) of the CSA.

Walmart argues that I should dismiss Count III for three reasons: First, neither § 842(a)(1) nor § 829 makes it unlawful to fail to adhere to the usual course of the professional practice of pharmacy in filling prescriptions for controlled substances, D.I. 84 at 21–22; D.I. 94 at 10–11; second, civil penalties and injunctive relief are not available remedies for violations of § 1306.06, D.I. 84 at 20–23; and third, the Complaint does not allege facts that plausibly imply that Walmart violated the terms of § 1306.06, D.I. 84 at 24–26.

Even though the phrase “usual course” does not appear in § 842, § 829(a), or § 829(b) of the CSA, the Government argued in the Complaint, D.I. 109 ¶¶ 62–68, in its briefing in opposition to Walmart’s motion, D.I. 93 at 23–24, and initially at oral argument, Tr. 78:21–25, that the statutory text of the CSA imposed a requirement under both § 829(a) and § 829(b) to adhere to the usual course of professional practice of pharmacy in filling prescriptions for controlled substances. The Government wisely abandoned this position at oral argument. Tr. 83:1–2 (“We’ll abandon [relying solely on § 829], Your Honor[.]”). It continues to insist, however, that a pharmacist’s failure to comply with § 1306.06’s requirement that “a prescription may only be filled by a pharmacist[] acting in the usual course of

his professional practice” constitutes a violation of § 829 that can be remedied with civil penalties and injunctive relief under § 842(c)(1)(A) and § 843(f). In the Government’s words: “§ 1306.06’s usual course of professional practice requirement, as with the other regulations within Part 1306, delineates the scope of authorized dispensing under § 829.” D.I. 93 at 25; *see also* Tr. 83:17–23.

This liability theory trips right out of the gate because neither § 829(a) nor § 829(b) authorizes the dispensing of controlled substances. Instead, both subsections merely prohibit the dispensing of specified controlled substances by a pharmacist without a prescription. *See* § 829(a) (prohibiting pharmacists from dispensing Schedule II controlled substances without a prescription); § 829(b) (prohibiting pharmacists from dispensing Schedule III and IV controlled substances without a prescription). A pharmacist violates § 829(a) or § 829(b) if—and only if—she dispenses one of the covered controlled substances without a prescription. Thus, unless a pharmacist has dispensed a Schedule II, III, or IV controlled substance “without” a prescription, there is no violation of § 829(a) or § 829(b), and there is no basis for imposing a civil penalty under § 842(c)(1)(A) or granting an injunction under § 843(f).

A person violates § 1306.06, by contrast, only if “*a prescription is filled*”—that is, only if a controlled substance is dispensed *with* a prescription. As noted above, § 1306.06 provides that “[a] prescription for a controlled substance may

only be filled by a pharmacist, acting in the usual course of his professional practice[.]” Thus, § 1306.06 can be violated only in two situations: (1) when a person who is not a pharmacist fills a prescription for a controlled substance, and (2) when a pharmacist fills a prescription not in the usual course of his professional practice. It follows that a pharmacist cannot simultaneously violate § 1306.06 and § 829, as the very act of filling a prescription takes a pharmacist outside the ambit of § 829.

In this case, the Government does not allege in Count III that Walmart violated § 829(a), § 829(b), or § 1306.06 by its pharmacists dispensing controlled substances without a prescription. Rather, the Government alleges violations based on Walmart pharmacists’ alleged failures “to perform key professional duties to identify, resolve, and document the resolution of red flags.” D.I. 93 at 23–24; *see also* D.I. 109 ¶¶ 545–56. Under the Government’s liability theory, a pharmacist who resolved a “red flag” before filling a valid prescription but failed to document that resolution violated § 1306.06. That pharmacist, however, did not dispense a controlled substance “without the written prescription of a practitioner” in violation of § 829. And without a violation of § 829, the penalty provisions of § 842(c)(1)(A) and injunctive relief provisions of § 843(f) are not triggered.

Accordingly, I agree with Walmart that Count III fails to state a cognizable claim. Neither § 842(a)(1) nor § 829 make it unlawful to fail to adhere to the usual

course of the professional practice of pharmacy in filling prescriptions for controlled substances; and civil penalties and injunctive relief are not available remedies for violations of § 1306.06. *Accord United States v. Howen*, 2022 WL 18420744, at *8 (E.D. Cal. Aug. 9, 2022) (“[A] violation of § 1306.06 does not by its own text subject one to civil penalties or provide for injunctive relief.”). I need not and do not address Walmart’s argument that the Complaint does not allege facts that plausibly imply that Walmart violated § 1306.06.

III.

Count II of the Complaint alleges that Walmart “repeatedly violated 21 U.S.C. §§ 842(a)(1) and 829[(a) and (b)], and 21 C.F.R. § 1306.04(a), because it, through its agents and employees, knowingly dispensed controlled substances pursuant to prescriptions that were either not issued in the usual course of professional treatment, not for a legitimate medical purpose, or both.” D.I. 109 ¶ 766. As noted above, each of § 829(a) and § 829(b), in combination with § 842(a)(1), make it unlawful for a pharmacist to dispense specified controlled substances without a prescription. Section 1306.04(a) provides:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription

issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

21 C.F.R. § 1306.04(a) (emphasis added). The Government contends—and Walmart expressly concedes, *see* D.I. 84 at 22–23—that knowingly filling an ineffective prescription in violation of § 1306.04(a) constitutes a violation of § 829, which in turn constitutes a violation of § 842(a)(1) that subjects the violator to a civil penalty under § 842(c)(1)(A) and a potential injunction under § 843(f).

For each violation of § 1306.04 covered by Count II, the Government alleges that “[w]hen Walmart dispensed controlled substances pursuant to prescriptions that were issued not in the usual course of professional treatment, not for a legitimate medical purpose, or both, it did so with the knowledge of one or more of the compliance team members, but not with knowledge of the pharmacists who were presented with the prescriptions.” D.I. 109 ¶ 767. Walmart argues that I should dismiss Count II because “black-letter agency law” prohibits the Government from establishing a corporation’s liability “by combining one employee’s knowledge with another employee’s unknowing actions.” D.I. 84 at 7–8; *see also* Tr. 145:23–25 (Walmart counsel arguing that “under the common law of agency, you need to have the relevant act and the relevant knowledge merge

in a single agent”). The Government counters that Walmart’s “argument is legally incorrect and, if accepted, would have profound ramifications for corporate liability.” D.I. 93 at 8.

In support of its position, Walmart relies primarily on commentary to § 275 of the Restatement (Second) of Agency. That commentary provides that “[i]f knowledge, as distinguished from reason to know, 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 affected by the fact that the agent has the knowledge.” Restatement (Second) of Agency § 275 cmt. b (Am. L. Inst. 1958). For its part, the Government relies primarily on *U.S. ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908 (4th Cir. 2003). In *Harrison*, Westinghouse sought to overturn a jury’s verdict that Westinghouse violated the False Claims Act, 31 U.S.C. §§ 3729(a)(1)–(2), when its agent submitted to the Department of Energy as part of a contract bid a false certification of no organizational conflict of interest. *Id.* at 917–18. Westinghouse argued in its appeal that the district court’s jury instructions “improperly allowed the jury to piece together knowledge of more than one of [Westinghouse’s] employees to find that the corporation knowingly made a false statement.” *Id.* at 918. According to Westinghouse, no evidence had been adduced at trial to show either that the agent who made the certification had knowledge of the conflict or that the agent who

knew of the alleged conflict had knowledge of the no-conflict certification, and therefore “there was no ‘single actor’ at Westinghouse who possessed the requisite scienter for [False Claims Act] liability to attach.” *Id.* The court in *Harrison*, however, “decline[d] to adopt Westinghouse’s view that a single employee must know both the wrongful conduct and the certification requirement.” *Id.* at 919. The court explained that “if [it] established such a rule, corporations would establish segregated ‘certifying’ offices that did nothing more than execute government contract certifications, thereby immunizing themselves against [False Claims Act] liability.” *Id.*

The Supreme Court cited *Harrison* and the commentary to § 275 in *Staub v. Proctor Hospital*, 562 U.S. 411, 418 (2011) as evidence that “the answer” to the question of whether “the discriminatory motive of one of [an] employer’s agents . . . can be aggregated with the act of another agent . . . to impose liability” on the employer “is not so clear.” The Court did not decide the answer to that question in *Staub* because “the governing text” of the statute at issue in *Staub* made it “unnecessary” for the Court to make that determination. *Id.*

In this case, neither side identifies, and I do not see, language in the CSA that would make it unnecessary for me to answer the related but narrower question presented here—whether the knowledge of a corporation’s employee can be aggregated with the act of another employee to impose liability on the corporation.

But in *Browning v. Fidelity Trust Co.*, 250 F. 321 (3d Cir. 1918), a case neither party cited in its briefing or at oral argument, the Third Circuit gave a clear answer to this question that requires me to reject Walmart’s request that I dismiss Count II.

The plaintiff in *Browning* held bonds secured by a mortgage of which the defendant, Fidelity Trust Company, was the trustee. The court described Fidelity as “a trust company conducting the usual business of such an institution by the customary means of departments having to do separately with banking, titles, trusts, savings, mortgages, and real estate.” *Id.* at 323. Under the terms of the mortgage, “[t]he trustee was empowered and required to execute releases when requested by the mortgagor, provided there was at the time no existing default in the payment of interest of which the trustee had knowledge.” *Id.* at 324.

Browning alleged that Fidelity breached its fiduciary duties by executing a release of land secured by the mortgage when the mortgagor was in default on interest payments.

Fidelity admitted that the mortgagor was in default when it executed the release and that a teller in its banking department knew at the time of the release that the mortgagor was in default. It argued, however, that “its trust department, which alone was charged with the performance of the mortgage trusts, had no knowledge of the existing default, and, [that] therefore, it, the corporate trustee, acting through its trust officers without knowledge of the default, committed no

breach of trust.” *Id.* The Third Circuit, as the district court had in the first instance, rejected this argument:

On the bare question of knowledge we agree with the learned district judge that the trustee cannot thus divide itself into units or parts and cannot escape liability, when based upon knowledge, because one of its parts was without it while another possessed it. Clearly the knowledge of the paying teller that default had been made in interest payments was knowledge chargeable to the corporation itself. This knowledge, if not actual in the sense of being complete in detail, was quite sufficient to put the corporation on inquiry, which, had it been made, would have revealed the actual default. We therefore agree with the learned district judge that knowledge of the default was chargeable to the trustee, and that the execution of the release, with the knowledge of the existing default imputed to it, constituted technically a violation of the trustee’s duty, occasioned either by the negligence of one of its officers or by itself, for which it is liable, unless there is some provision in the mortgage relieving it of liability.

Id.

As it turned out, the mortgage at issue in *Browning* had a provision that purported to relieve Fidelity of liability “for any act, default or neglect or misconduct of any of its agents or employees.” *Id.* The court held, however, that “considerations of public policy” “dictated” that the clause could not immunize Fidelity “from liability for acts of gross negligence or for acts done in bad faith.” *Id.* at 325. The court noted that “the terms ‘gross negligence’ and ‘bad faith’ are used in the law in many connections and with many shades of meaning,” but had

distinct meanings with respect to a trustee's obligations and conduct. *Id.* In that specific context, the court held, "bad faith" "contemplates a state of mind affirmatively operating with a furtive design or some motive of interest or ill will" and "contains the element of intent to do wrong in some degree, actual or necessarily inferable." *Id.* "Gross negligence" in that context "involves the additional and affirmative element of intent to do or willfulness with which is done the negligent act" and "is defined to be the intentional failure to perform a manifest duty in reckless disregard of the consequences as affecting the life or property of another." *Id.* (internal quotation marks and citation omitted).

Applying these definitions, the court held that even though Browning had established that Fidelity knew of the mortgagor's default when it released the land to the mortgagor and thus was negligent in executing the release, Browning failed to show that Fidelity acted with gross negligence or in bad faith because the undisputed evidence established that "[t]he paying teller did not inform the trust department or any of the officers of the trust company of the default in interest payments." *Id.* at 326. As the court explained:

The evidence, not being refuted, is conclusive that the officers, who, acting for the corporation, executed the release, were in ignorance of the default. It is further shown, likewise conclusively, that, in executing the release, the officers acted solely in what they thought was a correct performance of the trust prescribed by the mortgage, and that they acted entirely without ulterior motive, furtive purpose or design to injure anyone.

While the knowledge of the existing default imputed to the corporation extended to its officers, their lack of actual knowledge has a bearing on the intent or motive that entered into the gross negligence and bad faith with which the corporate trustee is charged. Their actual knowledge and their sole knowledge apparently was limited to what was conveyed to them by [certain] letters . . . In so far as these letters gave them information, it was, we think, information not that there would be default, but rather that there would be no default. While they were not justified in relying upon the lack of information contained in the letters or in executing the release in view of the knowledge imputed to the corporation for which they were acting, yet it seems clear from these circumstances that their act, though technically negligent, was not characterized by recklessness, indifference, willfulness or ulterior design, and did not amount to gross negligence or to bad faith, and that, therefore, the corporation for which they were acting is relieved from liability by the broad but valid terms of the immunity clause.

Id. at 326–27.

Two holdings are made clear in *Browning*. First, the knowledge of a corporation’s employee can be aggregated with the act of another employee to impose liability on the corporation for knowingly or negligently engaging in a prohibited act. Second, at least in some circumstances, the knowledge of a corporation’s employee cannot be aggregated with the act of another employee to impose liability on the corporation for recklessly, willfully, intentionally, purposefully, or with ulterior motive engaging in a prohibited act.

As I am bound by Third Circuit precedent, *Browning* requires me to deny Walmart's motion insofar as it seeks dismissal of Count II. Section 1306.04(a) prohibits any "person"—including a corporation, *see* 21 C.F.R. § 1300.01—from "knowingly filling" an ineffective prescription. The *mens rea* for liability under § 1306.04(a) is knowingly. It is not recklessly, willfully, intentionally, or purposely. The motive for filling a prescription is irrelevant under § 1306.04(a). Under *Browning*, a Walmart compliance team member's knowledge of the ineffectiveness of a prescription is "chargeable to the corporation itself" and the filling of that prescription by Walmart "with the knowledge of the [ineffective prescription] imputed to it," constitutes a violation of § 1306.04(a). The fact that only a compliance team member—the analogue to the teller in *Browning*—had the requisite knowledge, and that an unknowing pharmacist—the analogue to the trust officer in *Browning*—filled the prescription is of no moment.

In a supplemental letter brief filed at my invitation after I brought *Browning* to the parties' attention, Walmart argues that it "cannot be liable for criminal and civil CSA penalties for 'knowingly' filling invalid prescriptions absent 'actual knowledge' on the part of the pharmacists 'acting for the corporation'—just like the trust company in *Browning* could not be liable for 'gross negligence' absent 'actual knowledge' on the part of the officers who took the action that allegedly breached the mortgage agreement there." D.I. 114 at 1. But this contention cannot

be squared with the express holding of *Browning* that “[o]n the bare question of knowledge” Fidelity “cannot escape liability.” 250 F. at 324. As discussed above, the court took pains in *Browning* to distinguish knowledge from gross negligence and bad faith. And the court emphasized that in the context of a trustee’s obligations and conduct, gross negligence—unlike mere knowledge—“involves the additional and affirmative element of intent to do or willfulness.” 250 F. at 325. There is, however, no element of intent or willfulness in the prohibitions imposed by § 1306.04(a). A person violates § 1306.04(a) if she “knowingly fill[s]” an ineffective prescription full stop. Accordingly, the court’s discussion of gross negligence in *Browning* has no bearing on what must be shown to establish liability under § 1306.04(a).

Walmart also argues that “neither the Third Circuit nor any court within it has ever cited *Browning* for th[e] point” that “the teller’s knowledge was ‘chargeable to the corporation,’ thereby creating, at least ‘technically,’ a ‘violation of the trustee’s duty’” D.I. 114 at 3. But Walmart cites no Third Circuit case that calls *Browning* into question on this “point” (or any other point). More important, Walmart cites no Third Circuit case that prohibits the aggregation of the knowledge of a corporation’s employee with the act of another employee to impose liability on the corporation. Thus, even though *Browning* may be old law, it remains good law that I must follow. *See Mallory v. Norfolk S. Ry. Co.*, 600 U.S.

122, 146 (2023) (“This case poses a very old question indeed—one this Court resolved more than a century ago in *Pennsylvania Fire [Ins. Co. of Philadelphia v. Gold Issue Mining & Milling Co.]*, 243 U.S. 93 (1917)]. Because that decision remains the law, the judgment of the Supreme Court of Pennsylvania is vacated, and the case is remanded.”); *see also* *Buck Consultants, Inc. v. Glenpointe Assocs.*, 217 F. App’x 142, 152 (3d Cir. 2007) (citing *Browning* favorably for its discussion of the meaning of bad faith).

Walmart also suggests in its supplemental letter that *Browning* has no application here because it “addressed the legal consequences of imputed knowledge in the context of contracts.” D.I. 114 at 3. As an initial matter, the premise of this argument is not accurate. *Browning* addressed the legal consequences of imputed knowledge in the context of both torts and contracts. As the court stated in the first sentence of its opinion: “The principal question on this appeal concerns the exemption from liability afforded a trustee of a mortgage by its immunity clause for a breach of duty under the attendant circumstances.” *Browning*, 251 F. at 322. The immunity clause in question was contained in the mortgage and was therefore contractual. The alleged breach of the trustee’s fiduciary duties, however, lies in the realm of tort law. *See generally* Restatement (Second) of Torts § 874 (Am. L. Inst. 1965) (treating breach of fiduciary duty as a tort that subjects a fiduciary to liability to the beneficiary for harm caused by the

breach). But in any event, the court in *Browning* did not limit in any way its holding that “[o]n the bare question of knowledge . . . [c]learly the knowledge of the paying teller that default had been made in interest payments was knowledge chargeable to the corporation itself.” 250 F. at 324.

Finally, Walmart argues that *Browning* is “factually inapposite, because it involved the knowledge of the teller, ‘whose business it was to be informed and to learn of defaults.’” D.I. 114 at 4. Walmart insists that “[h]ere it was the ‘business’ of the *pharmacists* to determine whether to fill any given prescription, and Count II admits those pharmacists did not know any particular prescriptions were invalid.” D.I. 114 at 4 (emphasis in the original). It was, however, the “business” of the *compliance team members* to gather and distribute information to ensure that Walmart complied with the law. The knowledge of the compliance team members was therefore “knowledge chargeable to the corporation itself.” 250 F. at 324. Like Fidelity in *Browning*, Walmart in this case “cannot . . . divide itself into units or parts” to “escape liability.” *Id.* When, as here, the *mens rea* for liability is “based upon knowledge,” that “one of [Walmart’s] parts was without [that knowledge] while another possessed it” is of no consequence. *Id.* The Government’s allegations that Walmart filled ineffective prescriptions known by

compliance team members to be ineffective are sufficient to state violations of § 1306.04(a).²

Accordingly, I will not dismiss Count II.

* * * *

For the reasons stated above, I will grant in part and deny in part Walmart's motion to dismiss. I will grant the motion insofar as it seeks dismissal of Counts III and IV. I will deny the motion insofar as it seeks dismissal of Count II.

The Court will issue an Order consistent with this Memorandum Opinion.

² Walmart also argues that the Government “fails to plausibly allege that the compliance team *knew* of any specific invalid prescription when it was filled (or even after).” D.I. 84 at 14 (emphasis in the original). But the Complaint alleges that specific compliance team members knew that specific doctors prescribed invalid prescriptions that were continually presented to Walmart pharmacies and that, despite this knowledge, Walmart pharmacists continued to fill specific numbers of those doctors' invalid prescriptions. *See e.g.*, D.I. 109 ¶¶ 242, 252, 261, 275, 285. These allegations plausibly imply that a Walmart compliance team member knew or was willfully blind to the fact that Walmart filled ineffective prescriptions. *See Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011) (“[T]he evidence in this case was plainly sufficient to support a finding of [Defendant's] knowledge under the doctrine of willful blindness.”); *United States v. One 1973 Rolls Royce, V.I.N. SRH-16266 By & Through Goodman*, 43 F.3d 794, 813 (3d Cir. 1994) (holding that under the CSA, willful blindness “is an alternative way of proving knowledge”).