

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

UNITED STATES OF AMERICA,)
)
Plaintiff,)
) No. _____
v.)
)
OAKLEY PHARMACY, INC., d/b/a)
DALE HOLLOW PHARMACY; XPRESS)
PHARMACY OF CLAY COUNTY, LLC;)
THOMAS WEIR; MICHAEL GRIFFITH;)
JOHN POLSTON, and LARRY LARKIN,) **FILED *EX PARTE***
) **AND UNDER SEAL**
Defendants.)

**UNITED STATES’ MEMORANDUM OF LAW SUPPORTING ITS *EX PARTE* MOTION
FOR A TEMPORARY RESTRAINING ORDER AND A PRELIMINARY INJUNCTION**

Pharmacists frequently are the last line of defense before a controlled substance that was prescribed without any legitimate medical purpose is sold to a patient. The Defendant pharmacies, pharmacists, and the pharmacies’ owner here failed to muster that defense. Between at least May 2016 through August 2018, Defendant-pharmacies Oakley Pharmacy, Inc., doing business as Dale Hollow (“Dale Hollow”), and Xpress Pharmacy of Clay County, LLC (“Xpress”), illegally filled thousands of prescriptions for powerful opioid painkillers and other controlled substances that had no legitimate medical purpose. The pharmacies’ majority owner, Defendant Thomas Weir, was responsible for their operations. Defendants Michael Griffith, John Polston, and Larry Larkin were the pharmacists who illegally filled those prescriptions. By filling those thousands of illegitimate prescriptions, Defendants crossed the legal line between pharmacy practice and violating the Controlled Substances Act (“CSA”). The United States files this motion to stop Defendants from distributing or dispensing any more controlled substances.

The CSA authorizes the Attorney General “to commence a civil action for appropriate declaratory or injunctive relief relating to” unlawfully dispensing controlled substances. 21

U.S.C. § 843(f)(1). As the attached evidence shows, and as discussed below, Defendants' actions over the last several years have fed opioid drug addiction in Tennessee and contributed to the nation's opioid epidemic. Absent immediate injunctive relief, Defendants will be free to continue distributing and dispensing controlled substances, and thereby inflicting further harm on the community. To protect the public, the United States thus moves for a temporary restraining order (TRO) and preliminary injunction under 21 U.S.C. §§ 843(f) and 882(a), Federal Rule of Civil Procedure 65(a) and (b), and Local Rule 65.01 to immediately halt Defendants' illegal activities.

BACKGROUND

I. The Controlled Substances Act

The CSA establishes “a closed regulatory system” under which it is “unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA.” *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). All controlled substances are categorized onto one of five schedules “based on their accepted medical uses, the potential for abuse, and their psychological and physical effects on the body.” *Id.*; see 21 U.S.C. § 812 (schedules I through V). Accordingly, the CSA requires those who manufacture, distribute, or dispense controlled substances to obtain a registration from the United States Drug Enforcement Administration (“DEA”). See 21 U.S.C. § 822(a); 21 C.F.R. § 1301.11(a).

A pharmacy that fills prescriptions for patients “dispenses” controlled substances within the meaning of the CSA and must register with DEA. 21 U.S.C. § 802(10) (defining “dispense” as “to deliver a controlled substance to an ultimate user [*i.e.*, a patient] . . . by, or pursuant to the lawful order of, a practitioner, including the prescribing . . . of a controlled substance”); see also *id.* § 802(21) (defining a practitioner to include a “pharmacy . . . licensed, registered, or otherwise

permitted . . . to distribute [or] dispense . . . a controlled substance in the course of professional practice”). A pharmacy registered with DEA may only dispense or distribute controlled substances “to the extent authorized by [the pharmacy’s] registration and in conformity with the” CSA. 21 U.S.C. § 822(b).

The CSA limits physicians’ authority to issue prescriptions for controlled substances. A prescription written by a physician “in a manner that is not authorized by law – *i.e.*, the prescription is issued without ‘a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice’” – violates the CSA. *United States v. Volkman*, 797 F.3d 377, 392 (6th Cir. 2015) (quoting 21 C.F.R. § 1306.04(a)); *see United States v. Moore*, 423 U.S. 122, 140 (1975) (noting that the CSA “limit[s] a registered physician’s dispensing authority to the course of his ‘professional practice’”).

The CSA also limits pharmacists’ authority to fill prescriptions. “Although the prescribing physician has a responsibility to prescribe and dispense controlled substances properly, ‘a corresponding responsibility rests with the pharmacist who fills the prescription.’” *Brown v. CVS Pharmacy, LLC*, 982 F. Supp. 2d 793, 802-03 (M.D. Tenn. 2013) (quoting 21 C.F.R. § 1306.04(a)). In other words, pharmacists have an “independent duty, apart from the prescribing physician, to ensure that prescriptions are issued for medically legitimate purposes before filling them.” *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823, 832 (11th Cir. 2018); *see, e.g., Med. Shoppe-Jonesborough v. DEA*, 300 F. App’x 409, 412 (6th Cir. 2008) (citations omitted) (“‘When [pharmacists’] suspicions are aroused as reasonable professionals,’ they must at least verify the prescription’s propriety, and if not satisfied by the answer they must ‘refuse to dispense’”; *United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979) (“What is required of [the

pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows that the issuing practitioner issued it outside the scope of medical practice.”). An owner of a pharmacy that dispenses or distributes controlled substances also has a responsibility to act in conformity with the CSA. *See United States v. Patel*, 2017 WL 4418995, *2-3 (E.D. Mich. Oct. 5, 2017) (upholding CSA guilty plea of the beneficial owner of a pharmacy).

II. Defendants and Their Illegal Activities

The individual pharmacists and the majority owner Weir all acted unlawfully with regard to dispensing controlled substances in violation of the CSA. In so doing, their conduct was on behalf of the respective pharmacy Defendants – Dale Hollow and Xpress – and renders the pharmacy’s dispensing conduct unlawful in violation of the CSA as well.

A. Defendant Thomas Weir: Xpress and Dale Hollow Majority Owner

A resident of Celina, Tennessee, Defendant Weir is the majority owner of both Dale Hollow and Xpress and serves as Dale Hollow’s CEO and Xpress’ managing member. Weir was fully knowledgeable about his businesses’ activities – both their long history of violations and their ongoing illegal conduct. Declaration of Samantha Rogers (“Rogers Decl.”) (filed separately) at 3.

In January 2016, the Tennessee State Board of Pharmacy entered an agreed order signed by Weir describing Dale Hollow’s numerous violations of Tennessee pharmacy requirements and placing Dale Hollow’s pharmacy license on probation for five years. The order detailed how Dale Hollow staff admitted to, *inter alia*, dispensing early refills without documenting any necessity, failing to locate hard copies of controlled substance prescriptions for a family member of

pharmacist-in-charge (Polston), and possessing bottles of medication from other pharmacies. *See id.* at 7.

In April 2016, following an alarm call at Dale Hollow, a Clay County Sherriff's Officer arrived and saw some pill bottles laying on the floor. After the office called Weir as the owner, Weir said that the employees had probably put them there to sort them out and then yelled at the officer and refused to let him clear and secure the building. *See id.*

On May 12, 2016, DEA audited Dale Hollow due to information showing it was the second largest purchaser of buprenorphine in the DEA Nashville District Office 2016 coverage area and had filled numerous prescriptions for customers who travelled long distances. In October 2016, DEA confronted Weir with DEA's findings from the inspection and identified the various CSA violations that DEA had found. DEA also educated Weir and Dale Hollow's pharmacist-in-charge, Defendant Polston, about its improper, early refills of controlled substance prescriptions, its ranking in the top three pharmacy purchasers of buprenorphine in Tennessee, and its having filled prescriptions from patients who live far away from the pharmacy. *See id.* at 8.

In March 2017, Weir signed a memorandum of agreement (MOA) between Dale Hollow and the DEA, which noted the CSA discrepancies uncovered at Dale Hollow and – in lieu of revoking Dale Hollow's DEA registration number – memorialized Dale Hollow's agreement that it would comply with the CSA and Tennessee State requirements, including “regulations pertaining to the dispensation of buprenorphine products for opioid addiction treatment.” *See id.* at 8-9.

In June 2018, DEA conducted a scheduled investigation of Dale Hollow. On the first day of that inspection on June 12, 2018, Weir stated that he buys troubled business and turns them

around. He said that doctors need to be investigated, since they are the ones writing prescriptions and that the pharmacist and pharmacies are not responsible because they only fill the prescription. Weir further said that he did not believe there is an opioid problem and that it is media hype. Regarding the DEA MOA, Weir said that he was badgered to sign it and that the DEA is out to get him. In addition, Weir said that he cannot tell a board certified doctor, “no.” Weir also remarked that pharmacies are like car lots, such that if you put several pharmacies together, business increases. On the final inspection date of June 14, 2018, Weir said that in his construction business, he knows guys that only function using Subutex (buprenorphine). Throughout the inspection, DEA investigators observed several customers show up multiple times, including several times in one day and on back-to-back days. *See id.* at 9.

During a June 14, 2016 interview, Polston told DEA investigators that he was concerned about activities taking place at Dale Hollow as well as Weir’s actions. According to Polston, Weir preferred for the pharmacy to order 17 bottles of buprenorphine per day to ensure they had sufficient supply and would never turn customers away. At the end of each day, Weir asked for total daily burprenorphine sales and the buprenorphine in stock. Dale Hollow charged \$4 per buprenorphine pill then, and Polston said that Subutex and Suboxone (the buprenorphine formula with naloxone) accounted for approximately 60% of their controlled substances sales. Polston said that Weir sometimes asked him to fill controlled substance prescriptions one or two days earlier than the refill date. Polston said he felt he was in an awkward position, because he did not want to jeopardize his employment or his license. Polston reported that Weir had told him that, if we get past this inspection, we are going to take this business to a whole new level. *See id.* at 3-4.

The DEA again inspected Dale Hollow in June 2018. On June 19, 2018, DEA called Weir and asked him to surrender Dale Hollow's DEA registration number, but Weir declined to do so. *Id.* at 9-10.

During a December 2018 interview with a former employee of both Dale Hollow and Xpress, the former employee disclosed that on one occasion after she had refused to fill a prescription for Percocet early, Weir called her and directed her to fill the prescription early because the patient was a good customer. *See id.* at 11.

B. Defendant Michael Griffith: Xpress Pharmacist-in-Charge

Defendant Griffith is Xpress' pharmacist-in-charge and is licensed to practice pharmacy by the State of Tennessee. Under Tennessee law, as pharmacist-in-charge, Griffith is "the supervisory pharmacist who has the authority and responsibility for compliance with laws and rules pertaining to the practice of pharmacy at the practice site of the pharmacist-in-charge." Tenn. Code Ann. § 63-10-204(31). In June 2011, Griffith signed a voluntary statement acknowledging that he had been abusing medications and had stolen medications from his then-employer, Walgreens. In January 2012, Griffith entered into a consent order with the Tennessee Board of Pharmacy that indefinitely suspended his pharmacy license due to his addiction to alcohol, narcotics or other drugs and unprofessional conduct. In March 2012, the Board of Pharmacy reinstated Griffith's license and put him on probation for five years. *See Declaration of Randy D'Antoni ("D'Antoni Decl.")* (filed separately) at 2-4.

On January 26, 2018, Griffith called 911 from Xpress and requested an ambulance for a woman who was passed out in the Xpress bathroom from a possible "overdose." The woman was a 37 year old TennCare beneficiary and was apparently at Xpress to fill a controlled substance

prescription dated January 25, 2018. When the police arrived, they administered Narcan, and the woman's condition improved. *See id.* at 6.

During DEA's August 2018 administrative inspection of Xpress, Griffith said that Xpress has over \$2 million in annual sales, and that approximately 32% of prescriptions are paid for with cash, which are almost exclusively for controlled substances. When asked about his prior consent order, Griffith said that he had been addicted to alcohol and hydrocodone and stolen about 50 hydrocodone tablets from Walgreens. When asked why Xpress is one of the top 20 purchasers of buprenorphine in Tennessee, Griffith replied that a lot of patients in the area are on buprenorphine and that he was working to reduce these amounts. *See id.* at 4.

C. John Polston: Dale Hollow Pharmacist-in-Charge

Defendant Polston is Dale Hollow's pharmacist-in-charge and is licensed to practice pharmacy by Kentucky and Tennessee. On July 30, 2015, the Tennessee State Board of Pharmacy placed Polston's license on probation for two years for giving early refills and dispensing controlled substances to a family member without a prescription. *See Rogers Decl.* at 3.

In a June 14, 2016 interview, Polston acknowledged that some customers visit Dale Hollow in small groups to fill prescriptions for the same drug. During the October 2016 meeting with Weir, Polston and DEA, Polston stated that there is a big drug abuse problem in their area and that many people are on buprenorphine products just to stay functional. Polston also said that he had seen an increase in gabapentin prescriptions and had heard they sold for \$15 per tablet on the street. *See id.*

During the DEA's June 2018 inspection of Dale Hollow, Polston said that Dale Hollow charges \$5 for each Subutex (buprenorphine) pill. During an interview with a former employee

in December 2018, federal agents were told that Polston would regularly ask patients coming in to filled controlled prescriptions to also fill non-controlled prescriptions at the pharmacy to generate more revenue and make the pharmacy look good in terms of the percentage of controlled versus non-controlled prescriptions filled. Federal agents were also told that Polston instructed a Dale Hollow employee to fill controlled substance prescriptions early. *See id.* at 4.

During an interview with a former Dale Hollow employee in December 2018, DEA agents were told that Polston would regularly ask patients coming into Dale Hollow to fill controlled substance prescriptions to fill non-controlled prescriptions too. The former employee said that he thought that Polston did this to generate more revenue and to make the pharmacy look good with its the percentage of controlled versus non-controlled prescriptions it filled. Federal agents were also told that if a regular customer came in for an early refill of a controlled substance prescription and the former employee refused to fill it early, that former employee would often get a call from Polston to fill the prescription anyway. *Id.*

D. Defendant Larry Larkin: Shared Pharmacist at Both Dale Hollow and Xpress

Defendant Larkin is a pharmacist who acts as a shared employee of Dale Hollow and Xpress and works at both pharmacies as a pharmacist or fill-in pharmacist. Larkin is licensed to practice pharmacy by the State of Tennessee. In 2004, Larkin entered into a consent order with the Tennessee Board of Pharmacy in which his pharmacy license was revoked due to his use of cocaine, benzodiazepines and alcohol. He later acknowledged in writing that he had become addicted to crack cocaine during late 2003 through 2005. Following his 2006 license reinstatement, in December 2008 Larkin entered into a second consent order with the Board of Pharmacy in which he paid a \$500 fine due to allegations that he had mis-filled a patient's

prescription. *See id.*

In September 2016, Larkin spoke to DEA investigators. Larkin discussed some drug addicts who came to Dale Hollow to get prescriptions filled. He said that we don't have to fill them, but we do. Larkin said that he would fill prescriptions a day early and that it was his right to do so. Regarding Xpress, Larkin said that people come in hoards to Xpress on Saturdays for Suboxone, since Dale Hollow was closed on Saturdays during that period. Larkin stated that he had heard that a lot of people are selling their pills and that the pharmacies' biggest sellers are oxycodone and gabapentin. *See id.* at 4-5.

LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 65(a) and (b), the Court's inherent equitable authority, and the CSA, the United States seeks a TRO and a preliminary injunction to prohibit Defendants from distributing or dispensing controlled substances, to surrender all controlled substances in their possession to the DEA, and from destroying or otherwise making unavailable to the United States any documents related to their distribution or dispensation of controlled substances.

This Court may grant injunctive relief under 21 U.S.C. § 843(f)(1) to remedy Defendants' violations of 21 U.S.C. § 842(a)(1) for dispensing controlled substances without a valid prescription, as alleged in Count 1 of the Complaint. *See* Compl. ¶ 138. And it may grant injunctive relief under 21 U.S.C. § 882(a) to remedy Defendants' violations of 21 U.S.C. § 841(a)(1) for distributing and dispensing controlled substances outside the usual course of professional practice, as alleged in Count 2 of the Complaint. *See id.* ¶ 141.

The United States seeks both a TRO and a preliminary injunction. To obtain a TRO, issuing without notice, the United States must show the factors to support a preliminary injunction,

and that “immediate and irreparable injury, loss, or damage will result to the movant before the adverse party can be heard in opposition.” Fed. R. Civ. P. 65(b)(1)(A); *see, e.g., Solis v. Tenn. Commerce Bancorp, Inc.*, 713 F. Supp. 2d 701, 716 (M.D. Tenn. 2010).

Traditionally, courts weighing a preliminary injunction motion consider whether (1) the movant has established a strong likelihood of success on the merits; (2) the movant would suffer irreparable injury without the injunction; (3) substantial harm to others would result; and (4) the public interest would be served by issuance of the injunction. *Doe v. Univ. of Cincinnati*, 872 F.3d 393, 399 (6th Cir. 2017); *City of Pontiac Retired Emps. Ass’n v. Schimmel*, 751 F.3d 427, 430 (6th Cir. 2014) (en banc).

But “when a court is called upon to enforce a federal statutory injunction, its reliance upon the traditional practices of equity must be conditioned by the necessities of the public interest which Congress has sought to protect.” *United States v. City of Painesville*, 644 F.2d 1186, 1193 (6th Cir. 1981) (quotation omitted); *see Tenn. Commerce*, 713 F. Supp. 2d at 716 (“Where the government seeks a statutory injunction, a lesser showing of the public interest, irreparable injury or the balance of hardship may be made.”). Because the CSA “is a Congressional Act to protect the public health, the United States only needs to establish that [Defendants] violated the statute and there is some cognizable danger of recurrent violation.” *United States v. S. Serra Cheese Co.*, 2015 WL 6156961, at *6 (E.D. Mich. Oct. 20, 2015); *see, e.g., City of Painesville*, 644 F.2d at 1193-94; *United States v. Am. Mercantile Corp.*, 889 F. Supp. 2d 1058, 1083 (W.D. Tenn. 2012).

Regardless of the test, the United States must prove – and the attached evidence sufficiently demonstrates – that Defendants violated the CSA by abdicating their corresponding responsibility and filling prescriptions for controlled substances that they knew or had reason to know lacked a

legitimate medical purpose, and there is a danger that Defendants will continue their CSA violations and further harm the public. To protect Defendants' customers and the public, the Court should issue a TRO immediately.

ARGUMENT

I. Defendants Violated 21 U.S.C. § 842(a)(1) by Knowingly Distributing or Dispensing Controlled Substances without a Valid Prescription

On at least 150 occasions in 2018, and hundreds and likely thousands of times over the past three years, Defendants dispensed controlled substances in violation of 21 U.S.C. § 842(a)(1). Section 842(a)(1) makes it unlawful for a person “subject to the requirements of part C to distribute or dispense a controlled substance in violation of section 829 of this title.” Part C of the CSA encompasses the CSA’s registration provisions and a host of others, including the prescription requirements in 21 U.S.C. § 829. *See generally* 21 U.S.C. §§ 821-31 (Part C of the CSA).

Subject to two exceptions not relevant to this case, Sections 829(a) and (b) generally require that no controlled substance in schedules II, III, or IV be dispensed except upon a practitioner’s “prescription.” A prescription issued without “a legitimate medical purpose” and outside “the usual course of [] professional practice” is not a lawful prescription. 21 C.F.R. § 1306.04(a); *see Volkman*, 797 F.3d at 392. Concomitant with a physician’s responsibility to properly prescribe controlled substances, a pharmacist bears a “corresponding responsibility” for ensuring “the proper . . . dispensing of controlled substances.” 21 C.F.R. § 1306.04(a). A pharmacist who knowingly fills an unlawful prescription violates their corresponding responsibility and the CSA. *Id.*; *see United States v. Darji*, 609 F. App’x 320, 333 (6th Cir. 2015) (observing, in part, that 21 C.F.R. § 1306.04(a) “clearly defines the pharmacist’s responsibilities that give rise to conduct that constitutes an unlawful distribution of a prescription drug”).

Here, Defendants routinely filled prescriptions for large quantities of powerful opioids and other controlled substances that they knew or had reason to know lacked any legitimate medical purpose. Thus, and as described below, Defendants violated § 842(a)(1) of the CSA because: (1) they were subject to the relevant CSA requirements; (2) they distributed or dispensed controlled substances that are prescription drugs under the Federal Food, Drug, and Cosmetic Act; and (3) they did so despite knowing or remaining deliberately ignorant that the underlying prescriptions lacked a legitimate medical purpose.

A. Defendants Are Subject to Part C of the CSA

Section 842(a)(1)'s applicability to "any person . . . who is subject to the requirements of part C" of the CSA simply refers to those persons whose activities are governed or affected by the requirements imposed throughout Part C of the CSA. *See* 21 U.S.C. §§ 821-31. Section 842(a)(1) applies to both registrants and non-registrants. *See Moore*, 423 U.S. at 134 n.11 (observing that section 842(a)(1) reaches non-registrants); *United States v. City Pharmacy, LLC*, 2016 WL 9045859, at *2 (N.D. W. Va. Dec. 19, 2016) (same); *United States v. Stidham*, 938 F. Supp. 808, 813-14 (S.D. Ala. 1996) (finding that owner of methadone clinic was liable for CSA violations); *but see United States v. Anderson*, 271 F. Supp.3d 950, 958 (M.D. Tenn. 2017) (finding that the United States' amended complaint did not sufficiently allege that a defendant-shadow owner, who was not the named owner in fact, of pain clinics that functioned as Pill Mills had dispensed illegal controlled substances to ultimate users under 21 U.S.C. § 829). Here, by virtue of the activities and involvement of each Defendant in filling prescriptions, Defendants here are governed by Part C.

Xpress and Dale Hollow pharmacies are DEA registrants and certainly subject to Part C.

See, e.g., 21 U.S.C. § 822(b) (requiring that pharmacy registrants may only dispense controlled substances “to the extent authorized by their registration and in conformity with the other provisions of” the CSA). As the pharmacists employed by Xpress and Dale Hollow and who unlawfully filled the prescriptions at issue here, Griffith, Polston, and Larkin must comply with the CSA, including its corresponding responsibility requirement. *See United States v. City Pharmacy, LLC*, 2017 WL 1405164, at *4 (N.D.W. Va. Apr. 19, 2017) (holding “licensed pharmacist in charge” of two pharmacies liable under section 842(a)(1) for “repeatedly fill[ing] prescriptions for controlled substances that were not valid); *United States v. Williams*, 416 F. Supp. 611, 614 (D.D.C. 1976) (holding pharmacist liable under § 842(a)(1) for unlawfully filling prescriptions). So too is Weir liable as the primary owner and ultimate authority for Xpress and Dale Hollow’s operations. *See City Pharmacy*, 2016 WL 9045859, at *3 (holding that pharmacy owner who “was actively involved in the management of the pharmacies” may be liable under section 842(a)(1)).

B. Defendants Distributed or Dispensed Controlled Substances that Are Prescription Drugs

The CSA defines both “distribute” and “dispense” to include the delivery – “the actual, constructive, or attempted transfer” – of a controlled substance to a patient. *Compare* 21 U.S.C. § 802(11) (defining “distribute” as “to deliver (other than by administering or dispensing) a controlled substance”) *and* 21 U.S.C. § 802(10) (defining “dispense” as including “to deliver a controlled substance to an ultimate user . . . by, or pursuant to the lawful order of, a practitioner”), *with* 21 U.S.C. § 802(8) (defining “deliver”). A pharmacist’s filling of a prescription order clearly constitutes distributing or dispensing under the CSA. Each controlled substance dispensed is also a prescription drug under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*

C. Defendants Violated their Corresponding Responsibility by Distributing or Dispensing Controlled Substances When They Knew or Had Reason to Know That There Was No Legitimate Medical Purpose to Do So

Pharmacists exercise a “corresponding responsibility” for the proper dispensing of controlled substances and must not knowingly fill an unlawful prescription. 21 C.F.R. § 1306.04(a). If a pharmacist “knows or has reason to know that the prescription was not written for a legitimate medical purpose,” then she must not fill the prescription. *Med. Shoppe-Jonesborough*, 300 F. App’x at 412 (quoting *Medic-Aid Pharmacy*, 55 Fed. Reg. 30,043, 30,044 (DEA July 24, 1990)). A pharmacist who “fills a prescription notwithstanding her actual knowledge that the prescription lacked a legitimate medical purpose” or who “was willfully blind or deliberately ignorant to the fact that the prescription lacked a legitimate medical purpose” violates the corresponding responsibility requirement. *Pharmacy Doctors Enterprises*, 83 Fed. Reg. 10,876, 10,896 (DEA Mar. 13, 2018); *see, e.g., United States v. Lawson*, 682 F.2d 480, 482 (4th Cir. 1982) (stating that a pharmacist illegally distributed controlled substances when the pharmacist “deliberately closed his eyes to the true nature of the prescription”).

Pharmacists must “use common sense and professional judgment” in carrying out their corresponding responsibility. *Med. Shoppe-Jonesborough*, 300 F. App’x at 412 (quoting *Ralph J. Bertolino*, 55 Fed. Reg. 4,729, 4,730 (DEA Feb. 9, 1990)). Frequently that means scrutinizing prescriptions for red flags, or signs of illegitimacy. A red flag is “a circumstance arising during the presentation of a prescription which creates a reasonable suspicion that the prescription is not, on its face, legitimate.” *City Pharmacy*, 2017 WL 1405164, at *4; *see Lawson*, 682 F.2d at 483 n.6 (citing approvingly expert pharmacist testimony about “the flags of illegitimacy . . . which would signal a pharmacist that the prescriptions were not legitimate”).

When a red flag or combination of red flags arouses or should arouse a pharmacist’s

suspicious, he must “at least verify the prescription’s propriety.” *Med. Shoppe-Jonesborough*, 300 F. App’x at 412. A pharmacist who tries to verify a prescription’s propriety but is “not satisfied by the answer . . . must ‘refuse to dispense.’” *Id.* (quoting *Ralph J. Bertolino*, 55 Fed. Reg. at 4,730). And equally, a pharmacist cannot simply ignore red flags and make no attempt to resolve them before filling a prescription. *See, e.g., Jones Total*, 881 F.3d at 830 (affirming DEA determination that pharmacy violated 21 C.F.R. § 1306.04(a) by unlawfully filling prescriptions with “at least one red flag that Jones Pharmacy did not attempt to resolve and that could not have been resolved”); *Med. Shoppe-Jonesborough*, 300 F. App’x at 413 (concluding that pharmacy violated its duties under the CSA when prescriptions “should have raised red flags” and pharmacy “fill[ed] these prescriptions anyway”).

A pharmacist’s conduct is evaluated objectively against “the usual course of ... professional practice.” 21 C.F.R. § 1306.06; *see, e.g., United States v. Joseph*, 709 F.3d 1082, 1097 (11th Cir. 2013) (“We have held that whether a defendant acts in the usual course of his professional practice must be evaluated based on an objective standard, not a subjective standard.”). The inquiry is informed by state pharmacy rules and regulations. *See Med. Shoppe-Jonesborough*, 300 F. App’x at 413 (considering pharmacists’ responsibilities under Tennessee law “to prevent improper prescriptions from being filled” when reviewing whether pharmacy violated its federal corresponding responsibility); *Brown*, 982 F. Supp. 2d at 802-03 (same); *see also United States v. Brown*, 553 F.3d 768, 790-91 (5th Cir. 2008) (concluding that handbook of Texas pharmacy laws and regulations, in criminal prosecution of pharmacists for unlawful dispensing, was relevant to whether pharmacists’ suspicious should have been aroused about prescriptions’ illegitimacy). And it incorporates notions of “common sense and professional judgment.” *Med. Shoppe-*

Jonesborough, 300 F. App'x at 412 (quotation omitted).

As described below, Defendants' filling of prescriptions fell far below the standards of professional practice. The United States' expert pharmacist, Dr. Carl Gainor, reviewed records related to scores of prescriptions filled by Defendants and found that the conduct of the Dale Hollow and Xpress pharmacists in dispensing the prescriptions summarized in his declaration deviated from the accepted standards of the professional practice of pharmacy. *See* Declaration of Carl Gainor ("Gainor Decl.") (filed separately).

II. Alternatively, Defendants Violated 21 U.S.C. § 841(a)(1) by Knowingly and Intentionally Distributing and Dispensing Controlled Substances outside the Usual Course of Pharmacy Practice

Defendants' conduct alternatively constitutes a violation of 21 U.S.C. § 841(a)(1). Section 841(a)(1) makes it unlawful for any person, except as authorized by the CSA, to knowingly or intentionally distribute or dispense a controlled substance. "Pharmacists . . . are protected from liability when they dispense controlled substances in the course of professional practice." *United States v. Hughes*, 895 F.2d 1135, 1143 n.11 (6th Cir. 1990). The regulations implementing the CSA similarly require 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 (emphasis added); *see United States v. Seelig*, 622 F.2d 207, 210-11 & n.1 (6th Cir. 1980) (holding, in prosecution of pharmacists under section 841(a)(1), that "a violation of the promulgated rules constitutes an unlawful act under the Controlled Substances Act").

Here, regardless of the corresponding responsibility in 21 C.F.R. § 1306.04(a), Defendants distributed or dispensed controlled substances outside the usual course of the professional practice of pharmacy. As Dr. Gainor explains, significant red flags exist in controlled substance prescriptions filled by Dale Hollow and Xpress, such that Defendants filled those prescriptions in

violation of their corresponding duty and outside of the usual course of the professional practice of pharmacy. *See generally* Gainor Decl. at ¶¶ 24 & 32. The unresolved red flags included combinations of dangerous opioids known for potential abuse, high dosage levels of opioids, long distances travelled by patients presenting prescriptions, insufficient diagnoses to support certain prescriptions, cash payments, fills of brand names rather than generic medications, family groups receiving similar controlled substance regimes, doctor shopping, and pharmacy shopping. Dr. Gainor even identified an unsigned prescription for a controlled substance that Dale Hollow filled, which was a facially invalid dispensation. *See id.* ¶ 26. Thus, the evidence shows that Defendants acted outside the usual course of pharmacy practice. Accordingly, their distribution and dispensation of controlled substances violated section 841(a)(1).

III. An Injunction Is Necessary to Prevent Defendants from Unlawfully Distributing and Dispensing Controlled Substances and the Harm Resulting Therefrom

Tennessee pharmacists must “hold the health and safety of patients to be the first consideration and render to each patient the full measure of the pharmacist’s ability as an essential health practitioner.” Tenn. Comp. R. & Regs. 1140-02-.01(1) (2017). Tennessee pharmacists also must utilize their “education, skill, experience, and professional judgment” to “make every reasonable effort to prevent the abuse of drugs which the pharmacist dispenses.” *Id.* 1140-02-.01(10). Defendants failed to abide by those professional commands.

Over the past three years, Defendants filled at the very least hundreds and likely thousands of illegal prescriptions for controlled substances at Dale Hollow and at Xpress, including the opioids oxycodone and buprenorphine. It also appears that Defendants are continuing to fill controlled substance prescriptions through 2019 for the majority of patients for whom Dr. Gainor concluded that past controlled substance prescriptions were improperly and illegitimately

dispensed by Defendants. *See* Rogers Decl. at 10 & D’Antoni Decl. at 5. By illegally filling prescriptions, Defendants “put public health and safety at risk.” *Med. Shoppe-Jonesborough*, 300 F. App’x at 413. The equities strongly favor this Court’s enjoining Defendants from distributing or dispensing any controlled substances.¹

A. Defendants’ Unlawful Filling of Prescriptions Harms the Community

1. Defendants Have Contributed to the Opioid Crisis in Tennessee

In 2016 alone, 116 Americans died each day from an opioid-related overdose and 11.5 million Americans misused prescription opioids, 2.1 million of them for the first time. Compl. ¶ 15. Within Tennessee, in 2017, 644 people died of an unintentional overdose. Compl. ¶ 24. Of those, 58% received an opioid prescription in the previous 30 days. Defendants have contributed to this crisis. For example, two Xpress customers – patient E and F – tragically died shortly after filling two or more controlled substance prescriptions from Xpress. *See* Gainor Decl. at 13-14. Further, Dale Hollow filled multiple prescriptions for the “particularly dangerous” combination drug cocktail known as the “Trinity.” *Id.* at 11-12.

2. The Scope of Defendants Unlawful Conduct Likely Exceeds the Prescriptions Currently Known to the United States

While the prescriptions illegally filled by Defendants set forth in this memorandum are significant, the scope of the harm likely far exceeds that alleged here. Tennessee Controlled Substance Monitoring Data indicates that Dale Hollow and Xpress filled more than 20,000

¹ The DEA is separately considering issuance of an Immediate Suspension Order (“ISO”) pursuant to 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36€ and the authority granted to DEA under 28 C.F.R. § 0.100 for the DEA registration numbers of Dale Hollow and Xpress. If issued, such orders would only apply to suspend the two Defendant pharmacies’ DEA registration number, but would not restrain anything with regard to the individual Defendants. An ISO is an administrative remedy subject to administrative process and challenges and may lack the finality of the injunctive relief sought in this lawsuit.

controlled substance prescriptions in 2018 alone. *See* Rogers Decl. at 10 and D’Antoni Decl. at 5.

IV. The Relief Requested Is Tailored to Defendants’ CSA Violations and the Harm Caused by Them

This Court has ample authority to enjoin the Defendants based on their CSA violations. *See* 21 U.S.C. §§ 843(f) and 882(a); *see also De Beers Consol. Mines v. United States*, 325 U.S. 212, 220 (1945) (“A preliminary injunction is always appropriate to grant intermediate relief of the same character as that which may be granted finally.”). An injunction under section 843(f) should be “tailored to restrain” the CSA violations. 21 U.S.C. § 843(f)(3).

Courts have previously enjoined registrants who violated the CSA and limited their ability to further deal in controlled substances. *See Advance Pharm., Inc. v. United States*, 391 F.3d 377, 390, 400 (2d Cir. 2004) (injunction against pharmaceutical company); *United States v. Salcedo*, 2003 WL 21196843, at *1 (E.D.N.Y. Feb. 19, 2003) (injunction against physician); *United States v. Chemicals for Research & Industry*, 10 F. Supp. 2d 1125, 1130 (N.D. Cal. 1998) (preliminary injunction against company); *see also United States v. Oakland Cannabis Buyers’ Co-op.*, 532 U.S. 483, 496 (2001). Defendants repeatedly and unlawfully filled prescriptions for controlled substances and should be enjoined from further dealing in those substances.

V. The TRO Should Be Issued Without Notice

Federal Rule of Civil Procedure 65 permits a court to issue a temporary restraining order without notice only if “specific facts . . . clearly show that immediate and irreparable injury, loss, or damage will result to the movant.” Fed. R. Civ. P. 65(b)(1)(A); Local Rule 65.01(c).

On February 8, 2019, the United States anticipates executing search warrants to obtain certain dispensing records, files and evidence of illegal conduct located at Dale Hollow and Xpress

pharmacies. If Defendants are provided advance notice of this action and the United States' request for temporary restraining order, they may take steps to alter, delete, or destroy records within their possession, custody, or control related to their unlawful dispensing, causing irreparable harm to the United States. The United States anticipates notifying Defendants of this action and order during the search warrant executions. The United States thus requests this TRO be issued without advance notice and further asks that the Court Order Defendants to preserve all records related to dispensing practices. *See Gen. Ret. Sys. of the City of Detroit v. Onyx Capital Advisors, LLC*, 2010 WL 2231885, at *3-4 (E.D. Mich. June 4, 2010).

CONCLUSION

The United States has established that Defendants have repeatedly and routinely violated the CSA, and that unless enjoined will continue to do so to the great detriment of their customers and the public. The evidence presented establishes that the United States has fully met its burden to obtain the requested injunctive relief.

Therefore, based on the above, pursuant to the CSA, Federal Rule of Civil Procedure 65(a) and (b), and Local Rule 65.01, a temporary restraining order without notice and a preliminary injunction should be issued to enjoin Defendants from distributing or dispensing any controlled substances, to surrender all controlled substances in their possession to the DEA, and from destroying or otherwise making unavailable to the United States any documents related to their distribution or dispensation of controlled substances.

Respectfully submitted,

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CERTIFICATE OF SERVICE

No service was made upon Defendants at this time because this motion was made ex parte and under seal. I hereby certify that, when the seal is lifted, the United States will serve a copy on Defendants.

s/ Ellen Bowden McIntyre
ELLEN BOWDEN MCINTYRE
Assistant United States Attorney