UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA	§	
	§	
Plaintiff,	§	
	§	
v.	§	SA: 5:22-cv-00047
	§	
ZARZAMORA HEALTHCARE LLC,	§	
RITE-AWAY PHARMACY &	§	
MEDICAL SUPPLY #2, and	§	
JITENDRA CHAUDHARY	§	
	§	
Defendants.	§	

MOTION FOR PRELIMINARY INJUNCTION

Pursuant to the Controlled Substances Act, 21 U.S.C. §§ 822(a), 843(f), and Rule 65 of the Federal Rules of Civil Procedure, the United States of America ("the United States") seeks a preliminary injunction and other equitable relief to prevent Defendants Zarzamora Healthcare LLC ("Zarzamora"), Rite-Away Pharmacy & Medical Supply #2 ("Rite-Away"), and Jitendra Chaudhary ("Defendant Chaudhary") (collectively "the Defendants") from committing further violations of the Controlled Substances Act ("CSA"). The sworn Declarations of DEA Investigators Leroy Hartley ("Hartley Decl."), Carla Ramirez ("Ramirez Decl."), and Ron Redmon ("Redmon Decl.") are attached in support of this motion, along with evidentiary exhibits and the sworn Declaration of Dr. Amy Witte, Pharm.D. ("Witte Decl.").

INTRODUCTION

Opioid abuse is dangerous and can be deadly. Pharmacies and pharmacists are critical gate-keepers the legitimate distribution of controlled substances like opioids. Defendants unlawfully dispensed controlled substances pursuant to prescriptions with no legitimate medical purpose and not issued in the usual course of professional practice. Defendants betrayed the

professional practice of pharmacy and have violated the Controlled Substances Act ("CSA"). The United States filed this case to stop Defendants' unlawful distribution of controlled substances and seeks a preliminary injunction to protect the public while the action is pending.

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 effects on the body." *Raich*, 545 U.S. at 13; *see* 21 U.S.C.§ 812 (schedules I through V). The CSA requires those who manufacture, distribute, or dispense controlled substances, including pharmacies, to obtain a registration from the United States Drug Enforcement Administration. *See* 21 U.S.C. §§ 802(21) and 822(a).

DEA registrants are required to comply with the CSA and its implementing regulations. This includes record-keeping requirements, *see* 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.21(a), and notification requirements for any theft or significant loss of any controlled substances within one-business day, *see* 21 U.S.C. § 830(b)(1)(c); 21 CFR§ 1301.74(c). Failure to do so constitutes a violation of 21 U.S.C. § 842(a) and associated regulations.

The CSA's prescription requirement confers a responsibility on pharmacists to ensure that the controlled substances they distribute or dispense are for a legitimate medical purpose. 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." 21 C.F.R. § 1306.04(a). A pharmacist must act in the usual course of his or her

professional practice as a pharmacist when filling a prescription. 21 C.F.R. § 1306.06. This means that a pharmacist may dispense a controlled substance only in accord with a generally accepted, objective standard of pharmacy practice and only when a prescription is issued for a legitimate medical purpose. This also means complying with relevant state law related to the general practice of pharmacy and, in particular, related to dispensing controlled substances.

II. FACTS SUPPORTING INJUNCTIVE RELIEF

Defendant Chaudhary works at Rite-Away as the pharmacist in charge (Texas pharmacist license #44855), and also holds an ownership interest in Defendant Zarzamora. Defendant Zarzamora, in turn, is a business entity that owns Defendant Rite-Away. Defendant Rite-Away, located at 2716 SW Military Drive, Suite 102, San Antonio, Texas 78224, is a retail pharmacy registered with DEA under DEA Registration Number FR2421496. Defendants have acted unlawfully in dispensing controlled substances in violation of the CSA and have taken steps to conceal their unlawful dispensing practices in further violation of the CSA.

A. Defendants Failed to Keep Required Records and Altered Prescriptions

DEA investigators inspected Rite-Away on September 18, 2014. At the conclusion of the inspection, Defendants were notified of several record-keeping violations related to missing information regarding numerous controlled substance prescriptions and inventory. Defendants were provided formal written notification of the record-keeping violations via a DEA Warning Letter on October 10, 2014. (Exhibit 1). Defendant Chaudhary responded to the DEA Warning Letter on October 27, 2014 on behalf of Defendant Rite-Away and promised to take corrective action. (Exhibit 1).

On August 17, 2018, DEA inspected Rite-Away once again and found numerous instances in which the pharmacy failed to keep accurate records, which were reflected in significant

discrepancies between a controlled substances inventory logs and a physical count. (Exhibits 2, 3). Despite earlier representations of corrective action, the inspection revealed inventory shortages totaling 44,958 dosage units or pills among five different controlled substances compared with written records over a one-year audit period. (Exhibit 3).

On August 17, 2018, the DEA also identified 50 prescriptions for controlled substances which Defendants filled even though the written prescriptions did not conform in essential respects to the law and regulations. (Exhibit 4). Given the discrepancies, these prescriptions should not have been filled.

On April 30, 2019, representatives from DEA and the United States Attorney's Office met with Defendant Chaudhary and his legal counsel to address the above-referenced violations. During the meeting, the DEA and USAO representatives expressly stated that the above conduct constituted violations of the Controlled Substance Act.

On August 6, 2019, Inspector Jim Clark with the Texas State Board of Pharmacy conducted a routine inspection of Rite-Away. Defendant Chaudhary signed the Notice of Inspection as the Pharmacist-In-Charge. Inspector Clark noted that Rite-Away was filling controlled substance prescriptions that lacked information required under federal law and regulations. (Exhibit 5).

On October 16, 2019, the government notified Defendant Chaudhary through counsel that on the following day, DEA agents would visit Rite-Away to pick up the 50 original, hard-copy prescriptions identified as lacking required information under the law and regulations during the 2018 Inspection. On October 17, 2019, DEA Investigators Hartley and Ramirez entered Rite-Away and observed Defendants' employees in the process of deliberately altering controlled substance prescriptions, including the 50 sought by the investigators. (Hartley Decl. at ¶¶1-3; Ramirez Decl. at ¶¶ 2, 3). Defendants' conduct resulted in the alteration of the 50 original

prescriptions sought and an additional 192 defective prescriptions. (Exhibit 6). All of these 242 altered controlled substance prescriptions had been filled for members of the public despite the lack of required information.

On October 12, 2021, Inspector Jim Clark with the Texas State Board of Pharmacy conducted another routine inspection of Rite-Away. Defendant Chaudhary signed the Notice of Inspection as the Pharmacist-In-Charge once more. The public inspection report contains comments included concerns as to controlled substances corresponding responsibility; Defendants were "[a]dvised to dispense only prescriptions for a legitimate medical purpose, starting immediately…" (Exhibit 7).

B. Rite-Away Pharmacy Unlawfully Distributed or Dispensed Controlled Substances in Violation of the CSA

Defendants knowingly filled prescriptions for controlled substances despite indicia, commonly called "red flags," that the prescriptions were not issued for a legitimate medical purpose by a practitioner acting in the usual course of practice. Those red flags indicated that the controlled substances the pharmacy dispensed were not for legitimate medical purposes.[1] By ignoring or failing to resolve the red flags, Defendants failed to exercise independent professional judgment in determining the validity of the prescriptions that were presented and violated the CSA when it knowingly filled purported prescriptions under these circumstances.

[1] The Texas State Board of Pharmacy's "Red Flags" Checklist for Pharmacies, "You Might Be a Pill Mill If" publication contains 23 possible indicators and recommends a pharmacist who identifies any occurring at their pharmacy "review the laws and rules regarding non-therapeutic dispensing, especially Board rule § 291.29 in the law book or on [the Board of Pharmacy's] website… Failure of pharmacies and pharmacists to detect patterns of inappropriate dispensing of prescription drugs is unprofessional practice and constitutes grounds for disciplinary action." Copies of this Checklist were provided to the Defendants at each inspection by Inspector Clark; Defendant Chaudhary signed an acknowledgment of review of this Checklist in each inspection and the acknowledgement appears with both Inspection Reports (Exhibits 5 and 7).

Under the Texas Pharmacy Act, a pharmacist must evaluate all new and refill prescriptions for medical appropriateness given each patient's unique circumstances. Pharmacists must be vigilant for risks of patient harm from improper drug-drug interactions, contraindications, duration of use, or other circumstances. Witte Decl. at 10. The standard of care for the practice of pharmacy requires pharmacists to recognize signs of illegitimate prescriptions, drug diversion, or abuse, which are commonly known as "red flags." Witte Decl. at 11, 12. Red flags may include, among other factor, the amount, strength, or combination of controlled substances prescribed; repeated prescriptions for the same drugs, quantities, and strengths from the same doctor, i.e., "pattern prescribing"; customers traveling long distances to fill controlled substance prescriptions; customers living at the same address and filling the same prescriptions; and customers paying cash. Witte Decl. at 12. The standard of care also requires that pharmacists consider, evaluate, and resolve any red flags before dispensing prescription drugs. Witte Decl. at 12, 14, 15. The prescriber, the patient, or the prescription may present a red flag. Witte Decl. at 12

Defendants knowingly filled prescriptions for controlled substances that they knew raised numerous red flags, which Defendants failed to resolve or ignored. Witte Decl. at 19, 35. Those red flags indicated that the prescriptions being presented to the pharmacy were not being filled for legitimate medical purposes. Witte Decl. at 19, 34, and 35. By filling these prescriptions without resolving the readily apparent red flags, the Defendants failed in their duty to exercise independent professional judgment in determining the validity of the prescriptions presented. Witte Decl. at 35. In particular, Defendants repeatedly filled prescriptions that raised obvious red flags, such as:

- a lack of individual drug therapy, including "pattern prescribing" in which a physician writes the same prescriptions for many patients, a patient receives the same controlled substances over and over again with no adjustments or changes

in therapy, or multiple individuals residing at the same household receive the same or substantially similar controlled substance prescriptions;

- prescribers who routinely or almost exclusively prescribe controlled substances known to be abused, including opioids, benzodiazepines, muscle relaxers, psychostimulants, and/or cough syrups containing codeine, or combinations of such drugs;
- controlled substance prescriptions with non-specific diagnoses or no diagnoses indicated, or with the intended use of the drug omitted;
- information indicating unusual geographic distances between a patient's home address and the pharmacy, or prescriber, or both. Witte Decl. at 34, 35.

C. Patient-Specific Examples Demonstrate that Defendants Ignored Red Flags and Unlawfully Distributed or Dispensed Controlled Substances

Defendants' own records, as reviewed by an independent expert in the practice of pharmacy, show that Rite-Away and Chaudhary dispensed controlled substances to individuals without resolving significant red flags of abuse or diversion. Witte Decl. at 19-35.

Patient M.P.

Patient M.P. presented to Rite-Away prescriptions for a high volume of opioids, fentanyl, and benzodiazepines from multiple prescribers, which is itself a red flag. Witte Decl. at 20. The patient's pharmacy records did not clearly specify a condition or indication to warrant the use of narcotics, benzodiazepines, or fentanyl patches. *Id.* The pharmacist dispensing the controlled substances to M.P. knew or should have known that the dosages and combinations posed serious risks. *Id.* Further, the pharmacist knew or should have known that these medications were not for a legitimate medical purpose and should not have been filled. *Id*. Any reasonable pharmacist

would recognize these circumstances as an indication that the controlled substance prescriptions presented were not for a legitimate medical purpose. *Id.*

According to medical examiner records, M.P. suffered a fatal fentanyl overdose on September 11, 2017, nine days after Defendant Rite-Away filled her latest prescription for fentanyl. Witte Decl. at 20.

Patients T.B. and R.B.

Patients T.B. and R.B. (a married couple) each presented to Rite-Away prescriptions for high volumes of oxycodone and hydrocodone by multiple providers. Witte Decl. at 22, 23. Both patients received the same strength, quantity, and directions for use of the narcotics. *Id.* These red flags were raised independently for each individual, and additionally demonstrate a lack of individualized therapy. *Id.* Defendants knew or should have known that the controlled substance prescriptions dispensed to T.B. and R.B. were not for a legitimate medical purpose and, and Defendants should not have filled them. *Id*. Any reasonable pharmacist would know that these controlled substance prescriptions were not for a legitimate medical purpose. *Id*.

Patients J.C. and N.C.

Patients J.C. and N.C. are also a married couple. Witte Decl. at 24, 25. J.C. presented to Rite-Away a high volume of oxycodone and OxyContin prescriptions. Witte Decl at. 24. J.C. received prescriptions for both the brand name and generic versions of these drugs from the same doctor, Dr. A.H., on the same day, which is a red flag. *Id*. The pharmacy's records show that J.C. obtained narcotic prescriptions from different providers each month, which is another red flag. *Id.* For example, in October 2018, Dr. A.H. supplied J.C. with a prescription for 30-day supplies of oxycodone 30 mg and OxyContin 60 mg. In November 2018, Dr. S.G. supplied the same

prescriptions to J.C. *Id*. The Dr. A.H. also prescribed Narcan to J.C. *Id.* Narcan is an opioid antagonist and is designed to reverse the effects of an opioid overdose. Witte Decl. at 32.

J.C.'s wife, N.C., also presented to Rite-Away a high volume of prescriptions for oxycodone, OxyContin, and fentanyl. Witte Decl. at 25. Like J.C., N.C. received both brand name and generic oxycodone prescriptions from Dr. A.H. and Dr. S.G. on the same day, which raises multiple red flags indicated by the doses, overlapping therapy, and multiple prescribers. *Id*. N.C. also presented to Rite-Away a Narcan prescription. *Id*. The pharmacy's records noted no clinical purpose for benzodiazepines to be prescribed to N.C. *Id*. The records also showed N.C. used different providers each month for narcotic prescriptions. *Id*. For instance, N.C. obtained prescriptions for oxycodone, OxyContin, and fentanyl from Dr. A.H. in July 2018. The following month, another Dr. S.G. prescribed the patient oxycodone and methadone. *Id.*

The lack of individualized therapy for J.C. and N.C. raised another red flag regarding their prescriptions. Witte Decl. at 24, 25. N.C. and J.C. both received narcotics prescriptions with the same strength, quantity, and directions for use. *Id*. The Defendants failed to identify or document a resolution to any of these red flags. *Id*. Any reasonable pharmacist would know that the controlled substance prescriptions presented by J.C. and N.C. were not for a legitimate medical purpose. *Id*.

Patient L.W.

Patient L.W. presented to Rite-Away prescriptions for hydrocodone, oxycodone, and alprazolam from Dr. A.H. and Dr. S.G., raising significant red flags regarding drug combinations, doses, and multiple prescribers. Witte Decl. at 33. The prescriptions by those same two doctors also lacked individualized drug therapy for L.W., that is, L.W. received the same drug, strength, and directions for use as other patients seen by the doctors, as reflected in other prescriptions filled

by Rite-Away. *Id*. L.W. also was prescribed Narcan. *Id*. Several of the alprazolam prescriptions lacked indications for use or a diagnosis. *Id*. The Defendants failed to identify or document resolutions to these numerous red flags. *Id*. Any reasonable pharmacist would know that the controlled substance prescriptions presented by L.W. were not for a legitimate medical purpose. *Id.*

Patient B.O.

Patient B.O. presented to Rite-Away hydrocodone, oxycodone, morphine and benzodiazepine prescriptions written by three different doctors, Dr. A.H., Dr. S.G., and Dr. D.C., raising significant red flags regarding drug combinations, doses, and multiple prescribers. Witte Dec. at 32. The pharmacy's records also show that B.O.'s morphine prescription lacked an indication for use. *Id*. In addition, Dr. A.H. also prescribed Narcan to B.O. *Id*. Based on pharmacy records, Defendants failed to identify or document a resolution to these red flags. *Id*. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose. *Id*.

Patient Y.A.

Patient Y.A. presented to Rite-Away excessive prescriptions for multiple short- and long-acting narcotics written by Dr. A.H. and Dr. S.G., a red flag that the pharmacy did not resolve. Witte Decl. at 21. Additionally, there was no indication for use on multiple schedule II prescriptions documented in the pharmacy's records. *Id*. Patient Y.A. was receiving substantially similar controlled substance prescriptions as many other patients from the same doctors, which is also a red flag because it reflects a lack of individualized therapy. *Id*. The prescriptions presented by Y.A. also suggested that the patient was using multiple providers to obtain multiple prescriptions (known as "prescription shopping"), which presents a red flag. *Id*. For example,

Y.A. presented a prescription from Dr. S.G., dated September 25, 2017, for a 30-day supply of Embeda (naltrexone and morphine). *Id*. Patient Y.A. also presented another prescription from Dr. A.H. with the same date for a 30-day supply of oxycodone. *Id*. Defendants knew or should have known that the controlled substance prescriptions dispensed to Y.A. were not for a legitimate medical purpose and should not have been filled. *Id*. Any reasonable pharmacist would recognize the above circumstances as an indication that the controlled substance prescriptions presented were not for a legitimate medical purpose. *Id*.

Patient C.F.

Patient C.F. presented to Rite-Away monthly prescriptions for opioids, benzodiazepines, and amphetamines from different providers, raising several red flags. Witte Decl. at 30. It is a red flag when a customer receives controlled substance prescriptions from multiple providers. *Id*. The combination of opioids and benzodiazepines also poses a significant risk of respiratory depression and overdose. *Id*. The addition of amphetamines, another schedule II controlled substance prone to abuse, raises yet another red flag. *Id*. Defendants' records do not document any indication for use for the prescriptions, and also demonstrate that the pharmacy failed to identify or document a resolution to these red flags. *Id*. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose. *Id*.

Patient M.L.

Patient M.L. presented to Rite-Away hydrocodone and methadone prescriptions from Dr. A.H, Dr. S.G., and Dr. D.C. over time. Witte Decl. at 28. M.L's spouse, G.L., received substantially similar controlled substances from the same providers. *Id*. Additionally, M.L. received hydrocodone prescribed to be taken twice daily, which indicates a lack of legitimate

medical use because hydrocodone is a short-acting opioid, and two doses per day typically would not be sufficient to provide pain relief for a full day. *Id.* M.L. and G.L. traveled an unusual distance to Rite-Away Pharmacy in San Antonio, which was located approximately 3.5 hours' driving distance from their home. *Id.* The Defendants failed to identify or document a resolution to the above-described red flags. *Id.* Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose. *Id.*

Patients A.M. and J.M.

Patients A.M. and J.M., a married couple according to the pharmacy's records, both received prescriptions for opioids, benzodiazepines, and amphetamine every month from Dr. A.H., Dr. S.G., and Dr. D.C., which raises several red flags. Witte Decl. at 29. A.M. and J.M. each received a prescription for phentermine that was filled monthly from 2017 to 2019, which raises a red flag because phentermine is generally approved only for short-term use of no more than six weeks. *Id.* According to the pharmacy's records, there was no indication for use on the phentermine prescriptions. *Id.* Pharmacy records show that the Defendants failed to identify or document a resolution to these red flags. *Id.* Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose. *Id.*

Patient C.F.

Patient C.F. regularly presented to Rite-Away opioid prescriptions for both short- and long-acting opioids, including high volumes of oxycodone and hydrocodone. Witte Decl. at 26. A patient who fills mostly opioid prescriptions, particularly for high volumes of oxycodone and hydrocodone, presents a red flag. *Id.* C.F.'s prescriptions were issued by Drs. A.H., S.G., and

D.C. *Id*. The same prescribers exhibiting a pattern of writing substantially similar, high-dose prescriptions for opioids is a significant red flag. *Id*. According to pharmacy records, some of the Schedule II prescriptions lacked indications for use. *Id*. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose. *Id.*

Patient L.H.

Patient L.H. presented to Rite-Away prescriptions for two short-acting opioids, hydrocodone and oxycodone, written by Drs. A.H., S.G., and D.C. on a monthly basis. Witte Decl. at 27. Pharmacy records show that L.H. received from these doctors the same prescription drug strength, quantity, and directions for use as other patients of the same providers, which is a red flag. *Id*. The fact that L.H. received prescriptions for two immediate release, or short-acting opioids, is a another red flag. *Id*. Defendants failed to identify or document a resolution to these red flags. *Id*. Under these circumstances, any reasonable pharmacist would know that the controlled substance prescriptions presented were not for a legitimate medical purpose. *Id*.

ARGUMENT

Defendants violated 21 U.S.C. § 842(a)(1) by dispensing controlled substances in violation of 21 U.S.C. § 829 (Count 2) and violated 21 U.S.C. § 856 by maintaining a drug-involved premises (Count 5). *See* Compl. ¶¶ 1-108; 112-114; 122-125. The Court may grant injunctive relief under 21 U.S.C. § 843(f)(1) and 21 U.S.C. § 882(a) to enjoin Defendants from further violations. *See id*. ¶ 94. The United States seeks a preliminary injunction to prohibit the Defendants from dispensing or distributing Schedule II, III, or IV controlled substances during the course of this litigation.

The facts set forth above, and in the attached exhibits and declarations of DEA Supervisory Diversion Investigator Leroy Hartley, DEA Diversion Investigator Carla Ramirez, and pharmacy expert Dr. Amy Witte, establish that the Defendants' conduct violates the Controlled Substances Act. That conduct specifically included the unlawful dispensing of 242 prescriptions of controlled substances listed in Schedule II, III, or IV that did not conform with 21 U.S.C. § 503(b), in violation of 21 U.S.C. §§ 829(b) and 842(a)(1), and 21 CFR § 1306.05(f), and the unlawful alteration of 192 Schedule II, III, or IV controlled substance prescriptions to attempt to cover up the unlawful dispensing. Further, the Defendants unlawfully distributed controlled substances in violation of the CSA's requirement that pharmacists dispense controlled substances in accordance with their corresponding responsibility and in the usual course of professional pharmacy practice. The Defendants' well-documented unlawful conduct poses a significant risk to the public health through further diversion of controlled substances in the Western District of Texas. Therefore, this Motion for Preliminary Injunction should be granted.

I. LEGAL STANDARD

A court may grant injunctive relief under 21 U.S.C. § 843(f)(1) and 21 U.S.C. § 882(a) to address violations of the CSA. The statute empowers the United States to seek relief "tailored to restrain violations of this section or section 842 of this title." 21 U.C.S. § 843(f)(3). Here, the United States seeks to restrain Defendants' well-documented violations of 21 U.S.C. § 842(a)(1) related to unlawful dispensing, as alleged in Counts II and IV of the Complaint. *See* Compl. ¶¶ 1-108; 112-114; 118-121.

Traditionally, courts weighing a preliminary injunction motion consider whether the movant has established (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable harm in the absence of preliminary relief, (3) that the balance of equities tips in his

favor; and (4) that the injunction is in the public interest. *Miller v. Doe* 422 F.Supp.3d 1176, 1186-1187 (W.D. Tex. 2019); *Buchanan v. U.S. Postal Service* 508 F.2d 259, 266 (5th Cir. 1975).

In contrast to injunctive relief sought by private parties, "[w]hen 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), *citing Hecht Co. v. Bowles*, 321 U.S. 321, 330 (1944); *see also U.S. v. Edward Rose & Sons*, 246 F. Supp. 2d 744, 753 (E.D. Mich. 2003). As the CSA is "a Congressional Act to protect the public health, the Government only needs to establish that [the defendants] violated the statute and there is some cognizable danger of recurrent violation." *United States v. S. Serra Cheese Co.*, No. 14-13077, 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). Courts generally consider "several factors to determine the likelihood of future violations including, but not limited to (1) the isolated to repeated nature of the violations, (2) the defendant's recognition of the wrongful nature of his conduct, and/or (3) the likelihood that the defendant's occupation will present opportunities for future violations." *S. Serra Cheese Co*. 2015 WL 6156961 at *6; *citing Edward Rose & Sons*, 246 F. Supp. at 753-54.

II. THE EVIDENCE SHOWS THE DEFENDANTS VIOLATED THE CSA

The evidence demonstrates that the Defendants violated the CSA by unlawfully dispensing controlled substances, failing to maintain an accurate inventory of controlled substances, and deliberately altering controlled substance prescriptions. Defendants violated the trust granted to pharmacies and pharmacists under the law by failing in their duty to exercise professional judgment to ensure controlled substance prescriptions are for legitimate medical purposes and

dispensed in the usual course of professional pharmacy practice. Defendants' illegal conduct harmed numerous patients, including multiple patients specifically described here. The government seeks injunctive relief to protect the public health, as Congress envisioned in enacting the CSA.

A. Defendants' Conduct was Repetitive and Continuous

After receiving a Warning Letter issued by DEA in 2014, Defendants promised to take corrective action to address prescription and record-keeping violations. However, a 2018 inspection revealed that Defendants were still engaged in the same pattern of violations. Defendants were informed again in April 2019 of their CSA violations, yet a routine inspection by the Texas State Board of Pharmacy identified still more violations involving controlled substance prescriptions that lacked required information. In October 2019, DEA investigators actually caught Defendants' employees in the act of physically altering controlled substance prescriptions to conceal misconduct. Some of those prescriptions were dated as far back as March 2016, well before the 2018 inspection. As described above, a more recent analysis shows that the pharmacy has regularly dispensed powerful opioids and other controlled substances without a legitimate medical purpose and outside the usual course of professional pharmacy practice since at least 2017.

The timeline clearly shows the Defendants' conduct has been repetitive and continuous with no regard for the CSA requirements for registrants, the harm to patients, or the risk of harm to the public health.

III. DEFENDANTS' CSA VIOLATIONS WILL CONTINUE ABSENT INJUNCTIVE RELIEF

Defendants acknowledged their CSA violations in response to the 2014 DEA Warning Letter. They subsequently failed to track more than 44,900 dosage units of five different controlled substances over a one-year period, with no accounting for where those drugs ended up. Defendants

received specific instruction in August 2019 from state board of pharmacy regulators regarding their responsibility to ensure controlled substances were dispensed only for legitimate medical purposes. They then continued to engage in a pattern of filling unlawful prescriptions that resulted in harm to patients and contributed to one customer's death. When notified that DEA inspectors would be coming to retrieve certain prescriptions, Defendants took steps to alter and conceal their wrongdoing. Two years after they were thwarted in altering prescriptions, Defendants continue to fail in exercising their corresponding responsibility to ensure the prescriptions they dispense are for legitimate medical purposes.

The facts demonstrate that if left unchecked, Defendants will commit further violations of the CSA. Defendant Chaudhary, as the Pharmacist-in-Charge and as a part owner of the pharmacy, has filled controlled substance prescriptions without concern for his corresponding responsibility to ensure the prescriptions were for legitimate medical purposes. He has also ordered his staff to alter records to avoid the consequences of his actions. Defendants have demonstrated that their promises to remediate and even notice of imminent, on-site government inspections are insufficient to prevent recurrent violations. Absent injunctive relief, Defendants' violations will continue.

The equities and the government's interest in protecting the public health strongly favor this Court's enjoining the Defendants from dispensing controlled substances. Defendants' conduct has contributed to the opioid epidemic. Rather than uphold their responsibilities under the CSA to ensure controlled substances are dispensed only for legitimate medical purposes and track the controlled substances entrusted to them, the Defendants have repeatedly distributed controlled substance in violation of the prescription requirement by filling facially invalid prescriptions and

by knowingly dispensing or distributing purported prescriptions that lack a legitimate medical purpose.

Rather than resolve red flags or reject prescriptions with red flags as non-legitimate, the Defendants filled and dispensed such prescriptions regardless of the harm to individual patients or to the community. Rather than maintain a complete and accurate inventory of the controlled substances in their possession, the Defendants allowed more than 44,900 dosage units of controlled substances to go missing. Rather than reject prescriptions for controlled substances that lacked required information under the CSA, or require patients return to their prescribing practitioner to have the prescription reissued correctly, the Defendants filled and unlawfully dispensed such prescriptions without regard to the law. When confronted, the Defendants chose to alter prescriptions in an ill-conceived attempt to conceal their conduct. Despite twice being notified by the Texas State Board of Pharmacy that their conduct failed to adequately exercise corresponding responsibility to ensure dispensing of controlled substances only for legitimate medical purposes, Defendants' misconduct continues.

The Defendants' unlawful dispensing of controlled substances and failure to maintain records has harmed the public health. Their willingness to obstruct a federal investigation by altering records reflects their lack of accountability for their misconduct.

IV. THE RELIEF REQUESTED IS TAILORED TO DEFENDANTS' CSA VIOLATIONS AND THE HARM CAUSED BY THOSE VIOLATIONS

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). CSA precedent supports

injunctions that limit the ability of registrants and non-registrants to further deal in controlled substances. *United States v. WeCare Pharmacy et al.,* Case No. 8:21-cv-188 (M.D. Fla. Jan. 26, 2021); *Advance Pharmaceutical v. United States*, 391 F.3d 377, 389-90, 400 (2d Cir. 2004); *United States v. Oakley Pharmacy et al.,* Case No. 2:19-cv-0009, Doc. 10 (M.D. Tenn. Feb. 21, 2019); *United States v. Gerber*, Case No. 3:18-cv-1908, Doc. 12) (N.D. Ohio Aug. 30, 2018); *United States v. Salcedo*, 2003 WL 21196843, *3 (E.D.N.Y. Feb. 19, 2003; *United States v. Chemicals for Research & Industry*, 10 F. Supp. 2d 1125, 1130 (N.D. Cal. 1998); *see also United States v. Oakland Cannabis Buyers' Co-op*., 532 U.S. 483, 496 (2001).

The Defendants here repeatedly dispensed controlled substances in violation of the law. They should now be enjoined from dispensing those substances. Enjoining the Defendants from handling controlled substances will not unreasonably prevent them from conducting any other business; they still could sell and dispense non-controlled substance prescription medications, as well as sell other medical supplies and items. The relief sought is narrowly tailored to specifically address the harm caused by Defendants' knowing and repeated illegal activity.

CONCULSION

Defendants Zazamora, Rite-Away, and Chaudhary have been unlawfully dispensing controlled substances for invalid prescriptions, ignoring red flags as to the legitimacy of controlled substance prescriptions, and neglecting their controlled substance inventory records such that a loss of 44,900 dosage units loss in a single year went undetected until the DEA conducted an audit. The facts summarized above and set forth in the attached declarations, and the exhibits supporting these facts, provide a detailed and troubling demonstration that the Defendants' conduct violates the CSA and presents a continued grave harm to the public health. There can be little doubt that

the Defendants will continue to unlawfully dispense controlled substances unless enjoined by the Court.

Accordingly, the United States requests that this Court enter a preliminary injunction against the Defendants in the form of the proposed order accompanying this Motion.

Dated: January 21, 2022

Respectfully submitted,

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