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.	§	

COMPLAINT UNDER THE CONTROLLED SUBSTANCES ACT
PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF REQUESTED

INTRODUCTION

1. Plaintiff, the United States, brings this civil enforcement action against Defendants ZARZAMORA HEALTHCARE LLC ("Zarzamora"), RITE-AWAY PHARMACY & MEDICAL SUPPLY #2 ("Rite-Away"), and JITENDRA CHAUDHARY, seeking injunctive relief and civil monetary penalties under the Controlled Substances Act ("CSA"), as amended, 21 U.S.C. § 801 *et seq*.

2. Opioid abuse is a national public health emergency. The dispensing and distributing of controlled substances, including prescription opioid painkillers, without a legitimate medical purpose and outside the usual course of professional practice exacerbates this crisis.

3. Defendants have both fueled and profited from the opioid epidemic by repeatedly dispensing powerful opioids prone to abuse in violation of the CSA. Defendants' violations include knowingly dispensing controlled substances without a valid prescription in violation of 21 U.S.C. § 842(a)(1); knowingly and intentionally distributing and dispensing controlled substances outside

the usual course of the professional practice of pharmacy, in violation of 21 U.S.C. § 841(a); dispensing controlled substances based on purported prescriptions that were not issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice, in violation of 21 U.S.C. § 829; altering records required to be kept under the CSA, in violation of 21 U.S.C. § 842(a)(5); and maintaining drug-involved premises for the unlawful distribution of controlled substances in violation of 21 U.S.C. § 856. *See* 21 C.F.R. §§ 1306.01, 1306.04(a).

4. To protect the public health, the United States seeks to enjoin Defendants' unlawful conduct and impose civil monetary penalties for their past violations.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 21 U.S.C. §§ 842(c)(1)(A) and 882(a), 28 U.S.C. §§ 1331, 1345, 1355, and 1367(a).

6. Defendants conduct their business in San Antonio, Texas, and the incidents alleged in this Complaint occurred in San Antonio, Texas. Venue is proper in the Western District of Texas pursuant to 21 U.S.C. § 843(f)(2) and 28 U.S.C. § 1395.

PARTIES

7. The United States is the Plaintiff for whom relief is sought pursuant to the CSA.

8. At all times relevant to this action, Defendant Zarzamora was located at 2716 SW Military Drive, Suite 102, San Antonio, Texas 78224. Zarzamora is the business entity that owns Defendant Rite-Away.

9. At all times relevant to this action, Defendant Rite-Away operated a pharmacy located at 2716 SW Military Drive, Suite 102, San Antonio, Texas 78224.

10. At all times relevant to this action, Defendant Chaudhary was the Pharmacist-in-charge of Rite Away. Defendant Chaudhary also holds an ownership interest in Defendant Zarzamora.

APPLICABLE LAW

I. The Controlled Substances Act

11. The CSA established a system to deter, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply of controlled substances and listed chemicals is available for legitimate medical, scientific, research, and industrial purposes.

12. The CSA categorizes controlled substances in five schedules. As relevant here, Schedule II contains drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence" but that have "a currently accepted medical use in treatment." 21 U.S.C. § 812(b)(2). Schedule III contains drugs in which, although the abuse potential is less than a Schedule II drug, such abuse may lead to moderate "physical dependence or high psychological dependence." 21 U.S.C. § 812(b)(3).

13. The CSA renders it "unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance" except as specifically authorized by the CSA. 21 U.S.C. § 841(a)(1).

14. Accordingly, the CSA requires those who manufacture, distribute, or dispense controlled substances to obtain a registration from the DEA. 21 U.S.C. § 822(a). A registrant is permitted to dispense or distribute controlled substances only "to the extent authorized by their registration and in conformity with the [CSA]." 21 U.S.C. § 822(b).

II. The CSA Maintains Integrity and Accountability Through Recordkeeping Requirements

15. The CSA provides for a "closed system" of controlled substances in the United States by imposing strict recordkeeping obligations on DEA registrants. *See* 21 C.F.R. § 1304.03.

The CSA gives the DEA authority to inspect DEA registrants to verify recordkeeping and inventory controls. *See* 21 C.F.R. § 1316.

16. It is 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 the CSA. 21 U.S.C. § 842(a)(5). A person who violates this provision is subject to a penalty of up to $15,876 per violation. Federal Register Vol. 86, No. 236.

17. A DEA registrant must notify the DEA of any theft or significant loss of any controlled substances and must also provide to DEA a "Form 106" regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. 21 U.S.C. § 830(b)(1)(c); 21 CFR § 1301.74(c).

18. It is unlawful for any person to negligently fail to keep a record or make a report of theft or loss of controlled substances under the CSA. 21 U.S.C. § 842(a)(10). A person who violates this provision is subject to a penalty of up to $15,876 per violation. Federal Register Vol. 86, No. 236.

19. While a prescription may be prepared by the secretary or agent for the signature of a practitioner, a prescribing practitioner is responsible in the case the prescription does not conform in all essential respects to the law and regulations. A corresponding responsibility rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations. 21 CFR § 1306.05(f).

III. The CSA Imposes a Prescription Requirement with Responsibilities for Pharmacies and Pharmacists

20. At all times relevant to this complaint, Rite-Away Pharmacy was registered with DEA as a retail pharmacy.

21. Agents and employees of a registered pharmacy, such as a pharmacist, are not required to register with DEA "if such agent or employee is acting in the usual course of his business or employment." 21 U.S.C. § 822(c)(1). Defendant Chaudhary is not separately registered with the DEA.

22. Unless dispensed directly by a non-pharmacist practitioner, no Schedule II controlled substance may be dispensed without the written prescription of a practitioner, such as a physician, except in an emergency. 21 U.S.C. § 829(a). Similarly, unless directly dispensed, no Schedule III or IV controlled substance may be dispensed without a written or oral prescription from a practitioner. 21 U.S.C. § 829(b).

23. Defendants "distributed" or "dispensed" controlled substances. The term "dispense" means to deliver a controlled substance to an end user pursuant to a lawful order of a practitioner, or prescription. See 21 U.S.C. § 802(10); 21 C.F.R. §§ 1300.01 & 1306.03(a). The term "distribute" means to deliver a controlled substance (other than by administering or dispensing). See 21 U.S.C. § 802(11).

24. The Attorney General has promulgated, in 21 C.F.R. Part 1306 ("Prescriptions"), rules for when controlled substances may be dispensed pursuant to an order from a prescriber in accordance with 21 U.S.C. § 829. See 21 C.F.R. § 1306.01 ("Rules governing the issuance, filling, and filing of prescriptions pursuant to [21 U.S.C. § 829] are set forth generally in this section and specifically by the sections of this part.").

25. As relevant here, 21 C.F.R. Part 1306 sets forth three rules pharmacies must follow when dispensing controlled substances. For each controlled-substance prescription, a pharmacist must (1) determine that the prescription was issued by a medical practitioner adhering to the usual course of her professional practice, (2) determine that the prescription is for a legitimate medical

purpose, and (3) in filling the prescription, adhere to the usual course of her own professional pharmacy practice.

26. Pharmacies are critical gate-keepers in distributing or dispensing controlled substances. The CSA's prescription requirement confers a responsibility on pharmacists to ensure that prescriptions 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).

27. Thus, a pharmacist must refuse to fill a controlled substance prescription if the pharmacist knows or was willfully blind to the fact that the prescription was not written for a legitimate medical purpose or in the usual course of the prescriber's professional practice. 21 C.F.R. § 1306.04.

28. Additionally, pharmacists must act in the usual course of professional practice as pharmacists 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. This also means complying with relevant state law related to the general practice of pharmacy and, in particular, related to dispensing controlled substances.

IV. Texas Law Relevant to the Practice of Pharmacy Informs the Usual Course of Professional Pharmacy Practice

29. Texas state law also regulates the practice of pharmacy. For example, under the Texas Pharmacy Act, the "Practice of pharmacy" is defined to include instances of a pharmacist exercising professional judgment about the pharmacological appropriateness of prescriptions. This includes, for example, a pharmacist exercising independent judgment regarding the patient's treatment such as appropriateness of prescription duration, dose, and combination drug therapy. *See* generally Texas OC Chapter 551.003. A "Pharmacist-in-charge" is the pharmacist designated who

is responsible for the pharmacy's compliance with statutes and rules relating to the practice of pharmacy. *Id.* at 29.

30. In practical terms, this means that a pharmacist must perform certain steps prior to filling any new or refill prescription. This includes evaluating prescription drug or medication orders and patient medication records for: (A) a known allergy; (B) a rational therapy-contraindication; (C) a reasonable dose and route of administration; (D) reasonable directions for use; (E) duplication of therapy; (F) a drug-drug interaction; (G) a drug-food interaction; (H) a drug-disease interaction; (I) an adverse drug reaction; and (J) proper use, including overuse or underuse. *See* Texas OC Chapter 551.033(19).

31. When evaluating any prescription, whether for controlled substances or not, a pharmacist must evaluate the medical appropriateness for the prescription given a patient's unique circumstances and be vigilant for risks of patient harm from improper drug-drug interactions, contraindications, duration of use, or other circumstances. For example, intervention by a pharmacist would be required when a pharmacy patient who takes daily aspirin presents a prescription for warfarin. Warfarin is an anti-coagulant and aspirin has anti-coagulant properties indicating duplicative therapy and potentially putting a patient at risk for unintended adverse outcomes. As another example, a pharmacist must intervene upon learning a patient receiving prescription-strength ibuprofen is pregnant because of the risks associated with pregnancy and ibuprofen.

32. When distributing or dispensing controlled substances, the standard of care in the state of Texas requires a pharmacy to comply with all federal and laws and rules governing the practice of pharmacy. 22 Texas Administrative Code § 295.3. A pharmacist is required to exercise sound professional judgment with respect to any prescription drug order dispensed. *See* 22 TAC § 291.29(a). A pharmacist must make every reasonable effort to ensure that a prescription has been issued for a legitimate medical purpose by a practitioner in the course of medical practice. 22 TAC

§ 291.29(b). A pharmacist must not dispense a controlled substance if the pharmacist knows or should know that a prescription was issued illegitimately. 22 TAC § 291.29(b).

33. Indeed, a pharmacist "shall make every reasonable effort to prevent inappropriate dispensing due to fraudulent, forged, invalid, or medically inappropriate prescriptions in violation of a pharmacist's corresponding responsibility." 22 TAC § 291.29(f).

34. The standard of care also requires compliance with 21 C.F.R. § 1306.04, which imposes a corresponding responsibility on every pharmacist to ensure that a prescription for a controlled substance was issued for a legitimate medical purpose in the usual course of the prescriber's professional medical practice.

35. The standard of care for the practice of pharmacy requires that pharmacists recognize certain signs of illegitimate prescriptions, drug diversion, or abuse, commonly known as "red flags." The standard of care for the practice of pharmacy also requires that a pharmacist consider, evaluate, and resolve any "red flags" prior to dispensing a prescription drug. The prescriber, the patient, or the prescription may present a red flag.

36. Red flags may include 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.

37. Under 21 U.S.C. § 842(a)(1) it is "unlawful for any person who is subject to the requirements of Part C" of the CSA—*i.e.*, the registration requirements of the CSA—"to distribute or dispense a controlled substance in violation of [21 U.S.C. § 829]." Thus, to satisfy the requirements of 21 C.F.R. § 1306.04(a), a DEA-registered pharmacy must ensure that every prescription for a controlled substance dispensed (1) was issued by a medical practitioner adhering

to the usual course of his or her professional medical practice, and (2) was ordered for a legitimate medical purpose. The pharmacy must also comply with 21 C.F.R. § 1306.06 by ensuring that the controlled substance prescription (3) is filled by a pharmacist acting the usual course professional pharmacy practice.

38. Additionally, the CSA prohibits maintaining a drug-involved premises. A person maintains a drug-involved premises by (1) knowingly opening, leasing, renting, using, or maintaining any place for the purpose of unlawfully distributing a controlled substance, or (2) managing or controlling any place and knowingly making that place available for use for the purpose of unlawfully distributing a controlled substance. 21 U.S.C. § 856.

V. The CSA Imposes Penalties and Injunctive Remedies to Address Violations

39. Under 21 C.F.R. § 1306.04, "[a]n order purporting to be a prescription but not issued in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829.]" Thus, "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." A "person" includes "any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity." 21 C.F.R. § 1300.01.

40. Thus, both the pharmacy and the pharmacist who knowingly fill a prescription in violation of 21 U.S.C. § 829 and 21 C.F.R. § 1306.04(a), are subject to civil penalties under 21 U.S.C. § 842(a)(1). Additionally, a both the pharmacy and the pharmacist who fill a controlled-substance prescription not in the usual course of professional pharmacy practice, in violation of 21 C.F.R. §1306.06, violates the CSA's prescription requirement and are subject to civil penalties under 21 U.S.C. § 842(a)(1).

41. The penalty for a person who violates 21 U.S.C. § 842(a)(1) is up to $68,486 for each violation. *See* 21 U.S.C. § 842(c)(1)(A); 28 C.F.R. § 85.5, Federal Register Vol. 86, No. 236.

42. The penalty for any person who violates 21 U.S.C. § 856 is no more than the greater of (1) $379,193 or (2) two times the gross receipts, either known or estimated, that were derived from each violation that is attributable to the person. 28 C.F.R. § 85.5, Federal Register Vol. 86, No. 236.

43. The CSA authorizes federal courts to enjoin violations of the CSA, including violations of Sections 842(a)(1) and 856.

FACTUAL ALLEGATIONS

I. Defendants Failed to Keep Accurate Records Relating to Controlled Substances.

44. DEA diversion investigators inspected Rite-Away on September 18, 2014. At the conclusion of the inspection, Defendants were notified of several recordkeeping violations related to missing information for numerous controlled substance prescriptions and separate recordkeeping violations related to inventory controls. Defendants were provided written notification of the recordkeeping violations via a DEA Warning Letter on October 10, 2014. Defendant Chaudhary responded to the DEA Warning Letter on October 27, 2014, acknowledging the violations, stating that corrective actions were taken for the violations, and affirming that the content of his letter was true and practiced on a regular basis.

45. Approximately four years later, on August 17, 2018, DEA diversion investigators inspected Rite-Away again. DEA again found numerous inaccurate records that showed significant discrepancies between a physical count of controlled substance doses and Rite-Away's written inventory logs.

46. In sum, the 2018 inspection found that for an audit period of approximately one year, the physical inventory at Rite-Away was short by 44,958 dosage units across five different controlled substances compared with the records Rite-Away furnished to the DEA.

47. The CSA requires pharmacies to keep accurate records of controlled substances. *See* 21 U.S.C. § 827(a)(3), 21 C.F.R. § 1304.21(a). Defendants' failure to make, keep and furnish to the DEA required records concerning controlled substances violates the CSA and subjects them to civil penalties. 21 U.S.C. § 842(a)(5).

II. Defendants Dispensed Controlled Substances Based on Facially Invalid Prescriptions.

48. A valid prescription for controlled substances must contain certain information, such as the patient name and type of drug prescribed, and be signed by an ordering practitioner. 21 C.F.R. § 1306.05. A pharmacist who distributes or dispenses controlled substances pursuant to prescriptions lacking basic required information violates the law. *See* 21 C.F.R. § 1306.05(f).

49. During the 2018 inspection, based on only a limited sample of prescription records, DEA identified 50 prescriptions for controlled substances that Defendants filled despite the fact that the written prescriptions did not conform to basic requirements of 21 C.F.R. § 1306.05.

50. On April 30, 2019, representatives of the DEA and the United States Attorney's Office met with Defendant Chaudhary and his legal counsel to address the violations. During the meeting, Chaudhary was expressly told that filling prescriptions lacking information required under 21 C.F.R. § 1306.05 constituted violations of the Controlled Substance Act.

51. On August 6, 2019, an inspector with the Texas State Board of Pharmacy conducted a routine inspection of the premises at Rite-Away. Defendant Chaudhary signed the Notice of Inspection as the Pharmacist-In-Charge. The inspector noted that numerous controlled substance prescriptions again lacked information required under 21 C.F.R. § 1306.05.

52. On October 16, 2019, Defendant Chaudhary was notified through counsel that the following day, DEA agents would pick up the original, hard-copy prescriptions from Rite-Away identified during the 2018 inspection as lacking information required under 21 C.F.R. § 1306.05.

53. On October 17, 2019, DEA diversion investigators entered Rite-Away and observed Defendants' employees in the process of deliberately altering controlled substance prescriptions, including the specific 50 prescriptions sought by the investigators.

54. DEA investigators found that in addition to the 50 prescriptions previously identified, Defendants also caused to be falsified an additional 192 controlled substance prescriptions that were defective under 21 C.F.R. § 1306.05. In total, each of the 242 altered prescriptions constitutes a violation of 21 U.S.C. § 829(b), giving rise to liability under 21 U.S.C. 842(a)(1).

III. Defendants Violated the CSA by Ignoring "Red Flags" of Abuse or Diversion.

55. From at least as early as 2017 to in or around April 2021, Defendants knowingly filled prescriptions for controlled substances that raised obvious "red flags" of potential abuse or diversion. Defendants deliberately ignored or were willfully blind to circumstances indicating that controlled substance prescriptions were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. By filling controlled-substance prescriptions without evaluating and resolving obvious red flags, Defendants violated the pharmacist's corresponding responsibility under 21 C.F.R. § 1306.04(a), and Defendants acted outside the usual course of professional pharmacy practice in violation of 21 C.F.R. § 1306.06.

a. Red Flag No. 1 – Unusual Amounts and Dosages

56. Although the prescribing of any controlled substance should bring heightened scrutiny because of the potential for abuse, a prescription for an unusually large quantity or strength of a drug is a red flag that the prescription is not written for a legitimate medical purpose or in the usual course of professional practice.

57. Rite-Away Pharmacy repeatedly dispensed prescriptions for high doses of opioid medications in amounts that far exceeded the daily morphine milligram equivalent ("MME") dose

recommended by the Centers for Disease Control and Prevention.[1] Defendants repeatedly dispensed high dosages of controlled substances without resolving this red flag.

b. Red Flag No. 2 – Lack of Individual Drug Therapy

58. When a prescriber repeatedly writes for many patients prescriptions for the same drugs, quantities, and strengths, this is a red flag known as "pattern prescribing." Pattern prescribing can consist of (1) a physician writing the same drugs, quantities, and strengths for his patients or (2) a patient receiving the same controlled substances over and over again with no adjustment to or change in therapy. Pattern prescribing results in a lack of individualization of drug therapy.

59. It is also a red flag when multiple individuals residing at the same household receive the same or substantially similar controlled substance prescriptions. This type of pattern prescribing to members of the same household also indicates a lack of individualized treatment and is a significant indicator that controlled substance prescriptions issued to members of the same household are not issued in the usual course of professional practice or not for a legitimate medical purpose.

c. Red Flag No. 3 – Routinely Abused Controlled Substances

60. It is a red flag to dispense prescriptions for controlled substances when a prescriber exhibits a pattern of routinely prescribing controlled substances known to be abused drugs including opioids, benzodiazepines, muscle relaxers, psychostimulants, and/or cough syrups containing codeine, or any combination of these drugs. While many prescribers may issue prescriptions for controlled substances, is it a red flag when a prescriber routinely and predominantly prescribes commonly abused drugs, particularly in combinations.

[1] CDC Guideline for Prescribing Opioids for Chronic Pain, United States, 2016, available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

d. Red Flag No. 4 – Prescriptions Containing No Diagnosis or Intended Use

61. It is a red flag for controlled substance prescriptions to be issued with a non-specific or no diagnosis. It is also a red flag for controlled substance prescriptions to omit the intended use of the drug.

e. Red Flag No. 5 – Unusual Geographic Distances

62. A person traveling an usually long distance to the pharmacy from their home address or their prescriber's address or both, including travel past many other pharmacies, can be a red flag that the prescription is not written for a legitimate medical purpose or in the usual course of professional practice.

f. Red Flag No. 6 – Controlled Substances from Multiple Providers

63. Persons presenting prescriptions for controlled substances from multiple prescribers indicates "doctor shopping" and is a red flag. Controlled substances often have powerful interactions with other drugs, so it is important that each provider is aware of other drugs being prescribed to an individual. Individuals who receive multiple controlled substance prescriptions from multiple providers may experience adverse drug interactions. A red flag is also raised when multiple providers reissue the same or similar high-dose opioid therapy in excessive durations that indicate factory or rote prescribing without a legitimate medical purpose or outside the usual course of professional practice.

g. Red Flag No. 6 – Immediate Release Opioids

64. The prescribing of immediate release ("IR") opioids on a schedule or for a length of time is a red flag that the prescription is not written for a legitimate medical purpose or in the usual course of professional practice. In a legitimate pain management practice, an extended release ("ER") opioid generally accompanies an IR opioid. The patient takes the ER opioid on a schedule

and the IR opioid as needed. Filling IR opioids, such as oxycodone 30 milligrams, on a schedule and without an ER opioid increases the risk of abuse, dependence, and diversion.

Patients T.B. and R.B.

65. Patients T.B. and R.B., a married couple, regularly filled controlled substance prescriptions at Rite Away from June 2018 until at least April 2021. During that time, T.B. and R.B. presented to Defendants prescriptions for high volumes of oxycodone and hydrocodone written by three different providers. T.B. and R.B. both received high-strength opioids with the same direction for use and in large dosages. This red flag reflects a lack of individualized therapy. For example, T.B. and R.B. routinely received prescriptions the same day for as many as 180 tablets of hydrocodone-acetaminophen 10-325 mg and 120 tablets of oxycodone 30 mg. Both of those drugs are immediate-release opioids. Such high quantities of immediate-release opioids raise red flags indicating that the prescriptions for these drugs were not medically legitimate.

66. Based on the red flags described above, Defendants knew or were willfully blind to the fact that the controlled substance prescriptions T.B. and R.B. presented were not for a legitimate medical purpose. A pharmacist acting in the usual course of professional pharmacy practice would not fill the controlled substance prescriptions presented by T.B. and R.B. without first resolving the red flags.

Patients J.C. and N.C.

67. Patients J.C. and N.C., also a married couple, received similar, high-dose combination opioid prescriptions. From July 2018 to April 2019, J.C. repeatedly presented to Rite-Away monthly prescriptions for 90 OxyContin 60 mg tablets and 120 oxycodone 30 mg tablets, a high volume that presents a red flag. Patient J.C. received both brand name and generic versions of oxycodone prescriptions from the same doctor on the same day, which is duplicative therapy and a red flag. Defendants' records also show that J.C. presented narcotic prescriptions from different

providers each month, and in some months switched providers who continued to write the same prescriptions by rote.

68. One physician also prescribed Narcan for J.C. Narcan is an opioid overdose prevention medication and presents a red flag because it indicates the potential that an individual is taking opioids in quantities that may lead to an overdose.

69. J.C.'s wife, N.C., was routinely prescribed oxycodone, OxyContin, and fentanyl in unusually large doses. From November 2017 to November 2019, N.C. presented to Rite-Away prescriptions for as many as 120 OxyContin 80 mg tablets and 180 oxycodone 30 mg tablets, both for brand name and generic medications, and frequently from multiple doctors. The prescriptions raised multiple red flags because of the doses, overlapping therapy, and multiple prescribers.

70. Rite-Away also filled for N.C. prescriptions for benzodiazepines with no clinical purpose noted in the pharmacy's records. N.C. often received narcotic prescriptions from multiple providers. For instance, N.C. obtained prescriptions for oxycodone, OxyContin, and fentanyl from one prescriber in July 2018. In August 2018, N.C. obtained from a second provider prescriptions for OxyContin, oxycodone and methadone. One week later, Rite-Away filled a prescription for N.C. from the first prescriber for fentanyl lollipops. Over an approximately two-year period, Rite-Away filled controlled substance prescriptions for N.C. issued by at least seven different providers.

71. N.C. also presented a Narcan prescription to Rite-Away, raising a red flag that the prescriber knew there was a risk of opioid overdose connected to the other prescriptions issued to N.C.

72. Based on the red flags described above, Defendants knew or should have known that many of the controlled substance prescriptions J.C. and N.C. presented were not for a legitimate medical purpose. A pharmacist acting in the usual course of professional pharmacy practice would

not fill the controlled substance prescriptions presented by J.C. and N.C. without first resolving the red flags.

Patient L.W.

73. From August 2017 to December 2019, Patient L.W. presented to Rite-Away prescriptions for hydrocodone, oxycodone, and alprazolam from multiple prescribers, raising significant red flags regarding drug combinations, dosages, and multiple prescribers. For example, L.W. was routinely prescribed two immediate-release opioids; namely, 120 oxycodone 30 mg tablets and 180 hydrocodone-acetaminophen 10-325 mg tablets. L.W. also received prescriptions for alprazolam, a benzodiazepine that poses serious drug-drug interaction risks when taken in combination with opioids. Moreover, many of the alprazolam prescriptions lacked documented indications for use. L.W. was also prescribed Narcan, indicating that the high-quantity opioid regime for L.W. was dangerous.

74. L.W. received prescriptions with the same drug, strength, and directions for use as other Rite-Away customers seen by the same doctors, which reflects a pattern of dangerous opioid prescribing that Rite-Away would have recognized in the course of filling prescriptions for L.W. and other individuals. The pharmacy failed to identify or document a resolution to these red flags.

75. Based on the red flags described above, Defendants knew or should have known that many of the controlled substance prescriptions presented by L.W. were not for a legitimate medical purpose. A pharmacist acting in the usual course of professional pharmacy practice would not fill the controlled substance prescriptions presented by L.W. without first resolving the red flags.

Patient M.P.

76. Patient M.P. presented to Rite-Away prescriptions for opioids, fentanyl, and benzodiazepines from August 2017 to September 2017. M.P. received 180 hydrocodone-acetaminophen 10-325 mg in addition to 50 mcg/hour fentanyl patches. This high dosage is a red

flag. In addition to opioids, M.P. received prescriptions for alprazolam (common brand name Xanax), a benzodiazepine, from a different prescriber, and also received zolpidem tartrate (common brand name Ambien), yet another controlled substance that can interact dangerously with opioids. M.P. received these dangerous high-volume, combination prescriptions for controlled substances from multiple prescribers, which is also a red flag. Rite-Away's records did not clearly specify a condition or indication to warrant M.P.'s use of narcotics, benzodiazepines, or fentanyl patches.

77. Based on the red flags described above, Defendants knew or should have known that many of the controlled substance prescriptions M.P. presented were not for a legitimate medical purpose and should not have been filled. A pharmacist acting in the usual course of professional pharmacy practice would not fill the controlled substance prescriptions presented by M.P. without first resolving the red flags.

78. According to medical examiner records, M.P. died as a result of toxic effects of fentanyl on September 11, 2017, within nine days of Rite-Away filling her prescription for fentanyl.

Patient B.O.

79. From July 2018 until at least April 2021, B.O. presented to Rite-Away prescriptions for hydrocodone, oxycodone, morphine, and benzodiazepine written by multiple prescribers, which raises significant red flags regarding drug combinations, dosages, and multiple prescribers. B.O. routinely received prescriptions for 180 hydrocodone-acetaminophen 10-325 mg tablets and as much as 90 morphine 60 mg tablets.

80. Rite-Away also filled B.O.'s prescriptions for alprazolam, a benzodiazepine, and zolpidem tartrate, a hypnotic sedative, both of which have dangerous drug-drug interactions when taken with opioids and raise a red flag. Rite-Away's records also showed that B.O.'s morphine prescription lacked an indication for use.

81. B.O. also presented prescriptions for Narcan, which indicated a known risk of opioid overdose based on the combination of prescriptions provided.

82. Based on the red flags described above, Defendants knew or should have known that many of the controlled substance prescriptions B.O. presented were not for a legitimate medical purpose and should not have been filled. A pharmacist acting in the usual course of professional pharmacy practice would not fill the controlled substance prescriptions presented by B.O. without first resolving the red flags.

Patient Y.A.

83. From August 2017 until at least April 2021, Patient Y.A. presented to Rite-Away prescriptions for multiple short- and long-acting narcotics written by multiple prescribers. For example, Y.A. frequently presented prescriptions for 180 hydrocodone-acetaminophen 10-325 mg tablets and 60 oxycodone 10 mg tablets, which reflect high doses of opioids in two immediate-release forms. These opioids frequently were co-prescribed with alprazolam and zolpidem tartrate, controlled substances that can pose dangers when taken in combination with opioids. Rite-Away failed to resolve these red flags.

84. Patient Y.A. presented controlled substance prescriptions substantially similar to those presented by many other patients from the same providers, which is a red flag that reflects a lack of individualization of therapy. Y.A. obtained controlled substance prescriptions from different providers, which also is a red flag. For example, on the same date in September 2017, Rite-Away filled one prescription for Embeda (naltrexone and morphine) presented by Y.A. as well as a prescription for oxycodone written by another provider.

85. Based on the red flags described above, Defendants knew or should have known that many of the controlled substance prescriptions presented by Y.A. were not for a legitimate medical

purpose. A pharmacist acting in the usual course of professional pharmacy practice would not fill the controlled substance prescriptions presented by Y.A. without first resolving the red flags.

Patients M.L. and G.L.

86. Between July 2018 and December 2019, M.L. regularly presented to Rite-Away high-dosage prescriptions for hydrocodone and methadone, including prescriptions for 180 hydrocodone-acetaminophen 10-325 mg tablets and 90 methadone 10 mg tablets.

87. During the same time period between July 2018 and December 2019, M.L.'s husband, G.L., presented similarly large opioid dosage prescriptions from some of the same providers, including 180 hydrocodone-acetaminophen 10-325 mg tablets and between 90-120 oxycodone in 20 or 30 mg strengths. The high dosages of immediate-release opioid presents a red flag.

88. To fill prescriptions at Rite-Away, M.L. and G.L. would need to drive more than three-and-one-half hours each way from their home address listed in Defendants' records. The distance M.L. and G.L. traveled to file their opioid prescriptions presents another red flag.

89. Based on the red flags described above, Defendants knew or should have known that many of the controlled substance prescriptions presented by M.L. and G.L. were not for a legitimate medical purpose. A pharmacist acting in the usual course of professional pharmacy practice would not fill the controlled substance prescriptions presented by M.L. and G.L. without first resolving the red flags.

Patients A.M. and J.M.

90. From August 2017 until at least April 2021, A.M. and J.M., a married couple according to the pharmacy's records, both routinely presented prescriptions for opioids,

benzodiazepines, and stimulants from multiple prescribers. These prescriptions raised multiple red flags.

91. For example, A.M. presented monthly prescriptions for 180 hydrocodone-acetaminophen 10-325 mg and 60 OxyContin 80 mg tablets, high dosages that raise a red flag. In addition, A.M. routinely presented concurrent prescriptions for alprazolam, a benzodiazepine that potentially can interact with opioids in dangerous ways, which also raises a red flag.

92. A.M. routinely presented prescriptions for phentermine, a stimulant, over a period of more than two years. This raises a red flag because phentermine is generally approved only for short-term uses of no more than six weeks. Moreover, the phentermine prescription included no indication for use.

93. J.M. received the same controlled substance prescriptions as A.M. exhibiting the same red flags, raising yet another red flag concerning the apparent lack of individualized care for these two individuals.

94. A.M. and J.M. traveled an unusual distance to obtain controlled substances from Rite-Away Pharmacy, which is more than a one-hour drive in each direction from their home, according to Rite-Away's records.

95. Based on the red flags described above, Defendants knew or should have known that many of the controlled substance prescriptions presented by A.M. and J.M. were not for a legitimate medical purpose. A pharmacist acting in the usual course of professional pharmacy practice would not fill the controlled substance prescriptions presented by A.M. and J.M. without first resolving the red flags.

Patient C.F.

96. From August 2017 until at least April 2021, C.F. routinely presented to Rite-Away prescriptions from multiple prescribers for high doses of opioids. For example, C.F. received

prescriptions for 180 hydrocodone-acetaminophen 10-325 mg and 60 oxycodone 30 mg tablets on a monthly basis, a red flag the reflects a high opioid dose and two immediate-release opioids. Pharmacy records do not include indications for use on some of these opioid prescriptions filled for C.F. With the limited exception of a vitamin supplement, the only prescription medications provided by Rite-Away to C.F. were for opioids.

97. The prescriptions Rite-Away filled for C.F. were issued by the same series of prescribers who wrote similar prescriptions for other Rite-Away customers, which is a significant red flag.

98. Based on the red flags described above, Defendants knew or should have known that many of the controlled substance prescriptions presented by C.F. were not for a legitimate medical purpose. A pharmacist acting in the usual course of professional pharmacy practice would not fill the controlled substance prescriptions presented by C.F. without first resolving the red flags.

COUNT I
Controlled Substances Act
21 U.S.C. § 842(a)(5)
Recordkeeping Violations

99. Plaintiff repeats and re-alleges paragraphs 1 through 98 as if fully set forth herein.

100. Defendants Zarzamora Healthcare LLC, Rite-Away Pharmacy & Medical Supply #2, and Jitendra Chaudhary failed to maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of, in violation of 21 C.F.R. § 1304.21(a) and 21 U.S.C. §§ 827(a)(3), and 842(a)(5).

101. Namely, in a number of instances to be determined at trial, Defendants failed to record a complete and accurate inventory of five different controlled substances regularly dispensed at Rite-Away Pharmacy.

102. Defendants are liable to the United States for a civil penalty in the amount of not more than $10,000 for each violation occurring on or before November 2, 2015 and not more than $15,876 for each violation after November 2, 2015, pursuant to 21 U.S.C. §842(c)(1)(B) and 28.8 C.F.R. § 85.5.

COUNT II
Controlled Substances Act
21 U.S.C. § 842(a)(5)
Altering Records Furnished to the United States

103. Plaintiff repeats and re-alleges paragraphs 1 through 98 as if fully set forth herein.

104. Defendants Zarzamora Healthcare LLC, Rite-Away Pharmacy & Medical Supply #2, and Jitendra Chaudhary altered prescription records required to be kept pursuant to 21 U.S.C. § 827(b) and 1304.04(h)(2) and (4), and furnished those altered records to the United States in violation of 21 U.S.C. § 842(a)(5).

105. Defendants are liable to the United States for a civil penalty in the amount of not more than $10,000 for each violation occurring on or before November 2, 2015 and not more than $15,876 for each violation after November 2, 2015, pursuant to 21 U.S.C. §842(c)(1)(B) and 28.8 C.F.R. § 85.5.

COUNT III
Controlled Substances Act
21 U.S.C. § 842(a)(1)
Prescription Requirement Violations - Filling Facially Invalid Prescriptions

106. Plaintiff repeats and re-alleges paragraphs 1 through 98 as if fully set forth herein.

107. Defendants Zarzamora Healthcare LLC, Rite-Away Pharmacy & Medical Supply #2, and Jitendra Chaudhary dispensed controlled substances pursuant to facially invalid prescriptions that were not issued in accordance with 21 C.F.R. § 1306.05, and that were filled by the pharmacy in violation of 21 C.F.R. § 1306.05(f). The filling of these facially invalid prescriptions violated 21 U.S.C. § 829(b) and subjects Defendants to the penalties under 21 U.S.C. § 842(a)(1).

108. Namely, in at least 242 instances, the total number of instances to be determined at trial, Defendants filled controlled substance prescriptions that were facially invalid in violation of 21 C.F.R. § 1306.05(f).

109. Defendants are liable to the United States for a civil penalty in the amount of not more than $25,000 for each violation occurring on or before November 2, 2015, and not more than $68,426 for each violation after November 2, 2015, pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

COUNT IV
Controlled Substances Act
21 U.S.C. § 842(a)(1)
Prescription Requirement Violations – Corresponding Responsibility

110. Plaintiff repeats and re-alleges paragraphs 1 through 98 as if fully set forth herein.

111. Defendants, acting through Rite-Away Pharmacy & Medical Supply #2, violated 21 U.S.C. § 829 by filling prescriptions for controlled substances t outside the usual course of pharmacy practice in violation of 21 C.F.R. § 1306.06; and in violation of its "corresponding responsibility" by knowingly filling controlled substances pursuant to prescriptions that were issued outside the usual course of professional practice or not for a legitimate medical purpose in violation of 21 C.F.R. § 1306.04.

112. Defendants are liable to the United States for a civil penalty in the amount of not more than $25,000 for each violation occurring on or before November 2, 2015, and not more than $68,426 for each violation after November 2, 2015, pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

COUNT V
Controlled Substances Act
21 U.S.C. §§ 843(f)(1) and 882(a)
Permanent Injunctive Relief

113. Plaintiff repeats and re-alleges paragraphs 1 through 98 as if fully set forth herein.

114. Under 21 U.S.C. § 843(f), the Attorney General of the United States is authorized to seek appropriate declaratory or injunctive relief relating to violations of 21 U.S.C. § 842. More broadly, 21 U.S.C. § 882(a) provides for any violation of the CSA to be enjoined.

115. Based on the violations set forth herein, and Defendants' years-long pattern of conduct, the United States requests that the Court enter a preliminary and permanent injunction (i) prohibiting Defendants from administering, dispensing, or distributing any controlled substance; (ii) prohibiting Defendant Chaudhary from serving as a manager, owner, operator, or pharmacist-in-charge of any entity, including a pharmacy, that administers, dispenses, or distributes controlled substances; (iii) prohibiting Defendant Chaudhary from applying for or seeking renewal of any DEA Certificate of Registration on their behalf or on behalf of any corporate entity; and (iv) any other injunctive relief the Court deems appropriate and just.

COUNT VI
Controlled Substances Act
21 U.S.C. § 856
Drug-Involved Premises

116. Plaintiff repeats and re-alleges paragraphs 1 through 98 as if fully set forth herein.

117. Defendants Zarzamora Healthcare LLC and Jitendra Chaudhary knowingly used, managed, or controlled 2716 SW Military Drive, Suite 102, San Antonio, Texas 78224 for the purpose of operating Rite-Away Pharmacy & Medical Supply #2 to unlawfully distribute controlled substances.

118. As a result, Defendants Zarzamora Healthcare LLC and Jitendra Chaudhary are liable to the United States under 21 U.S.C. § 856 for (1) not more than $250,000 for each violation occurring on or before November 2, 2015, and not more than $379,193 for each violation after November 2, 2015; or (2) two times the gross receipts, either known or estimated, that were derived from each violation that is attributable to each of them. 21 U.S.C. § 856(d); 28 C.F.R. § 85.5.

119. Additionally, Defendants Zarzamora Healthcare LLC and Jitendra Chaudhary are subject to an injunction to restrain further violations of Section 856 under 21 U.S.C. § 843(f).

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that judgment be entered in its favor and against Defendants as follows:

1. Impose civil penalties up to the maximum amount allowed by law for each violation of 21 U.S.C. § 842(a)(1) committed by Defendants;

2. Impose civil penalties up to the maximum amount allowed by law for each violation of 21 U.S.C. § 856(a) committed by Defendants;

3. Enter a preliminary and permanent injunction to prevent future violations, as described above;

4. Award the costs associated with the investigation, prosecution, and collection of the penalties and other relief in this matter; and

5. Award any other relief deemed just by the Court.

Dated: January 21, 2022

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General
Civil Division

GUSTAV W. EYLER
Director, Consumer Protection Branch

/s/ Scott B. Dahlquist
SCOTT B. DAHLQUIST
Trial Attorney
RYAN E. NORMAN
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
Ryan.E.Norman@usdoj.gov
Scott.B.Dahlquist@usdoj.gov
Telephone No. (202) 532-4602
Facsimile No. (202) 514-8742

ASHLEY C. HOFF
UNITED STATES ATTORNEY

ERIN VAN DE WALLE Digitally signed by ERIN VAN DE WALLE
Date: 2022.01.21 08:56:31 -06'00'

ERIN M. VAN DE WALLE
Assistant United States Attorney
Florida Bar No. 0099871
601 NW Loop 410 Suite 600
San Antonio, TX 78216
Tel: (210) 384-7320
Fax: (210) 384-7322
Erin.Van.De.Walle@usdoj.gov

Attorneys for the United States