IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SHAFFER PHARMACY, INC.; THOMAS TADSEN; and WILSON BUNTON, Defendants.	CASE NO.: 3:21 CV 22 JUDGE ZOUHARY COMPLAINT **FILED TEMPORARILY UNDER SEAL**

Plaintiff, the United States of America, by its undersigned counsel, brings this action against Shaffer Pharmacy, Inc., Thomas Tadsen, and Wilson Bunton (collectively, "Defendants") seeking injunctive relief and monetary penalties for violations of the Controlled Substances Act, 21 U.S.C. § 801, *et seq.* (the "CSA").

1. The opioid abuse epidemic is a state and national public health emergency. Pharmacies and pharmacists who dispense and distribute prescription opioid painkillers and other controlled substances without a legitimate medical purpose and outside the usual course of professional practice violate the CSA and contribute significantly to the ongoing opioid crisis.

2. For at least five years, Shaffer Pharmacy, Inc., violated the CSA by knowingly dispensing controlled substances pursuant to prescriptions that its pharmacists, Thomas Tadsen

and Wilson Bunton, knew or should have known had no legitimate medical purpose and were dispensed outside the usual course of professional pharmacy practice.

3. The "prescriptions" Tadsen and Bunton unlawfully dispensed often involved highly abused opioid painkillers such as oxycodone, hydrocodone, oxymorphone, buprenorphine, and fentanyl, often in dangerous combination with other prescription drugs like benzodiazepines (i.e., sedatives indicated for the treatment of anxiety), such as alprazolam (also known by its brand name, Xanax), and muscle relaxants, such as carisoprodol (also known by its brand name, Soma).

4. Defendants continue to dispense controlled substances in violation of the CSA. The United States seeks an order to preliminarily and permanently enjoin Defendants and those acting in concert and participation with them from continuing to unlawfully dispense controlled substances. The United States also seeks civil penalties to address Defendants' past violations of the CSA.

I. JURISDICTION AND VENUE

5. This action is brought by the United States under the CSA, 21 U.S.C. §§ 801-971.

6. This Court has subject matter jurisdiction over CSA claims pursuant to 21 U.S.C. §§ 842(c)(1)(A) and 882(a), and 28 U.S.C. §§ 1345 and 1355.

7. Venue is proper in the Northern District of Ohio under 21 U.S.C. § 843(f)(2) and 28 U.S.C. §§ 1391(b), (c), and (d) and 1395(a) because Shaffer Pharmacy, Inc., is located, resides, and does business in this district, and a substantial part of the events or omissions giving rise to the claims occurred in this district. Defendants Thomas Tadsen and Wilson Bunton filled prescriptions within this District.

II. PARTIES

8. Plaintiff is the United States of America.

9. Defendant Shaffer Pharmacy, Inc. is an Ohio for-profit corporation. At all times relevant to this Complaint, Shaffer Pharmacy, Inc. ("Shaffer Pharmacy") was, and is currently, a retail pharmacy with its principal place of business at 3900 Sunflower Court, Toledo, Ohio, 43623.

10. Defendant Thomas Tadsen is the owner-operator and pharmacist in charge of Shaffer Pharmacy. Thomas Tadsen was first licensed as a pharmacist in Ohio in or around August 1977. He has owned Shaffer Pharmacy since 1979.

11. Defendant Wilson Bunton is a pharmacist at Shaffer Pharmacy. Wilson Bunton was first licensed as a pharmacist in Ohio in or around June 2016. He has worked at Shaffer Pharmacy since around October 2017.

12. At all times relevant to the allegations herein, Shaffer Pharmacy was registered with the U.S. Drug Enforcement Administration ("DEA") as a Retail Pharmacy under registration number AS8550243, and held pharmacy license number 020157850 in the state of Ohio.

III. LEGAL BACKGROUND

A. THE CONTROLLED SUBSTANCES ACT

13. The CSA and its implementing regulations set forth a comprehensive regulatory regime for the manufacture, distribution, and dispensing of controlled substances. Congress enacted the CSA to facilitate the availability of controlled substances for authorized medical use, while also preventing controlled substances from being diverted out of legitimate channels for illegal purposes. The CSA accordingly 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. 21 U.S.C. § 841(a)(1).

14. Under the CSA, controlled substances are categorized into five schedules based on several factors, including the substance's medical use, potential for abuse, and safety or dependence liability.

15. Schedule II contains drugs with "a high potential for abuse" that "may lead to severe psychological or physical dependence" but nonetheless have "a currently accepted medical use in treatment." 21 U.S.C. § 812(b)(2). Examples of schedule II controlled substances include oxycodone (brand names OxyContin and Percocet), oxymorphone (brand name Opana), morphine sulfate (brand name MS Contin), dextroamphetamine-amphetamine (brand name Adderall), methadone, and fentanyl (brand name Subsys).

16. Schedule III contains drugs with less abuse potential but that may lead to "moderate or low physical dependence or high psychological dependence." 21 U.S.C. § 812(b)(3). Schedule III drugs also have "a currently accepted medical use in treatment." *Id.* Examples of schedule III controlled substances include opioids like acetaminophen with Codeine, and buprenorphine (brand name Suboxone).

17. Schedule IV contains drugs with a lower abuse potential than schedule III drugs but that still may lead to physical or psychological dependence when abused. 21 U.S.C. § 812(b)(4). Examples of schedule IV controlled substances include alprazolam (brand name Xanax), diazepam (brand name Valium), zolpidem (brand name Ambien), zaleplon (brand name Sonata), and carisoprodol (brand name Soma).

18. The CSA requires pharmacies that distribute or dispense controlled substances to obtain a registration from the DEA. 21 U.S.C. § 822(a). A registered pharmacy is only permitted to distribute or dispense controlled substances "to the extent authorized by their registration and in conformity with" the CSA. 21 U.S.C. § 822(b).

19. Pharmacies may be registered to "dispense" controlled substances in schedule II through V. 21 U.S.C. § 823(f). The CSA defines dispensing to mean delivering a controlled substance to an ultimate user (e.g., a patient) by, or pursuant to a lawful order of, a practitioner (i.e., a prescription). *See* 21 U.S.C. § 802(10). Distributing means delivering a controlled substance other than by dispensing or administering. *See id.* at § 802(11).

20. The agents and employees of a dispenser of controlled substances are not required to have a separate DEA registration "if such agent or employee is acting in the usual course of his business or employment." 21 U.S.C. § 822(c)(1).

21. Pharmacies cannot dispense a schedule II controlled substance to an ultimate end user without the written prescription of a practitioner, such as a physician. 21 U.S.C. § 829(a). Under the CSA, pharmacies cannot dispense schedule III or IV controlled substances to an end user without a written or oral prescription from a practitioner. 21 U.S.C. § 829(b).

22. A prescription (written or oral) is legally valid under the CSA only if issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). "An order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent" of 21 U.S.C. § 829 "and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.* "Person" is defined to include an individual, a corporation, a partnership, an association, and any other legal entity. 21 C.F.R. §§ 1300.01, 1306.02.

23. "The responsibility for 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).

24. "A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy. . . ." 21 C.F.R. § 1306.06.

B. OHIO LAW GOVERNING THE PRACTICE OF PHARMACY

25. Ohio law defines the "practice of pharmacy" to mean "providing pharmacist care requiring specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences." Ohio Rev. Code § 4729.01(B). "Pharmacist care" in relevant part, includes:

> (1) Interpreting prescriptions; (2) Dispensing drugs and drug therapy related devices; . . . (4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances; (5) Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs; (6) Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber; (7) Advising an individual and the health care professionals treating an individual with regard to the individual's drug therapy . . . .

Ohio Rev. Code § 4729.01(B).

26. Record keeping is also required for the practice of pharmacy in Ohio, and essential for pharmacists in carrying out their responsibilities. Pharmacies are required to keep "a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from that pharmacy." Ohio Admin. Code 4729-5-18. The patient profile system is required to include a patient's identifying information, a

complete drug therapy record, any patient specific data, and is also required to contain the "pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug." Ohio Admin. Code 4729-5-18(f).

27. Ohio law requires that a pharmacist conduct a prospective drug utilization review. Ohio Admin. Code 4729-5-20. This means that a pharmacist is required to review a patient profile before dispensing any prescription to check for a variety of things, including over- and under-utilization, drug interactions, incorrect drug dosage, potential allergy interactions, abuse or misuse, whether the duration of the drug treatment is inappropriate, and interactions with food and nutritional supplements. *Id.*

28. Ohio pharmacists have access to the Ohio Automated Rx Reporting System ("OARRS"). The OARRS reports are compiled by an information system into which pharmacists in Ohio are required to enter data regarding the controlled substance prescriptions they dispense to patients. This information system allows Ohio pharmacists to review a patient's controlled substance prescription history before dispensing controlled substances. It also allows pharmacists to review prescriptions that patients filled at other pharmacies. For example, the pharmacists can determine which doctors have prescribed controlled substances, which pharmacies have dispensed them, the quantities and dosages that have been prescribed and dispensed and when. OARRS provides a readily available data source pharmacists can use to detect, and potentially resolve, red flags prior to dispensing.

IV. FACTUAL BACKGROUND

A. DEFENDANTS VIOLATED THE CSA

29. As a retail pharmacy, Shaffer Pharmacy purchases, stores, and dispenses controlled substances. At all relevant times, Shaffer Pharmacy was subject to the registration and dispensing requirements of the CSA.

30. Between 2015 and 2019, Shaffer Pharmacy purchased hundreds of thousands of dosage units of schedule II and III controlled substances. Shaffer Pharmacy's purchasing volume exceeded Ohio state averages. For example, for the first three quarters of 2019, Shaffer Pharmacy purchased 8.4 times more oxycodone, 58.7 times more oxymorphone, 28.8 times more buprenorphine, and 61 times more fentanyl than Ohio state averages.

31. Shaffer Pharmacy, Thomas Tadsen, and Wilson Bunton failed to detect and address indicators of diversion. Common indicators of diversion, called "red flags," indicate that a prescription is not legitimate.

32. Defendants were presented with multiple red flags and failed to conduct further and sufficient inquiry to determine whether the prescriptions they filled were legitimate.

33. The CSA, 21 U.S.C. § 829, authorizes the dispensing of controlled substances only pursuant to a valid prescription. Common indicators of diversion, called red flags, indicate that a prescription is not legitimate and that the prescription should not be filled.

34. The dispensing of controlled substances in the face of such warning signals, without first ensuring the prescription was issued for a legitimate purpose by a practitioner acting in the usual course of professional practice, violates both 21 U.S.C. § 842(a) and 21 U.S.C. § 841(a). A pharmacist who fills a prescription in the face of one or more red flags without taking sufficient steps to resolve the red flag(s) exceeds his authorization to dispense controlled substances under the CSA.

B. SPECIFIC EXAMPLES OF CSA VIOLATIONS

35. From on or about January 1, 2015 to at least on or about February 20, 2020, Defendants violated the CSA by dispensing controlled substances in violation of their corresponding responsibility and outside the usual course of pharmacy practice. 21 C.F.R. §§ 1306.04; 1306.06.

36. Specifically, Defendants repeatedly failed to identify and address suspicious circumstances and indicators of diversion, described above as red flags. Defendants knowingly filled prescriptions for controlled substances without resolving those red flags over and over again.

1. Patient M.J.-P.

37. Shaffer Pharmacy filled prescriptions for Patient M.J.-P. for over four years, during which time Shaffer Pharmacy failed to identify or ignored red flags associated with those prescriptions.

38. Opioids are assigned morphine milligram equivalent ("MME"), which provides a mechanism to assess the cumulative daily strength of all opioid prescriptions a patient is taking in a way that is standardized across different drugs, formulations, strengths, and dosage forms. Opioids can depress respiration, and very high doses can arrest respiration. A daily MME of 50 is considered high, and the U.S. Centers for Disease Control recommends avoiding or carefully justifying dosages beyond 90 MME per day. Defendants filled opioid prescriptions for Patient M.J.-P. with MMEs in excess of 200 MME per day for more than three years.

39. Defendants also filled dangerous combinations of prescriptions for Patient M.J.-P. For example, Defendants filled prescriptions for opioids at the same time they filled prescriptions for benzodiazepines, muscle relaxants, and sedatives. This combination of drugs produces heightened risks of an adverse event, including possible respiratory failure. Dangerous combinations such as those dispensed to Patient M.J.-P. are red flags because they are sought after by those who seek prescriptions for the non-medical purpose of increasing the euphoric effects of opioids.

40. The International Classification of Diseases (ICD)-10 code used to support the prescriptions for M.J.-P. in Shaffer Pharmacy's records is "Sacroiliitis, not elsewhere classified." This diagnosis is insufficient to justify the level and duration of therapy for the patient.

41. All of the schedule II-IV controlled substance prescriptions that Defendants filled for Patient M.J.-P. from March 2016 through February 2020 are identified in a chart attached to this Complaint as Exhibit 1. The chart reflects which prescriptions were filled by Tadsen and which were filled by Bunton. No other pharmacist at Shaffer Pharmacy filled any prescriptions for Patient M.J.-P.

42. Each of the controlled substances listed in the chart in Exhibit 1 is a prescription drug under the Food Drug and Cosmetic Act ("FDCA").

43. Defendants knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1); and 21 C.F.R. § 1306.04.

44. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

2. Patient S.B.

45. Shaffer Pharmacy filled prescriptions for Patient S.B. for more than four years, and during that time Shaffer Pharmacy failed to identify or ignored red flags associated with those prescriptions.

46. Defendants filled opioid prescriptions for Patient S.B. with MMEs in excess of 200 per day for more than three years. By the end of 2016, Defendants were filling prescriptions

with MMEs of 360 per day, and MMEs of 450 in 2017 and in 2018. While the MME levels dropped by 2020, Defendants were still filling prescriptions with MME levels of 225.

47. Defendants also filled prescriptions for Patient S.B. from multiple prescribers. Defendants filled controlled substance prescriptions from seventeen different prescribers, and schedule II opioid prescriptions from eleven different prescribers.

48. Defendants also filled prescriptions for Patient S.B. that were dangerous to be taken in combination with one another. For example, Defendants filled prescriptions for opioids at the same time that they filled prescriptions for benzodiazepines and skeletal muscle relaxants. This combination of drugs could lead to respiratory failure, and it is also commonly sought by those with substance use disorder.

49. Defendants also dispensed frequent early refills to Patient S.B.

50. The ICD-10 code used to support the prescriptions for Patient S.B. in Shaffer Pharmacy's records is "Cough variant asthma." This diagnosis is insufficient to justify the level and duration of therapy for the patient.

51. All of the schedule II-IV controlled substance prescriptions that Defendants filled for Patient S.B. from March 2016 through February 2020 are identified in a chart attached to this Complaint as Exhibit 2. The chart reflects which prescriptions were filled by Tadsen and which were filled by Bunton. No other pharmacist at Shaffer Pharmacy filled any prescriptions for Patient S.B.

52. Each of the controlled substances listed in the chart in Exhibit 2 is a prescription drug under the FDCA.

53. Defendants knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course

of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1); and 21 C.F.R. § 1306.04.

54. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

3. Patient N.W.

55. Shaffer Pharmacy filled prescriptions for Patient N.W. for more than four years, and during that time Shaffer Pharmacy failed to identify or ignored red flags associated with those prescriptions.

56. Defendants filled opioid prescriptions for Patient N.W. with MMEs in excess of 1900 per day for more than four years.

57. Defendants also filled opioid prescriptions for Patient N.W. from four different prescribers.

58. For a three-year period, Defendants frequently provided Patient N.W. refills of prescription opioids even though one to three days of supply remained on an already dispensed opioid prescription.

59. The ICD-10 code used to support the prescriptions for N.W. in Shaffer Pharmacy's records is "Other chronic pain." This diagnosis is insufficient to justify the level and duration of therapy for the patient.

60. All of the schedule II-IV controlled substance prescriptions that Defendants filled for Patient N.W. from March 2016 through February 2020 are identified in a chart attached to this Complaint as Exhibit 3. The chart reflects which prescriptions were filled by Tadsen and which were filled by Bunton. No other pharmacist at Shaffer Pharmacy filled any prescriptions for Patient N.W.

61. Each of the controlled substances listed in the chart in Exhibit 3 is a prescription drug under the FDCA.

62. Defendants knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1); and 21 C.F.R. § 1306.04.

63. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

4. Patient C.S.

64. Shaffer Pharmacy filled prescriptions for Patient C.S. for more than three years, and during that time Shaffer Pharmacy failed to identify or ignored red flags associated with those prescriptions.

65. Defendants filled opioid prescriptions for Patient C.S. with MMEs in excess of 150 per day for more than three years. In 2016 and 2017, Defendants were filling prescriptions with MMEs of 900 to 1500 per day. In 2018, the MME levels dropped for the prescriptions Defendants filled but were still in the high range of 140 to 260 per day.

66. Defendants also filled, concurrent with the opioid prescriptions for Patient C.S., prescriptions for an amphetamine drug, which is dangerous when taken in combination with opioids. Defendants additionally filled prescriptions for benzodiazepines during the time frame Patient C.S. was also receiving opioid therapy. For over a year, extending into 2020, Defendants were concurrently dispensing dangerous combinations of opioids, benzodiazepines, and amphetamines.

67. For a three-year period, Defendants frequently provided Patient C.S. refills of prescription opioids even though one to three days of supply remained on an already dispensed opioid prescription.

68. The ICD-10 code used to support the prescriptions for C.S. in Shaffer Pharmacy's records is "Chronic pain syndrome." This diagnosis is insufficient to justify the level and duration of therapy for the patient.

69. All of the schedule II-IV controlled substance prescriptions that Defendants filled for Patient C.S. from April 2016 through March 2020 are identified in a chart attached to this Complaint as Exhibit 4. The chart reflects which prescriptions were filled by Tadsen and which were filled by Bunton. No other pharmacist at Shaffer Pharmacy filled any prescriptions for Patient N.W.

70. Each of the controlled substances listed in the chart in Exhibit 4 is a prescription drug under the FDCA.

71. Defendants knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1); and 21 C.F.R. § 1306.04.

72. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

5. Patient D.B.

73. Shaffer Pharmacy filled prescriptions for Patient D.B. for more than four years, and during that time Shaffer Pharmacy failed to identify or ignored red flags associated with those prescriptions.

74. Defendants filled opioid prescriptions for Patient D.B. with MMEs in excess of 140 per day for over more than four years.

75. Defendants also filled concurrent prescriptions for fentanyl and hydrocodone for Patient D.B. In addition, during that same time period, Defendants filled prescriptions for benzodiazepines, anti-depressants, and stimulants, which are dangerous when taken in combination.

76. The ICD-10 code used to support the prescriptions for D.B. in Shaffer Pharmacy's records is "Chronic pain syndrome." This diagnosis is insufficient to justify the level and duration of therapy for the patient.

77. All of the schedule II-IV controlled substance prescriptions that Defendants filled for Patient D.B. from March 2016 through March 2020 are identified in a chart attached to this Complaint as Exhibit 5. The chart reflects which prescriptions were filled by Tadsen and which were filled by Bunton. No other pharmacist at Shaffer Pharmacy filled any prescriptions for Patient D.B.

78. Each of the controlled substances listed in the chart in Exhibit 5 is a prescription drug under the FDCA.

79. Defendants knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1); and 21 C.F.R. § 1306.04.

80. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

6. Patient D.V.

81. Shaffer Pharmacy filled prescriptions for Patient D.V. for almost four years, and during that time Shaffer Pharmacy failed to identify or ignored red flags associated with those prescriptions.

82. Defendants filled opioid prescriptions for Patient D.V. with MMEs in excess of 120 per day for more than three years. From March 2016 through March 2018, Defendants were filling prescriptions with MMEs of 300 to 500 per day. In 2019, the MME levels dropped for the prescriptions Defendants filled but were still at the high level of 120 per day.

83. Defendants also filled prescriptions for buprenorphine without naloxone for Patient D.V. In addition, during that same time period, Defendants filled prescriptions for oxycodone. This combination indicates that the medications were not being used for a legitimate medical purpose.

84. The ICD-10 code used to support the prescriptions for D.V. in Shaffer Pharmacy's records is "Chronic pain syndrome." One of the opioids dispensed to Patient D.V. was Subsys, a powerful and expensive fentanyl product indicated for use for in the treatment of breakthrough pain for patients diagnosed with cancer. Shaffer Pharmacy's records do not contain diagnosis information that would justify the level and duration of prescription drug therapy dispensed to Patient D.V.

85. All of the schedule II-IV controlled substance prescriptions that Shaffer Pharmacy filled for Patient D.V. from March 201 through January 2020 are identified in a chart attached to this Complaint as Exhibit 6. The chart reflects which prescriptions were filled by Tadsen and which were filled by Bunton. No other pharmacist at Shaffer Pharmacy filled any prescriptions for Patient D.V.

86. Each of the controlled substances listed in the chart in Exhibit 6 is a prescription drug under the FDCA.

87. Defendants knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1); and 21 C.F.R. § 1306.04.

88. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

7. Patient K.K.

89. Shaffer Pharmacy filled prescriptions for Patient K.K. for four years, and during that time Shaffer Pharmacy failed to identify or ignored red flags associated with those prescriptions.

90. Over the course of four years, Defendants filled opioid prescriptions for Patient K.K. pursuant to prescriptions written by twenty-one different prescribers.

91. Defendants dispensed buprenorphine pursuant to prescriptions from five different prescribers. The ICD-10 code used to support the prescriptions for K.K. in Shaffer Pharmacy's records is "Opioid dependence." In addition to buprenorphine, which is indicated for the treatment of opioid dependence, Defendants dispensed dangerous combinations of drugs associated with drug abuse, including oxycodone, fentanyl, morphine, hydrocodone, buprenorphine, benzodiazepines, skeletal muscle relaxants, sedatives, and stimulants.

92. Patient K.K.'s diagnosis is insufficient to justify the level and duration of prescription drug therapy dispensed.

93. All of the schedule II-IV controlled substance prescriptions that Shaffer Pharmacy filled for Patient K.K. from April 2016 through April 2020 are identified in a chart attached to this Complaint as Exhibit 7. The chart reflects which prescriptions were filled by Tadsen and which were filled by Bunton. No other pharmacist at Shaffer Pharmacy filled any prescriptions for Patient K.K.

94. Each of the controlled substances listed in the chart in Exhibit 7 is a prescription drug under the FDCA.

95. Defendants knowingly dispensed these controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1); and 21 C.F.R. § 1306.04.

96. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

Count I
Unlawful Dispensing of Controlled Substances
21 U.S.C. §§ 829, 842(a)(1), 842(c)(1)(A)
Civil Penalties
(All Defendants)

97. The United States repeats and realleges Paragraphs 1 through 96 as if fully set forth herein.

98. Defendants knowingly dispensed controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1); and 21 C.F.R. § 1306.04.

99. Defendants dispensed controlled substances while acting outside the usual course of the professional practice of pharmacy and not in compliance with its "corresponding responsibility" in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

100. As a result of the foregoing, 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 $67,627 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 II
Unlawful Dispensing of Controlled Substances
21 U.S.C. §§ 829, 842(a)(1), 843(f), 882(a)
Injunctive Relief
(All Defendants)

101. The United States repeats and realleges Paragraphs 1 through 96 as if fully set forth herein.

102. Defendants knowingly dispense controlled substances pursuant to prescriptions that are issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1); and 21 C.F.R. § 1306.04.

103. Defendants dispense controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

104. Based on the foregoing, unless enjoined by this Court pursuant to 21 U.S.C. §§ 843(f) and 882(a), Defendants will continue to violate the Controlled Substances Act in the manner set forth above.

DEMAND FOR RELIEF

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

A. On Count I, impose a civil penalty on Defendants of not more than $25,000, for each violation occurring on or before November 2, 2015, and not more than $67,627, for each violation after November 2, 2015, for each and every violation of 21 U.S.C. §§ 829(a) and 842(a)(1) and 21 C.F.R. §§ 1306.04 and 1306.06, and

B. On Count II, order appropriate injunctive relief pursuant to 21 U.S.C. §§ 843(f) and 882(a).

Respectfully submitted,

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