McGREGOR W. SCOTT
United States Attorney
STEVEN S. TENNYSON
Assistant United States Attorney
501 I Street, Suite 10-100
Sacramento, CA 95814
Telephone: (916) 554-2700
Facsimile: (916) 554-2900

Attorneys for the United States

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. LAWRENCE HOWEN and NOR-CAL PHARMACIES, INC. D/B/A LOCKEFORD DRUG, Defendants.	CASE NO. COMPLAINT FOR CIVIL PENALTIES AND INJUNCTIVE RELIEF

The United States of America files this Complaint against Lawrence Howen and Nor-Cal Pharmacies, Inc. d/b/a Lockeford Drug and alleges as follows:

INTRODUCTION

1. The United States brings this civil enforcement action for damages and injunctive relief against Defendants for violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970 ("Controlled Substances Act" or "CSA"), 21 U.S.C. §§ 801 *et seq*.

2. The CSA comprehensively regulates every participant in the supply chain for controlled substances, from manufacturers to wholesale distributors to retail pharmacies. Because controlled substances by definition are drugs with the potential for abuse, this comprehensive scheme is designed to prevent the "diversion"—*i.e*., the illegal misuse—of controlled substances, including prescription opioids.

3. Under the CSA, every participant in the supply chain bears responsibility for preventing

the misuse of controlled substances. Defendants—a pharmacy registered with Drug Enforcement Administration and its pharmacist—assumed critical gatekeeping responsibilities under the CSA to prevent the diversion of controlled substances, including prescription opioids.

4. At two stages—when deciding whether to fill individuals' prescriptions for controlled substances and when deciding whether to complete and maintain certain records—the CSA required Defendants to take steps to prevent the diversion of the prescription drugs they sold. Yet, for years, as the prescription drug abuse epidemic ravaged the country, Defendants abdicated those responsibilities, filling 702 invalid prescriptions that exhibited one or more clear red flags indicating that the prescriptions were likely illegitimate. Defendants did so in open disregard of the CSA's dispensing requirements.

5. As a result of Defendants' failures to take seriously these gatekeeping duties, they—during the prescription drug abuse epidemic—unlawfully dispensed over a hundred thousand opioid pills based on invalid prescriptions.

6. Predictably, Defendants' violations of the CSA had disastrous results, leading to the diversion of controlled substances and exacerbating the prescription opioid epidemic.

PARTIES

7. Plaintiff is the United States of America.

8. Defendant Nor-Cal Pharmacies, Inc. d/b/a Lockeford Drug ("Lockeford Drug") is incorporated under the laws of the State of California. Lockeford Drug was a pharmacy located in Lockeford, California that dispensed controlled substances to customers, including substances listed on Schedules II through V until at least September 2019. All at relevant times, Lockeford Drug was registered with DEA as registrant number BN3982938.

9. Defendant Lawrence Howen ("Howen") is an individual residing in Calaveras County, which is within the Eastern District of California. He was a pharmacist licensed to dispense controlled substances by the State of California. Howen was the owner and Pharmacist in Charge at Lockeford Drug.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1345,

and 1355(a), and 21 U.S.C. § 842(c)(1) and § 843(f)(2).

11. This Court has personal jurisdiction over Defendants because they can be found in, reside in, transact business in, and have committed the alleged acts in the Eastern District of California.

12. Venue is proper in this district under 28 U.S.C. § 1395(a) and 21 U.S.C. § 843(f) because the alleged acts giving rise to the United States' claims occurred within the Eastern District of California.

DEFENDANTS' CSA OBLIGATIONS

A. Regulations of Controlled Substances under the CSA.

13. The CSA creates a category of drugs, known as "controlled substances," that are subject to federal monitoring and regulation based on their potential for abuse. Controlled substances are categorized into five schedules based on several factors, including whether they have a currently accepted medical use to treat patients, their abuse potential, and the likelihood they will cause dependence if abused. A drug becomes a "controlled substance" when it is added to one of these schedules.

14. Schedule I drugs are those deemed not to have an accepted medical use. The remaining schedules—Schedules II through V—are relevant to this case. The drugs in these schedules have legitimate medical purposes and, in the case of Schedules II through IV, require a prescription.

15. Schedule II lists controlled substances that have "a high potential for abuse," that, if abused, "may lead to severe psychological or physical dependence," but that nonetheless have "a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions." 21 U.S.C. § 812(b)(2). Schedule II includes opioid based painkillers such as oxycodone, hydrocodone, and methadone, and stimulants such as amphetamine. *See* 21 C.F.R. § 1308.12.

16. Schedule III lists controlled substances that have "a potential for abuse less than the drugs or other substances in schedules I and II," that, if abused, "may lead to moderate or low physical dependence or high psychological dependence," but that nonetheless have "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(3). Schedule III includes buprenorphine, a medication approved to treat opioid use disorder. *See* 21 C.F.R. § 1308.13.

17. Schedule IV lists controlled substances that have "a low potential for abuse relative to the drugs or other substances in schedule III," that, if abused, "may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III," but that nonetheless have "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(4). Schedule IV includes alprazolam (commonly sold under the brand name Xanax), diazepam (commonly sold under the brand name Valium), and lorazepam (commonly sold under the brand name Ativan). *See* 21 C.F.R. § 1308.14. Each of these three drugs belongs to a class of medications called benzodiazepines, which act on the brain and nerves to produce a calming effect. Schedule IV also includes carisoprodol, a muscle relaxant that is often sold under the brand name Soma, and zolpidem, an insomnia medication that is often sold under the brand name Ambien. Carisoprodol and zolpidem are components of dangerous drug "cocktails" sought by individuals known to abuse or misuse prescription drugs.

18. Schedule V lists controlled substances that have "a low potential for abuse relative to the drugs or other substances in schedule IV," that, if abused, "may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV," but that nonetheless have "a currently accepted medical use in treatment in the United States." 21 U.S.C. § 812(b)(5). Schedule V includes certain dosages of promethazine-codeine. *See* 21 C.F.R. § 1308.15.

B. The CSA Creates a Closed System for Regulating Controlled Substances.

19. Through the CSA, Congress sought to prevent diversion and abuse of controlled substances. To accomplish this goal, the CSA created a "closed" system for regulating and monitoring controlled substances, under which it is unlawful to distribute, dispense, or possess any controlled substance except in a manner authorized by law. The CSA and its implementing regulations govern every step in the handling of scheduled drugs, including from their prescription by a medical practitioner to their dispensing by a pharmacy.

20. The system is "closed" in that each part of the supply chain—including pharmacies like Lockeford Drug—must register with DEA and comply with the CSA and its implementing regulations. 21 U.S.C. §§ 822(a)(2) and 823(f).

21. Entities who register with DEA ("Registrants") agree to comply with the CSA and its

implementing regulations, and may manufacture, distribute, prescribe, or dispense controlled substances only to the extent authorized by their registration and the law. *See* 21 U.S.C. §§ 822(a)-(b), 823(f).

C. A Pharmacy Must Comply with Federal Law in Filling Controlled Substance Prescriptions.

22. Ordinarily, the last step in the closed distribution system is the pharmacy that, after being presented with a valid prescription, dispenses a controlled substance to the end user.

23. The CSA designates pharmacies as "practitioners" that are permitted to handle controlled substances if they adhere to the course of "professional practice." 21 U.S.C. § 802(21).

24. The CSA makes it unlawful "for any person . . . to . . . dispense a controlled substance in violation of section 829." 21 U.S.C. § 842(a)(1).

25. The Attorney General has promulgated, in 21 C.F.R. Part 1306 ("Prescriptions"), rules for when prescriptions may be filled pursuant to a prescription 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").

26. As relevant here, Part 1306 sets forth three rules pharmacies must follow when dispensing controlled substances. For each controlled substance prescription, a pharmacist must (1) ensure that the prescription was issued by a medical practitioner adhering to the usual course of his or her professional practice, (2) ensure that the prescription is for a legitimate medical purpose, and (3) in filling the prescription, adhere to the usual course of his or her own professional pharmacy practice.

27. At all relevant times to this action, Lockeford Drug, as a Registrant with DEA, had agreed to and was required to comply with the CSA and its implementing regulations governing the dispensing of controlled substances.

i. Pharmacists Must Ensure Prescriptions Were Issued in the Usual Course of Professional Medical Practice and for a Legitimate Medical Purpose.

28. 21 C.F.R. § 1306.04(a) defines requirements for a controlled substance prescription to be valid or "effective" and also imposes obligations on both the medical practitioner who issues the prescription and the person who fills the prescription.

29. To be valid, a prescription for a controlled substance must meet two requirements: (1) a

prescription must be issued by a medical practitioner acting in the usual course of his professional practice and (2) the prescription must be issued for a legitimate medical purpose.

30. While section 1306.04(a) imposes a responsibility on prescribers to issue valid prescriptions, it also imposes a "corresponding responsibility" on the pharmacist who fills the prescription to ensure that the prescription is valid—that is, was issued for a legitimate medical purpose and in the usual course of the prescriber's professional practice.

31. A pharmacist violates this corresponding responsibility when, in dispensing a controlled substance, a "red flag" was or should have been recognized at or before the time the controlled substance was dispensed, and the pharmacist does not resolve the question created by the red flag conclusively prior to dispensing the controlled substance.

32. Red flags that must be resolved prior to dispensing a controlled substance include: cash payments; long distances traveled from the patient's home to the prescriber's office or to the pharmacy; prescriptions written for duplicative drug therapy; prescriptions written for an unusually large quantity of drugs; initial prescriptions written for strong opiates; irregularities in the prescriber's qualifications in relation to the type of medication prescribed; prescriptions that are written outside of the prescriber's medical specialty; irregularities on the face of the prescription itself; irregularities concerning the presentation of the patient; multiple patients all with the same address; requests for early refills of prescriptions; and prescriptions for medications with no logical connection to an illness or condition.

33. In extreme circumstances, prescriptions may raise a combination of red flags that provide such strong evidence of diversion that they are unresolvable.

ii. The Pharmacist Must Adhere to their Own Standards of Professional Pharmacist Practice.

34. In filling prescriptions for controlled substances, a pharmacist's conduct must also adhere to the usual course of his or her professional practice as a pharmacist. 21 C.F.R. § 1306.06 (requiring that "[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice . . . .").

35. Pharmacists are professionals who must be licensed by the states in which they practice.

36. In California, when evaluating the validity of a controlled substance prescription,

pharmacists cannot rely exclusively on the fact that it was issued by a medical practitioner. Rather, pharmacists must assess a prescription's validity by considering signs that it may be invalid or that the controlled substances may be abused or misused.

37. One of the key professional responsibilities of California pharmacists, when presented with a prescription for controlled substances, is to identify and resolve any warning signs that the prescription is valid before filling the prescription. These warning signs may arise based on the prescriber who issued the prescription, the prescription itself, or the individual presenting the prescription.

38. This responsibility—to identify any red flags and resolve them before filling a controlled substance prescription—is well-recognized in the professional field of pharmacy. This responsibility is discussed in the training of pharmacists, by pharmacists at professional conferences, and in training materials prepared by pharmacy boards, including the California Board of Pharmacy.

39. When a pharmacist identifies red flags, the pharmacist must attempt to resolve them and document these attempts. In other words, pharmacists, when presented with a controlled substance prescription bearing a red flag, must—as part of the usual course of professional pharmacy practice—investigate and either (a) resolve the red flag before dispensing and document the resolution, or (b) refuse to fill the prescription.

iii. Violations of these Dispensing Rules Subject the Pharmacy to Civil Penalties and other Appropriate Relief.

40. A person dispensing controlled substances not in compliance with the requirements above violates 21 U.S.C. § 829 and thus 21 U.S.C. § 842(a)(1).

41. The CSA provides that a person who violates 21 U.S.C. § 842(a)(1) shall, with respect to any such violation, be subject to a civil penalty. 21 U.S.C. § 842(c)(1)(A); 28 C.F.R. § 85.5.

42. When a corporation's agents or employees violate the rules for dispensing controlled substances, the corporate entity may be held liable for the civil penalty.

43. The CSA also authorizes the Attorney General to seek injunctive relief relating to violations of the CSA. 21 U.S.C. § 843(f)(1).

DEFENDANTS VIOLATED THE CSA IN DISPENSING CONTROLLED SUBSTANCES

44. Defendants violated the CSA's dispensing rules, filling enormous numbers of invalid prescriptions, without exercising any corresponding responsibility to ensure the proper dispensing of controlled substances.

45. These numerous, widespread dispensing violations were the inevitable result of Defendants' failure to take seriously their duty to comply with their CSA obligations.

A. The Red Flags

46. From 2016 until 2019, Defendants dispensed 702 controlled substance prescriptions to individuals with purported prescriptions from Monterey County physician Dr. Deane Crow.

47. On October 31, 2019, a federal grand jury in the Northern District of California returned a criminal indictment against Dr. Crow, charging him with a conspiracy to trade controlled substances prescriptions for cash. The indictment alleged that Dr. Crow "signed blank paper prescriptions and provided them" to co-conspirator Joe Bernal, who was indicted on the same date, that allowed Bernal to fill in the name of the patient, the name of the controlled substance to be prescribed, and the quantity of the controlled substances to be dispensed.

48. Joe Bernal and his associates (collectively, the "Crow Customers") took purported prescriptions signed by Dr. Crow to Lockeford Drug to get them filled.

49. The Crow Customers' prescriptions, described with specificity in Appendix 1, exhibited obvious red flags that indicated a high probability that the prescriptions were invalid. Defendants were required to resolve these red flags before filling these prescriptions by dispensing controlled substances, but failed to do so.

i. Cash Payments

50. Of the 702 controlled substances prescriptions Lockeford Drug dispensed to the Crow Customers, 700—or 99.7%—were for cash payment.

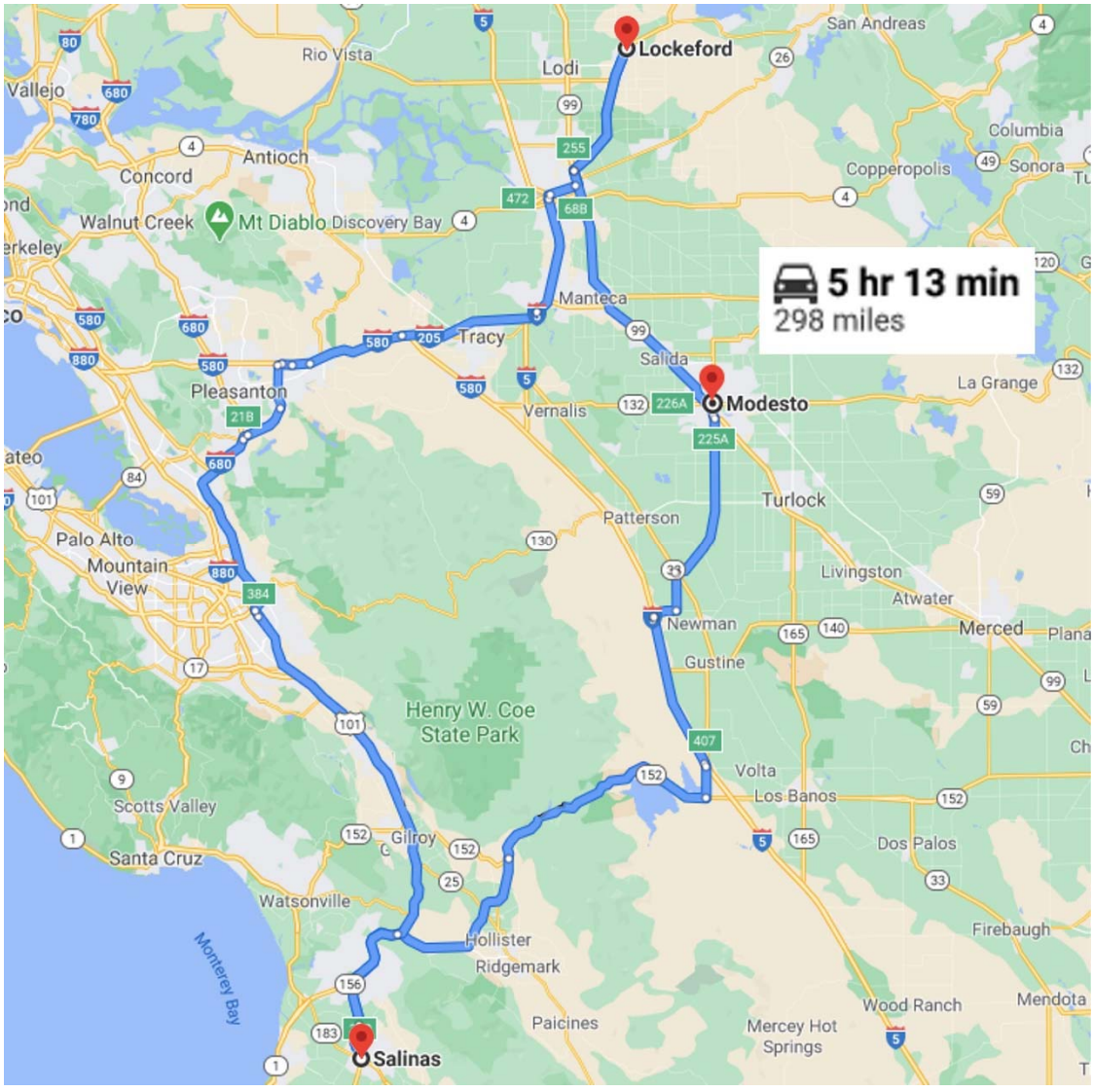
51. Cash payment by patients, especially by patients with no history with a pharmacy, is a red flag. Generally, patients do not desire to pay high out-of-pocket costs for medications and therefore use insurance to defray the up-front costs of obtaining medications. However, controlled substances obtained pursuant to invalid prescriptions are frequently paid with cash to avoid insurance tracking

software.

ii. Long Distances

52. All of the Crow Customers traveled long distances to obtain controlled substances from Lockeford Drug.

53. In over 500 instances, Defendant's own records warned them that the Crow Customers were driving 300 miles from their addresses in Modesto, to Dr. Crow's office in Salinas, to Lockeford Drug, and then back to Modesto, in order to fill large controlled substances prescriptions for cash payment—rather than fill a prescription from a local physician at a local neighborhood pharmacy, as follows:



54. It was a red flag of illegitimacy for so many patients to drive significant distances and the same circuitous route to fill opioid prescriptions.

iii. Identical Treatments

55. Dr. Crow prescribed, and Lockeford Drug dispensed, nearly identical treatments to almost all of the Crow Customers, despite their different types of presentations.

56. Due to the variety of presentations of pain symptoms, medications with differing mechanisms of actions are typically prescribed. The prescribing patterns for legitimate pain treatment typically include medications for neuropathic pain, inflammation, and muscle relaxants.

57. None of these common pain treatments were prescribed by Dr. Crow and dispensed by Lockeford Drug.

58. There is variability among patients which necessitates different doses. Oxycodone, for example, is available in 5, 10, 15, 20, and 30 milligram tablets. Normal use would typically involve starting at a lower dose and titrating the dose upwards based on specific patient's needs.

59. Only the highest available strengths for controlled substances were prescribed by Dr. Crow and dispensed by Lockeford Drug. There was no adjustment in the prescribing pattern from Dr. Crow for age, weight, renal or hepatic function, diagnosis, or other patient-related factors.

60. As an example, on ten separate dates during February 2019, Lockeford Drug dispensed identical or nearly identical treatments to multiple Dr. Crow patients on the exact same day. All of these patients received at least 180 tablets of the highest available dose of Oxycodone and 180 tablets of a high dose of Hydrocodone. All of them had traveled long distances. And all of them paid cash.

61. This uniformity of treatment, both in general and on the exact same days, was a red flag of illegitimacy.

iv. High Initial Starting Doses

62. Lockeford Drug dispensed high initial starting doses of opioids to the Crow Customers, including to patients who had never previously been prescribed opioids.

63. Opioid tolerance renders patients less susceptible to the effects of opioids, including some adverse effects. In contrast, patients without opioid tolerance who receive high initial starting doses of opioids are at greater risk for complications, especially sedation and respiratory depression,

which may result in death.

64. If a patient lacks an opioid tolerance, *i.e.* are opioid naïve, treatment requires dose escalation while monitoring of the patient's response. For these patients, the recommended starting dose of Oxycodone is 5 to 15 milligrams every 4 to 6 hours as needed, and the recommended starting dose of Methadone is 2.5 milligrams every 8 to 12 hours.

65. In sixteen instances, Defendants dispensed initial doses of Oxycodone at 30 milligrams every 4 to 6 hours and initial doses of Methadone at 10 milligrams every 8 to 12 hours, to Dr. Crow's opioid naïve patients. This was two to four times the appropriate initial dose.

66. On twelve of those sixteen instances during which Defendants dispensed two to four times the appropriate initial dose of Oxycodone or Methadone to the Crow Customers, Defendants also dispensed 120 tablets of Hydrocodone to those patients.

67. Were these patients to ingest the controlled substances that Lockeford Drug dispensed, rather than divert them, they would be at risk for adverse effects, such as sedation and respiratory depression, which could result in death.

68. These high initial doses to opioid naïve patients raises a significant red flag that these individuals were diverting the opioids, rather than consuming them for a legitimate medical purpose.

v. Early Refills of Schedule II Drugs

69. Because a prescription for a given controlled substance requires the dosage, quantity, and directions for use, *see* 21 C.F.R. § 1306.05(a), there is a specific date on which the supply of drugs dispensed pursuant to that prescription will be exhausted. For example, if a prescriber prescribes a drug of a particular dose, directs that it be taken six times per day, and prescribes a total of 180 tablets, the prescription authorizes a 30-day supply of drugs for the individual. If the individual follows the prescriber's directions, the 180 tablets will run out on the 30th day of taking the drugs.

70. When an individual requests to fill a prescription before the previous supply has been exhausted or before the date that the prescriber has authorized the prescription to be filled, it raises a significant red flag that the individual may have been abusing the drugs by taking more than the directed dose or that the individual has been diverting the drugs by distributing them to others.

71. Upon the Crow Customers' request, Defendants filled prescriptions for Schedule II

controlled substances early, before that individual should have exhausted the previously dispensed supply from an earlier prescription in five instances.

vi. Late Filling of Opioid Prescriptions

72. Opioids are prescribed for pain when alternative treatment options are inadequate. Almost always, they are prescribed for a 30-day period per prescription. It would be irregular for such a prescription to be presented which had been written more than one month previously. And a reasonable and prudent pharmacist would make inquiries to determine if these potent controlled substances were still required, or if the patient's condition had changed since receiving the prescription.

73. In five instances, Defendants dispensed large quantities of opioids to the Crow Customers, even though they presented prescriptions that had been written more than one month previously.

vii. Other Irregularities

74. The Crow Customers requested that Lockeford Drug dispense specific brands of opioids associated with diversion. For instance, rather than generic Oxycodone, the Crow Customers specifically requested the "blue ones," which have a higher resale price on the street.

75. One common opioid cocktail consists of a prescription for an opioid, such as Oxycodone, combined with a prescription for a benzodiazepine, such as Diazepam. This cocktail combination is a red flag for possible abuse because it enhances the "high" experienced by those using the opioid. It is also dangerous because it increases the risk of complications, especially sedation and respiratory depression, which may result in death.

76. Dr. Crow prescribed, and Lockeford Drug dispensed, opioid cocktails—consisting of an opioid and benzodiazepine—to the Crow Customers, often every month for years at a time.

77. The circumstances—requests for particular brands of opioids and prescriptions for drug cocktails—were all warning signs that the Crow Customers' prescriptions were illegitimate.

viii. Groups of Patients

78. Groups of patients all arriving with prescriptions for the same controlled substances from the same doctor is a red flag that the prescriptions are illegitimate.

79. The Crow Customers routinely arrived in groups at Lockeford Drug, and all of them had

prescriptions for identical or nearly identical powerful controlled substances, prescribed by Dr. Crow.

ix. Multiple Red Flags Surrounding Bernal

80. Defendants regularly permitted one of the Crow Customers, Bernal, to fill prescriptions for his associates, who had no prior relationship with Lockeford Drug and who had never been to Lockeford Drug.

81. Defendants only required Bernal to provide a paper prescription and picture of the associates' identification.

82. During single visits to Lockeford Drug, Bernal filled prescriptions for over five associates at a time.

83. Bernal only paid cash.

84. Bernal traveled the circuitous route described above.

85. Nearly all of these patients had identical treatments—180 Oxycodone 30 milligram tablets, 180 Hydrocodone 325 milligram tablets, and 120 Diazepam 10 milligram tablets—and all of them had the same prescriber, Dr. Crow.

86. As a result, Bernal traveled long distances to obtain identical opioid treatments for multiple patients who had never been to Lockeford Drug, paying Defendants thousands of dollars in cash during each visit.

87. These circumstances were highly suggestive that these Crow Customers were not presenting legitimate prescriptions to Defendants.

88. When asked whether the situation described above raised red flags, Howen admitted, "yes, it does."

B. <u>Defendants Violated their Dispensing Obligations</u>

89. All of the Crow Customers' 702 prescriptions were so questionable, and so indicative of prescription drug abuse or diversion, that Defendants were required to resolve these numerous red flags before dispensing and document the resolution, or refuse to fill the prescription.

90. Howen knew that drug abusers engaged in pharmacy shopping, looking for easy places to fill opioid prescriptions.

91. Defendants took no steps to determine the validity of the Crow Customers' prescriptions.

92. There was no explanation, verified and documented by Defendants, for the prescriptions in question despite the significant red flags described above.

93. Defendants did nothing to ensure that the Crow Customers were not diverting the controlled substances they dispensed.

94. Defendants did nothing to ensure that the Crow Customers were not abusing the controlled substances that they dispensed.

95. Defendants did not have any written policies concerning opioid dispensing or to prevent the diversion of opioids.

96. Without exercising any corresponding responsibility, Defendants filled at least 702 illegitimate prescriptions for the Crow Customers, dispensing at least the following quantities of controlled substances to them:

Name	Dose	Quantity
Oxycodone	30mg	52,530
Hydrocodone	325mg	51,980
Methadone	10mg	6,480
Diazepam	10mg 5mg	5,220 120
	Total:	116,330

97. By failing to resolve the red flags discussed above prior to dispensing controlled substances to the Crow Customers, Defendants knew or deliberately ignored that they were dispensing controlled substances pursuant to prescriptions that were either not issued in the usual course of professional treatment, not for a legitimate medical purpose, or both.

98. By failing to resolve the red flags discussed above prior to dispensing controlled substances to the Crow Customers, Defendants violated 21 C.F.R. § 1306.06, which requires that a pharmacist's conduct, when filling controlled-substance prescriptions, must adhere to the usual course of his or her professional practice as a pharmacist.

99. Defendants' dispensing violations resulted in the improper dispensing of over 116,000 doses of controlled substances, some of which was diverted. For instance, the Crow Customers traded the controlled substances that Lockeford Drug dispensed for cash in a fast food restaurant's parking lot.

///

100. Defendants profited by shirking their professional responsibilities, collecting hundreds of thousands of dollars in cash from the Crow Customers for filling improper prescriptions that should have been rejected.

DEFENDANTS FAILED TO MAINTAIN REQUIRED RECORDS

101. Defendants repeatedly and systemically violated federal law by failing to make and maintain complete and accurate records of controlled substances that they handled and claim to have destroyed.

102. Any person who negligently fails 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), is subject to a civil penalty under 21 U.S.C. § 842(c)(1)(B).

103. 21 C.F.R. § 1304.11(c) requires registrants to "take a new inventory of all stocks of controlled substances on hand at least every two years."

104. 21 C.F.R. § 1305.13(e) requires registrants to record on their copy of the "DEA Form 222" the number of commercial or bulk containers furnished on each item and the dates on which the containers are received or transferred by them.

105. 21 C.F.R. § 1304.21(a) requires registrants to "maintain, on a current basis, a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by" him or her.

106. 21 C.F.R. § 1304.21(e) requires registrants that destroy "a controlled substance pursuant to §1317.95(d), or causes the destruction of a controlled substance pursuant to §1317.95(c), [to] maintain a record of destruction on a DEA Form 41." The records must be complete and accurate, and include the name and signature of the two employees who witnessed the destruction.

107. In the midst of the United States' investigation into Defendants' dispensing violations, Lockeford Drug suddenly ceased operations in September 2019, and Defendants removed controlled substances from its registered location.

108. In violation of 21 C.F.R. § 1304.11(c), Defendants could not produce a complete and accurate biennial inventory of their controlled substances.

///

109. In two instances, Defendants could not provide a DEA Form 222 accurately reflecting the quantity of controlled substances that they had provided to reverse distributors in violation of 21 C.F.R. § 1304.13(e).

110. In 442 instances, Defendants failed to maintain complete and accurate records of transactions reflected in their dispensing records in violation of 21 C.F.R. § 1304.21(a).

111. In 72 instances, Defendants failed to maintain a complete and accurate record of the substances that they claim were destroyed in violation of 21 C.F.R. §1304.21(e).

112. In January 2019, Howen stated to one of his employees that he was not afraid of government regulators and therefore felt entitled to disregard his obligations under the CSA.

113. Defendants' sudden closure of Lockeford Drug and failure to make and maintain complete and accurate records prevented the DEA from accurately auditing them and determining whether controlled substances have been diverted for illegal use.

COUNT I

Failure to Exercise Corresponding Responsibility in Violation of 21 C.F.R. § 1306.04(a)

114. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

115. Defendants repeatedly violated 21 U.S.C. §§ 842(a)(1) and 829, and 21 C.F.R. § 1306.04(a), by knowingly dispensing controlled substances pursuant to prescriptions that were either not issued in the usual course of professional treatment, not issued for a legitimate medical purpose, or both.

116. Defendants violated these provisions on at least 702 occasions, with the precise number of violations to be established at trial.

117. For each violation, Defendants are liable for a civil penalty as provided under 21 U.S.C. § 842(c)(1)(A).

COUNT II

Failure to Adhere to the Usual Course of Professional Practice in Violation of 21 C.F.R. § 1306.06

118. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

///

119. Defendants repeatedly violated 21 U.S.C. §§ 842(a)(1) and 829, and 21 C.F.R. § 1306.06 by failing to adhere to the usual course of the professional practice of pharmacy in filling prescriptions for controlled substances.

120. Defendants violated these provisions on at least 702 occasions, with the precise number of violations to be established at trial.

121. For each violation, Defendants are liable for a civil penalty as provided under 21 U.S.C. § 842(c)(1)(A).

COUNT III
Failure to Maintain Required Records

122. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

123. On at least 517 occasions, Defendants failed to make and maintain complete and accurate records of the controlled substances, as required by the CSA.

124. Defendants' failure to make and maintain complete and accurate records was intentional, reckless, or at the very least, negligent.

COUNT IV
Claim for Injunctive Relief

125. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

126. Defendants repeatedly violated 21 U.S.C. § 842(a)(1).

127. Pursuant to 21 U.S.C. § 843(f), an order permanently enjoining Defendants from dispensing controlled substances is appropriate.

///

///

///

///

///

///

PRAYER FOR RELIEF

WHEREFORE, the United States requests that judgment be entered in its favor and against Defendants Lawrence Howen and Nor-Cal Pharmacies, Inc. d/b/a Lockeford Drug, as follows:

a) Imposing a civil penalty upon Defendants in the maximum amount allowed by law;

b) Enjoining Defendants' violations of law; and

c) Granting the United States such further relief as the Court may deem proper.

Dated: January 25, 2021

McGREGOR W. SCOTT
United States Attorney

By: */s/ Steven S. Tennyson*
STEVEN S. TENNYSON
Assistant United States Attorney