UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA TAMPA DIVISION

UNITED STATES OF AMERIC

Plaintiff,

v. Case No.:

TOBIAS BACANER, M.D.; TOBIAS & JILL BACANER REVOCABLE TRUST; THEODORE FERGUSON, II; TIMOTHY FERGUSON; PARAGON COMMUNITY HEALTHCARE, INC.; and COBALT PHARMACY, INC.,

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

INTRODUCTION

- 1. The United States of America sues for injunctive relief and civil monetary penalties based on the defendants' violations of the Controlled Substances Act, 21 U.S.C. § 801, et seq. (the "CSA") and its implementing regulations, 21 C.F.R. § 1301, et seq.
- 2. Opioid abuse is a national public health emergency. The prescribing, 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 and harms the public health.

- 3. Defendant Tobias Bacaner, a medical doctor licensed in Florida, wrote prescriptions for potent and dangerous opioids despite obvious signs of immediate peril to his patients from those drugs. His business partners and co-defendants, Theodore and Timothy Ferguson, profited from Dr. Bacaner's dangerous and unlawful prescribing at the Fergusons' cash-only pain clinic, Paragon Community Healthcare. The Fergusons and Dr. Bacaner profited again when patients from Paragon went to their jointly owned pharmacy, Cobalt Pharmacy, where the defendants charged inflated cash prices to fill opioid prescriptions.
- 4. Some patients who received the drugs the defendants unlawfully prescribed and filled have died or suffered irreparable physical harm because of drug overdoses and addiction. The United States seeks to enjoin defendants' unlawful conduct to protect the public health and impose civil monetary penalties for past violations of the CSA.

JURISDICTION AND VENUE

- 5. This Court has jurisdiction over the subject matter and all parties to 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. This Court has personal jurisdiction over the defendants, and venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1391(c) because the defendants either reside in this District or transact business in this District.

PARTIES

7. Plaintiff is the United States of America.

- 8. Defendant Tobias Bacaner is a medical doctor licensed to practice in Florida, British Columbia, Indiana, and Utah. Dr. Bacaner is trained and board-certified in general surgery. Beginning in 2014, he practiced pain management at Paragon Community Healthcare, Inc.
- 9. Defendant Paragon Community Healthcare, Inc. (the "Paragon Clinic") is a Florida not-for-profit corporation owned by Timothy and Theodore Ferguson. Paragon Clinic has a principal address of 6131 U.S. Highway 19, New Port Richey, Florida, 34652.
- 10. Defendant Cobalt Pharmacy, Inc. ("Cobalt Pharmacy"), is a Florida corporation that operated as a retail pharmacy and is located at 7135 State Road 52, Suite 103, Hudson, Florida, 34667. The Fergusons incorporated Cobalt Pharmacy on February 15, 2016. Shortly thereafter, Dr. Bacaner became an owner individually and then through the Trust. On approximately January 22, 2021, DEA was notified by Cobalt Pharmacy that it had ceased operations as a pharmacy.
- 11. Defendant Timothy Ferguson co-owns the Paragon Clinic and co-owned Cobalt Pharmacy together with Dr. Bacaner and Theodore Ferguson.
- 12. Defendant Theodore Ferguson, II, co-owns Paragon Clinic and co-owned Cobalt Pharmacy together with Dr. Bacaner and Timothy Ferguson.
- 13. Defendant Tobias & Jill Bacaner Revocable Trust (the "Trust") is a trust through which Dr. Bacaner co-owned Cobalt Pharmacy.

LEGAL BACKGROUND

A. The Controlled Substances Act

- 14. The CSA and its implementing regulations govern the manufacturing, distributing, and dispensing of controlled substances in the United States. Congress recognized the importance of preventing the diversion of drugs from legitimate to illegitimate uses. The CSA establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. § 841(a).
 - 15. The CSA categorizes controlled substances in five schedules.
- 16. Schedule I consists of substances that have "a high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use under medical supervision." 21 U.S.C. § 812(b)(1); 21 C.F.R. § 1308.11.
- 17. 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).
- 18. 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." Schedule III drugs also have "a currently accepted medical use." 21 U.S.C. § 812(b)(3).
- 19. Schedule IV contains drugs that, although having a lower abuse potential than Schedule III drugs, still may lead to a physical or psychological

dependence when abused. 21 U.S.C. § 812(b)(4).

- 20. Schedule V contains drugs that, although having a lower abuse potential than Schedule IV drugs, still may lead to a physical or psychological dependence when abused. 21 U.S.C. § 812(b)(5).
- 21. As relevant here, the following substances are controlled substances regulated under the CSA:
 - a. Methadone (Schedule II);
 - b. Hydromorphone (Schedule II);
 - c. Oxycodone (Schedule II).
- 22. 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).
- 23. 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).
- 24. The CSA also prohibits maintaining a drug-involved premises. This means (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.

B. Obligations of Physicians

- 25. The CSA requires every person who dispenses any controlled substance to obtain a registration from the DEA. 21 U.S.C. § 822(a)(2); 21 C.F.R. § 1306.03. A physician who prescribes a controlled substance "dispenses" the controlled substance within the meaning of the CSA and, therefore, must register with the DEA. 21 U.S.C. §§ 802(10), (21).
- 26. At all relevant times, Dr. Bacaner was registered under DEA No. FB4117695 to dispense controlled substances.
- 27. A prescription for a controlled substance is valid 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); *United States v. Moore*, 423 U.S. 122, 140 (1975). A physician order purporting to be a prescription but not issued for a legitimate medical purpose or in the usual course of professional practice is not a prescription within the meaning of 21 U.S.C. § 829.
- 28. This means that a physician may prescribe a controlled substance only in accord with a generally accepted, objective standard of medical practice.
- 29. Acting in the usual course of professional practice includes complying with all relevant state law.
- 30. In Florida, the "prevailing professional standard of care for a given health care provider shall be that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers." Fla. Stat. § 766.102.

- 31. A physician who prescribes a controlled substance in Schedules II through IV must also abide certain minimum standards of practice for controlled substances prescribing. Fla. Stat. § 456.44(2)-(3).
- 32. Florida House Bill 21, effective July 1, 2018, amended state law to require that a provider consult a patient's profile in the prescription drug monitoring program ("PDMP") database before prescribing a controlled substance. Fla. Stat. § 893.055(8).
- 33. Finally, the CDC Guidelines for Prescribing Opioids for Chronic Pain, published in March, 2016, provide a relevant guidepost of physicians and inform the standard of care for prescribing opioids to chronic pain patients.¹

C. Obligations of Pharmacies and Pharmacists

- 34. At all times relevant to this complaint, Cobalt Pharmacy was registered as a retail pharmacy under DEA No. FC6995748 effective August 31, 2017.
- 35. 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).
- 36. 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).

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¹ Deborah Dowell, M.D. et al., CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, 65 MORBIDITY & MORTALITY WKLY. REP. 1 (2016) [hereinafter, CDC Guideline]

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).

- 37. 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).
- 38. Thus, a pharmacist must refuse to fill a controlled substance prescription if the pharmacist knows or has reason to know that the prescription was not written for a legitimate medical purpose or in the usual course of the physician's professional practice. 21 C.F.R. §§ 1306.04.
- 39. Additionally, a pharmacist must act in the usual course of her professional practice as a pharmacist when filling a prescription. 21 C.F.R. § 1306.06. This means that a pharmacist may dispense a controlled substance only in accord with a generally accepted, objective standard of pharmacy practice and only when a prescription was issued for a legitimate medical purpose. This also means complying with relevant state law.
- 40. In Florida, only a "pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances " Fla. Stat. § 893.04(1).
- 41. Florida law requires that, as a condition of obtaining a pharmacy permit, the pharmacy designate a licensed pharmacist as a "prescription department

manager," commonly known as a pharmacist-in-charge (a "PIC"). Fla. Stat. § 465.018(2). The PIC is "responsible for ensuring . . . compliance with all statutes and rules governing the practice of the profession of pharmacy, including maintenance of all drug records and ensuring the security of the prescription department, and shall competently and diligently exercise their responsibilities." Fla. Admin. Code. § 64B16-27.450(2).

42. A pharmacist must exercise sound professional judgment in determining the legitimacy of a controlled substance prescription. Fla. Admin. Code § 64B16-27.831. "[W]hen a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment." Fla. Admin. Code § 64B16-27.831(2). A pharmacist must also conduct a prospective drug use review for each new and refill prescription, which includes identifying clinical abuse/misuse, over-utilization, therapeutic duplication, and an incorrect duration of treatment. Fla. Admin. Code § 64B16-27.810. Since June 2018, Florida law requires all pharmacists to complete continuing education on detecting illegitimate prescriptions. Fla. Admin. Code § 64B16-27.831(6).

D. "Red Flags" of Opioid Diversion and Abuse

43. The standard of care for the practice of pharmacy requires that a pharmacist recognize certain signs of an illegitimate prescription, 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" before dispensing a prescription drug. The prescriber, the patient, or the prescription may present a red flag.

- 44. 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 substances; customers living at the same address and filling the same prescriptions; and customers paying cash.
- 45. 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, pharmacies and pharmacists must ensure that every prescription for a controlled substance (1) was issued by a medical practitioner adhering to the usual course of his or her professional medical practice, (2) was ordered for a legitimate medical purpose, and (3) is filled by a pharmacist acting in the usual course of professional pharmacy practice.
- 46. When a pharmacist ignores red flags indicating that a prescription may not be legitimate, and fails to take steps required in the usual course of professional pharmacy practice to address those red flags and knowingly dispenses a controlled substance, they violate their corresponding responsibility under 21 C.F.R. § 1306.04(a), and thereby dispense controlled substances in violation of the prescription requirement of 21 U.S.C. § 829, and are subject to penalties under the

CSA, including 21 U.S.C. § 842(a)(1).

E. Penalties and Other Remedies for CSA Violations

- 47. 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.
- 48. 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. Part 1306, are subject to civil penalties under Section 842(a)(1).
- 49. A physician who knowingly issues a prescription in violation of 21 U.S.C. § 829 and 21 C.F.R. Part 1306, subjects himself to civil penalties under Section 842(a)(1).
- 50. The penalty for a person who violates 21 U.S.C. § 842(a)(1) is as much as \$67,627 for each violation. *See* 21 U.S.C. § 842(c)(1)(A); 28 C.F.R. § 85.5.
- 51. The penalty for any person who violates 21 U.S.C. § 856 is no more than the greater of (1) \$374,763 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.

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

FACTUAL ALLEGATIONS

53. Defendants profited from the illegal dispensing of controlled substances. Dr. Bacaner wrote medically illegitimate prescriptions outside the usual course of professional practice while working for Theodore and Timothy Ferguson at the Paragon Clinic. Dr. Bacaner and the Fergusons, as co-owners of Cobalt Pharmacy, then filled these patients' illegitimate prescriptions without scrutiny for inflated cash prices.

A. The Paragon Clinic

- 54. Theodore and Timothy Ferguson own the Paragon Clinic, which at all relevant times was a cash-only clinic that accepted no form of insurance. Each patient's first visit cost approximately \$230, and subsequent visits cost approximately \$195.
- 55. Dr. Bacaner worked as a prescribing physician at Paragon Clinic.

 While working at Paragon Clinic, Dr. Bacaner prescribed opioids to nearly every individual who received a controlled substance, predominantly in the highest strength formulations available, such as oxycodone 30 milligrams, hydromorphone 8 milligrams, and morphine 30 milligrams. Dr. Bacaner wrote prescriptions for oxycodone more than any other controlled substance.
- 56. A large number of Dr. Bacaner's patients received prescriptions for the same amounts and strengths of drugs, often involving dangerous combinations

contrary to recommended guidelines. Some of those patients purportedly resided together at the same addresses. These facts show a lack of individualized treatment and present significant red flags of unlawful prescribing.

- 57. Dr. Bacaner ignored obvious signs of drug abuse, diversion, or non-medical use in the individuals to whom he prescribed powerful opioids. For example, Dr. Bacaner documented that some individuals had track marks and drug screens showing illicit drug use, yet he prescribed to them powerful and addictive opioids.
- 58. Dr. Bacaner, Timothy Ferguson, and Theodore Ferguson all knew how to recognize signs of diversion, abuse, and misuse of controlled substances. For example, Theodore Ferguson told DEA investigators that he was very knowledgeable about diversion and illicit activity related to prescription narcotics because of his own law enforcement background. Dr. Bacaner said he knew his patients included groups of individuals with the same purported addresses, but told DEA investigators that it must be the result of Paragon Clinic's "family discount."
- 59. Theodore Ferguson and Timothy Ferguson have been closely involved in the operation of Paragon Clinic. They claimed to participate in screening new patients and claimed to terminate patients for problems such as using illicit drugs or having track marks. They participated in crafting patient agreements and imposing rules to minimize pain clinic red flags, such as barring groups from loitering or congregating outside the clinic. Rules such as these are typically not needed or found at a legitimate medical clinic, but instead occur at clinics trying to avoid

attention from law enforcement.

B. Dr. Bacaner

- 60. Dr. Bacaner's conduct at Paragon Clinic fell egregiously below the professional standard of care.
- 61. CDC Guidelines warn against concurrent prescribing of opioids and benzodiazepines: "Clinicians should avoid prescribing opioid pain medications and benzodiazepines concurrently whenever possible." This is because "[c]oncurrent use is likely to put patients at a greater risk for potentially fatal overdose." One study cited by the CDC found "concurrent benzodiazepine prescription with opioid prescription to be associated with a near quadrupling of risk for overdose death compared with opioid prescription alone." Moreover, the FDA-approved labeling for clonazepam includes a "black box warning"—the most serious type of warning issued by FDA designed to call attention to life-threatening risks—with the bold, all-caps heading: "WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS." The warning further states: "Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death."
- 62. Despite the known risks involved in prescribing combinations of central nervous system depressants like opioids and benzodiazepines, Dr. Bacaner frequently prescribed drug cocktails including an opioid with a benzodiazepine, and

² CDC Guideline at p. 13.

³ CDC Guideline at pp. 31-32.

often adding a third sedative, a muscle relaxer. These combinations of controlled substances are extremely dangerous and can easily lead to an overdose or overdose death because of the drugs' effect on a person's central nervous system and ability to breathe. Moreover, these drug cocktails, especially when combined with a muscle relaxer, are commonly sought after by drug abusers because of the heroin-like euphoria or high they can induce.

- 63. Between 2013 and 2019, at least 16 individuals to whom Dr. Bacaner provided dangerous opioid prescriptions died soon thereafter from some form of drug toxicity. Data from E-FORSCE, Florida's PDMP database, shows that all 16 received opioid prescriptions from Dr. Bacaner within 40 days of their deaths.
- 64. Each patient described below illustrates how Dr. Bacaner routinely ignored multiple warning signs of drug abuse or diversion, including inconsistent urine drug screens, "track marks," reports of stolen medications, and individuals with multiple addresses and pharmacies listed on PDMPs. Despite these clear warning signs, Dr. Bacaner prescribed high-dose opioids, along with multiple other mind-altering substances, even when patients did not have a medical condition requiring the use of opioids. Dr. Bacaner repeatedly issued controlled substance prescriptions in these circumstances to numerous individuals in violation of federal law.

Patient L.D.

65. Dr. Bacaner prescribed patient L.D. a total of five mind-altering

substances, including opioids and benzodiazepines. In his medical records, Dr. Bacaner failed to indicate a legitimate medical basis for the high opioid doses prescribed and stated that the individual did not have a condition to warrant benzodiazepine prescriptions. Dr. Bacaner conducted only a cursory physical examination of L.D. and appears to have simply copied the same notes from visit to visit.

- 66. Dr. Bacaner's documentation for L.D. contains the wrong doses or number of pills for opioids multiple times and was missing a record of several controlled substance prescriptions.
- 67. Dr. Bacaner ignored six aberrant urine drug screens for L.D. over a period of 18 months. Patient L.D. repeatedly tested positive for multiple controlled substances that were not being prescribed, such as methadone, Valium, buprenorphine and lorazepam. Patients taking controlled substances other than as prescribed pose a serious risk of overdose. Dr. Bacaner's records do not indicate that he ever addressed why or how L.D. was receiving controlled substances other than those prescribed.
- 68. Dr. Bacaner never referred patient L.D. for additional treatment with an addiction specialist, even after patient L.D. displayed clear signs of drug misuse and abuse. Additionally, because patient L.D. had a history of depression and anxiety, Dr. Bacaner should have referred patient L.D. to a psychiatrist for treatment, especially when continuing to prescribe controlled substances. Although Dr. Bacaner documented that he referred the patient to a psychiatrist for a risk

assessment, there is no documentation that this actually occurred, nor did Dr. Bacaner record any follow up on this item at subsequent visits.

- 69. Patient L.D. died on December 12, 2019. The medical examiner identified the cause of death as oxycodone toxicity, with several contributory factors. Documentation regarding the scene of death noted marijuana residue, crushed up pills with a straw, and alcoholic beverages.
- 70. Dr. Bacaner failed to address patient L.D.'s significant and obvious warning signs of substance abuse while continuing to prescribe high-dose opioids along with multiple other controlled substances.

Patient T.D.

- 71. Dr. Bacaner prescribed patient T.D. powerful opioids while failing to ever document a physical exam for this patient. Dr. Bacaner documented no clinical justification for the controlled substance prescriptions issued. Dr. Bacaner copied many patient notes from visit to visit, and in several instances provided patient T.D. with a controlled substance prescription without adequately documenting a patient visit.
- 72. Dr. Bacaner ignored six out of seven aberrant urine drug screens given by T.D. over a period of two and one-half years. Patient T.D. tested positive for multiple controlled substances that were not prescribed, including morphine, buprenorphine and oxycodone. T.D. also tested negative for one prescribed medication (oxymorphone). Dr. Bacaner noted that patient T.D. had "old track

marks" on an arm and that T.D.'s PDMP report showed several prescriptions for controlled substances issued by other providers. Each of these circumstances alone signifies a significant risk of drug abuse and diversion. Dr. Bacaner failed to address any of these with T.D. and never referred this patient for additional treatment with an addiction specialist.

73. Patient T.D. died on February 23, 2019. The medical examiner identified the cause of death as fentanyl toxicity. The autopsy noted that the patient had needle track marks/scars of the extremities. Records of the scene of death noted various drug paraphernalia, including syringes, a metal spoon, and a rubber band along with prescription bottles (all prescribed by Dr. Bacaner). Dr. Bacaner failed to recognize and address T.D.'s significant and obvious warning signs of substance abuse while continuing to prescribe high dose opioids.

Patient C.H.

- 74. Dr. Bacaner prescribed patient C.H. multiple powerful controlled substances, including opioids, benzodiazepines and Soma, a muscle relaxer. Dr. Bacaner documented no clinical justification for the extremely high dose he provided to C.H. In fact, Dr. Bacaner documented that C.H. did not have anxiety, yet he prescribed benzodiazepine, which is used to treat anxiety, with no rationale. Dr. Bacaner apparently conducted only a cursory physical examination of C.H. and copied notes from visit to visit.
- 75. Dr. Bacaner ignored every one of seven aberrant urine drug screens C.H. provided over a period of two and one-half years. Dr. Bacaner also ignored

multiple indications of heart problems in C.H., including an abnormal EKG, a significant warning signal for patients taking the powerful opioid methadone.

76. Dr. Bacaner ignored multiple, obvious warning signs of substance abuse and misuse, and prescribed extremely high-dose opioids along with a benzodiazepine, Soma and other mind-altering substances for more than two years.

Dr. Bacaner made no referral for C.H. to seek psychiatric or addiction treatment.

Dr. Bacaner's actions contributed to a high risk of overdose or death in this patient.

Patient A.M.

- 77. Dr. Bacaner prescribed patient A.M. multiple controlled substances, including two different classes of opioids, despite no medical justification for doing so. Dr. Bacaner conducted only a cursory physical examination of A.M. and copied notes from visit to visit. Dr. Bacaner failed to obtain any urine drug screen from A.M., despite prescribing controlled substances for more than 14 months and the presence of signs of abuse of controlled substances.
- 78. Dr. Bacaner never referred A.M. for treatment with an addiction specialist, despite clear signs of drug misuse and abuse. Dr. Bacaner's documentation notes that A.M. should have had a psychiatric risk assessment, but Dr. Bacaner never completed such a referral.
- 79. Patient A.M. died on March 8, 2018. The medical examiner identified the cause of death as oxycodone toxicity. A.M.'s postmortem blood and urine toxicology reports were positive for multiple substances, including oxycodone. At the scene of death, patient A.M.'s wife reported to police that the patient had a

drinking problem and would often drink until he passed out. Dr. Bacaner failed to address A.M.'s significant and obvious warning signs of substance abuse, while continuing to prescribe high-dose opioids along with multiple other controlled substances.

Patient W.T.

- 80. Dr. Bacaner prescribed patient W.T. multiple controlled substances, including an opioid and benzodiazepine, despite no medical justification for doing so. In fact, Dr. Bacaner increased patient W.T.'s opioid dosages and number of pills at several visits with no rationale. Moreover, Dr. Bacaner documented that W.T. did not have anxiety, yet he prescribed a benzodiazepine, which is used to treat anxiety, without any basis.
- W.T. had a "mild foot drop." A foot drop is a significant finding that can indicate damage to the spinal cord, but Dr. Bacaner failed to follow up on this alarming condition. Dr. Bacaner copied notes from visit to visit, and on multiple occasions W.T. received controlled substances from Dr. Bacaner without documentation of any corresponding visit.
- 82. W.T. reported to Dr. Bacaner at four separate visits that his controlled substance medications had been lost or stolen, a significant indication of abuse or misuse. Dr. Bacaner also ignored six aberrant urine drug screens showing that W.T. was not taking controlled substances as medically prescribed. Dr. Bacaner failed to adequately address these significant signs of abuse or diversion.

83. Dr. Bacaner continued to prescribe high-dose opioids along with benzodiazepine and other mind-altering substances for more than a year to W.T. under circumstances representing a significant risk of overdose or death.

C. Cobalt Pharmacy

- 84. Defendants Timothy and Theodore Ferguson and Dr. Bacaner used Cobalt Pharmacy as a means for filling and profiting from illegitimate controlled substance prescriptions.
- 85. Beginning in at least 2018 and continuing until at least January 22, 2021, the Timothy and Theodore Ferguson and Dr. Bacaner (individually and later through the Trust) jointly owned and operated Cobalt Pharmacy.
- 86. In connection with issuing a DEA registration for Cobalt Pharmacy, DEA investigators conducted an interview of Timothy and Theodore Ferguson and presented a PowerPoint presentation to them explaining the pertinent CSA requirements for pharmacy registrants. Among other things, the DEA's PowerPoint presentation and interview notified the Fergusons of the CSA's prescription requirement, with a specific focus on a pharmacy's corresponding responsibility to ensure that a prescription is issued for a legitimate medical purpose by a physician acting in the usual course of professional practice. The DEA described red flags of diversion as including the geographic distance of a patient from his prescriber or pharmacy, cash payments, physicians prescribing outside their scope of training, pattern prescribing, and customers living at the same address and obtaining the same drugs. The DEA also provided the Fergusons a DEA Pre-Registration Packet

containing a copy of 21 C.F.R. § 1306.04 and other regulations and guidance on the handling of controlled substances by a pharmacy. Timothy and Theodore Ferguson both agreed to abide by the law as owners of the pharmacy and said they would share this information with Dr. Bacaner.

- 87. The DEA also advised Timothy Ferguson that neither Paragon Clinic nor Dr. Bacaner should refer patients to Cobalt Pharmacy or require patients to fill prescriptions at Cobalt Pharmacy, and that all patients of Paragon must have an opportunity to fill prescriptions at a pharmacy of their choice. Timothy Ferguson stated that he understood and that he would inform Theodore Ferguson and Dr. Bacaner.
- 88. Cobalt Pharmacy began dispensing controlled substances on March 2, 2018. The first two prescriptions dispensed were for Schedule II opioids written by Dr. Bacaner to Timothy and Theodore Ferguson.
- 89. From March 2, 2018, to September 8, 2020, more than 68 percent of the total controlled substance prescriptions dispensed by Cobalt Pharmacy were written by Dr. Bacaner. Specifically, Cobalt Pharmacy filled 1,526 controlled substance prescriptions written by Dr. Bacaner for 127,438 dosage units.
- 90. From March 2, 2018, until approximately September 8, 2020, Cobalt Pharmacy knowingly filled prescriptions for controlled substances written by Dr. Bacaner and other practitioners that presented significant red flags signaling that the prescriptions were not for a medically legitimate purpose or not written in the usual course of professional practice. Cobalt Pharmacy ignored or otherwise failed to take

sufficient steps to resolve these red flags before filling the prescriptions. They also failed to satisfy the minimum standards of pharmacy practice established under Florida law.

Red Flag No. 1 – Unusual Amounts and Dosages

- 91. 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.
- 92. Cobalt Pharmacy repeatedly dispensed prescriptions for the highest doses of a particular medication—e.g., oxycodone 30 milligrams—in amounts that far exceeded the daily morphine milligram equivalent ("MME") dose recommended by the Centers for Disease Control and Prevention.⁴ They repeatedly dispensed these controlled substances without resolving this red flag.

Red Flag No. 2 – Cash Payment

- 93. Cash payments, particularly at inflated prices, is a red flag that the prescription is not written for a legitimate medical purpose or in the usual course of professional practice.
 - 94. Cobalt Pharmacy charged, and its patients paid, extremely high cash

⁴ CDC Guideline for Prescribing Opioids for Chronic Pain, United States, 2016, available at https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

prices over several years for controlled substances such as hydromorphone and oxycodone. Cobalt Pharmacy collected at least twice the cash price per pill that a patient would pay at another, legitimate pharmacy.

Red Flag No. 3 – Drug Cocktails

- 95. Prescriptions for a cocktail or combination of substances that are unlikely to serve a legitimate medical purpose or are frequently abused present a significant red flag. For example, the combination of an opioid, a benzodiazepine, and a muscle relaxer enhances the euphoric effect of the opioid and also increases the risk of an adverse outcome, such as an overdose.
- 96. Cobalt Pharmacy repeatedly dispensed drug cocktails and dangerous combinations known for abuse without resolving this red flag.

Red Flag No. 4 - Pattern Prescribing

- 97. 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.
- 98. Cobalt Pharmacy repeatedly filled the same controlled substances for individual patients month after month, with no adjustment to or change in therapy.

Red Flag No. 5 – Immediate Release Opioids

- 99. 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.
- 100. Cobalt Pharmacy dispensed to numerous patients IR opioids on a schedule, without ER opioids, over the course of several months and years, without resolving this red flag.

Red Flag No. 6 – Geographic Distance

- 101. A person traveling an usually long distance 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.
- 102. Cobalt Pharmacy repeatedly dispensed controlled substances to people who traveled 30 or more miles from their home to a physician's office and then traveled even further to Cobalt Pharmacy, passing many other pharmacies and physicians along the way. They also consistently failed to document why such patients would travel so far to the pharmacy.

Patient Z.S.

- 103. Cobalt Pharmacy filled 35 controlled substance prescriptions for Patient Z.S. between 2018 and 2020.
- 104. Patient Z.S. started using Cobalt Pharmacy with prescriptions from Dr. Bacaner for hydromorphone 8 milligrams, which is the highest strength of that drug, and morphine sulfate ER 60 milligrams. This amounted to a total daily MME far exceeding the CDC recommendation. Cobalt Pharmacy filled the prescriptions, and continued to fill identical prescriptions for Z.S. from Dr. Bacaner each month for two years.
- 105. Patient Z.S. filled IR opioids other than morphine sulfate on a schedule for two years. Cobalt Pharmacy apparently never resolved this red flag, but instead consistently filled the IR opioid prescriptions.
- 106. Patient Z.S. paid extremely high prices at Cobalt Pharmacy each month. Z.S. paid approximately \$3.50 per pill for hydromorphone, which is more than twice the average cash price for that drug.
- 107. Patient Z.S. drove more than 30 miles to Dr. Bacaner's office at Paragon Clinic and an additional seven miles to reach Cobalt Pharmacy. Z.S. made this 80-mile round trip at least 19 times over the course of two years. Z.S.'s records contain no explanation of why Z.S. would drive so far from home to obtain and fill prescriptions.
- 108. Based on the red flags described above, Cobalt Pharmacy knew or should have known that the prescriptions Z.S. presented were not for a legitimate

medical purpose. Cobalt Pharmacy should not have filled these prescriptions for Z.S., and doing so was unlawful.

Patient L.B.

- 109. Cobalt Pharmacy filled 45 controlled substance prescriptions for patient L.B. between 2018 and 2020.
- 110. Patient L.B. started using Cobalt Pharmacy with prescriptions from Dr. Bacaner for hydromorphone 8 milligrams, which is the highest strength of that drug, and methadone 10 milligrams. This amounted to a total daily MME far exceeding the CDC recommendation. Cobalt Pharmacy continued filling substantially unchanged prescriptions for L.B. for more than two years.
- 111. Patient L.B. filled IR opioid prescriptions at Cobalt Pharmacy on a schedule for two years. Cobalt Pharmacy apparently never resolved this red flag but instead consistently filled the IR opioid prescriptions for L.B.
- 112. Patient L.B. regularly filled prescriptions at Cobalt Pharmacy for a cocktail of drugs consisting of two opioids (hydromorphone and methadone), a benzodiazepine (valium), and a muscle relaxer (cyclobenzaprine). This is a well-known and extremely dangerous combination of drugs subject to abuse. L.B. consistently received this cocktail for two years with no resolution of this red flag by Cobalt Pharmacy.
- 113. Patient L.B. paid extremely high prices each month for at least a year.

 L.B. paid approximately \$3.50 per pill for hydromorphone, which is more than twice the average cash price for that drug.

- 114. Patient L.B. drove more than 15 miles to Dr. Bacaner's office at Paragon Clinic and an additional seven miles to Cobalt Pharmacy. L.B. made this 45-mile round trip 18 times over the course of two years. Cobalt's records contain no explanation of why L.B. would drive so far from home to obtain and fill prescriptions.
- 115. Based on the red flags described above, Cobalt Pharmacy knew or should have known that the prescriptions L.B. presented were not for a legitimate medical purpose. Cobalt Pharmacy should not have filled these prescriptions for L.B., and doing so was unlawful.

Patient E.O.

- 116. Cobalt Pharmacy filled 43 controlled substance prescriptions for patient E.O. between 2018 and 2020.
- 117. Patient E.O. started using Cobalt Pharmacy with a prescription from Dr. Bacaner for oxycodone 30 milligrams, which is the highest strength of that drug. E.O. continued filling substantially similar oxycodone 30 milligrams at Cobalt for more than two years. This amounted to a total daily MME far exceeding the CDC recommendation. Cobalt Pharmacy never questioned the starting dose for this patient or the MME that, month after month, consistently exceeded the CDC's guideline.
- 118. Patient E.O. filled IR opioids on a schedule for two years and without a corresponding ER opioid. Cobalt Pharmacy apparently never resolved this red flag, but instead consistently filled the IR opioids for E.O.

- 119. Patient E.O. paid a high cash price each month for opioids for at least ten months. E.O. paid approximately \$3 per pill for oxycodone 30 milligrams, which is more than twice the average cash price for that drug.
- 120. Patient E.O. regularly filled prescriptions at Cobalt Pharmacy for a cocktail of drugs consisting of an opioid (oxycodone) and a benzodiazepine (clonazepam). This is a well-known and extremely dangerous combination of drugs subject to abuse. E.O. consistently received this cocktail for two years with no resolution of this red flag by Cobalt Pharmacy.
- 121. Based on the red flags described above, Cobalt Pharmacy knew or should have known that the prescriptions for E.O. were not for a legitimate medical purpose. Cobalt Pharmacy should not have filled these prescriptions for E.O., and doing so was unlawful.

Patient D.H.

- 122. Cobalt Pharmacy filled 78 controlled substance prescriptions for patient D.H. between 2018 and 2020.
- 123. Patient D.H. started using Cobalt Pharmacy with prescriptions from Dr. Bacaner for hydromorphone 8 milligrams, which is the highest strength of that drug, and morphine sulfate ER 30 milligrams. D.H. continued filling more or less the same amount of those drugs at Cobalt Pharmacy for more than two years. This amounted to a total daily MME far exceeding the CDC recommendation. Cobalt Pharmacy never questioned the starting dose for this patient or the MME that, month after month, consistently exceeded the CDC's guideline.

- 124. Patient D.H. filled prescriptions at Cobalt Pharmacy for IR opioids on a schedule for two years. Cobalt Pharmacy apparently never resolved this red flag but instead consistently filled the IR opioids for D.H.
- 125. Patient D.H. regularly filled prescriptions at Cobalt Pharmacy for a cocktail of drugs consisting of two opioids (hydromorphone and morphine sulfate), a benzodiazepine (alprazolam), and a muscle relaxer (tizanidine). This is a well-known and extremely dangerous combination of drugs subject to abuse. D.H. consistently received this cocktail for several months with no resolution of this red flag by Cobalt Pharmacy.
- 126. Patient D.H. paid extremely high prices each month for opioids for at least a year. L.B. paid approximately \$3.20 per pill for hydromorphone, which is more than twice the average cash price for that drug.
- 127. Based on the red flags described above, Cobalt Pharmacy knew or should have known that the prescriptions for D.H. were not for a legitimate medical purpose. They should not have filled these prescriptions for D.H., and doing so was unlawful.
- D. The threat of harm remains despite efforts by the defendants to avoid further law enforcement scrutiny.
- 128. On August 19, 2019, and December 19, 2019, the DEA served administrative subpoenas for Dr. Bacaner's patient records on the Fergusons at the Paragon Clinic. On May 14, 2020, Timothy Ferguson informed the DEA that Dr. Bacaner was no longer associated with the Paragon Clinic.

- 129. On July 15, 2020, the DEA served an administrative subpoena on Cobalt Pharmacy for certain patient records. After August 20, 2020, according to the PDMP records, Cobalt Pharmacy no longer filled prescriptions for Dr. Bacaner's patients.
- 130. Dr. Bacaner's controlled substance prescribing continued well beyond his departure from Paragon Clinic. Data from the PDMP database shows Dr. Bacaner writing controlled substance prescriptions as of January 13, 2021. At present, Dr. Bacaner's Florida medical license still contains Paragon Clinic as his address of record. Dr. Bacaner remains licensed to practice medicine in Florida and other states and able to issue controlled substance prescriptions.
- 131. Until closing and surrendering the pharmacy's DEA registration on or around January 21, 2021, the Fergusons and Dr. Bacaner (through the Trust) owned Cobalt Pharmacy. PDMP data shows no controlled substance dispensing by Cobalt Pharmacy after September 8, 2020.
 - 132. At present, the Fergusons still own and operate Paragon Clinic.
- 133. But for their awareness of United States' investigation, the defendants would have continued writing and filling illegitimate prescriptions for dangerous and highly addictive opioids.
- 134. Accordingly, a substantial likelihood exists that, absent injunctive relief, the irreparable harm demonstrated here will continue if defendants are permitted to engage in similar conduct in the future.

COUNT I

Controlled Substances Act 21 U.S.C. § 842(a)(1) Civil Penalty Liability - Clinic

- 135. The United States re-alleges paragraphs 1-33, 47-83, and 128-134.
- 136. Title 21, U.S.C. § 842(a)(1) makes it unlawful for any person subject to Part C of the CSA to distribute or dispense a controlled substance in violation of 21 U.S.C. § 829. Defendants are subject to Part C of the CSA.
- 137. Defendants Tobias Bacaner, M.D.; Paragon Community Healthcare, Inc.; Theodore Ferguson; and Timothy Ferguson violated 21 U.S.C. § 829 by distributing or dispensing prescriptions without a legitimate medical purpose and issued outside the usual course of professional practice for Schedule II, III, or IV controlled substances that also were prescription drugs under the Federal Food, Drug, and Cosmetic Act, in violation of 21 C.F.R. § 1306.04.
- 138. Defendants Tobias Bacaner, M.D.; Paragon Community Healthcare, Inc.; Theodore Ferguson; and Timothy Ferguson are liable to the United States for a civil penalty of not more than \$67,627 for each violation pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

COUNT II

Controlled Substances Act 21 U.S.C. § 842(a)(1) Civil Penalty Liability - Pharmacy

139. The United States re-alleges paragraphs 1-24, 34-52, 84-134.

- 140. Defendant Cobalt Pharmacy violated 21 U.S.C. § 829 by filling prescriptions for Schedule II, III, or IV controlled substances that also were prescription drugs under the Federal Food, Drug, and Cosmetic Act, 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 dispensing 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.
- 141. As a result, the defendant Cobalt Pharmacy, Inc., is liable for as much as \$67,627 for each violation pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.
- 142. The defendants Tobias Bacaner, the Tobias & Jill Bacaner Revocable Trust, Timothy Ferguson, and Theodore Ferguson are also liable for as much as \$67,627 for each violation pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

COUNT III

Controlled Substances Act 21 U.S.C. § 856 Drug-Involved Premises – Pharmacy

- 143. The United States re-alleges paragraphs 1-24, 34-52, 84-134.
- 144. Dr. Bacaner, the Trust, and the Fergusons knowingly used, managed, or controlled 7135 State Road 52, Suite 103, Hudson, Florida, 34667 for the purpose of operating Cobalt Pharmacy to unlawfully distribute controlled substances.
 - 145. As a result, the defendants Tobias Bacaner, the Tobias & Jill Revocable

Trust, Timothy Ferguson, and Theodore Ferguson are liable to the United States under 21 U.S.C. § 856 for not more than the greater of (1) \$374,763 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.

146. Additionally, the defendants Tobias Bacaner, the Tobias & Jill Revocable Trust, Timothy Ferguson, and Theodore Ferguson are subject to an injunction to restrain further violations of Section 856 under 21 U.S.C. § 843(f).

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

- 147. The United States re-alleges paragraphs 1-33, 47-83, and 128-134.
- 148. The Fergusons knowingly used, managed, or controlled 6131 U.S. Highway 19, New Port Richey, Florida, 34652 for the purpose of operating Paragon Clinic to unlawfully distribute controlled substances.
- 149. As a result, the defendants Theodore and Timothy Ferguson are liable for not more than the greater of (1) \$374,763 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.
- 150. Additionally, the defendants Theodore and Timothy Ferguson are subject to an injunction to restrain further violations of Section 856 under 21 U.S.C. § 843(f).

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

- 151. The United States re-alleges paragraphs 1-134.
- 152. Under 21 U.S.C. § 843(f), the Attorney General of the United States may seek declaratory or injunctive relief for violations of 21 U.S.C. § 842 and 21 U.S.C. § 856. More broadly, 21 U.S.C. § 882(a) provides for any violation of the CSA to be enjoined.
- 153. Based on the violations alleged in this complaint, the United States requests both a preliminary and permanent injunction (i) prohibiting the defendants from prescribing, administering, dispensing, or distributing any controlled substance, either directly or through employees, including at a pain clinic or pharmacy; (ii) prohibiting any defendant from serving as a manager, owner, operator, or pharmacist-in-charge of any entity, including a pain clinic or pharmacy, that administers, dispenses, or distributes controlled substances; (iii) prohibiting the defendants from applying for or seeking renewal of any DEA Certificate of Registration on their behalf or on behalf of any corporate entity; (iv) prohibiting the defendants from altering, destroying, or disposing of any records of Paragon Clinic or Cobalt Pharmacy; and (v) any other injunctive relief the Court deems appropriate and just.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests that judgment be entered in its favor and against the 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 the 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 the 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: February 19, 2021 Respectfully submitted,

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