UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF GEORGIA
BRUNSWICK DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	No. 2:19-CV-_____
AGAPE PRESCRIPTIONS "R" US, INC., d/b/a DARIEN PHARMACY, and JANICE ANN COLTER,	)	
	)	
Defendants.	)	

COMPLAINT

The United States of America, by and through the United States Attorney for the Southern District of Georgia, brings this action against defendants Agape Prescriptions "R" Us, d/b/a Darien Pharmacy (Darien Pharmacy), and Janice Ann Colter (Colter), for civil penalties for violations of the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq*.

INTRODUCTION

1. The United States is in the midst of a nationwide public health emergency. According to the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC), nearly 400,000 people died from drug overdoses involving opioids between 1999 and 2017.[1] By 2017, nearly 130 Americans were dying each day from opioid overdoses, accounting for more than

[1] Lawrence Scholl et al., *Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017*, 67 Morbidity and Mortality Weekly Report 1419 (available at: https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm675152e1-H.pdf).

67% of all drug overdoses.[2] The National Safety Council estimates that the odds of dying of an accidental opioid overdose now exceed those of dying in a motor vehicle crash.[3]

2. In 2015 alone, the White House Council of Economic Advisors estimated that the economic cost of the opioid crisis was $504 billion, accounting for 2.8% of that year's gross domestic profit.[4]

3. For years, prescription opioids, and other controlled substances taken in conjunction with them to heighten their effects, have been prescribed, dispensed, and distributed without a legitimate medical purpose and outside the usual course of professional practice.

4. Pharmacists are the last line of defense before dangerous drugs, prescribed without a legitimate medical purpose and outside the usual course of professional practice, are sold to patients.

5. Rather than serving as a bulwark against unlawful diversion, defendants have instead perpetuated and profited from the opioid crisis, routinely ignoring "red flags" or warning signs that controlled substances prescriptions they filled were written without a legitimate medical purpose or outside the usual course

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[2] *Id.*

[3] Press Release, Nat'l Safety Council, For the First Time, We're More Likely to Die from Accidental Opioid Overdose than Motor Vehicle Crash (Jan. 14, 2019) (available at https://www.nsc.org/in-thenewsroom/for-the-first-time-were-more-likely-to-die-from-accidental-opioid-overdose-thanmotor-vehicle-crash).

[4] The Council of Economic Advisors, The Underestimated Cost of the Opioid Crisis (Nov. 2017) (available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf).

of professional practice.

6. Defendants also cannot account for the controlled substances provided to Darien Pharmacy by its suppliers, suggesting that they have permitted significant quantities of highly abused drugs to have been diverted for unlawful purposes.

JURISDICTION AND VENUE

7. The Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345 and 1355(a).

8. The Court has personal jurisdiction over Darien Pharmacy because its principal place of business is in McIntosh County, Georgia and it transacts business within this district.

9. The Court has personal jurisdiction over Colter because she resides at 411 Waverly Lane, White Oak, Georgia 31568, which is within this district.

10. Venue lies in this district pursuant to 28 U.S.C. § 1391(b) because both defendants reside in this district and a substantial part of the events giving rise to the government's claims against them occurred in this district.

THE PARTIES

11. The plaintiff is the United States of America.

12. Defendant Agape Prescriptions "R" Us does business as Darien Pharmacy and is registered and organized as a domestic profit corporation with the State of Georgia. Its principal place of business is 1229 North Way, Darien, GA 31305, located in this judicial district. It has three corporate officers including Janice Ann

Colter, who serves as Chief Financial Officer. It may be served through its registered agent, Janice Ann Colter.

13. Defendant Janice Ann Colter is an individual who resides at 411 Waverly Lane, White Oak, GA 31568, which is located in this judicial district.

GENERAL ALLEGATIONS

14. At all times material to the allegations in this complaint, Darien Pharmacy was registered by the United States Drug Enforcement Administration (DEA) with Schedule II-V controlled substances under registration number BD7581968.

15. At all times material to the allegations in this complaint, Darien Pharmacy was licensed by the State of Georgia as a retail pharmacy under license number PHRE008564.

16. At all times material to the allegations in this complaint, Darien Pharmacy employed Colter as its Pharmacist-in-Charge, and Colter owned a 30% share of Darien Pharmacy.

17. At all times material to the allegations in this complaint, Colter was licensed as a pharmacist by the State of Georgia under license number RPH013915.

18. At all times material to the allegations in this complaint, Colter actively participated in the management of Darien Pharmacy, its operations, its inventory, and its personnel.

19. In 1965, Congress enacted Title XVIII of the Social Security Act, known

as the Medicare program, to pay for healthcare services for certain individuals. 42 U.S.C. § 1395 *et seq*.

20. Acting through the Department of Health and Human Services, the United States also administers the Grants to States for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq*., also known as the Medicaid program.

THE CONTROLLED SUBSTANCES ACT

21. At all times material to the allegations in this complaint, defendants were subject to the requirements of Part C of the CSA, 21 U.S.C. § 821 *et seq*.

22. 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. *See* 21 U.S.C. § 841(a).

I. Pharmacists' Corresponding Responsibility to Ensure Prescriptions for Controlled Substances Are Valid

23. Under 21 U.S.C. § 842(a)(1), it is unlawful for any person who is subject to Part C of the CSA to distribute or dispense a controlled substance in violation of 21 U.S.C. § 829.

24. Section 829 provides requirements for issuing and filling prescriptions of controlled substances, as do the CSA's implementing regulations located at 21 C.F.R. § 1306.01 *et seq*.

25. To be valid, a prescription must be issued for a legitimate medical purpose by a provider acting in the usual course professional practice. 21 C.F.R. §

1306.04(a).

26. A pharmacist has a corresponding responsibility to ensure a prescription is valid. 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 is subject to civil penalties. 21 C.F.R. § 1306.04(a).

27. A pharmacist must refuse to fill a prescription if he or she knows or has reason to know that the prescription was not written for a legitimate medical purpose. *See* 21 C.F.R. §§ 1306.04(a), 1306.06.

28. "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.

29. Stated differently, pharmacists may dispense controlled substances only if such dispensation would be in accordance with a generally accepted, objective standard of practice, *i.e.*, "the usual course of his professional practice" of pharmacy. *Id.*

30. Under the CSA, pharmacists must use sound professional judgment to determine the legitimacy of a controlled substance prescription, including paying attention to the number of prescriptions issued, the strength and number of dosage units prescribed, the doctor writing the prescriptions, and the risk and rate of abuse

of the drugs prescribed. Pharmacists have a legal duty to recognize "red flags" or warning signs that raise or should raise reasonable suspicions that a prescription or class of prescriptions for controlled substances is illegitimate. If those red flags exist, the pharmacist must conduct a sufficient investigation to determine that the prescription actually is legitimate before dispensing it.

II. Pharmacists' Duty to Make, Keep, and Furnish Complete and Accurate Records

31. The CSA's closed regulatory system is designed to track and trace controlled substances from manufacture to delivery to ensure they are not illegally diverted for improper uses.

32. DEA registrants, including pharmacies, must maintain, on a current basis, a complete and accurate record of each controlled substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. § 827(a)(3); 21 C.F.R. § 1304.21(a).

33. It is unlawful for any person to refuse or negligently fail to make, keep or furnish any record, report, notification, declaration or order form, statement, invoice or information required by the CSA. 21 U.S.C. § 842(a)(5).

34. Pharmacies must provide effective controls and procedures to guard against theft and diversion of controlled substances and must report to DEA any theft or significant loss of controlled substances within one business day of discovery of the theft or loss. 21 C.F.R. § 1301.71(a); 21 C.F.R. § 1301.74(c).

FACTS

35. For years, Darien Pharmacy has filled prescriptions for controlled substances that it knew or should have known were not issued for legitimate medical reasons and by a provider not acting within the regular course of professional practice.

36. In doing so, Darien Pharmacy has ignored numerous red flags, including:

- patients travelling long distances to obtain prescriptions from high-volume opioid prescribers despite the presence of multiple, equally or better qualified practitioners within shorter distances;
- prescriptions for concurrent doses of multiple controlled substances from the same category, *e.g.*, concurrent, long-term prescriptions for two or more opioids such as oxycodone and hydromorphone;
- prescriptions for concurrent doses of multiple strengths of the same controlled substance, *e.g.*, concurrent, long-term prescriptions for oxycodone 30mg and oxycodone 15mg;
- prescriptions with daily dosages that are greater than necessary for medical purposes;
- prescriptions for drug combinations that are well known in the medical and pharmacy community as carrying a high risk of drug abuse;
- prescriptions from providers who consistently prescribe the most potent strength available for controlled substances, known to command the highest "street value;"
- prescriptions for large quantities of controlled substances presented by multiple members of the same household with the same last name;
- providers whose patients disproportionately pay for controlled substances in cash;

- patients who request and pay an out-of-pocket surcharge for pills with specific markings or colors; and
- early refills of controlled substances by patients who should have had remaining doses available.

I. Defendants' Relationship with Dr. Bynes

37. From September 11, 2015 through September 20, 2017, defendants routinely filled controlled substances prescriptions written by Dr. Frank H. Bynes, Jr., an internal medicine physician.

38. Dr. Bynes voluntarily surrendered his DEA registration for cause on September 21, 2017 and has been indicted by a grand jury in this judicial district with 14 counts of unlawfully dispensing controlled substances and three counts of health care fraud. *See United States v. Bynes*, No. 4:18-CR-153, Doc. 71 (S.D. Ga.). Among other allegations, the superseding indictment alleges that Dr. Bynes prescribed controlled substances while or after engaging in unprofessional conduct with female patients; to patients taking cocaine, methamphetamine, and heroin; to patients seeking treatment for dependence or addiction to opioids; and while falsely claiming to patients that he was affiliated with the Department of Justice or DEA and displaying a fake badge. *Id.*

39. Most pharmacies in Southeast Georgia recognized the irreconcilable red flags presented by Dr. Bynes' prescriptions and refused to fill his controlled substances prescriptions.

40. In fact, Darien Pharmacy's majority shareholder, who until October

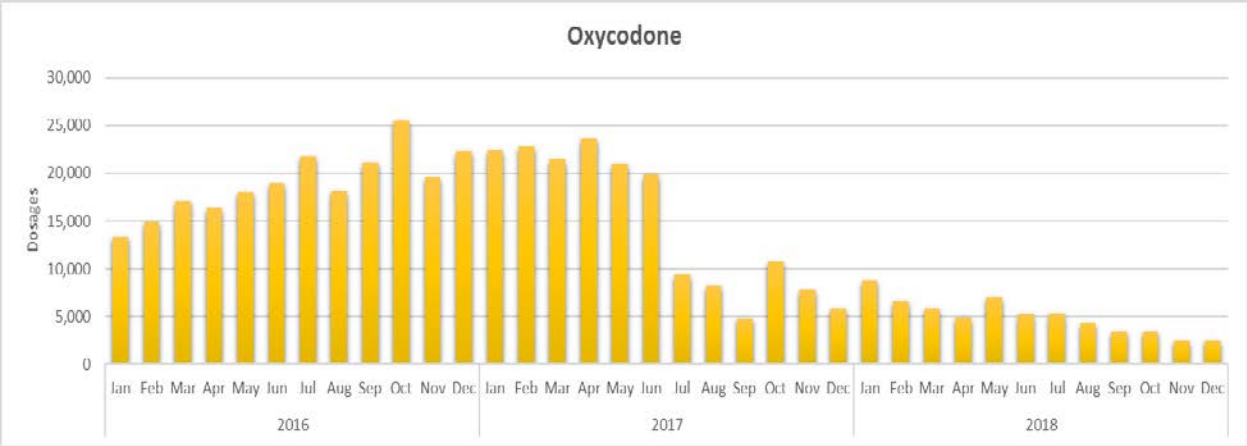
2018 was the Pharmacist-in-Charge at Altama Discount Pharmacy in Brunswick, Georgia, testified in connection with the United States' investigation into Darien Pharmacy that by 2014 or 2015, word had circulated throughout Southeast Georgia that Dr. Bynes "was prescribing narcotics in combinations that were way more frequent and not necessarily used for the people he was seeing and treating." While this pharmacist worked at Altama Pharmacy, he estimated that he turned away "maybe a hundred" of Dr. Bynes' patients attempting to fill his prescriptions.

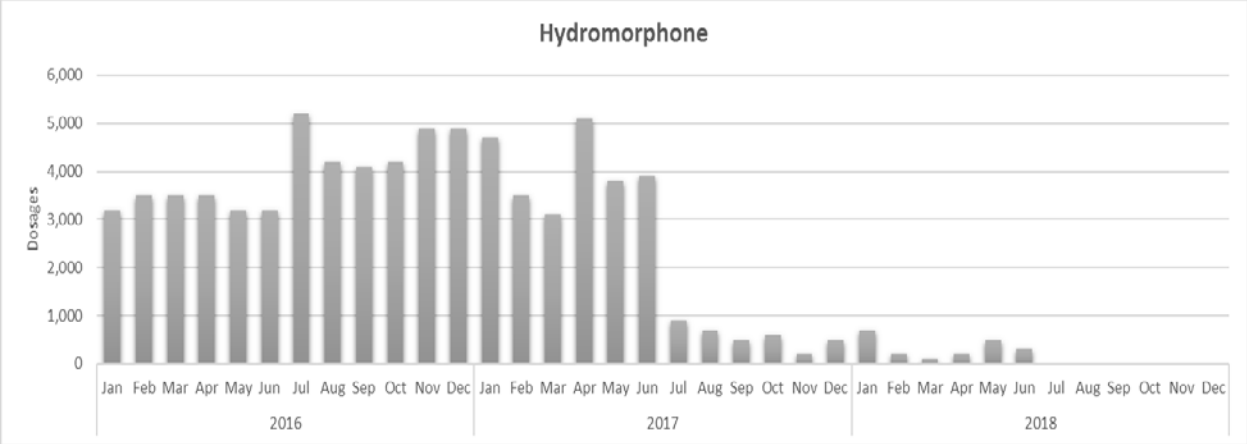
41. Colter additionally acknowledged that patients told her that Dr. Bynes was running a "pill mill" prior to July 17, 2017, when defendants were forced by their suppliers to adopt a policy in which they would no longer fill Dr. Bynes' prescriptions.

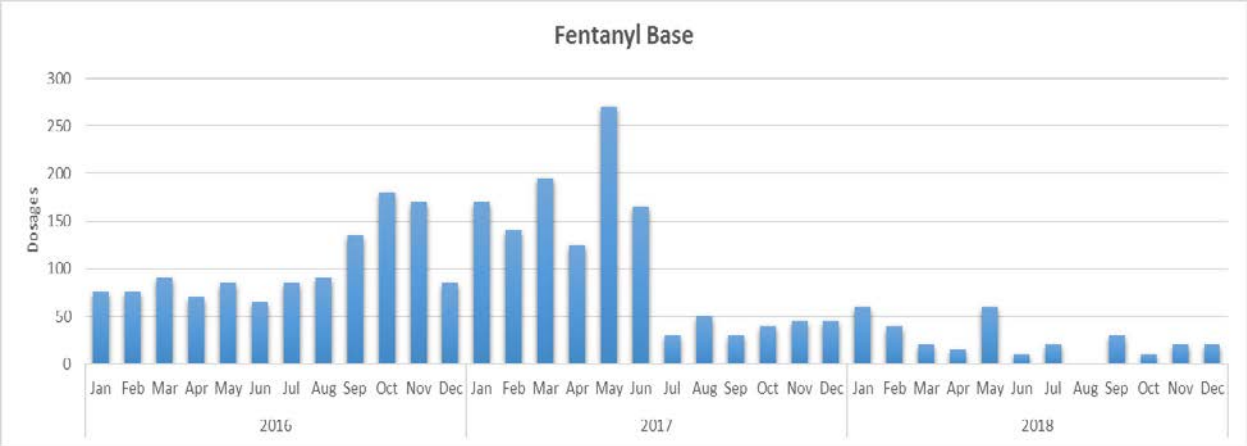
42. Yet even after defendants represented to their suppliers that they would not fill Dr. Bynes' prescriptions, defendants did not entirely cease doing so, and instead continued to fill Dr. Bynes' prescriptions for controlled substances until as late as September 20, 2017.

43. Defendants' reluctant decision to cease filling most of Dr. Bynes' prescriptions in July 2017 had a marked effect on their business, illustrating their reliance on business generated by Dr. Bynes' illegitimate prescriptions.

44. A query of Darien Pharmacy's ordering history shows a precipitous drop-off in orders for the opioids oxycodone, hydromorphone, and fentanyl, for example:







45. Defendants ignored multiple red flags that Dr. Bynes was writing prescriptions for controlled substances lacking a legitimate medical purpose and that

were not issued in the usual course of professional practice. Instead of exercising their corresponding responsibility to ensure the controlled substances they dispensed were supported by valid prescriptions, defendants effectively rubberstamped countless prescriptions without any scrutiny, allowing untold quantities of opioids and other high-risk drugs to be diverted for illegitimate uses.

46. From September 11, 2015 through September 20, 2017, Darien Pharmacy dispensed over 350,000 dosage units of controlled substances to Dr. Bynes' patients. During that period, defendants dispensed more controlled substances dosage units to Dr. Bynes' patients than for the patients of any other prescriber—nearly as many as the next four prescribers combined.

A. Red Flags Presented by Dr. Bynes' Prescriptions

i. Distance

47. During the period between September 11, 2015 and September 20, 2017, Dr. Bynes was practicing from clinics located at 624 U.S. Highway 80, Garden City, Georgia 31408, and 4395 Ogeechee Road, Savannah, Georgia 31405, both in Chatham County.

48. The majority of defendants' customers are located in McIntosh and Glynn counties.

49. In filling Dr. Bynes' prescriptions, defendants knew that most of Dr. Bynes' patients were driving approximately one hour to office visits and another hour to return to Darien Pharmacy, despite the presence of numerous other internal

medicine doctors located within far shorter distances.

ii. Dangerously High Daily Doses of Opioids

50. On March 18, 2016, the CDC published the *CDC Guideline for Prescribing Opioids for Chronic Pain*.[5] The CDC cited research finding no difference in pain or function between groups with escalating opioid dosages versus maintenance at lower dosages. At the same time, the CDC cited evidence that higher opioid dosages are associated with increased risks for overdose, opioid use disorder, and motor vehicle injury.

51. The *CDC Guideline* warned that clinicians "should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents[6] (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day."

52. Large percentages of the prescriptions written by Dr. Bynes and filled by defendants exceeded the 90 MME/day benchmark the CDC advises clinicians to avoid—some by a factor of five or more. Defendants knew or should have known that an internal medicine doctor writing these prescriptions at such high rates was not doing so for a legitimate medical purpose or in the usual course of professional

[5] CDC, *CDC Guideline for Prescribing Opioids for Chronic Pain* 2016, 65 Morbidity and Mortality Weekly Report 1 (March 18, 2016) (available at: https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf).

[6] Morphine milligram equivalents are a standard value representing the relative potency of different opioids. The strength of every opioid can be converted to the equivalent of one medication—morphine—thereby enabling comparisons of opioid potency. For example, a 30mg dose of oxycodone is equivalent in strength and risk to approximately 45mg of morphine. Thus, a 30mg dose of oxycodone can be expressed as 45 MMEs.

practice.

53. More than half of the patients who filled Dr. Bynes' prescriptions at Darien Pharmacy were able to obtain prescriptions for 120 units of oxycodone 30mg, the highest available strength of oxycodone available at Darien Pharmacy. A patient dispensed 120 dosage units would be expected to take an oxycodone pill four times a day for a month. This single prescription equals 180 MME/day, double the amount the CDC advises clinicians to avoid.

54. Defendants dispensed far greater daily doses of opioids to many of Dr. Bynes' patients. For example, between October 22, 2016 to October 27, 2016, defendants dispensed to G.T., a patient of Dr. Bynes, prescriptions including 120 units of oxycodone 30mg, 120 units of hydromorphone 8mg, and 5 fentanyl 100 mcg/hr patches, amounting to 548 MME/day. On six occasions between July 2016 and May 2017, defendants dispensed to a different Dr. Bynes' patient, J.D., prescriptions including 120 dosage units of oxycodone 30mg; 120 dosage units of oxycodone 15mg; and 10 fentanyl 100mcg/hr patches, totaling 510 MME/day.[7]

iii. *Therapeutic Duplication*

55. In further dereliction of their corresponding responsibility, defendants routinely dispensed combinations of controlled substances with therapeutic duplication pursuant to prescriptions written by Dr. Bynes.

[7] Darien Pharmacy's utilization record reveals it became aware on or about May 1, 2017, that patient J.D. was filling prescriptions for other doctors at other pharmacies. Darien Pharmacy provided patient J.D. with a verbal warning yet continued filling her controlled substance prescriptions.

56. Therapeutic duplication occurs when two or more drugs from the same drug class, such as immediate-release opioids, are taken concurrently.

57. Therapeutic duplication presents a red flag that the patient is either abusing the drugs or providing some or all of the drugs to individuals who are not the subject of the prescription.

58. Under Georgia law, pharmacists must identify therapeutic duplication as part of their prospective drug review and "take appropriate steps to resolve the problem" before filling a prescription. *See* Ga. Comp. R. & Regs. § 480-31-.01(b)(1)(ii).

59. Instead of taking steps to resolve the danger posed by such prescriptions, defendants repeatedly filled them.

60. Indeed, the majority of Dr. Bynes' patients who filled prescriptions at Darien Pharmacy were able to obtain concurrent prescriptions for multiple immediate-release opioids. For example, defendants dispensed three immediate-release opioids to patient E.G. on October 19, 2016, consisting of 120 dosage units of oxycodone 30mg, 120 dosage units of hydromorphone 8mg, and 240mL of cheratussin AC syrup with codeine.

61. Defendants also dispensed multiple extended-release opioids at the same time pursuant to Dr. Bynes' prescriptions. Colter testified in connection with the United States' investigation into Darien Pharmacy that she was unaware of any legitimate medical purpose for a patient to receive two different extended-release opioids at the same time.

62. Defendants provided patient M.K., for example, 60 dosage units of morphine extended release 100mg and 15 fentanyl 100mcg/hr patches on six occasions between December 2016 and July 2017. Because defendants were dispensing 120 dosage units of oxycodone 30mg to M.K. during most months in this period, defendants were providing M.K. 620 MME/day for months. Another example is patient D.V., to whom defendants also provided concurrent morphine extended release tablets and fentanyl patches—in addition 120 dosage units of oxycodone 30mg—in March and June of 2017 pursuant to prescriptions written by Dr. Bynes.

iv. Multiple Strengths of Oxycodone for Concurrent Use

63. One particularly obvious form of therapeutic duplication commonly dispensed by defendants for Dr. Bynes' patients consisted of concurrent prescriptions for multiple strengths of oxycodone.

64. This combination typically consisted of 120 dosage units of oxycodone 30mg and 120 dosage units of oxycodone 15mg, indicating the patients would be expected to take both strengths simultaneously four times a day for 30 days. This combination amounts to 270 MMEs/day, triple the amount the CDC advises clinicians to avoid.

65. This combination was so routine that the first two patients ever to fill Dr. Bynes' prescriptions at Darien Pharmacy on September 11, 2015 presented identical prescriptions for 120 units of oxycodone 30mg and 120 units of oxycodone 15mg. Defendants filled these prescriptions without any indication in the records that

they made an attempt to resolve the associated red flags.

66. Darien Pharmacy's own internal records confirm defendants' awareness of the highly suspicious nature of the combination. A notation entered in the patient comments of Darien Pharmacy's utilization record on January 18, 2016 reflects that patient T.H. "WILL GET MD TO CHANGE [the prescription], I WILL NOT FILL TWO STRENGTHS OF OXY."

67. Despite this recognition, defendants continued to fill prescriptions written by Dr. Bynes for multiple strengths of oxycodone to be taken concurrently and dispensed these drugs to numerous patients, even including, on five occasions after the January 18, 2016 note, to patient T.H.

v. Drug Cocktails

68. The *CDC Guideline* released in 2016 also warned of the dangers of combining opioids with benzodiazepines, advising clinicians to "avoid prescribing opioids and benzodiazepines whenever possible." It explained that both drugs cause central nervous system depression and can decrease respiratory drive, and, when combined, result in a near quadrupling of risk of overdose death compared to opioid use alone.

69. On May 31, 2016, the Federal Drug Administration (FDA) issued a drug safety communication that required boxed warnings on drug labels—the FDA's strongest warning—highlighting the risks of using opioids and benzodiazepines at

the same time.[8]

70. The CDC and FDA's warnings against combining opioids with benzodiazepines were not new, but instead added to the chorus of warnings issued by professional organizations regarding these drugs. For example, in 2012, the American Society of Interventional Pain Physicians published Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain, warning prescribers not to combine opioids with benzodiazepines unless there is a specific medical indication for the combination.

71. The inclusion of the muscle relaxant carisoprodol to the combination of opioids and benzodiazepines further exacerbates patient risk. Carisoprodol reportedly potentiates the euphoric effects sought out by drug abusers. Yet carisoprodol can depress respiratory and central nervous system function even further, resulting in increased risk of death.

72. Among drug abusers and within the health industry, the combination of opioids, benzodiazepines, and carisoprodol is "a well-known and highly abused drug cocktail," *United States v. Evans*, 892 F.3d 692, 706 (5th Cir. 2018), and frequently is referred to as the "holy trinity," the "unholy trinity," the "trinity," or the "Houston cocktail."

73. Indeed, Darien Pharmacy's majority shareholder agreed that "it is

[8] Food and Drug Administration, Safety Announcement, "FDA Warns about Serious Risks and Death When Combining Opioid Pain or Cough Medicines with Benzodiazepines; Requires Its Strongest Warning" (August 31, 2016) (available at https://www.fda.gov/media/99761/download).

pretty well known" that the combination of an opioid, a benzodiazepine, and carisoprodol is dangerous and should not be filled by a pharmacy. During testimony as part of the United States' investigation into Darien Pharmacy, he was unable to identify any accepted medical use for such a combination.

74. During a June 27, 2017 telephone conversation with a supplier, Colter acknowledged that the combination of oxycodone (an opioid), alprazolam (a benzodiazepine), and carisoprodol presented a red flag. She further acknowledged that Dr. Bynes frequently prescribed that combination.

75. Despite the notoriety and lethal danger posed by the "holy trinity" combination of opioids, benzodiazepines, and carisoprodol, defendants filled this cocktail hundreds of times when presented prescriptions written by Dr. Bynes.

76. More than half of Dr. Bynes' patients who filled prescriptions at Darien Pharmacy obtained the "holy trinity" cocktail from defendants.

77. Frequently, defendants filled additional controlled substances prescribed by Dr. Bynes to patients beyond the "holy trinity" cocktail. For example, during most months between March 2016 and June 2017, defendants gave patient L.G. a regimen of six controlled substances consisting of:

- 120 dosage units of either oxycodone 20mg or 30mg;
- 120 dosage units of hydrocodone 10/325mg;
- 90 dosage units of alprazolam 2mg;
- 90 dosage units of carisoprodol 350mg;
- 30 dosage units of zolpidem 10mg; and
- 30 dosage units of phentermine 37.5mg.

78. On January 30, 2017, and again between February 28 and March 3,

2017, defendants provided Dr. Bynes' patient L.I. with eight controlled substances—five of which were opioids—consisting of:

- 120 dosage units of oxycodone 30mg;
- 120 dosage units of oxycodone/acetaminophen 10/325mg;
- 10 patches of fentanyl 75mcg/hr;
- 240 mL of promethazine-codeine syrup 6.25mg-10mg/5mL;
- 60 dosage units of butalbital/caffeine/acetaminophen/codeine 50/325/40/30mg;
- 90 dosage units of alprazolam 2mg;
- 90 dosage units of carisoprodol 350mg; and
- 60 dosage units of amphetamine salts 30mg.

79. In addition to the "holy trinity" cocktail, defendants frequently filled another well-known and dangerous cocktail consisting of an opioid combined with a stimulant such as amphetamine salts and phentermine, known to produce a sought-after upper and downer effect.

80. Defendants knew or should have known that the frequency with which an internal medicine doctor prescribed these cocktails indicated the prescriptions were not supported by a legitimate medical purpose or issued in the usual course of professional practice.

vi. *Highest Available Strength*

81. It is well known, and therefore a red flag that pharmacists must look for, that the highest strength of a controlled substance will command the highest street value and is therefore the most desired by patients who are abusing or selling these drugs.

82. Defendants knew or should have known of the illegitimacy of Dr. Bynes'

prescriptions because he consistently and disproportionately prescribed the highest available strength of controlled substances.

83. During the times material to this complaint, Darien Pharmacy stocked oxycodone in 30mg, 20mg, 15mg, 10mg, and 5mg strengths.

84. The vast majority of Dr. Bynes' prescriptions filled by defendants for oxycodone were for the 30mg strength.

85. During the times material to this complaint, Darien Pharmacy stocked hydromorphone in 8mg, 4mg, and 2mg strengths.

86. The vast majority of Dr. Bynes' prescriptions filled by defendants for hydromorphone were for the 8mg strength.

87. During the times material to this complaint, Darien Pharmacy stocked fentanyl patches in 100mcg/hr, 75mcg/hr, 50mcg/hr, 37.5mcg/hr, 25mcg/hr, and 12mcg/hr strengths.

88. Nearly all of Dr. Bynes' prescriptions filled by defendants for fentanyl patches were either the 100mcg/hr or 75mcg/hr strengths.

89. During the times material to this complaint, Darien Pharmacy stocked hydrocodone/acetaminophen tablets in 10/325mg, 7.5/325mg, 5/325mg, and 2.5/325mg strengths.

90. All of Dr. Bynes' prescriptions filled by defendants for hydrocodone/acetaminophen tablets were for the 10/325mg strength.

91. During the times material to this complaint, Darien Pharmacy stocked

alprazolam in 2mg, 1mg, 0.5mg, and 0.25mg strengths.

92. Nearly all of Dr. Bynes' prescriptions filled by defendants for alprazolam were in the 2mg strength.

vii. Disproportionate Cash Sales

93. Large numbers of patients paying cash for controlled substances is a red flag that the drugs are being diverted for illicit uses.

94. In this context, "cash" means the patient paid the full price for the drug out of pocket as opposed to commercial insurance or government programs like Medicare, Medicaid, or worker's compensation.

95. Darien Pharmacy reported to one of its suppliers in June 2017 that 5% or less of its controlled substances prescriptions were paid for by cash.

96. Nationwide, approximately 9% of patients paid cash for prescription medications at independently owned community pharmacies in 2015.[9] The remaining 91% of prescriptions were paid through commercial insurance or government programs such as Medicare, Medicaid, or workers' compensation.

97. According to information submitted to the Georgia Prescription Drug Monitoring Program by Darien Pharmacy from August 2016 to September 2017, only 53% of Dr. Bynes' controlled substance prescriptions filled at Darien Pharmacy were paid through insurance, Medicare, Medicaid, or workers' compensation. For the

[9] National Community Pharmacists, *NCPA 2016 Digest*, at 19 (available at http://www.ncpa.co/pdf/digest/2016/2016-ncpa-digest-spon-cardinal.pdf).

remaining 47%, Darien Pharmacy reported that the method of payment was "unknown,[10]" indicating cash transactions at more than quintuple the national rate, and nearly ten times the rate reported by defendants.

98. In other cases, defendants submitted claims for reimbursement of Dr. Bynes' illegitimate prescriptions to government programs, including Medicare and Medicaid.

viii. Early Refills

99. An early refill occurs when a patient who receives a 30-day supply of a controlled substance seeks to refill the prescription several days before that period expires.

100. Early refills raise a red flag of drug abuse and diversion because they indicate that the patient may have run out of the controlled substance by either taking more than prescribed or providing it to others.

101. Defendants filled numerous early refill prescriptions for Dr. Bynes' patients, including:

- a prescription for oxycodone 30mg filled for patient E.M. 6 days early on January 13, 2017;
- a prescription for hydrocodone/acetaminophen 10/325mg filled for patient C.B. 7 days early on May 15, 2017; and
- prescriptions for carisoprodol 350mg filled for patient P.H. between 10 and 20 days early on October 20, 2016; November 29, 2016; and February 17, 2017.

[10] For three prescriptions, Darien Pharmacy reported merely a "paid" status.

102. Defendants knew or should have known that Dr. Bynes' patients were not taking his prescriptions as prescribed when refilling these patients' controlled substances early.

ix. Multiple Patients at the Same Address

103. Multiple patients who report the same address and receive multiple prescriptions for controlled substances from the same physician present a red flag.

104. Colter agreed that patients with the same last name who live at the same address and receive multiple prescriptions for controlled substances prescribed by the same physician present a red flag.

105. Defendants nevertheless filled numerous prescriptions for highly addictive controlled substances written by Dr. Bynes for patients living at the same address.

106. For example, between August 2016 and June 2017, defendants regularly filled prescriptions written by Dr. Bynes for patients E.T. and K.T., both of whom reported the same address to defendants. During this period, defendants generally provided E.T. with monthly supplies of two immediate-release opioids (consisting of a combination of oxycodone 30mg, oxycodone/acetaminophen 10/325mg, hydromorphone 8mg, hydromorphone 4mg, and/or hydrocodone/acetaminophen 10/325mg); alprazolam 2mg; carisoprodol 350mg; and zolpidem tartrate 10mg. During this same time, defendants generally provided K.T. with monthly supplies of two immediate-release opioids (consisting of a combination of oxycodone 30mg,

hydromorphone 8mg, and/or hydrocodone/acetaminophen 10/325mg); alprazolam 2mg or 1mg; carisoprodol 350mg; phentermine 37.5mg; and zolpidem tartrate 10mg. For seven months during this period, defendants additionally provided K.T. with 10 fentanyl 100mcg/hr patches.

107. As another example, defendants filled prescriptions written by Dr. Bynes for patients J.J. and B.J., both of whom reported the same address, from August 2016 to June 2017. Defendants typically provided patient J.J. with two immediate-release opioids (consisting of a combination of oxycodone 30mg, hydromorphone 8 mg, and/or oxycodone/acetaminophen 10/325mg) and alprazolam 2mg, and provided patient B.J. with two immediate-release opioids (oxycodone 30mg and hydromorphone 8 mg) and alprazolam 2mg.

x. *Out-of-Pocket Surcharges*

108. Patients who request pills with specific markers and colors present a known red flag of abuse and diversion. Many abusers seek out specific markings or colors because they command higher street value, as such pills are less likely to be counterfeits or known to contain a specific drug from appearance alone.[11]

109. Colter herself acknowledged that she was aware—even before working at Darien Pharmacy—that drug diverters frequently request pills with specific colors or markings for this reason.

[11] *See, e.g.*, *Vinci v. Ohio State Bd. of Pharm.*, Nos. 2008-AP-08-0052 & 2008-AP-08-0053, 2010 WL 529468, at *2-3, 13 (Ohio Ct. App. Feb. 10, 2010).

110. Not only did defendants' customers request pills with specific markings or colors, but defendants frequently required customers to pay an out-of-pocket surcharge for those drugs.

111. For example, Darien Pharmacy's utilization records reveal countless notations of Dr. Bynes' patients who "WILL PAY $15 FOR YELLOW 10/325" in reference to hydrocodone prescriptions.

* * *

112. These red flags, taken together, show a very obvious and clear dereliction of defendants' corresponding duty under the CSA. Defendants failed to act upon the red flags described in this section, and dispensed hundreds of thousands of pills to drug seekers that ordinary pharmacists acting in the course of their duties would not have dispensed.

B. Defendants' False Representations to Suppliers Regarding Florida Physicians

113. In 2016 and 2017, Darien Pharmacy's controlled substance suppliers engaged in reviews of Darien Pharmacy, including requesting documentation that DEA would inspect and review as part of any regulatory compliance audit.

114. In recognition of the inherent red flag presented by controlled substances prescriptions written by far-away doctors, defendants repeatedly told Darien Pharmacy's suppliers that they would not or were not filling prescriptions for controlled substances written by physicians located out of state.

115. On or about July 28, 2016, Colter advised one supplier in an email that

"DARIEN PHARMACY WILL NOT FILL ANY CII PRESCRIPTIONS WRITTEN BY FLORIDA PHYSICIANS THAT COME FROM [the supplier]." Defendants in fact dispensed tens of thousands of dosage units of Schedule II controlled substances originating from doctors located in Florida after making this representation.

116. On or about June 21, 2017, Colter answered "no" when asked by a supplier in a written questionnaire whether Darien Pharmacy "fill[ed] controlled substance prescriptions written by out of state providers."

117. After formally adopting a controlled substances policy on or about July 17, 2017 providing that Darien Pharmacy "will not fill controlled substances from any out of state physician, unless affiliated with a specialty clinic or hospital," one supplier asked why Darien Pharmacy continued filling prescriptions written by doctors located in Florida. Colter responded in an email dated August 21, 2017 that "we will no longer fill pain medications for Florida physicians."

118. That representation, too, was false, as defendants filled nearly ten thousand dosage units of Schedule II controlled substances originating from doctors located in Florida after the August 22, 2017 email.

C. Ignoring Internal Warnings

119. Defendants failed to exercise their corresponding responsibility even in the face of their own internal warnings.

120. For example, Colter entered a note into Darien Pharmacy's utilization record on November 10, 2016 that the pharmacy would not fill oxycodone

prescriptions for patient E.P. Defendants nevertheless filled oxycodone/acetaminophen 10/325mg prescriptions for E.P. on 7 occasions after November 10, 2016.

121. In another example, a record dated February 18, 2016 warned Darien Pharmacy employees, "DO NOT FILL DILAUDID," the brand name for hydromorphone, for patient T.S. Defendants nevertheless filled prescriptions for hydromorphone 8mg for this patient on four separate occasions after this date.

122. Colter also ignored the pleas of her own employees not to fill suspicious prescriptions. On one occasion, Darien Pharmacy received a report that patient J.A. entered a drug rehabilitation program while displaying track marks on J.A.'s arms and carrying a prescription bottle from Darien Pharmacy for a prescription written by Dr. Bynes. Less than a month after receiving this report, and despite employee protests, Colter dispensed controlled substances to J.A. without taking any additional steps to verify the legitimacy of the prescription beyond J.A.'s bare denial of having sought treatment for drug addiction.

123. On another occasion, a pharmacist employed by Darien Pharamcy expressed concern to Colter regarding the legitimacy of controlled substances prescriptions written by a doctor who relocated to St. Marys, Georgia—approximately 50 miles from Darien Pharmacy—after the State of Florida Board of Medicine permanently restricted the doctor from prescribing or ordering controlled substances in Florida. Colter responded by threatening to fire the pharmacist unless the

pharmacist filled the doctor's controlled substances prescriptions.

II. DEA's On-Site Inspection

124. From February 15 to February 22, 2018, DEA conducted an on-site inspection at Darien Pharmacy to determine whether it was in compliance with the CSA and its implementing regulations.

125. DEA uncovered several categories of violations that are actionable under 21 U.S.C. § 842(a)(5).

126. A pharmacy that orders Schedule II controlled substances must create a record of the quantity of each item received and the date received, either by completing a hardcopy DEA Form-222 or, for electronic orders, linking such a record to the original electronic order. *See* 21 C.F.R. §§ 1305.13(e), 1305.22(g).

127. Pharmacies must retain confirmation records for all orders of Schedule II controlled substances for two years. *See* 21 C.F.R. §§ 1305.17(c), 1305.27(a).

128. Pharmacies must preserve the prescriptions for controlled substances at their registered location for at least two years from the date of the record. 21 C.F.R. § 1304.04(a), (h)(2) and (4).

129. During the on-site inspection, Colter advised DEA diversion investigators that only she is authorized to order controlled substances on behalf of Darien Pharmacy.

130. Defendants negligently failed to make, keep, and furnish records of the quantity of each item received and the date received for numerous shipments of

Schedule II controlled substances.

131. DEA also conducted an audit of certain controlled substances by comparing Darien Pharmacy's inventories against its ordering and utilization records to determine whether each dosage unit provided to or on hand at the pharmacy was accounted for.

132. To assist in the audit, DEA requested and defendants provided the most recent biennial inventory of controlled substances, which was taken on April 27, 2017.

133. Pharmacies must take an inventory of all controlled substances on hand every two years and maintain those inventories for two years after they are made. 21 U.S.C. § 827(a); 21 C.F.R. § 1304.11. The inventory must indicate the name of the substances, each finished form of the substance, the number of units or volume of each finished form in each commercial container, and the number of commercial containers of each finished form on hand. 21 C.F.R. § 1304.04(e)(1)(iii), (e)(6). The inventory must indicate whether it was taken either as of opening of business or as of close of business on the inventory date. 21 C.F.R. 1304.11(a).

134. In violation of 21 C.F.R. § 1304.11(a), defendants negligently failed to record whether the April 27, 2017 biennial inventory was taken at either the beginning of business or the close of business.

135. Colter orally advised DEA diversion investigators that the April 27, 2017 biennial inventory was taken at the close of business.

136. The results of the controlled substances audit revealed that defendants

were unable to account for all dosage units of oxycodone/acetaminophen 10/325mg and amphetamine salts 20mg, as the audit produced a shortage of more than 1,500 dosage units for these medications.

COUNT ONE

Action for Civil Penalties under 21 U.S.C. § 842(a)(1)

137. Plaintiff repeats and realleges each allegation of paragraphs 1 through 136 as if fully set forth herein.

138. The CSA prohibited defendants Darien Pharmacy and Colter from filling prescriptions for controlled substances unless they were supported by valid prescriptions.

139. Despite this prohibition, defendants Darien Pharmacy and Colter filled tens of thousands of prescriptions for controlled substances that they knew or should have known were not supported by valid prescriptions.

140. Each time defendants Darien Pharmacy and Colter filled a prescription knowing, or having reason to know, that it was not issued for a legitimate medical purpose or by a practitioner not acting in the usual course of professional practice, they violated 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

141. Each of the thousands of violations subjects defendants Darien Pharmacy and Colter to a civil penalty of up to $64,820.00. *See* 21 U.S.C. § 842(c)(1)(A); 28 C.F.R. § 85.5.

COUNT TWO

Action for Civil Penalties under 21 U.S.C. § 842(a)(5)

142. Plaintiff repeats and realleges each allegation of paragraphs 1 through 136 as if fully set forth herein.

143. The CSA required defendants to make, keep, and furnish certain records prescribed by the CSA and its implementing regulations.

144. Defendants Darien Pharmacy and Colter negligently failed to make a record of whether the April 27, 2017 inventory was taken at the beginning or close of business as required by 21 C.F.R. § 1304.11(a).

145. Defendants Darien Pharmacy and Colter negligently failed to make, keep, and furnish a record of the date and quantity of Schedule II controlled substances Darien Pharmacy received for numerous shipments from its suppliers as required by 21 C.F.R. §§ 1305.13(e) and 1305.22(g).

146. Each shipment of Schedule II controlled substances for which defendants Darien Pharmacy and Colter failed to make, keep, and furnish a record of the date and quantity of received constitutes a separate violation of 21 U.S.C. § 842(a)(5).

147. Between the close of business on April 27, 2017 and the close of business on February 15, 2018, defendants Darien Pharmacy and Colter negligently failed to make, keep, and furnish accurate records of each dosage unit of oxycodone/acetaminophen 10/325mg and amphetamine salts 20mg "received, sold, delivered, or otherwise disposed of" as required by of 21 U.S.C. § 827(a)(3) and 21 C.F.R. §§ 1304.21, 1304.22(c).

148. Each of the more than a thousand dosage units for which defendants Darien Pharmacy and Colter are unable to account represents a separate violation of 21 U.S.C. § 842(a)(5).

149. Each of the more than a thousand violations subjects defendants Darien Pharmacy and Colter to a civil penalty of up to $15,040.00. *See* 21 U.S.C. § 842(c)(1)(B); 28 C.F.R. § 85.5.

PRAYER FOR RELIEF

The United States therefore requests that the Court:

1. Enter judgment for the United States against defendants Darien Pharmacy and Colter on each Count of this complaint;

2. Impose a civil penalty on defendants Darien Pharmacy and Colter of not more than $64,820.00 for each of the thousands of violations of 21 U.S.C. § 842(a)(1);

3. Impose a civil penalty on defendants Darien Pharmacy and Colter of not more than $15,040.00 for each of the more than a thousand violations of 21 U.S.C. § 842(a)(5);

4. Award the United States all costs associated with the investigation, prosecution and collection of the civil penalties in this matter; and

5. Grant any other and further relief as is just and proper.

Date: August 20, 2019

Respectfully submitted,

BOBBY L. CHRISTINE
UNITED STATES ATTORNEY

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CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

United States of America

(b) County of Residence of First Listed Plaintiff
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Bradford C. Patrick, Jonathan A. Porter
US Attorney's Office, PO Box 8970, Savannah GA 31412 (912) 652-4422

DEFENDANTS

Agape Prescriptions "R" Us, d/b/a Darien Pharmacy, and Janice Colter

County of Residence of First Listed Defendant McIntosh
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

Keith Hasson, Hasson Law Group, 3379 Peachtree Rd, Suite 625, Atlanta, GA 30326 (678) 701-2870; Wrix McIlvaine, Williams Litigation Group, PO Box 279, Brunswick, GA 31521 (866) 299-1378

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☒ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
21 USC 842

Brief description of cause:
Unlawful dispensing of controlled substances; failure to make, keep, and furnish records

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE DOCKET NUMBER

DATE
08/20/2019

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE